DEPARTMENT OF HEALTH & HUMAN SERVICES

Office of Inspector General
Offices of Audit Services

Region VII
601 East 12th Street
Room 284A
Kansas City, Missouri 64106

APR 15 2008

Report Number: A-07-08-03105

Brendan Joyce, PharmD
Administrator, Pharmacy Services
North Dakota Department of Human Services
600 East Boulevard Avenue, Department 325
Bismarck, North Dakota 58505-0250

Dear Dr. Joyce:

Enclosed is the U.S. Department of Health and Human Services (HHS), Office of Inspector General (OIG), final report entitled "Follow-Up Audit of the Medicaid Drug Rebate Program in North Dakota." We will forward a copy of this report to the HHS action official noted on the following page for review and any action deemed necessary.

The HHS action official will make final determination as to actions taken on all matters reported. We request that you respond to this official within 30 days from the date of this letter. Your response should present any comments or additional information that you believe may have a bearing on the final determination.

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If you have any questions or comments about this report, please do not hesitate to call me, or contact Greg Tambke, Audit Manager, at (573) 893-8338, extension 30, or through e-mail at Greg.Tambke@oig.hhs.gov. Please refer to report number A-07-08-03105 in all correspondence.

Sincerely,

for Christopher B. Breault

Patrick J. Cogley
Regional Inspector General
for Audit Services

Enclosure

Direct Reply to HHS Action Official:

Ms. Jackie Garner
Consortium Administrator
Consortium for Medicaid and Children's Health Operations
Centers for Medicare & Medicaid Services
233 North Michigan Avenue, Suite 600
Chicago, Illinois 60601

Department of Health and Human Services

OFFICE OF INSPECTOR GENERAL

FOLLOW-UP AUDIT OF THE MEDICAID DRUG REBATE PROGRAM IN NORTH DAKOTA

Daniel R. Levinson
Inspector General

April 2008
A-07-08-03105

Office of Inspector General

http://oig.hhs.gov

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OFFICE OF AUDIT SERVICES FINDINGS AND OPINIONS

The designation of financial or management practices as questionable, a recommendation for the disallowance of costs incurred or claimed, and any other conclusions and recommendations in this report represent the findings and opinions of OAS. Authorized officials of the HHS operating divisions will make final determination on these matters.

EXECUTIVE SUMMARY

BACKGROUND

The Medicaid drug rebate program, which began in 1991, is set forth in section 1927 of the Social Security Act. For a manufacturer's covered outpatient drugs to be eligible for Federal Medicaid funding under the program, the manufacturer must enter into a drug rebate agreement with the Centers for Medicare & Medicaid Services (CMS) and pay quarterly rebates to the States. CMS, the States, and drug manufacturers each undertake certain functions in connection with the drug rebate program. In North Dakota, the Department of Human Services (the State agency) administers the Medicaid drug rebate program.

In 2005, we issued a report on the results of audits of the Medicaid drug rebate programs in 49 States and the District of Columbia (A-06-03-00048). Those audits found that only four States had no weaknesses in accountability for and internal controls over their drug rebate programs. As a result of the weaknesses, we concluded that States lacked adequate assurance that all of the drug rebates due to the States were properly recorded and collected. Additionally, CMS did not have reliable information from the States to properly monitor the drug rebate program.

In our previous audit of the North Dakota drug rebate program (A-07-03-04019), we determined that the State agency had adequate controls over its drug rebate program, with one exception: billing and tracking $0 unit rebate amount(s) (URA). (The term "$0 URAs" refers to drugs included on CMS's quarterly Medicaid drug data tape, distributed to the States, that lack pricing information.)

We recommended that the State agency develop and follow policies and procedures that included controls designed to (a) track $0 URA line items and (b) generate notifications to manufacturers when they fail to compute the proper URA amount and remit payment. Such controls would allow the State agency to identify the outstanding $0 URAs by manufacturer and to differentiate those that represent disputed amounts from those that were not paid when due.

The State agency agreed with our findings and recommendations.

This current review of the North Dakota drug rebate program is part of a nationwide series of reviews conducted to determine whether States have addressed the weaknesses in accountability for and internal controls over their drug rebate programs found in the previous reviews. Additionally, because the Deficit Reduction Act of 2005 (DRA) required States as of January 2006 to begin collecting rebates on single source drugs administered by physicians, this series of reviews will also determine whether States have complied with the new requirement.

OBJECTIVES

Our objectives were to determine whether the State agency had (1) implemented the recommendations made in our previous audit of the North Dakota drug rebate program and

(2) established necessary controls over the drug rebate program, including the collection of rebates on single source drugs administered by physicians.

SUMMARY OF FINDINGS

The State agency partially implemented procedures to correct the weakness relating to billing and tracking $0 URAs that we identified in our previous audit. The State agency implemented procedures to track $0 URAs and to notify manufacturers of $0 URAs. However, the State agency did not develop written policies and procedures to identify the process used by the State agency to bill and track $0 URAs.

During our review, we also identified additional weaknesses in the State agency's controls over its drug rebate program:

- The State agency does not have a mechanism in place to adequately monitor disputed drug rebates. Specifically, the State agency cannot determine the current number of open and closed disputes, nor can it identify whether disputes have been resolved within 60 days, as required by the rebate agreement.

- The State agency did not have written policies and procedures governing the calculation of interest on unpaid balances due to the State agency from manufacturers. As a result, the State agency may not have collected all interest due from manufacturers.

The State agency generally lacks comprehensive written policies and procedures over the drug rebate program.

Additionally, the State agency established controls over collecting rebates on single source drugs administered by physicians; however, it did not fully comply with the DRA. Specifically, the State agency did not generate invoices for single source physician-administered drugs for the quarter ended March 31, 1999, and did not properly report rebate collections, rebates invoiced, or accounts receivables amounts for single source physician-administered drugs on the Form CMS-64.9R.

RECOMMENDATIONS

We recommend that the State agency develop and follow written policies and procedures over the drug rebate program. More specifically, the State agency should develop and follow policies and procedures to:

- track $0 URA line items and frequently generate notifications to manufacturers when they fail to compute the proper URA amount and remit payment;

- track open and closed disputed drug rebates and make the State's hearing mechanism available to manufacturers;

- invoice manufacturers for interest upon interest, when appropriate; and

- ensure that the State agency properly reports all rebates invoiced, rebate collections, and accounts receivables on the Form CMS-64.9R as required by the State Medicaid Manual; and if necessary, prepare any prior period adjustments to ensure that CMS has received accurate drug rebate information.

We also recommend the State agency develop policies and procedures to ensure it complies with the specific timeframes for invoicing physician-administered drugs, as required by the DRA. Furthermore, we recommend that the State agency generate and mail invoices to manufacturers for single source physician-administered drugs for the quarter ended March 31, 1999, and report the information on the State agency's Form CMS-64.9R, as required by the DRA and the State Medicaid Manual.

STATE AGENCY'S COMMENTS

In written comments on our draft report, the State agency did not specifically indicate whether it concurred with our findings and recommendations. However, the State agency's response stated that it "will develop written policies and procedures surrounding the drug rebate program," and written policies and procedures specific to physician-administered drugs. The State agency also said that it has generated and mailed invoices to manufacturers for single source physician-administered drugs for the quarter ended March 31, 1999, and will report the information on the Form CMS-64.9R.

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

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INTRODUCTION

BACKGROUND

Pursuant to Title XIX of the Social Security Act (the Act), the Medicaid program provides medical assistance to certain low-income individuals and individuals with disabilities. The Federal and State Governments jointly fund and administer the Medicaid program. At the Federal level, the Centers for Medicare & Medicaid Services (CMS) administers the program. Each State administers its Medicaid program in accordance with a CMS-approved State plan. Although the State has considerable flexibility in designing and operating its Medicaid program, it must comply with applicable Federal requirements.

Drug Rebate Program

The Medicaid drug rebate program, which began in 1991, is set forth in section 1927 of the Act. For a manufacturer's covered outpatient drugs to be eligible for Federal Medicaid funding under the program, the manufacturer must enter into a drug rebate agreement with CMS and pay quarterly rebates to the States. CMS, the States, and drug manufacturers each undertake certain functions in connection with the drug rebate program. In North Dakota, the Department of Human Services (the State agency) is responsible for the rebate program.

Pursuant to section II of the rebate agreement and section 1927(b) of the Act, 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, its best price. Based on this information, CMS calculates a unit rebate amount (URA) for each covered outpatient drug and provides the amounts to States on a quarterly basis.

Section 1927(b)(2)(A) of the Act requires States to maintain drug utilization data that identifies, by National Drug Code (NDC), the number of units of each covered outpatient drug for which the States have reimbursed providers. The number of units is applied to the URA to determine the actual rebate amount due from each manufacturer. Section 1927(b)(2) of the Act requires States to provide the drug utilization data to CMS and the manufacturer. States also report drug rebate accounts receivable data on Form CMS-64.9R. This is part of Form CMS-64, "Quarterly Medicaid Statement of Expenditures for the Medical Assistance Program," which summarizes actual Medicaid expenditures for each quarter and is used by CMS to reimburse States for the Federal share of Medicaid expenditures.

Physician-Administered Drugs

Section 6002(a) of the Deficit Reduction Act of 2005 (DRA) amended section 1927 of the Act and requires States, as of January 1, 2006, to collect and submit utilization data for single source drugs administered by physicians so that States may obtain rebates for the drugs.[1] Single source drugs are commonly referred to as "brand name drugs" and do not have generic equivalents.

[1]This provision of the DRA expands the requirement to certain multiple source drugs administered by physicians after January 1, 2008.

In North Dakota, physician-administered drugs are billed to the State Medicaid program on a physician claim form using procedure codes that are part of the Healthcare Common Procedure Coding System. The NDC is not included on the physician claim form. The procedure code identifies a drug by its active ingredient(s) and identifies the number of drug units (billing units) allowed per reimbursement for that procedure code. Because rebates are calculated and paid based on NDCs, each procedure code must be converted to an NDC. Additionally, the billing units for a procedure code may differ from the units used for rebate purposes (e.g., grams versus liters). Therefore, to determine rebates, the procedure codes must be converted into NDCs for single source drugs, and procedure code billing units must be converted into equivalent NDC billing units.

Prior Office of Inspector General Reports

In 2005, we issued a report on the results of audits of the Medicaid drug rebate programs in 49 States and the District of Columbia.[2] Those audits found that only four States had no weaknesses in accountability for and internal controls over their drug rebate programs. As a result of the weaknesses, we concluded that States lacked adequate assurance that all of the drug rebates due to the States were properly recorded and collected. Additionally, CMS did not have reliable information from the States to properly monitor the drug rebate program.

In our previous audit of the North Dakota drug rebate program, we determined that the State agency had adequate controls over its drug rebate program, with one exception: billing and tracking $0 URAs.[3]

We recommended that the State agency develop and follow policies and procedures that included controls designed to (a) track $0 URA line items and (b) generate notifications to manufacturers when they fail to compute the proper URA amount and remit payment. Such controls would allow the State agency to identify the outstanding $0 URAs by manufacturer and to differentiate those that represent disputed amounts from those that were not paid when due.

The State agency agreed with our findings and recommendations.

North Dakota Drug Rebate Program

During the time period of July 1, 2005, through February 2006, the State agency was responsible for (1) preparing and mailing rebate invoices to manufacturers; (2) monitoring and working on the drug rebates accounts receivable, to include posting payments to subsidiary ledgers; (3) resolving disputes; and (4) monitoring outstanding balances. The State agency was also responsible for depositing funds and preparing the Form CMS-64 reports. In March 2006, the State agency contracted with Health Information Designs (HID) to convert procedure codes to

[2]"Multistate Review of Medicaid Drug Rebate Programs" (A-06-03-00048), issued July 6, 2005; Arizona was not included because it did not operate a drug rebate program.

[3]"Audit of the Medicaid Drug Rebate Program in North Dakota" (A-07-03-04019), issued October 8, 2003.

NDCs and to prepare and mail drug rebate invoices to manufacturers. Additionally, HID is also responsible for maintaining the accounts receivable for single source physician-administered drugs.

The State agency reported an outstanding drug rebate balance of $2,665,898 on the June 30, 2006, Form CMS-64.9R. However, $2,034,488 of this amount related to quarterly billings and was not past due as of June 30, 2006. Of the remaining $631,410 that was past due, $89,374 was more than 1 year past due. For the fiscal year ended June 30, 2006, the State agency reported rebate billings of approximately $14.0 million and collections of $16.1 million. It should be noted the above amounts do not include rebates invoiced, rebate collections, or accounts receivable amounts for single source physician-administered drugs, because the State agency did not begin invoicing these drugs until April 2007.

This current review of the North Dakota drug rebate program is part of a nationwide series of reviews conducted to determine whether States have addressed the weaknesses in accountability for and internal controls over their drug rebate programs found in the previous reviews. Because our previous review of North Dakota was limited primarily to controls over cash receipts, this review will determine whether the State agency had established controls over the drug rebate program. Additionally, because the DRA required States as of January 2006 to begin collecting rebates on single source drugs administered by physicians, this series of reviews will also determine whether States have complied with the new requirement.

OBJECTIVES, SCOPE AND METHODOLOGY

Objectives

Our objectives were to determine whether the State agency had (1) implemented the recommendations made in our previous audit of the North Dakota drug rebate program and (2) established necessary controls over the drug rebate program, including the collection of rebates on single source drugs administered by physicians.

Scope

We reviewed the State agency's current policies, procedures and controls over the drug rebate program and the accounts receivable data reported on Form CMS-64.9R as of June 30, 2006.

We conducted fieldwork at the State agency, located in Bismarck, North Dakota, during January 2008.

Methodology

To accomplish our objectives, we

- reviewed section 1927 of the Act, section 6002(a) of the DRA, CMS guidance issued to State Medicaid directors, and other information pertaining to the Medicaid drug rebate program;

- reviewed the previous Office of Inspector General audit report over the drug rebate program in North Dakota;

- reviewed the policies and procedures related to the State agency's drug rebate accounts receivable system;

- interviewed State agency officials to determine the policies, procedures, and controls that related to the Medicaid drug rebate program;

- reviewed copies of Form CMS-64.9R for the period July 1, 2005, through June 30, 2006;

- reviewed accounts receivable records during the four quarters ending June 30, 2006, and records of interest payments received for the four quarters ended June 30, 2006;

- interviewed State agency officials and reviewed documentation to identify procedures for billing and tracking $0 URAs;

- interviewed State agency officials to determine the processes used in converting physician services claims data into drug rebate data related to single source drugs administered by physicians; and

- reviewed Form CMS-64.9R as of December 31, 2007 to determine whether the State agency included single source physician-administered drugs that were invoiced to manufacturers in April 2007.

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.

FINDINGS AND RECOMMENDATIONS

The State agency partially implemented procedures to correct the weakness relating to billing and tracking $0 URAs that we identified in our previous audit. The State agency implemented procedures to track $0 URAs and to notify manufacturers of $0 URAs. However, the State agency did not develop written policies and procedures to identify the process used by the State agency to bill and track $0 URAs.

During our review, we also identified additional weaknesses in the State agency's controls over its drug rebate program:

- The State agency does not have a mechanism in place to adequately monitor disputed drug rebates. Specifically, the State agency cannot determine the current number of open and closed disputes, nor can it identify whether disputes have been resolved within 60 days, as required by the rebate agreement.

- The State agency did not have written policies and procedures governing the calculation of interest on unpaid balances due to the State agency from manufacturers. As a result, the State agency may not have collected all interest due from manufacturers.

The State agency generally lacks comprehensive written policies and procedures over the drug rebate program.

Additionally, the State agency established controls over collecting rebates on single source drugs administered by physicians; however, it did not fully comply with the DRA. Specifically, the State agency did not generate invoices for single source physician-administered drugs for the quarter ended March 31, 1999, and did not properly report rebate collections, rebates invoiced, or accounts receivables amounts for single source physician-administered drugs on the Form CMS-64.9R.

IMPLEMENTATION OF PRIOR RECOMMENDATIONS

In our prior audit of the North Dakota drug rebate program, we determined that the State agency did not have sufficient controls to track $0 URAs to ensure payment from the manufacturers.[4] In its comments on our prior audit finding, the State agency concurred with our finding and stated that it would implement additional procedures to more adequately track $0 URAs to ensure an amount was calculated and remitted by the manufacturers.

Since our prior audit, the State agency has partially corrected the weakness regarding billing and tracking $0 URAs. On May 26, 2006, the State agency sent notifications to manufacturers identifying outstanding $0 URAs. As of that date, the State agency had identified that approximately 5,764 $0 URAs existed. The State agency has since reduced the number of $0 URAs to 4,480, as of December 2007. However, as of the end of our fieldwork, the State agency has not developed written policies and procedures to identify the procedures the State agency follows to resolve $0 URAs or to specify the frequency with which the State agency plans to notify manufacturers of existing $0 URAs.

Federal regulations at 42 CFR § 433.32 require that the State agency ". . . (a) [m]aintain an accounting system and supporting fiscal records to assure that claims [reported on the CMS-64] for Federal funds are in accord with applicable Federal requirements . . . ." Federal regulations at 45 CFR § 92.20(a) also state: ". . . Fiscal control and accounting procedures of the State, as well as its subgrantees . . . must be sufficient to . . . establish that such [Medicaid] funds have not been used in violation of the restrictions and prohibitions of applicable statutes."

As a result of the absence of written policies and procedures concerning the tracking of $0 URAs, the drug rebate receivables were consistently understated, and the State agency may not have received all possible drug rebates due from manufacturers.

[4]CMS provides the URA information to the State agency on a quarterly computer tape. The term "$0 URAs" refers to drugs included on CMS's quarterly Medicaid drug data tape, distributed to the States, that lack pricing information. In instances of $0 URAs, the State agency is instructed to invoice the units, and the manufacturer is required to calculate the URA and remit the appropriate amount to the State agency.

TRACKING DISPUTED DRUG REBATES

The State agency does not have a mechanism in place to adequately monitor disputed drug rebates. The State agency cannot determine the current number of open and closed disputes, nor can it identify whether disputes have been resolved within 60 days, as required by the rebate agreement. Additionally, the State agency does not have written policies and procedures to identify and explain its dispute resolution procedures.

While the State agency has a State hearing mechanism available for use, the State agency does not offer the mechanism to manufacturers. Instead, State agency officials contact manufacturers directly and offer them access to claim-level detail, via the Internet, to resolve disputes or outstanding balances. Additionally, one representative from the State agency has attended two Dispute Resolution Program meetings in an attempt to resolve disputes. However, the State agency does not perform any follow-up on disputed rebates to ensure they have been resolved. The CMS Drug Rebate Agreement states:

> The State and the Manufacturer will use their best efforts to resolve [a] discrepancy within 60 days of receipt of such notification. In the event that the State and the Manufacturer are not able to resolve a discrepancy within 60 days, CMS shall require the State to make available to the manufacturer the State hearing mechanism available under the Medicaid Program.

As a result, the State agency may have not collected all possible drug rebates due from manufacturers.

CALCULATING INTEREST UPON INTEREST

The State agency does not calculate interest upon interest as required by CMS regulations and guidelines. According to Medicaid Drug Rebate Program release number 29 (published by CMS),

> . . . when a manufacturer pays the State for disputed rebate amounts or late rebate payments, the manufacturer must also pay all interest due. If a manufacturer fails to reimburse the State for the interest due, the interest calculations described above will apply to the unpaid balance. The unpaid interest will be treated as principal due, and interest will begin accruing as of the date the manufacturer paid the original disputed invoice amount. Interest will continue accruing on the unpaid balance of the principal for all quarters and stop accruing the date the check is mailed by the manufacturer.

The State agency did not have written policies and procedures governing the calculation of interest upon interest. As a result, the State agency may not have collected all interest due from manufacturers.

PHYSICIAN-ADMINISTERED SINGLE SOURCE DRUGS

The State agency has not fully complied with Section 6002(a) of the DRA because it did not invoice manufacturers for single source physician-administered drugs until April 2007.[5] The State agency submitted utilization data to CMS for single source physician-administered drugs dating back to the quarter ended March 31, 1997. However, our review determined that the State agency did not submit utilization data to CMS, or generate and mail invoices to manufacturers, for single source physician-administered drugs for the quarter ended March 31, 1999. We also determined that, as of September 2007, the State agency did not properly report rebates invoiced, rebate collections, and accounts receivable amounts for single source physician-administered drugs on the Form CMS-64.9R. As a result, the State agency has not fully complied with Section 6002(a) of the DRA and has, consequently, reported inaccurate information to CMS.

As stated earlier, the DRA amended section 1927(a) of the Social Security Act by adding the requirement for submission of utilization data for certain physician-administered drugs. The DRA § 6002 added section 1927(a)(7) to the Act, requiring that States collect rebates on single source physician-administered drugs. The section requires that the States begin submitting rebate invoices for single source physician-administered drugs by January 1, 2006.

42 CFR § 430.30(c) states:

> (1) The State must submit Form CMS–64 (Quarterly Medicaid Statement of Expenditures for the Medical Assistance Program) to the central office (with a copy to the regional office) not later than 30 days after the end of each quarter.
>
> (2) This report is the State's accounting of actual recorded expenditures. The disposition of Federal funds may not be reported on the basis of estimates.

According to the State Medicaid Manual § 2500(B), "[i]n order that the Secretary may determine that funds advanced to you for the operation of the Medicaid program have been accounted for properly, report your quarterly expenditures on Form HCFA-64 within 30 days after the end of each calendar quarter. (See 42 CFR 430.30(c).) It constitutes your claim for Federal reimbursement."

The State Medicaid Manual § 2500(C) also states: "If you later determine that an expenditure report submitted for a given quarter did not contain all expenditures for that quarter, include the additional expenditures on the next Form HCFA-64 report as a prior period adjustment."

According to State agency officials, HID loaded data into the Drug Rebate System for the quarter ended March 31, 1999; however, HID did not generate invoices or mail them to manufacturers, nor was utilization data submitted to CMS. State agency officials said that they would generate the invoices and mail them to manufacturers at the end of February 2008.

[5]As stated earlier, Section 6002(a) of the DRA mandates that, as of January 1, 2006, States collect and submit utilization data for single source drugs administered by physicians.

State agency officials also indicated that it was a management decision to exclude the rebates invoiced, rebate collections, and the accounts receivables for single source physician-administered drugs from the Form CMS-64.9R report because, according to these officials, they were not confident in the numbers reported by HID. Subsequent to that decision, the State agency reported rebate data for single source drugs dating back to January 1997 on its Form CMS-64.9R report for the quarter ended December 31, 2007. However, under the provisions of 42 CFR § 430.30(c), the State agency should have reported the single source drug rebate data on the Form CMS-64.9R for the quarter ended June 30, 2007. Thus, the State agency reported the drug rebate data more than two quarters late. Furthermore, the State agency did not include the drug rebate data for the quarter ended March 31, 1999, on its Form CMS-64.9R for the quarter ended December 31, 2007. Because the State agency did not report the single source drug rebate data in the proper reporting period, CMS received inaccurate drug rebate information.

The State agency paid $712,656 in claims for physician-administered drugs during the January through June 2006 time period and billed manufacturers for rebates totaling $206,839 in April 2007.

RECOMMENDATIONS

We recommend that the State agency develop and follow written policies and procedures over the drug rebate program. More specifically, the State agency should develop and follow policies and procedures to:

- track $0 URA line items and frequently generate notifications to manufacturers when they fail to compute the proper URA amount and remit payment;

- track open and closed disputed drug rebates and make the State's hearing mechanism available to manufacturers;

- invoice manufacturers for interest upon interest, when appropriate; and

- ensure that the State agency properly reports all rebates invoiced, rebate collections, and accounts receivables on the Form CMS-64.9R as required by the State Medicaid Manual; and if necessary, prepare any prior period adjustments to ensure that CMS has received accurate drug rebate information.

We also recommend the State agency develop policies and procedures to ensure it complies with the specific timeframes for invoicing physician-administered drugs, as required by the DRA. Furthermore, we recommend that the State agency generate and mail invoices to manufacturers for single source physician-administered drugs for the quarter ended March 31, 1999, and report the information on the State agency's Form CMS-64.9R, as required by the DRA and the State Medicaid Manual.

STATE AGENCY'S COMMENTS

In written comments on our draft report, the State agency did not specifically indicate whether it concurred with our findings and recommendations. However, the State agency's response stated that it "will develop written policies and procedures surrounding the drug rebate program," and written policies and procedures specific to physician-administered drugs. The State agency also said that it has generated and mailed invoices to manufacturers for single source physician-administered drugs for the quarter ended March 31, 1999, and will report the information on the Form CMS-64.9R.

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

APPENDIX

north dakota department of human services

John Hoeven, Governor
Carol K. Olson, Executive Director

Medical Services
(701) 328-2321
Toll Free 1-800-755-2604
Fax (701) 328-1544
TTY (701) 328-3480
Provider Relations (701) 328-4030

March 27, 2008

Mr. Patrick J. Cogley
Regional Inspector General for Audit Services
601 E 12th St, Room 284A
Kansas City, MO 64106

Re: Report Number A-07-08-03105

Dear Inspector General Cogley:

Below you will find our responses to the draft "Follow-up Audit of the Medicaid Drug Rebate Program in North Dakota," dated March 4, 2008.

Recommendation

"We recommend that the State agency develop and follow written policies and procedures over the drug rebate program."

Response

The State of North Dakota will develop written policies and procedures surrounding the drug rebate program. These will specifically include the following:

1) Policies and procedures for the billing and tracking of $0 URA line items and notifying manufacturers of the $0 URA line items, and

2) Policies and procedures to ensure the new drug rebate system being procured along with the new Medicaid Management Information System will have the functionality to track open and closed disputed drug rebates,

600 East Boulevard Avenue Department 325 -- Bismarck, ND 58505-0250
www.nd.gov/dhs

as well as ensuring that manufacturer communication in the new system includes standard language offering the State's hearing mechanism to manufacturers for dispute resolution, and

3) Policies and procedures to calculate and invoice manufacturers for interest upon interest, when appropriate, and

4) Policies and procedures for reporting of rebates invoiced, rebate collections, and accounts receivables properly on the Form CMS-64.R as required by the State Medicaid manual, including any necessary prior period adjustments.

Recommendation

"We also recommend the State Agency develop policies and procedures to ensure it complies with the specific timeframes for invoicing physician administration drugs, as required by the DRA. Furthermore, we recommend that the State agency generate and mail invoices to manufacturers for single source physician administered drugs for the quarter ended March 31, 1999 and report the information on the State agency's Form CMS-64.R, as required by the DRA and the State Medicaid Manual."

Response

The State of North Dakota will develop written policies and procedures surrounding the drug rebate program. These will include policies and procedures specific to invoicing for physician administered drugs, as required by the DRA. Since the time of the audit, the State of North Dakota has already generated and mailed invoices to manufacturers for single source physician administered drugs for the quarter ended March 31, 1999 and this information will be reported on the State agency's Form CMS-64.9R, as required by the DRA and the State Medicaid Manual.

Sincerely,

Brendan Joyce, PharmD
Administrator, Pharmacy Services