DEPARTMENT OF HEALTH & HUMAN SERVICES

Office of Inspector General
Office of Audit Services

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

July 28, 2003

Report Number A-07-03-04016

Mr. Rod Anderson, Administrator
Office of Recoveries and Fraud Investigations
Department of Social Services
700 Governors Drive
Pierre, South Dakota 57501

Dear Mr. Anderson,

Enclosed are two copies of the U.S. Department of Health and Human Services (HHS), Office of Inspector General, Office of Audit Service's (OAS) final report entitled *"Audit of the Medicaid Drug Rebate Program in South Dakota."*

The HHS action official named below will make final determination as to actions taken on all matters reported. We request that you respond to the HHS action 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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Sincerely,

Patrick Cogley For

James P. Aasmundstad
Regional Inspector General
for Audit Services

Direct Reply to HHS Action Official:

Mr. Alex Trujillo
Centers for Medicare and Medicaid Services
Regional Administrator, Region VIII
1600 Broadway, Suite 700
Denver, CO 80202

Enclosures—As stated

Department of Health and Human Services

OFFICE OF INSPECTOR GENERAL

AUDIT OF THE MEDICAID DRUG REBATE PROGRAM IN SOUTH DAKOTA

JULY 2003
A-07-03-04016

Office of Inspector General

http://oig.hhs.gov/

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THIS REPORT IS AVAILABLE TO THE PUBLIC
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In accordance with the principles of the Freedom of Information Act, 5 U.S.C. 552, as amended by Public Law 104-231, Office of Inspector General, Office of Audit Services, reports are made available to members of the public to the extent information contained therein is not subject to exemptions in the Act. (See 45 CFR Part 5.)

OAS FINDINGS AND OPINIONS

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

DEPARTMENT OF HEALTH & HUMAN SERVICES

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Report Number: A-07-03-04016

Mr. Rod Anderson, Administrator
Office of Recoveries and Fraud Investigations
Department of Social Services
700 Governors Drive
Pierre, South Dakota 57501

Dear Mr. Anderson:

This final report provides you with the results of our ***Audit of the Medicaid Drug Rebate Program in South Dakota.***

EXECUTIVE SUMMARY

OBJECTIVE

The audit objective was to evaluate whether the South Dakota Department of Social Services, Office of Recoveries and Fraud Investigations (State Agency) had established adequate accountability and internal controls over the Medicaid drug rebate program.

FINDINGS

Generally, the State Agency had adequate internal controls with regard to the Medicaid drug rebate program as required by Federal rules and regulations. However, we identified several areas that lacked sufficient internal controls. These areas included:

- Form CMS 64.9R and general ledger reconciliation.
- Write-offs.
- Interest accrual and collection.
- Tracking amounts related to $0 unit rebate amounts.
- Dispute resolution.

Federal regulations require effective control over and accountability for all funds, property and other assets. In addition, the rebate agreements between the Centers for Medicare and Medicaid Services (CMS) and the drug manufacturers require the payment of interest on all disputed, late, and unpaid drug rebates, as well as the use of the State hearings mechanism to resolve disputes.

In our opinion, these issues occurred because the State Agency did not develop or follow adequate policies and procedures with regard to the drug rebate program. As a result, the drug rebate receivables were perpetually understated and the lack of sufficient internal controls resulted in a potential risk for fraud, waste, or abuse of drug rebate program funds.

RECOMMENDATIONS

We recommend that the State Agency develop and follow policies and procedures that include:

- Reconciling the general ledger control account to the subsidiary ledgers/records and to the Form CMS 64.9R.
- Adhering to write-off thresholds established by CMS' program releases.
- Estimating and accruing interest on all overdue rebate balances.
- Tracking all $0 unit rebate amounts separately from disputed invoices.
- Offering the State's hearing mechanism to manufacturers to resolve disputes after 60 days.

The State Agency did not concur with the majority of our findings and recommendations. Their response is summarized after the recommendations section of the report and is included in its entirety in Appendix A.

Introduction

BACKGROUND

On November 5, 1990, Congress enacted the Omnibus Budget Reconciliation Act (OBRA '90) of 1990 legislation, which established the Medicaid drug rebate program. Responsibility for the rebate program is shared among the drug manufacturer(s), CMS, and the State(s). The legislation was effective January 1, 1991. The CMS also issued release memorandums to state agencies and manufacturers throughout the history of the rebate program to give guidance related to the Medicaid drug rebate program.

A manufacturer is required to have a rebate agreement in effect with CMS in order to have its products covered under the Medicaid program. The manufacturer is required to submit a listing to CMS of all covered outpatient drugs, and to report its average manufacturer price and best price information for each covered outpatient drug to CMS. Approximately 520 pharmaceutical companies participate in the program.

The CMS provides the unit rebate amount (URA) information to the State agency on a quarterly computer tape. However, the CMS tape may contain a $0 URA if the pricing information was not provided timely, or if the computed URA has a 50 percent variance from the previous quarter. 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. In addition, the manufacturers can change any URA based on updated pricing information, and submit this information to the State agency in a Prior Quarter Adjustment Statement (PQAS).

Each State agency is required to maintain drug utilization data for total units dispensed, by manufacturer, for each covered drug. That number is applied to the URA to determine the actual rebate amount due from each manufacturer. Each State agency is required to provide drug utilization data to the manufacturer and CMS on a quarterly basis. Approximately 56,000 National Drug Codes (NDC) are available under the program.

The manufacturer has 38 days to remit payment from the date an invoice is postmarked. The manufacturers provide the State agency with a Reconciliation of State Invoice (ROSI) detailing their payment by each NDC. A manufacturer can dispute utilization data that is believed to be erroneous, but the manufacturer is required to pay the undisputed portion by the due date. If the manufacturer and the State agency cannot in good faith resolve the discrepancy, the manufacturer must provide written notification to the State agency by the due date. If the State agency and the manufacturer are not able to resolve the discrepancy within 60 days, the State agency must make a hearing mechanism available under the Medicaid program to the manufacturer in order to resolve the dispute.

The manufacturer is required to calculate and remit interest for disputed rebates when settlement is made in favor of the State, and also when payments are late, or in some cases, not remitted. Tracking interest owed to the State agency is required by CMS. Furthermore, Governmental Accounting and Financial Reporting Standards require states to calculate and accrue a reasonable estimate of interest owed.

Each state agency reports, on a quarterly basis, rebate collections on the Form CMS 64.9R. This report is part of the Form CMS 64 report, which summarizes actual Medicaid expenditures for each quarter and is used by CMS to reimburse the Federal share of these expenditures.

The State Agency reported to CMS an uncollected rebate balance of $1,581,460 on the CMS 64.9R as of June 30, 2002. However, the general ledger did not support that figure. According to the general ledger $185,091 was outstanding for 90 days or longer. For the period July 1, 2001 through June 30, 2002, the State Agency reported rebate collections totaling $12,582,872.

OBJECTIVE, SCOPE AND METHODOLOGY

Objective

The audit objective was to evaluate whether the State Agency had established adequate accountability and internal controls over the Medicaid drug rebate program.

Scope

The drug rebate program became effective January 1, 1991. We concentrated our audit on current policies, procedures and controls that existed with regard to the State Agency. We examined uncollected rebate balances for the period January 1, 1991 through June

30, 2002. We also interviewed State Agency staff to understand how the Medicaid drug rebate program has operated for the year ending June 30, 2002.

Methodology

To achieve our objective, we reviewed the applicable Federal laws, regulations, and requirements including sections 1903 and 1927 of the Social Security Act, the Omnibus Budget Reconciliation Act of 1990 (OBRA 90) and the OMB Circular A-87.

We examined copies of the CMS 64.9R reports for the period July 1, 2001 through June 30, 2002 submitted to CMS by the State of South Dakota. We obtained and reviewed drug rebate accounts receivable records. Finally, we interviewed State Agency staff that performed functions related to the drug rebate program.

Our fieldwork was conducted at the State Agency office in Pierre, South Dakota, the week of December 16, 2002. Audit work continued in the Office of Audit Services field office in Omaha, NE through March 2003.

Our audit was conducted in accordance with generally accepted government auditing standards.

FINDINGS AND RECOMMENDATIONS

Generally, the State Agency had adequate internal controls with regard to the Medicaid drug rebate program as required by Federal rules and regulations. However, we identified several areas that lacked sufficient internal controls. These areas included:

- Form CMS 64.9R and general ledger reconciliation.
- Write-offs.
- Interest accrual and collection.
- Tracking amounts related to $0 unit rebate amounts.
- Dispute resolution.

INTERNAL CONTROLS

CMS 64.9R Reconciliation

The State Agency did not perform a reconciliation to verify the accuracy of the uncollected rebate balance reported on the Form CMS 64.9R as required by Federal regulations. The State Medicaid Manual sect. 2500.7 paragraph B, requires "...a complete, accurate, and full disclosure of all of your pending drug rebates and collections."

The Form CMS 64.9R is prepared by the Finance Department from various reports provided by the State Agency. However, prior period adjustments had not been input into the general ledger account because there were no instructions in the State Agency's

accounting manual on how to do so. Routine reconciliations of the general ledger to the subsidiary records would have identified the discrepancy.

In addition, the amounts reported on the CMS 64.9R should have been compared to the amounts reported in the subsidiary and general ledgers, providing additional verification of the amounts reported to CMS. That additional step would provide assurance that all necessary reports were used to compile the information reported on the form.

As a result, the State Agency did not report accurate information on the CMS Form 64.9R. Although the RFI reported $1,581,460 to the CMS as the outstanding accounts receivable balance as of June 30, 2002, that figure was not accurate, as routine adjustments to the subsidiary accounts were not being made.

Write-offs

The State Agency has written-off $2.3 million since the Medicaid drug rebate program was implemented in 1991. Of that amount, all but $1,200 was for the years prior to 1998.

The CMS allowed states to apply a $10 threshold for invoicing manufacturers under the premise that it would cost more than that to process the invoice and payment. Likewise, the CMS allowed a $50 threshold for processing adjustments made for changes in utilization. In either case, the State Agency was required to maintain detailed documentation for the application of either threshold. There were no provisions to write-off receivables the State Agency decided they did not want to pursue.

During the years 1991 through 1997, the State Agency did not have separate codes to indicate whether entries were made for normal adjustments or for amounts they deemed uncollectible. Research conducted by the State Agency subsequent to the issuance of our draft audit report indicated that more than $1.9 million of the $2.3 million in write-offs were normal adjustments. However, during that period, the number and size of the adjustments indicate the State Agency may have written-off the remainder of the receivables in order to clear the books of amounts they deemed uncollectible.

As a result, there may have been additional drug rebate receivables that should have been collected through the dispute resolution process.

Interest on Late, Disputed, and Unpaid Rebates

The State Agency did not have adequate procedures to accrue interest for late, disputed or unpaid rebate payments as required by Federal rules and regulations. The State Agency calculated interest owed to them and sent up to two letters notifying manufacturers that they owed interest. However, they did not accrue interest for late or disputed payments as required by Federal regulations, nor did they recalculate interest paid by manufacturers to verify that the correct amounts were paid.

According to CMS Medicaid Drug Rebate Program Release #65, it is the manufacturers' responsibility to calculate and pay interest for applicable rebate invoices and the State's responsibility to track collections and report those amounts to CMS. In addition, Program Release #29 requires that interest must be collected and cannot be disregarded as part of the dispute resolution process by either the manufacturer or the State. Finally, Governmental Accounting and Financial Reporting standards require the States to accrue revenue (interest) when it is measurable (a reasonable estimate) and available.

Because the State Agency did not accrue revenue as required, the drug rebate receivables were perpetually understated, and it is likely that they did not receive all interest owed by the manufacturers. Since 1991, the State Agency has collected $16,053 for interest through June 30, 2002.

$0 Unit Rebate Amounts

Although the State Agency made an effort to bill for unpaid $0 URA's, it did not effectively track them. When the State did not receive payment for a billed $0 URA, the State Agency sent the manufacturer a delinquency letter and listed it as "? RPU" (Rebate Per Unit) on a spreadsheet with disputed amounts. It was not possible to determine which invoices were disputed and which contained unpaid $0 URA's without reviewing each invoice in the hardcopy file. At a minimum, the State Agency should have listed the $0 URA items separately in order to identify the number of items and actual NDC's that were not calculated and paid by the manufacturer as required.

The Code of Federal Regulations, Title 45 Sec. 74.21 paragraph (b)(3) requires states to adequately safeguard assets. According to CMS Medicaid Drug Rebate Program Release #33, States are required to include $0 URA's on the quarterly invoices sent to the manufacturers. Manufacturers are required to calculate the correct URA and remit the appropriate rebate to the State. In many cases, the manufacturer does not comply, requiring the State Agency to track those amounts until payment is made in order to adequately safeguard assets.

As a result, the drug rebate receivables were perpetually understated and it is likely that the State Agency did not receive all drug rebate payments due from manufacturers.

Dispute Resolution

The State Agency did not offer manufacturers the option to utilize the State hearing mechanism for resolving disputes as required by the rebate agreement. Specifically, the agreement requires that the states and the manufacturers resolve rebate discrepancies within 60 days of receipt of notification of a dispute. It further states, "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's hearing mechanism available under the Medicaid program."

The State Agency did not establish procedures to incorporate the State's hearing mechanism into their dispute resolution process. Instead, they contacted manufacturers directly and attended Dispute Resolution Project (DRP) meetings. Because manufacturers were not required to attend DRP meetings, there were no incentives for them to resolve claims and there were no other sanctions provided in the regulations.

Therefore, we believe the State Agency could increase its drug rebate collections by offering the State's hearing mechanism to manufacturers when disputes are not settled within 60 days.

RECOMMENDATIONS

We recommend that the State Agency develop and follow policies and procedures that include:

- Reconciling the general ledger control account to the subsidiary ledgers/records and to the Form CMS 64.9R.
- Adhering to write-off thresholds established by CMS' program releases.
- Estimating and accruing interest on all overdue rebate balances.
- Tracking all $0 unit rebate amounts separately from disputed invoices.
- Offering the State's hearing mechanism to manufacturers to resolve disputes after 60 days.

AUDITEE RESPONSE AND OIG COMMENTS

The State Agency did not concur with all of our findings and recommendations. Their comments are summarized below and included in their entirety as Appendix A.

1) **Reconciling the general ledger control account to the subsidiary ledgers/records and to the Form CMS 64.9R.**

Auditee Response:

The State Agency has taken appropriate corrective action.

2) **Adhering to the write-off thresholds established by CMS' program releases.**

Auditee Response:

The State Agency responded that our finding was "incorrect, misleading and not based on any factual finding." They did not agree that the size and number of adjustments indicated they may have written-off receivables in order to clear their books. After the State received our draft audit report, the State Agency researched $2.1 million in adjustments that were recorded between 1991 and 1998. In their response to our draft report, the State provided a summary of their research.

The State asserted that only $222,423 of the $2.1 million adjustments was actually written off and the remaining $1.9 million was appropriate adjustments. The research was necessary because prior to 1998 the State's subsidiary accounting system did not have the capability to separate write-offs and adjustments.

OIG Comments:

Our finding was based on the following facts:

1. In an April 25, 2003 teleconference with the OIG, State Agency officials acknowledged that it was likely that amounts were written-off to clear the books prior to 1998.

2. The State Agency reported no outstanding drug rebate balances prior to June 1997. Other States routinely reported balances dating back to 1991 due to the fairly restrictive CMS write-off procedures.

3. The State Agency reported $2.3 million in adjustments and all but $1,200 of those adjustments occurred prior to 1998.

4. The State Agency did not have supporting documentation readily available for adjustments without manually researching each one individually.

5. The average adjustment was hundreds of dollars higher prior to 1998, indicating that most write-offs far exceeded the $50 threshold established by CMS.

We commend the State Agency for researching their adjustments and providing that information with their response. Since that documentation was not made available to us during our review, we were unable to verify the accuracy of their reports or determine the extent to which they were supported by sufficient documentation.

We also observed that these adjustments occurred under previous State Agency official's oversight and the State Agency's records indicate that they no longer routinely write-off significant amounts that are disputed.

The additional documentation provided by the State Agency subsequent to our audit further supported our findings. Narratives provided as part of that documentation indicated that the State Agency routinely avoided pursuit of disputes where the NDC line item questioned was less than $1000. The CMS' program release #19 does establish a $1000 threshold for not continuing the *pursuit* of disputes under the following requirements:

Steps in the Dispute Resolution

The following instructions are the steps that the dispute shall follow to reach a resolution.

1. Within 30 days of receipt of State utilization data, the manufacturer must pay rebates on all undisputed data. Within the same timeframe, if a manufacturer disputes specific utilization data, the manufacturer must identify by individual national drug code (NDC) the utilization data in question, specific reasons why that data is in question, and notify the State in writing, also within 30 days of receipt of the data.

2. Within the 30-day period, we encourage the manufacturers to distinguish between data inconsistencies and legitimate disputes. For inconsistencies involving, for example, unit types and incorrect NDCs the manufacturers should contact the State as soon as possible to determine the proper corrective action and attempt to resolve the dispute without further dispute resolution procedures (the disputed resolution timeframes and procedures apply, however, if informal negotiations do not resolve the problem).

3. The State must take steps to resolve the questionable data. The State may provide zip-code level data which the manufacturer will compare with its records to identify discrepancies. When pharmacy level data is requested the State may submit its State pharmacy data for comparison with the manufacturer's pharmacy data or, if State confidentiality laws prohibit the release of such information, request that the manufacturer make its data available to the State for comparison. If requested by the manufacturer, a State may opt to conduct sampling of a particular drug's utilization data to detect and resolve problems.

4. States must ensure that any exchange of data protects the confidentiality requirements of Section §1927(b)(3)(D) of the Social Security Act. That is, a particular manufacturer's identity and pricing data must not be disclosed by the State to outside parties, including resource information services.

Under section VII(b) of the rebate agreement, data released to the manufacturer by the State shall also be held confidential by the manufacturer.

5. Provided the State makes available zip-code data, pharmacy specific data, or other suitable data in response to the manufacturer, the State may consider cost effectiveness in deciding to pursue any remaining items in dispute.

In any quarter, States need not enter into further dispute resolution processes with a manufacturer if the disputed amount is: under $10,000 per manufacturer and under $1,000 per product code.

States maintain discretion to enter into the dispute resolution process in cases that fall below these thresholds.

As stated above in part 5, the State Agency was required to provide suitable data to the manufacturer in an effort to resolve the dispute before abandoning collection efforts.

None of the narratives indicated that such information was provided. In fact, the narratives, and in some cases the dates listed for billing and write-offs, indicated that the $1,000 threshold was routinely applied without making any collection effort whatsoever. For example, one narrative for a $2,489 write-off stated,

> ***"Rec'd pmnt for $11,184.23 Company disputed several NDCs for utilization. Dispute amounts are less than $1000 per NDC and less than $10,000 per labeler code and therefore will not be pursued.***

Another narrative described disputed NDC's as:

> **"...each was below the 1000.00 per NDC amount we use in determining whether be pursued or not."**

Clearly, the threshold established in program release #19 was not intended as a cut-off point for write-off authority. It did establish parameters for States to make a *reasonable* decision considering unresolved disputes with regard to the cost effectiveness of pursuing collections. However, no evidence was provided that indicated such consideration was made in their application of the provision.

Therefore, we believe the finding is accurate. Prior to 1998, the State Agency not only wrote-off amounts they deemed uncollectible, but also routinely wrote-off receivables without a reasonable collection effort and without complying with the requirements established in program release #19.

3) Estimating and accruing interest on all overdue rebate balances.

Auditee Response:

The State Agency contended that it does collect interest if it exceeds the $50 tolerance threshold allowed by CMS and they do not disregard interest in the dispute resolution process. They do not recalculate amounts paid, nor do they track interest owed, due to the lack of staff resources.

OIG Comments:

We believe that the accrual of interest is necessary because it would be difficult to determine whether the $50 threshold was met without calculating the amount. We further believe the State Agency should not accept an interest payment from a manufacturer as payment in full without determining the accuracy of the payment. We recognize that the drug rebate interest calculation is complex due to the weekly changes in interest rates. In fact, due to the complexity of the calculation, it is important for the State to verify the accuracy of the manufacturers' payments. Without comparing the interest paid by the manufacturer to the interest owed by the manufacturer, the State Agency does not have reasonable assurance that the manufacturer has complied with the terms of the rebate agreement.

4) Tracking all $0 unit rebate amounts separately from disputed invoices.

Auditee Response:

The State Agency did not concur with our finding. They stated that they do track $0 URA's on a spreadsheet and that all $0 URA amounts have been paid except for 189 that were billed in the fourth quarter of 2002.

OIG Comments:

The State Agency did not adequately track $0 URA's on their subsidiary spreadsheet. As we stated in the report, $0 URA's were recorded on a spreadsheet with disputed amounts. They were designated as "? RPUS" or "? NO RPUS." The figures cited in their response were not determinable from that spreadsheet but required researching individual invoices. We commend the State Agency for conducting that research subsequent to our audit.

The State Agency stated in their response, "All $0 URA's are billed and kept on the subsidiary system as unpaid until either paid or a dispute resolution occurs." Unpaid URA'S are not considered as disputed unless the manufacturer, as required for any other dispute, has presented proper notification.

Absent such notification, the unpaid URA amount should be treated as an unpaid item subject to interest. To facilitate collection efforts, the State Agency should routinely maintain a listing of $0 URA's by NDC and manufacturer to ensure proper tracking of these amounts and proper notification to the manufacturer as an unpaid item subject to interest. Likewise, disputed $0 URA items should be treated as any other dispute.

The figures presented in your response do not distinguish between disputed URA's and unpaid or delinquent URA's, nor is that information discernable from the subsidiary records. Therefore, we believe it is likely that the State Agency did not receive all rebates and interest on disputed or late rebate payments from manufacturers.

5) Offering the State's hearing mechanism to manufacturers to resolve disputes after 60 days.

Auditee Response:

The State Agency did not concur with our finding. They asserted that participation in the DRP was an adequate method to resolve any disputes and met guidelines issued by CMS. In addition, they question the cost effectiveness of using the State's hearing mechanism.

OIG Comments:

We recognize that DRP meetings are a valuable tool for the resolution of disputes. However, as stated in the State Agency's response, CMS' best practices guidelines

"require that the States' hearing mechanism be initiated" after exhausting all DRP efforts. Therefore, the State Agency did not meet the guidelines issued by CMS.

Regardless, the rebate agreement represents a binding, legal contract between the Federal Government, States and the drug manufacturers. That rebate agreement states that, "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's hearing mechanism available under the Medicaid Program."

Some manufacturers interpret this provision to mean that disputes are automatically resolved in their favor if states do not formally respond to their written disputes within 60 days, or offer a hearing. Therefore, we believe, at a minimum, the DHS should offer the State's hearing mechanism to settle disputes when the State has received a written notice of dispute from a manufacturer.

Sincerely,

James P. Aasmundstad
Regional Inspector General
for Audit Services

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June 16, 2003

James P. Aasmundstad, Regional Inspector General for Audit Services
Department of Health & Human Services
Office of Inspector General, Office of Audit Services
601 East 12th Street
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Kansas City, Missouri 64106

Re: Draft Audit Report A-07-03-04016

Dear Mr. Aasmundstad

Attached is the South Dakota response to the draft audit findings on the Drug Rebate Program. First we would like to question whether this was an audit or a review. At the entrance conference and again at the exit conference the OIG Audit staff made it quite clear that this was a review, not an audit. It was said to be a review of internal controls.

Regarding the findings, we noted several inaccuracies and errors in the finding statements in the draft. We feel these misstatements are largely due to the fact that the Auditors did not understand the drug rebate system and procedures utilized in South Dakota. We are hopeful our comments will be reflected in any further review and revision of the report.

If you have any questions let me know.

Rod Anderson, Administrator
Office of Recoveries & Fraud Investigations
Department of Social Services
700 Governors Drive
Pierre, SD 57501

AUDIT OF THE MEDICAID DRUG REBATE PROGRAM IN SOUTH DAKOTA

Executive Summary Page 1.

1. Finding: In the last paragraph on page one the draft report states "In our opinion, these issues occurred because the State Agency did not develop or follow adequate policies and procedures with regard to the drug rebate program. As a result, the drug rebate receivables were perpetually understated and the lack of sufficient internal controls resulted in a potential risk for fraud, waste, or abuse of the drug rebate funds."

Response: South Dakota follows the CMS Drug Rebate Operational Guide issued September 2001 and the Drug Rebate Program releases issued. The guide was specifically developed for states to utilize in the operation of the drug rebate program. That guide is our policy and procedure as are the numbered releases that provide additional guidance. We do not feel there is a lack of internal controls in the program and there is no indication of any fraud, waste or abuse.

Findings and Recommendations, Internal Controls, CMS 64.9R Reconciliation, p. 4 & 5.

2. Finding: In the last paragraph on page 4 it states "However, prior period adjustments had not been input into the general ledger account because there were no instructions in the State agency's accounting manual on how to do so. Routine reconciliations of the general ledger to the subsidiary records would have identified the discrepancy."

Response: The finding quoted above is incorrect. Prior period adjustments are not entered in the general ledger in Finance. The general ledger only reflects cash collections and any refunds. Prior period adjustments are done on the subsidiary records and those amounts are reported to Accounting and Financial Reporting staff to be included on the CMS 64.9R. The problem identified as a result of the Auditors' review was that since April of 2001, not all prior period adjustments were being picked up from the subsidiary records and reported in the CMS 64.9R. Thus the CMS 64.9R was inaccurate until the onsite review in December 2002. The corrections were made and reflected in the CMS 64.9R submitted in January, 2003.

The instructions for preparing the CMS 64.9R have also been updated and clarified to avoid any future problems. All CMS 64.9R prior period adjustment data is now properly reconciled with subsidiary records. The general ledger records are also reconciled with the subsidiary records. Thus, the findings regarding the CMS 64.9R report have been corrected.

Write-offs, page 5.

3. Finding: The first statement says "The State Agency has written-off $2.3 million since the Medicaid Drug rebate program was implemented in 1991."

Response: The above statement is incorrect. It was explained to the Auditors that the subsidiary accounting system did not have a debt adjustment recording capability prior to 1998 so debt adjustments were not clearly identified or separated from write-offs without a review of each case narrative to determine why the case was "written off". However, on February 28, 2003, data was submitted to OIG Parker showing drug rebate write-offs by year which totaled $2.3 million. We gave examples of two of those cases totaling over $1 million that were Drug Manufacturer errors in what they reported to HCFA and were appropriately adjusted on our subsidiary system, not written off. That information is not reflected in the draft findings.

Since it was apparent to us the OIG felt we were writing off cases that could be collected we have since reviewed every alleged write-off over $1,000 from 1991 through 1998 to determine which were actually written off and which were actually appropriate debt adjustments due to billing errors, price adjustments, etc. We looked at a total of $2.1 million debt records. Of that, $1,907,541.90 was actually an appropriate debt adjustment and only $222,422.92 was actually written off from 1991 through 1998. A copy of that research is attached. It identifies the debt and includes a narrative explaining the adjustment for each debt.

4. Finding: The second paragraph states "The CMS allowed states to apply a $10 threshold for invoicing manufacturers under the premise that it would cost more than that to process the invoice and payment."

Response: The above statement is incorrect. CMS allows a $50 tolerance threshold per labeler to its current quarter invoice. The CMS operations guide allows states to go below that threshold and South Dakota chose to set a $10 threshold.

5. Finding: The third paragraph under write-offs states "However, during that period, the number and size of the adjustments indicate the State Agency may have written-off receivables in order to clear the books of amounts they deemed uncollectible."

Response: That statement is incorrect, misleading and not based on any factual finding. As indicated in our data taken from the actual records, write-offs are minimal. There is no data to support the finding that the State "may" have written off receivables in order to clear the books.

Interest on Late, Disputed, and Unpaid Rebates, page 5 & 6.

6. Finding: The first paragraph states "However, they did not accrue interest for late or disputed payments as required by Federal regulations, nor did they recalculate interest voluntarily paid by manufacturers to verify that the correct amounts were paid." The finding goes on to state "In addition, Program Release #29 requires that interest must be collected and cannot be disregarded as part of the dispute resolution process by either the manufacturer or the state."

Response: South Dakota does collect interest for late payments above the $50 tolerance level per labeler per quarter as provided in the CMS operations guideline. We do not recalculate the interest paid. Manufacturers do not voluntarily pay, they are required to pay. We do not disregard interest in the dispute resolution process. We collect interest on all dispute settlements. However, we do not accrue interest under $50 on late payments. It is not cost effective for the state to fully track interest because of the minimal recovery potential. We also do not have the staff resources to do so.

$0 Unit Rebate Amounts, page 6.

7. Finding: The finding states "Although the State Agency made an effort to bill for unpaid $0 URA's, it did not adequately track them." It goes on "According to CMS Medicaid Drug Rebate Program Release #33, States are required to include $0 URA's on the quarterly invoices sent to the manufacturers." The finding concludes "it is likely that the state agency did not receive all drug rebates and interest on disputed or late rebate payments due from manufacturers."

Response: This finding is inaccurate. We bill for all $0 URA's and track them. We keep a spreadsheet that tracks all unpaid $0 URA's. All $0 URA's are established as debts on our subsidiary system. Delinquency notices are sent as appropriate. As an example, for the fourth quarter of 2002 we invoiced a total of 7,408 NDC's. Of that total, 1121 or 15% were invoiced at $0 URA's. All $0 URA's are billed and kept on the subsidiary system as unpaid until either paid or a dispute resolution occurs. To date, all but 189 of the $0 URA's for the fourth quarter of 2002 have been paid and these will receive delinquency notices. No $0 URA's are ignored. There is no data to support this finding. We disagree with this finding.

Dispute Resolution, page 6 & 7.

8. Finding: The finding states that because we do not utilize the State hearing mechanism for dispute resolution, we may not be collecting some disputed claims. It also states the drug rebate agreement says CMS shall require the State to make available to the manufacturer the State's hearing mechanism.

Response: We utilize the dispute resolution project (DRP) meetings to handle dispute resolutions. Utilizing those meetings to work out disputes with manufacturers on an ongoing basis we have kept unresolved disputes at a minimum. The assumption is that a state hearing decision would result in payment. The fact is that a hearing decision carries no sanction and can be appealed to higher courts. In our opinion, utilizing the State hearing mechanism for dispute resolution would not be cost effective. In addition, the HCFA publication, Best Practices for Dispute Resolution under the Medicaid Drug Rebate Program, states "If disputes remain unresolved and stalemated after exhausting DRP efforts, HCFA should require that the States' hearing mechanism be initiated." We feel our present methods of dispute resolution are adequate and within the guidelines recommended by HCFA (CMS) publications.

Recommendations, page 7.

- Reconciling the general ledger control account to the subsidiary ledgers/records and to the Form CMS 64.9R. *This was corrected with the January 2003 report and has been completed.*
  Adhering to write-off thresholds established by CMS' program releases. *This is done in South Dakota.*
  Estimating and accruing interest on all overdue rebate balances. *This is done in the most cost effective manner possible in South Dakota as indicated in our response.*
  Tracking all $0 unit rebate amounts separately from disputed invoices. *Given our sudsidiary accounting system we do not feel this is necessary. We track all $0 URA's as indicated in our response.*
  Offering the State's hearing mechanism to manufacturers to resolve disputes after 60 days. *We do not utilize this mechanism and question the cost effectiveness of doing so. We feel our existing methods are adequate.*

We question the overall conclusion in the draft findings that South Dakota lacks sufficient internal controls in the specified areas. We do not feel the data or the drug rebate procedures followed in South Dakota support that conclusion.

Sincerely;

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ACKNOWLEDGEMENTS

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