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

AUG 1 3 2008

Report Number: A-07-08-03110

Ms. Deborah K. Bowman
Secretary
South Dakota Department of Social Services
700 Governors Drive
Pierre, South Dakota 57501-2291

Dear Ms. Bowman:

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 South 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 at (816) 426-3591, 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-07-08-03110 in all correspondence.

Sincerely,

for 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 SOUTH DAKOTA

Daniel R. Levinson
Inspector General

August 2008
A-07-08-03110

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 South Dakota, the Department of Social 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 South Dakota drug rebate program (A-07-03-04016), we determined the State agency lacked sufficient internal controls over its Medicaid drug rebate program as required by Federal rules and regulations. Areas that lacked sufficient internal controls included: dispute resolution, Form CMS-64.9R and general ledger reconciliations, write-off adjustments, the tracking of amounts related to $0 unit rebate amounts (URA), and interest accrual and collection. (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 include:

- offering the State's hearing mechanism to manufacturers to resolve disputes after 60 days;
- 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's program releases;
- tracking all $0 URAs separately from disputed invoices; and
- estimating and accruing interest on all overdue rebate balances.

The State agency did not concur with the majority of our findings and recommendations.

This current review of the South 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 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 South Dakota drug rebate program and (2) established controls over the drug rebate program, including collection of rebates on single source drugs administered by physicians.

SUMMARY OF FINDINGS

The State agency partially corrected some of the weaknesses reported in our prior audit. The State agency had corrected the weakness relating to interest accrual and collection. However, it had not corrected the finding concerning offering the State's hearing mechanism to manufacturers to resolve disputes after 60 days. Also, the State agency only partially corrected the finding concerning tracking $0 URAs.

Additionally, the State agency: (1) did not apply drug manufacturers' adjustments to the National Drug Code (NDC) level; (2) had policies and procedures for write-offs, but did not follow all of CMS's guidance in that regard; (3) did not ensure that information on $0 URAs paid by manufacturers to the State agency agreed with information on $0 URAs that the manufacturers provided to CMS; and (4) misreported $35,491 in drug rebates for (a) family planning, (b) the State Children Health Insurance Program (SCHIP), and (c) breast and cervical cancer.

The State agency established controls over invoicing rebates on single source drugs administered by physicians.

RECOMMENDATIONS

We continue to recommend that the State agency develop and follow policies and procedures that include offering the State hearing mechanism to manufacturers to resolve disputes after 60 days.

We also recommend that the State agency:

- ensure that prior period adjustments are made to the NDC level;

- update current policies and procedures and develop and document additional policies and procedures:

- for write-off adjustments, to apply CMS's tolerance threshold for continuing with dispute resolution only after information has been exchanged and an attempt to resolve errors with manufacturers has occurred;

- for $0 URAs, to ensure that information on $0 URAs paid by manufacturers to the State agency agrees with the URA information provided by manufacturers to CMS to update the CMS quarterly drug tape; and

- reimburse the Federal Government $35,491 (Federal share) relating to misreporting drug rebates for family planning, SCHIP, and breast and cervical cancer, and ensure that all drug rebate activity is accurately allocated on the Form CMS-64, "Quarterly Medicaid Statement of Expenditures for the Medical Assistance Program."

STATE AGENCY COMMENTS AND OFFICE OF INSPECTOR GENERAL RESPONSE

In written comments on our draft report, the State agency said that it "agrees in part" with our finding and recommendation on the need to offer the State hearing mechanism to manufacturers to resolve disputes after 60 days, and it concurred with all of our other findings and recommendations. For the findings and recommendations with which the State agency concurred, its written comments included a discussion of implementation and corrective actions proposed. The State agency's comments are included in their entirety as the Appendix.

After reviewing the State agency's comments, we continue to support our findings and recommendations.

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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 South Dakota, the Department of Social Services (the State agency) administers the Medicaid drug 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" (CMS-64 report), 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 South Dakota, physician-administered drugs are billed to the State Medicaid program on a physician claim form. The State agency uses the Form CMS-1500 as the physician claim form. In addition, the State agency receives electronic claims by either the Form Health Insurance Portability and Accountability Act (HIPAA)-837P, for professional claims, or the Form HIPAA-837I, for institutional claims. Both forms use the procedure codes that are part of the Healthcare Common Procedure Coding System (HCPC). The HCPC 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 South Dakota drug rebate program, we determined the State agency lacked sufficient internal controls over its Medicaid drug rebate program as required by Federal rules and regulations. Areas that lacked sufficient internal controls included: dispute resolution, Form CMS-64.9R and general ledger reconciliations, write-off adjustments, the tracking of amounts related to $0 URAs, and interest accrual and collection.[3]

We recommended that the State agency develop and follow policies and procedures that include:

- offering the State's hearing mechanism to manufacturers to resolve disputes after 60 days;
- 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's program releases;

[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 South Dakota" (A-07-03-04016), issued July 28, 2003.

- tracking all $0 URAs separately from disputed invoices; and

- estimating and accruing interest on all overdue rebate balances.

The State agency did not concur with the majority of our findings and recommendations.

South Dakota Drug Rebate Program

The State agency was responsible for performing all drug rebate program functions. Its responsibilities included (1) monitoring and maintaining the drug rebates accounts receivable, to include posting payments to subsidiary ledgers; (2) monitoring outstanding balances; (3) resolving disputes; and (4) depositing funds and preparing the CMS-64 reports mentioned earlier. Additionally the State agency was responsible for administering the physician-administered drug rebates.

The State agency reported an outstanding drug rebate balance of $8,204,672 on the June 30, 2006, Form CMS-64.9R. However, $3,607,071 of this amount related to quarterly billings and was not past due as of June 30, 2006. Of the remaining $4,597,601 that was past due, $492,707 was more than 1 year past due. For the fiscal year ended June 30, 2006, the State agency reported rebate billings of approximately $20 million and collections of approximately $18.5 million.

This current review of the South 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 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 South Dakota drug rebate program and (2) established controls over the drug rebate program, including 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 in Pierre, South Dakota, during April and May 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 report concerning the drug rebate program in South Dakota;

- reviewed the policies and procedures relating 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 copies of Form CMS-64.9R for the quarter ending March 31, 2008;

- reviewed accounts receivable records for the State fiscal year ended June 30, 2006; and

- 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.

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 corrected some of the weaknesses reported in our prior audit. The State agency had corrected the weakness relating to interest accrual and collection. However, it had not corrected the finding concerning offering the State's hearing mechanism to manufacturers to resolve disputes after 60 days. Also, the State agency only partially corrected the finding concerning tracking $0 URAs.

Additionally, the State agency: (1) did not apply drug manufacturers' adjustments to the NDC level; (2) had policies and procedures for write-offs, but did not follow all of CMS's guidance in that regard; (3) did not ensure that information on $0 URAs paid by manufacturers to the State

agency agreed with information on $0 URAs that the manufacturers provided to CMS; and (4) misreported $35,491 in drug rebates for (a) family planning, (b) the State Children Health Insurance Program (SCHIP), and (c) breast and cervical cancer.

The State agency established controls over invoicing rebates on single source drugs administered by physicians.

IMPLEMENTATION OF PRIOR RECOMMENDATIONS

In our prior audit of the South Dakota drug rebate program, we determined the State agency lacked sufficient internal controls over its Medicaid drug rebate program as required by Federal rules and regulations. Areas that lacked sufficient internal controls included: dispute resolution, Form CMS-64.9R and general ledger reconciliations, write-off adjustments, the tracking of amounts related to $0 URAs, and interest accrual and collection.

Since then, the State agency has taken action to correct the weaknesses related to our prior findings. However, in some cases the action taken was not sufficient to correct the problem.

Dispute Resolution

In our prior audit, the State agency did not offer manufacturers the option to utilize the State agency's hearing mechanism for resolving disputes as required by the rebate agreement. Instead, the State agency contacted manufacturers directly and utilized Dispute Resolution Program meetings. In its comments on our prior audit finding, the State agency contended that its method of dispute resolution was adequate and within the guidelines recommended by CMS publications.

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 . . . ."

During this current audit, we noted that although the State agency developed policies and procedures for dispute resolution, these procedures do not have steps to offer the State agency's hearing mechanism for disputes that remain unresolved after 60 days.

Form CMS-64.9R and General Ledger Reconciliation

In our prior audit, we noted that the State agency did not perform a reconciliation to verify the accuracy of the uncollected rebate balance or collections reported on the Form CMS-64.9R as required by Federal regulations. In South Dakota, 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 for that procedure in the State agency's accounting manual. Routine reconciliations of the general ledger to the subsidiary records would have identified the fact that prior period

adjustments had not been input into the general ledger account. In addition, the amounts reported on the Form 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.

In its comments on our prior audit finding, the State agency did not agree that the finding was correct. It stated, "[p]rior period adjustments are not entered in the general ledger in Finance [department] . . . . 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."

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 report] 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 . . . [p]ermit the tracing of funds to a level of expenditures adequate to establish that such [Medicaid] funds have not been used in violation of the restrictions and prohibitions of applicable statutes."

During our fieldwork for this current audit, the State agency informed us that its current procedures for reconciling the Form CMS-64.9R have changed since the end of the current audit period. Therefore, we reviewed the reconciliation of the Form CMS-64.9R for the quarter ending March 31, 2008. We noted that the State agency prepared reconciliations of the subsidiary accounts receivable system, cash payments, and adjustment reports to the Form CMS-64.9R. However, during the review process we found that prior period adjustments were only applied at the invoice level and not at the NDC level. State agency officials are aware of this issue and say that they intend to correct it with the implementation of a new Medicaid Management Information System.

Write-off Adjustments

In our prior audit, we noted that the State agency had written off approximately $2.3 million since the Medicaid drug rebate program was implemented in 1991. 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 it deemed uncollectible. Although the State agency was able to determine that approximately $1.9 million of the approximately $2.3 million in write-offs were for normal adjustments, the number and size of the adjustments indicated that it may have written off the remainder of receivables in order to clear the books of amounts it deemed uncollectible. As a result, there may have been additional drug rebate receivables that should have been collected through the dispute resolution process.

In its comments on our prior audit finding, the State agency did not agree with this finding. It stated that the subsidiary accounting system did not have a debt adjustment recording capability prior to 1998; consequently, debt adjustments could not be clearly identified or separated from

write-offs without a review of each case narrative to determine why the case was written off. The State agency said that it reviewed every write-off over $1,000 from 1991 through 1998 to determine which amounts were actually written off and which were adjustments.

Medicaid Drug Rebate Program Release Number 44 states that ". . . States may apply a $50 tolerance per [manufacturer] for adjustments due to utilization changes."

Medicaid Drug Rebate Program Release Number 45 states that "[i]f the exchange of information fails to resolve dispute, and the disputed amount is BOTH: under $10,000 per [manufacturer's] labeler code, AND under $1,000 per product code of [manufacturer's] labeler code (at 9-digit NDC level) the State may choose to cease the dispute process."

During our fieldwork for this current audit, the State agency informed us it had not written off any amounts during our audit period, but was maintaining write-offs in a database. The State agency provided a list of the write-offs for calendar years 2006 and 2007 with a narrative of the write-offs. After reviewing the adjustments, we determined the amounts were under the threshold set by CMS of $50 per manufacturer for adjustments due to utilization changes. Accordingly, the State agency was making write-off adjustments pursuant to CMS guidelines.

However, the State agency would not have been making those adjustments correctly if it had been actually following its written policies and procedures for write-off adjustments. These written policies and procedures indicated that "No dispute resolution necessary per CMS" for amount less than $1,000 per NDC or $10,000 per manufacturer. Pursuant to Medicaid Drug Rebate Program Release Number 45, this threshold should only be applied if the exchange of information fails to resolve the dispute over units invoiced. Therefore, the State agency is not allowed to use the $1,000 per NDC or $10,000 per manufacturer threshold unless the State is unable to resolve the dispute by exchanging information with manufacturers. Because the State agency's written policies and procedures for write-off adjustments do not conform to CMS guidelines, those policies and procedures should be revised.

Tracking Amounts Related to $0 Unit Rebate Amounts

In our prior audit, we noted that the State agency made an effort to bill for unpaid $0 URAs, but it did not effectively track them.[4] When the State agency did not receive payment for a billed $0 URA, the State agency sent the drug manufacturer a delinquency letter and listed it as "? RPU" (Rebates Per Unit) on a spreadsheet with disputed amounts. Our prior audit report noted that it was not possible to determine which invoices were disputed and which contained unpaid $0 URAs without reviewing each invoice in the hardcopy file. In its comments on our prior audit, the State agency disagreed with this finding. It said that it maintained a spreadsheet that tracked all unpaid $0 URAs.

According to Medicaid Drug Rebate Program Release Number 33, ". . . data records containing zeroes in the URA are valid NDCs that are to be invoiced to the drug [manufacturers]. The drug

[4]The term "$0 URAs" refers to drugs included on CMS's quarterly Medicaid drug data tape, distributed to the States, that lack pricing information.

[manufacturers] continue to be responsible for computing the correct URA for each of their NDCs and must perform this function even when their prices are not submitted timely to [CMS]."

Federal regulations at 45 CFR § 92.20(a) state: "Fiscal control and accounting procedures of the State, as well as its subgrantees . . . must be sufficient to . . . [p]ermit the tracing of funds to a level of expenditures adequate to establish that such [Medicaid] funds have not been used in violation of the restrictions and prohibitions of applicable statutes."

During this current audit, we noted that the State agency rebated for NDCs that had $0 URAs and maintained this information in a spreadsheet. After manufacturers made payments to the State agency, the State agency updated the spreadsheets to indicate the manufacturers' URA. However, the State agency did not compare this information to the $0 URA information that the manufacturers reported to CMS (information that would ultimately be used to update the CMS quarterly drug tape). Pursuant to the Federal regulations quoted above, the State agency was responsible to perform this comparison, which was necessary to ensure that the $0 URA information the manufacturers provided (along with $0 URA payments) to the State agency agreed with the $0 URA information the manufacturers provided to CMS. Without performing this comparison, the State agency could not ensure that manufacturers were correctly paying $0 URAs to the State agency.

Additionally, although State agency personnel were employing policies and procedures to invoice for and track $0 URAs, those policies and procedures used were not documented in writing.

DRUG REBATE REPORTING FOR FAMILY PLANNING, STATE CHILDREN HEALTH INSURANCE PROGRAM, AND BREAST AND CERVICAL CANCER DRUGS

During this current audit, we noted that the State agency misreported drug rebates received for family planning, SCHIP, and breast and cervical cancer drugs. Although the State agency reported all rebates received, the rebates were not allocated accurately as an offset of the appropriate drug expenditures. The following table summarizes the errors—in terms of both overreporting and underreporting—by quarter.

Misreported Drug Rebates (Federal Share)				
	Over (Under) Reported			
Quarter Ending	**SCHIP**	**Family Planning**	**Breast/Cervical Cancer**	**Total for Quarter**
9/30/2005			($206)	($206)
12/31/2005	$1,519		(1,248)	271
3/31/2006	(13,575)	($14,955)	(1,069)	(29,599)
6/30/2006		(5,736)	(221)	(5,957)
Total	**($12,056)**	**($20,691)**	**($2,744)**	**($35,491)**

For the quarter ending December 31, 2005, the State agency allocated $58 as SCHIP rebates. During our review, the State agency determined that it actually received $10,573 for SCHIP rebates instead of $58. The remaining $10,515 was misreported as Family Planning rebates. Family planning rebates were reported at a 90 percent Federal medical assistance percentage (FMAP) rate while SCHIP rebates were reported at the enhanced FMAP rate.[5] We calculated the amount of the Federal share of the drug rebates that should have been reported based upon SCHIP's enhanced FMAP rate, compared it to the Federal share erroneously reported by the State agency (based upon the family planning 90 percent FMAP), and determined that the State agency overreported the Federal share of rebates by $1,519.

For the quarter ending March 31, 2006, the State agency did not allocate any SCHIP rebates. However, during our review the State agency determined that it received $129,536 in SCHIP rebates that were erroneously allocated as Title XIX drug rebates, which are reimbursed at the standard FMAP rate.[6] We calculated the amount of the Federal share of the drug rebates that should have been reported based upon SCHIP's enhanced FMAP rate, compared it to the Federal share reported by State agency (at the standard FMAP rate), and determined that the State agency underreported the Federal share of rebates by $13,575.

For the quarters ending March 31, 2006, and June 30, 2006, the State agency did not allocate any family planning rebates. Specifically:

- During our review, the State agency determined that for the quarter ending March 31, 2006, it had erroneously allocated $59,989 in family planning rebates as Title XIX rebates; therefore, the State agency underreported the Federal share of rebates by $14,955. To determine the amount of drug rebates the State agency underreported for this quarter, we compared the Federal share of the drug rebates that should have been reported to the actual amount reported by the State agency. We did so by using the 90 percent FMAP rate for family planning and comparing it to the amount the State agency actually reported when it incorrectly applied the rebates at the Title XIX standard FMAP rate for the quarter ending March 31, 2006.

- During our review, the State agency also determined that for the quarter ending June 30, 2006, it had erroneously allocated $39,696 in family planning rebates as SCHIP rebates; therefore, the State agency underreported the Federal share of rebates by $5,736. To determine the amount of drug rebates the State agency underreported for this quarter, we compared the Federal share of the drug rebates that should have been reported to the actual amount reported by the State agency. We did so by using the 90 percent FMAP rate for family planning and comparing it to the amount the State agency actually reported when it incorrectly applied the rebates at the SCHIP enhanced FMAP rate for the quarter ending June 30, 2006.

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[5]South Dakota's enhanced FMAP rate for October 1, 2004, through September 30, 2005, was 76.22 percent. The enhanced FMAP rate for October 1, 2005, through September 30, 2006, was 75.55 percent.

[6]South Dakota's FMAP rate for October 1, 2004, through September 30, 2005, was 66.03 percent. The FMAP rate for October 1, 2005, through September 30, 2006, was 65.07 percent.

In addition, for all four quarters of our audit period, the State agency did not allocate rebates for breast and cervical cancer drugs. During our review, the State agency determined that $26,244 in breast and cervical cancer rebates were reported as Title XIX drug rebates. However, breast and cervical cancer rebates should be reported at the enhanced FMAP rate. We compared the amount of drug rebates that should have been reported for breast and cervical cancer drugs using the enhanced FMAP rate, to the actual amount reported by the State agency using the standard FMAP rate. We determined that the State agency underreported the Federal share of rebates by $2,744.

The SCHIP rate is based on § 2105 (a)(1) of the Act, which refers to ". . . an amount for each quarter equal to the enhanced FMAP . . ." The enhanced FMAP is based on § 2105 (b) of the Act which states that the enhanced FMAP is ". . . equal to the Federal medical assistance percentage . . . for the State increased by a number of percentage points equal to 30 percent of the percentage points by which (1) such Federal medical assistance percentage for the State, is less than (2) 100 percent; but in no case shall the enhanced FMAP for a State exceed 85 percent."

The family planning FMAP is based upon § 1903 (a)(5) of the Act, which refers to ". . . an amount of 90 [percent] of the sums expended . . . which are attributable to the offering, arranging, and furnishing . . . of family planning services . . . ."

Pursuant to CMS's letter to State Health Officials, dated January 4, 2001: "The Federal matching rate for the [Breast and Cervical Cancer drugs] is equal to the enhanced [FMAP] used in the [SCHIP] (described in § 2105(b) of [the Act])."

After reviewing all of these amounts the State agency did not allocate properly, we determined that the State agency underreported the Federal share of rebates for family planning, SCHIP, and breast and cervical cancer drugs totaling $35,491.

PHYSICIAN-ADMINISTERED SINGLE SOURCE DRUGS

The State agency has established controls over, and accountability for, the collection of rebates on single source physician-administered drugs. The State agency has been rebating for the single-source physician-administered drugs since September 1, 2002. The State agency paid $764,381 in claims for physician-administered drugs during the January through June 2006 time period and billed manufacturers for rebates totaling $401,329.

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

RECOMMENDATIONS

We continue to recommend that the State agency develop and follow policies and procedures that include offering the State hearing mechanism to manufacturers to resolve disputes after 60 days.

We also recommend that the State agency:

- ensure that prior period adjustments are made to the NDC level;

- update current policies and procedures and develop and document additional policies and procedures:

    - for write-off adjustments, to apply CMS's tolerance threshold for continuing with dispute resolution only after information has been exchanged and an attempt to resolve errors with manufacturers has occurred;

    - for $0 URAs, to ensure that information on $0 URAs paid by manufacturers to the State agency agrees with the URA information provided by manufacturers to CMS to update the CMS quarterly drug tape; and

- reimburse the Federal Government $35,491 (Federal share) relating to misreporting drug rebates for family planning, SCHIP, and breast and cervical cancer, and ensure that all drug rebate activity is accurately allocated on the Form CMS-64, "Quarterly Medicaid Statement of Expenditures for the Medical Assistance Program."

STATE AGENCY COMMENTS

In written comments on our draft report, the State agency said that it "agrees in part" with our finding and recommendation on the need to offer the State hearing mechanism to manufacturers to resolve disputes after 60 days, and it concurred with all of our other findings and recommendations.

Regarding our recommendation on offering the State hearing mechanism to manufacturers to resolve disputes after 60 days, the State agency said that it follows CMS's Dispute Resolution Program Best Practices (Best Practices) and that it believes the State hearing mechanism should be offered as a last resort after all other Best Practices have failed. According to the State agency, "[i]t is not feasible to have all options exhausted within 60 days"; for instance, the dispute resolution meetings that are a part of the State agency's dispute resolution process take place only once or twice per year.

For the findings and recommendations with which the State agency concurred, its written comments included a discussion of implementation and corrective actions proposed.

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

OFFICE OF INSPECTOR GENERAL RESPONSE

After reviewing the State agency's comments, we continue to support our findings and recommendations. Specifically, we continue to believe the State agency should be offering the State agency's hearing mechanism to manufacturers who have unresolved disputes after 60 days. CMS's Best Practices, which the State agency cited in its written comments, specifies that, "[i]f all other options have been exhausted without success, a manufacturer may request that a state hearing be held to resolve the dispute(s)." The focus of this relevant portion of the Best Practices is thus on the manufacturers rather than the States. For guidelines relevant to the State agency, we refer (as the Best Practices do) to Section V of the rebate agreement between the Secretary of Health and Human Services and the manufacturers: "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 . . . ." Thus, notwithstanding the State agency's concerns about the feasibility of exhausting all Best Practices after 60 days, the rebate agreement requires the State agency to make its hearing mechanism available after 60 days.

APPENDIX

DEPARTMENT OF SOCIAL SERVICES
OFFICE OF THE SECRETARY
700 GOVERNORS DRIVE
PIERRE, SD 57501-2291
PHONE: 605-773-3165
FAX: 605-773-4855
WEB: dss.sd.gov

DSS
Strong Families - South Dakota's Foundation and Our Future

August 6, 2008

Patrick Cogley, Regional Inspector General for Audit Services
Office of Inspector General Region VII
601 East 12th Street
Kansas City, MO 64106

Dear Mr. Cogley:

Thank you for the opportunity to respond to the report "Follow-Up Audit of the Medicaid Drug Rebate Program in South Dakota Report Number A-07-08-03110" dated July 16, 2008. Following are our responses to the findings identified in the report.

DSS 07-O-01 Develop and follow policies and procedures that include offering the State hearing mechanism to manufacturers to resolve disputes after 60 days.

DSS agrees in part that procedures should be developed to include the offering of the State hearing mechanism to manufacturers to resolve disputes. We follow the CMS' Dispute Resolution Program Best Practices (Best Practices). The State hearing mechanism should be offered as a last resort after all other Best Practices have failed. It is not feasible to have all options exhausted within 60 days. For example, one of the steps is to attend dispute resolution meetings that are held either once or twice per year. We would express our support for a rule that offers the State hearing mechanism after DSS receives notice from the CMS Central Office that it has been unable to resolve a dispute, pursuant to CMS' Best Practices.

DSS has a good working relationship with the drug manufacturers and with our representatives from CMS Regional and Central Offices. DSS does not see the benefit to the Citizens of South Dakota or to Federal Government to implement a hearing mechanism after 60 days before exhausting all other options first.

DSS 07-O-02 Ensure that prior period adjustments are made to the NDC level;

As we identified at the time of the review, the Department of Social Services (DSS) is in the process of developing and implementing a new Medicaid Management and Information System (MMIS). One of the requirements of this system is a drug rebate program that records adjustments down to the NDC level.

DSS concurs with this finding and will implement the prior period adjustments to the NDC level with the implementation of the new MMIS System.

DSS 07-O-03 Update current polices and procedures and develop and document additional policies and procedures for write-off adjustments, to apply CMS's tolerance threshold for continuing with dispute resolution only after information has been exchanged and an attempt to resolve errors with manufacturers has occurred;

Even though DSS follows write-off adjustments policies pursuant to CMS Guidelines, we concur that our policies and procedures manual needed to be revised. We have updated our manual to conform to CMS guidelines (see attached).

DSS 07-O-04 Update current polices and procedures and develop and document additional policies and procedures for $0 URAs, to ensure that information on $0 URAs paid by manufacturers to the State agency agrees with the URA information provided by manufacturers to CMS to update the CMS quarter drug rebate tape.

DSS concurs that we need to verify $0 URAs paid by manufacturers correspond to the amount reported to CMS. We have updated our manual to include these policies and procedures (see attached).

DSS-07-O-05 reimburse the Federal Government $35,491 (Federal share) relating to misreporting drug rebates for family planning, SCHIP, and breast and cervical cancer, and ensure that all drug rebate activity is accurately allocated on the Form CMS-64, "Quarterly Medicaid Statement of Expenditures for the Medical Assistance Program."

DSS concurs that we need to reimburse the Federal Government $35,491 (Federal Share) relating to the reported drug rebate amounts. The CMS-64 will have a second level review to verify that the amounts reported on the CMS-64 tie to the work papers. A payment adjustment in the amount of $35,491 will be made with the October 2008 CMS-64 report.

Please contact myself or Brenda Tidball-Zeltinger at 605.773.3166 or via email at Brenda.Tidball-Zeltinger@state.sd.us if you have any questions or concerns regarding our response and plan to address these findings.

Sincerely,

Deborah K. Bowman

3. Keep track of unresolved disputes on CMS Report and use the account receivable report that is downloaded monthly as a log. Insert notes on the log and/or color code those labelers that you have contacted.

4. Keep notes in the file and narratives on the SS51 system

5. Actions within this process should be recorded on the CMS 64 Narrative.

6. Establish a separate file to maintain ALL of your dispute resolution material and keep this handy for quick reference.

7. Make sure your SS51 case shows a "Remaining Balance in the amount of the disputed NDC(s)

8. Document everything you do.

9. Work towards a resolution.

Must consider cost effectiveness of dispute: If the tolerance is applied, you (state) must maintain documentation which clearly identifies the labeler code, the NDC number, the applicable quarter and the amount to which the tolerance is applied. States which apply the tolerance level will not be at risk for loss of Federal Financial participation (FFP) for amounts at or below the tolerance. However, State must remember that the write-off is only after information has been exchanged and an attempt to resolve errors with manufacturers has occurred. Per CMS Guidelines, the State may use its discretion in pursuing disputes below $1000.00 per NDC or $10,000.00 per labeler.

References include: Program Release No. 71 dated 11/21/1997, State Program Release No. 45 dated 11/30/1994, State Program Release No. 44 dated 10/18/1994, State Program Release No. 45 (attachment item G)

PRIOR PERIOD PRICE ADJUSTMENTS

Manufacturers are permitted to submit adjusted AMP's to CMS on their NDC's (presently back to the beginning of the program). Submittal of new AMP's may result in positive or negative dollars for a quarter/year and we have to apply the adjustments accordingly to balance out periods.

NEGATIVE PRICE ADJUSTMENTS

Often, when this is done, the AMP's are lower than originally submitted to CMS. This creates an over paid rebate (credit balance) by the manufacturer for a particular quarter. To adjust accordingly, manufacturers will apply the "Negative Price Adjustment" to the current quarter's payment, causing a reduction in the payment by the amount of the over payment on previous quarters.

To ensure reporting accuracy on our end, when these negative price adjustments occur, we need to adjust our records accordingly. Dollars in the amount of the adjustments will be

e.) To ensure that all NDCs invoiced at $0 RPUs are collected, run a query from the drug rebate database and use it as a checklist as the labelers pay their invoices. Store each spreadsheet in the respective electronic folder.
Example - H:\DrugRebate\12008\NDCSBilled_at_ZERO_12008.

f) Verify $0 URAs reported and paid by manufacturers correspond to the amount reported to CMS. Down load the spreadsheet into the drug rebate access table. Run a query by joining this table to the LabelerRebateInfo table.

2.) Make the correct adjustments to each NDC

a.) Positive = Additional Dollars Paid
1. (DB) Debit Debt Adjustment completed on SS51
2. Add narrative to indicate why increase in dollar amount and fill in "NOTE" lines on screen

b.) Negative = Reduction in rebate dollars paid or no payment
1. (CR) Credit Debt Adjustment to adjust invoiced amount as a result of lowered RPU.
2. Unpaid dollars or disputed NDC's,
See dispute resolution section for details.

NOTE: *Often a check will include payment for more than one labeler code. Make sure amounts get applied to the correct period and labeler code and be sure to document your actions.*

3.) Apply payments to case accordingly. Be sure to verify that the amounts you are applying equal the check amount and no remaining balance on SS51 system.. *(The exceptions are prior period adjustments, disputed amounts, or products owned by another company)*

Complete your (DB) or (CR) Debt adjustments accordingly and prior to any entering of payment.

4.) Add narratives to each case to document what you have done and why the (CR) Debt Adjustment.

5.) To add a narrative, do an SS51 ADD NARR (debt number), then press [Enter]

6.) Type your narrative, documenting your processing of the payment.

7.) Print a copy of the narrative by doing [Ctrl] [P] [Enter]