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

JUL 0 1 2008

Report Number: A-07-07-03098

David Sundwall, M.D.
Executive Director
Utah Department of Health
P. O. Box 144102
Salt Lake City, Utah 84114-4102

Dear Dr. Sundwall:

Enclosed is the U.S. Department of Health and Human Services, Office of Inspector General (OIG), final report entitled "Follow-Up Audit of the Medicaid Drug Rebate Program in Utah." 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-07-07-03098 in all correspondence.

Sincerely,

for Christopher G. Breslette

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
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Department of Health and Human Services

OFFICE OF INSPECTOR GENERAL

FOLLOW-UP AUDIT OF THE MEDICAID DRUG REBATE PROGRAM IN UTAH

Daniel R. Levinson
Inspector General

July 2008
A-07-07-03098

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 Utah, the Department of Health (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 Utah drug rebate program (A-07-03-04012), we determined that the State agency lacked sufficient controls over its Medicaid drug rebate program. Areas that lacked sufficient internal controls included: (1) recording accounts receivable, (2) Form CMS-64.9R reconciliation, (3) tracking $0 unit rebate amounts (URA), (4) interest accrual and collection, (5) dispute resolution, and (6) record retention. (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:

- maintaining a general ledger accounts receivable control account;
- reconciling the general ledger control account to the subsidiary ledgers/records and to the Form CMS-64.9R;
- tracking and accounting for all $0 URAs;
- estimating and accruing interest on all overdue rebate balances;
- making use of the State's hearing mechanism to resolve disputes after 60 days; and
- ensuring that records are kept for an appropriate period of time.

The State agency generally concurred with our findings and recommendations.

This current review of the Utah 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 Utah drug rebate program and (2) established controls over collecting rebates on single source drugs administered by physicians.

SUMMARY OF FINDINGS

The State agency has not corrected the control weaknesses for any of the findings identified in our previous audit.

In addition, the State agency has not established controls over and accountability for collecting rebates on single source drugs administered by physicians. Further, the State agency has not reported rebates collected for single source drug administered by physicians totaling $389,203.

RECOMMENDATIONS

We recommend that the State agency:

- develop and follow policies and procedures to maintain a general ledger accounts receivable control account;

- develop and follow policies and procedures to reconcile the general ledger control account to the subsidiary ledgers/records and to the Form CMS-64.9R;

- develop and follow policies and procedures to track and account for all $0 URAs;

- develop and follow policies and procedures to estimate and accrue interest on all overdue rebate balances;

- develop and follow policies and procedures to make use of the State's hearing mechanism to resolve disputes after 60 days;

- develop and follow policies and procedures to ensure that records are kept for an appropriate period of time;

- develop and follow policies and procedures to establish controls over and accountability for collecting rebates on single source drugs administered by physicians; and

- make refund to the Federal Government by reporting $389,203 ($280,397 Federal share) in rebates for single source drugs, administered by physicians, that were collected but not reported.

STATE AGENCY COMMENTS AND OFFICE OF INSPECTOR GENERAL RESPONSE

In written comments on our draft report, the State agency concurred or agreed with all but two of our recommendations. The State agency disagreed with the recommendations regarding (1) developing and following policies and procedures to estimate and accrue interest on all overdue rebate balances and (2) developing and following policies and procedures to ensure that records are kept for an appropriate period of time. The State agency's comments included a discussion of corrective actions planned and taken, as well as explanations of the reasons for its disagreement with those two recommendations. 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 Utah, the Department of Health (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 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 Utah, 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 Utah drug rebate program, we determined that the State agency lacked sufficient controls over its program. Areas that lacked sufficient internal controls included: (1) recording accounts receivable, (2) Form CMS-64.9R reconciliation, (3) tracking $0 URAs, (4) interest accrual and collection, (5) dispute resolution, and (6) record retention.[3]

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

- maintaining a general ledger accounts receivable control account;
- reconciling the general ledger control account to the subsidiary ledgers/records and to the Form CMS-64.9R;
- tracking and accounting for all $0 URAs;
- estimating and accruing interest on all overdue rebate balances;
- making use of the State's hearing mechanism to resolve disputes after 60 days; and
- ensuring that records are kept for an appropriate period of time.

The State agency generally concurred with our findings and recommendations.

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

[3]"Audit of the Medicaid Drug Rebate Program in Utah" (A-07-03-04012), issued June 9, 2003.

Utah Drug Rebate Program

The State agency performs all of the functions for administering the drug rebate program in Utah.

The State agency reported an outstanding drug rebate balance of $5,549,559 on the June 30, 2006, Form CMS-64.9R. However, the amount should have been $1,596,188 (based on the State's rebates accounts receivables), of which $804,522 relates to quarterly billings and was not past due as of June 30, 2006. Of the remaining $791,666 that was past due, $364,309 was more than 1 year past due. For the fiscal year ended June 30, 2006, the State agency reported rebate billings of approximately $50.7 million and collections of $54 million.

This current review of the Utah 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 Utah drug rebate program and (2) established controls over collecting 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 Salt Lake City, Utah, from August through October 2007.

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 Utah;

- 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 records of interest payments received for the period July 1, 2005, through June 30, 2006;

- 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 rebate billings and reimbursements for procedure codes related to single source drugs administered by physicians for the period January 1 through June 30, 2006.

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 RECOMMENDATION

The State agency has not corrected the control weaknesses for any of the findings identified in our previous audit.

In addition, the State agency has not established controls over and accountability for collecting rebates on single source drugs administered by physicians. Further, the State agency has not reported rebates collected for single source drug administered by physicians totaling $389,203.

IMPLEMENTATION OF PRIOR RECOMMENDATIONS

In our prior audit of the Utah drug rebate program (A-07-03-04012), we determined that the State agency lacked sufficient controls over its Medicaid drug rebate program. Areas that lacked sufficient internal controls included: (1) recording accounts receivable, (2) Form CMS-64.9R reconciliation, (3) tracking $0 URAs, (4) interest accrual and collection, (5) dispute resolution, and (6) record retention.

Since our prior audit, the State agency has not implemented our recommendations.

Accounts Receivable

The State agency did not develop and follow policies and procedures to maintain a general ledger accounts receivable control account. In its comments on the prior audit finding, the State agency indicated that it concurred with our finding related to accounts receivable.

Notwithstanding that concurrence, we found that the condition we had identified in our prior audit was still in effect at the time of our fieldwork for this current review: specifically, that the State agency did not maintain a general ledger accounts receivable control account to account for uncollected rebate balances as required. While the State agency established a general ledger account for rebates accounts receivable, the balance in the account was only updated annually based on the year-end balance in the subsidiary ledger – thus maintaining the same incorrect and inadequate procedure that we had noted in our prior audit finding.

Because there was no current general ledger balance for accounts receivable to reconcile to the subsidiary ledger, the State agency did not have reasonable assurance that rebate receivables were accurate or were effectively safeguarded. As a result of these accounting weaknesses, rebate funds were subject to potential waste, fraud, and abuse.

Reconciliation of General Ledger to Subsidiary Ledgers/Accounts

The State agency did not develop and follow policies and procedures to reconcile the general ledger control account to the subsidiary ledgers/records and to the Form CMS-64.9R. In its comments on the prior audit finding, the State agency indicated that it concurred with our finding related to the Form CMS-64.9R reconciliation.

However, the State agency did not perform a reconciliation to verify the accuracy of the uncollected rebate balances reported on the Form CMS-64.9R as required by Federal regulations at 42 CFR § 433.32(a). The Form CMS-64.9R was prepared by the Finance Department within the State agency. The Finance Department calculated the rebate received balance by subtracting the ending quarter rebate receivables from the beginning balance rebate receivables. However, the Form CMS-64.9R, as prepared and submitted by the Finance Department of the State agency, was missing information for one quarter in each reporting period and for the adjustments made during that period. Subsequent calculations to determine the uncollected rebate balances thus resulted in inaccurate ending balances, which made the Form CMS-64.9R itself inaccurate. As a result, the State agency could not successfully perform a reconciliation to verify the accuracy of the Form CMS-64.9R as required by Federal regulations.

Further, the State agency does not generate all the reports necessary to accurately fill out the Form CMS- 64.9R, so the State agency has no assurances that the information reported was correct.

As a result of these errors, the State agency did not have reasonable assurance that receivables were adequately safeguarded or that drug rebate information reported to CMS was accurate.

$0 Unit Rebate Amounts

The State agency did not develop and follow policies and procedures to track and account for all $0 URAs.[4] In its comments on the prior audit finding, the State agency indicated that it concurred with our finding related to the $0 URAs.

State agency officials said that the State agency creates a list of $0 URAs on the CMS tape, and then manually checks that list against the Reconciliation of State Invoices (ROSIs) sent in by the manufacturers, indicating that it has been checked by annotating the list. However, the State agency does not retain in its records the original list it uses to check the ROSIs.

Further, upon review of 15 ROSIs and their matching State invoices, using a list of $0 URAs that was recreated by the State agency (rather than the original list with notes), we found that the information did not indicate the State agency was tracking the $0 URAs, because there were three URAs on the list that had not been invoiced. Also, the list used to check the ROSIs did not appear to include all the $0 URAs, because the list was missing five URAs that had in fact been invoiced.

As a result of these errors, 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. Moreover, the lack of sufficient internal controls resulted in a potential risk for fraud, waste, or abuse of drug rebate program funds.

Interest on Late, Disputed, and Unpaid Rebates

The State agency did not develop and follow policies and procedures to properly estimate and accrue interest on all overdue rebate balances. Our prior audit found that the State agency did not have adequate procedures to accrue interest for late or disputed rebate payments as required. In its comments on that prior audit finding, the State agency indicated that it concurred with our finding and said it would be implementing procedures to calculate interest. However, while the State agency has, since our prior audit, implemented policies and procedures for calculating interest, these policies and procedures conflict with CMS guidance for the calculation of interest.

CMS's guidelines on "Interest Calculation for Late Rebate Payments" specify that each State must begin accrual of interest on unpaid amounts beginning on the 38th day after the manufacturer receives utilization data from that State.

The State agency's current policies and procedures conflict with CMS guidelines for calculating interest due, because the State agency has in effect changed the time period after which interest begins to accrue, from 38 days to 43 days. That is, the State agency is not maintaining proper documentation to show when invoices are actually mailed; instead, the State agency is as a

[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.

matter of procedure adding 5 days for processing time before beginning accrual of interest on unpaid amounts. As a result of this deviation from CMS's guidelines, the State agency has inappropriately written off interest due. (The State agency also wrote off other interests due, but did not have adequate documentation of those writeoffs.)

Dispute Resolution

The State agency did not develop and follow policies and procedures to offer use of the State's hearing mechanism to manufacturers in order to settle disputes after 60 days. In its comments on the prior audit finding, the State agency indicated that it concurred with our finding related to the State agency's dispute resolution of past due amounts.

The rebate agreement states that in the event that the State agency and the manufacturer are not able to resolve a discrepancy within 60 days, CMS shall require the State agency to make available to the manufacturer the State's hearing mechanism available under the Medicaid program.

However, during our review of dispute resolution procedures, we found that the State agency did not offer State hearings to resolve disputes as required by the rebate agreement. In fact, the State agency's policies and procedures conflict with the rebate agreements, in that those policies and procedures, rather than providing the framework for the availability of the State hearing mechanism after 60 days, instead state only that disputes over 60 days old will be given priority for follow-up.

Records Retention

The State agency did not develop and follow policies and procedures to ensure that records are kept for an appropriate period of time. In its comments on the prior audit finding, the State agency indicated that it concurred with our finding concerning records retention.

Federal regulations at 45 CFR § 92.42(c)(1) require that records for a cooperative agreement (continued or renewed quarterly) be kept three years from "the day the grantee submits its expenditure report for the last quarter of the Federal fiscal year."

Additionally, 42 CFR § 433.32 states: "A State plan must provide that the Medicaid agency . . . .
(b) Retain records for 3 years from the date of submission of a final expenditure report;
(c) Retain records beyond the 3-year period if audit findings have not been resolved . . . ."

The State agency did not have policies and procedures to address record retention. Because the State agency does not have policies and procedures to ensure ROSIs are retained for the required length of time, the State agency may not be able to adequately track $0 URAs or resolve disputed rebate payments from prior years. As a result, the State agency may not have received all drug rebates due from manufacturers.

PHYSICIAN-ADMINISTERED SINGLE SOURCE DRUGS

The State agency has not established controls over and accountability for collecting rebates for single source drugs administered by physicians as required by the DRA. The State agency paid $467,975 in claims for physician-administered drugs during the January through June 2006 time period; however, as of the end of our fieldwork the State agency has not billed manufacturers for rebates in that time period.

Federal regulations at 42 CFR § 433.32(a) state that State Medicaid agencies must "[m]aintain an accounting system and supporting fiscal records to assure that claims for Federal funds are in accord with applicable Federal requirements."

During our audit period, the invoices for the rebates for physician-administered drugs were generated by manually pulling the claim information from a data warehouse to a spreadsheet. State agency personnel used the spreadsheet to perform a crosswalk to determine an NDC rebateable amount. This information was then sent to the Information Technology department, which used the spreadsheet to generate invoices sent to the manufacturers. No accounting entries were made in the State agency's accounting system for these rebates until the State agency received payment from the manufacturer. As a result of these practices, the State agency did not maintain adequate control over the physician-administered drug program to ensure that these rebates were recognized, billed, recorded as an account receivable, collected, or reported in a timely manner to assure effective control over and accountability for the program.

State agency officials said that going forward, the State agency plans to continue administering the physician-administered drug rebates program in the same manner, with the exception that it will now maintain hard copies of the generated invoices and periodically check to ensure the invoices are paid. The State agency will still not have these accounts receivables recorded in their accounting system until payment is made by the manufacturer.

The State agency's policies and procedures for the physician-administered drug rebates program indicates that "rebate requests will be sent to manufactures quarterly." However, our review indicated that the State agency has not invoiced any rebates for physician-administered drugs for claims after calendar year 2004.

We also found that the State agency has received rebates for physician-administered drugs that were not reported to CMS as of the start of our audit. Since the State agency started billing for single-source physician-administered drugs in 2004, it has received $390,486 in rebates. Of that amount, the State agency has only reported $1,283 on the Form CMS-64.9R. This amount was reported in the first quarter of State fiscal year 2007. Thus, the State agency's rebate records indicate that $389,203 still needs to be reported to CMS.

As a result, the State agency consistently understated drug rebate receivables, and it is likely that the State agency did not receive all drug rebate payments due from manufacturers. Moreover, 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 to maintain a general ledger accounts receivable control account;

- develop and follow policies and procedures to reconcile the general ledger control account to the subsidiary ledgers/records and to the Form CMS-64.9R;

- develop and follow policies and procedures to track and account for all $0 URAs;

- develop and follow policies and procedures to estimate and accrue interest on all overdue rebate balances;

- develop and follow policies and procedures to make use of the State's hearing mechanism to resolve disputes after 60 days;

- develop and follow policies and procedures to ensure that records are kept for an appropriate period of time;

- develop and follow policies and procedures to establish controls over and accountability for collecting rebates on single source drugs administered by physicians; and

- make refund to the Federal Government by reporting $389,203 ($280,397 Federal share) in rebates for single source drugs, administered by physicians, that were collected but not reported.

STATE AGENCY COMMENTS

In written comments on our draft report, the State agency concurred or agreed with all but two of our recommendations. The State agency disagreed with the recommendations regarding (1) developing and following policies and procedures to estimate and accrue interest on all overdue rebate balances and (2) developing and following policies and procedures to ensure that records are kept for an appropriate period of time. The State agency's comments included a discussion of corrective actions planned and taken, as well as explanations of the reasons for its disagreement with those two recommendations.

For our recommendation concerning the need to develop and follow policies and procedures to estimate and accrue interest on all overdue rebate balances, the State agency said that it "disagrees that no policy or procedures existed on calculating interest." The State agency also stated that it "incorrectly modified the Drug Rebate System to compute interest from 43 days instead of the CMS requirement of 38 days. This was done to allow extra time for mailing delays." The State agency added that beginning in November 2007, it corrected its system so that interest begins to accrue 38 days after the invoice mailing date.

For our recommendation concerning the need to develop and follow policies and procedures to ensure that records are kept for an appropriate period of time, the State agency disagreed with this finding and said that it "follows State of Utah records retention policy." However, due to "human error" the State agency was not always able to provide us "with original documentation for some items." The State agency added that in addition to continued staff training, it "plans to scan source documents and store them on CDs in the future, which will solve the problem of misplaced documentation."

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.

For our recommendation concerning the need to develop and follow policies and procedures to estimate and accrue interest on all overdue rebate balances, we reiterate that while the State agency had policies and procedures to calculate interest, these policies and procedures conflicted with CMS guidance for the calculation of interest. Although the State agency said that it disagreed with this recommendation, it also acknowledged that it has changed its procedures so that interest begins to accrue, not at 43 days after the invoice mailing date as before, but at 38 days after the invoice mailing date. The implementation of this change would bring the State agency into compliance with this aspect of CMS guidance.

Although the State agency disagreed with our recommendation regarding the retention of records, it acknowledged that it was not always able to provide us with original documentation. Therefore, we continue to recommend that the State agency develop policies and procedures to ensure that records are kept for an appropriate period of time.

APPENDIX

State of Utah

JON M. HUNTSMAN, JR.
Governor

GARY R. HERBERT
Lieutenant Governor

Utah Department of Health
Executive Director's Office

David N. Sundwall, M.D.
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A. Richard Melton, Dr. P.H.
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Health Care Financing

Michael T. Hales
Division Director

Report Number A-07-07-03098

June 6, 2008

Patrick J. Cogley
Office of Inspector General
Regional Inspector General for Audit Services
Region VII
601 East 12th Street
Room 284A
Kansas City, Missouri 64106

Dear Mr. Cogley:

The following are the Utah Department of Health written comments on the Office of the Inspector General (OIG) draft report, Follow-Up Audit of the Medicaid Drug Rebate Program in Utah.

Before responding to the specific findings, I would like to note that the Utah Department of Health (Department) has made significant improvement in the Medicaid Drug Rebate Program since the 2003 OIG audit. Prior to this audit, the Department used a spreadsheet-based system to keep track of rebates. Since then the Department contracted for a new automated Drug Rebate System with an outside vendor. The programming for the Oracle-based system became operational in May 2004.

The Oracle-based rebate system provides for better account balance control through a subsidiary ledger, recording of payments and invoice adjustments, tracking of rebate disputes, identification of $0 unit rate amounts (URA), and maintaining a perpetual transaction record of all entries affecting each manufacturer. The system also provides for the calculation of interest on outstanding balances, and is programmed to eliminate many of the $0 URAs.

The Department also improved internal control weaknesses noted in the 2003 OIG audit by separating duties. Tasks such as depositing of checks, check posting, entering of Reconciliation of State Invoices (ROSI) and Prior Quarter Adjustment Statements (PQAS), invoice mailing, and dispute resolutions are performed and reviewed by separate staff.

OIG Recommendation 1: Develop and follow policies and procedures to maintain a general ledger accounts receivable account.

Utah Department of Health Response:

As noted in the audit report, the Department does maintain a general ledger Accounts Receivable control account updated at fiscal year-end that is in accordance with Generally Accepted Accounting Principles and audited by the Office of the Utah State Auditors. The Department also implemented procedures (as a result of the 2003 OIG audit) for reconciling rebate collections to the subsidiary ledger and the CMS-64 report on a quarterly basis. The Department contends that fiscal controls currently in place are sufficient to ensure that Medicaid funds have been used and reported in accordance with applicable statutes. The amount of Federal reimbursement for Medicaid expenditures is affected by actual rebate collections. Uncollected rebate amounts do not affect claims for Federal reimbursement. The quarterly reconciliation procedures utilized by the Department ensure proper Federal reimbursement. However, the Department does concur with the auditors' recommendation that a general ledger Accounts Receivable control account updated on a quarterly basis would improve controls over the reporting of uncollected pharmacy rebate balances on the CMS-64.9R, and would allow more timely reconciliation of the general ledger control account and subsidiary ledger.

The Department has coordinated with the State Division of Finance on the process for updating the Accounts Receivable control account on a quarterly basis. This is the agency responsible for the state's General Ledger and which establishes policies and procedures for financial transactions.

The Department will take the following corrective actions:

- On a quarterly basis the Department will record in the Accounts Receivable control account the total amount invoiced to the Labelers offset with the current quarter adjustments to the initial invoice. The CMS-64.9R will identify the initial invoice amount and the current quarter's adjustments to reported rebates on line 2 of the CMS-64.9R.
- The Pharmacy Rebate tracking software used by the Department does not currently provide sufficient reporting detail on adjustments to an initial invoice by quarter on an ongoing basis. Labelers often make adjustments to an initial quarterly billing several months after the billing is submitted. This adjusted amount may change from quarter to quarter as additional errors are found in the initial billing. Manufacturers' rate adjustments, unit billing errors, and write-offs of account balances must be maintained by quarter in order to improve control over modifications to the original billing. This process requires modification to the Department's Pharmacy Rebate software. The Department has met with representatives from the Utah Department of Technology Services (DTS) to ensure that these programming changes can be accomplished and to develop a timetable for implementation. The estimated completion is October 2008.

OIG Recommendation 2: Develop and follow policies and procedures to reconcile the general ledger control account to the subsidiary ledgers and to the Form CMS-64.9R.

Utah Department of Health Response:

The Department concurs with this recommendation. The system reporting modifications described above will allow a reconciliation of initial invoice less current adjustments recorded in the subsidiary ledger to the general ledger as well as the CMS-64.9R. The Department currently reconciles rebate collections recorded in the general ledger to the subsidiary ledger and the CMS-64.9R on a quarterly basis.

The Department will complete the written policies and procedures relating to the control account and subsidiary ledger reconciliation when the system programming changes are complete. The Department has identified needed changes in responsibilities to improve accountability and internal control, and will complete the assignments when all documentation requirements have been met.

OIG Recommendations 3: Accurately report drug rebate activity on Form CMS-64.9R.

Utah Department of Health Response:

The Department concurs with the auditor recommendation to accurately report drug rebate activity on Form CMS-64.9R. The differences noted in the audit report were due to timing differences in reporting adjustments to initial Labeler invoices. The Department had been following CMS instructions to report the current quarter original invoice amount on the CMS-64.9R. Adjustments to the current quarter's billing were not reported until subsequent quarters. The actions identified above to reconcile uncollected rebates will ensure that the amounts reported on the CMS-64.9R are accurate.

OIG Recommendations 4: Develop and follow policy and procedures to track and account for all $0 URAs.

Utah Department of Health Response:

The Department concurs that not all $0 URAs have been accounted for in a timely manner. We agree that policy and procedures for tracking all $0 URAs were not in place during the original 2003 OIG audit. However, the Department implemented a programming change to the Drug Rebate System after the 2003 OIG audit. This procedure eliminates the majority of $0 URAs received from the CMS tape. If the CMS tape has a $0 URA for a National Drug Code (NDC), the program will replace the $0 with the prior quarter URA. However, all NDCs may not have a prior unit rate amount, so some $0 URAs will continue to exist and will have to be tracked. The new system has significantly reduced the workload as well as the understatement of the outstanding rebate balances. This process allows for a more accurate estimate of rebate receivables.

The Department has now implemented a log to track all $0 URAs. ROSI reviews will be made to assure that manufacturers have furnished the Department with the NDC pricing information. If the manufacturer has not provided the pricing information, follow-up action will be taken.

OIG Recommendations 5: Develop and follow policies and procedures to estimate and accrue interest on all overdue rebate balances.

Utah Department of Health Response:
The Department disagrees that no policy or procedures existed on calculating interest. The Drug Rebate System calculates interest due by manufacturers on all outstanding balances. The System does not currently have a summary report of total interest accrued, but does list it by manufacturer.

The Department incorrectly modified the Drug Rebate System to compute interest from 43 days instead of the CMS requirement of 38 days. This was done to allow extra time for mailing delays. Beginning in November 2007 the Department corrected the system for calculating interest. Interest now begins to accrue 38 days after the invoice mailing date. A record will be maintained that will verify the Department's invoice mailing date. Our procedures will include this change.

OIG Recommendations 6: Develop and follow policies and procedures to make use of the State's hearing mechanism to resolve disputes after 60 days.

Utah Department of Health Response:

The Department concurs with this recommendation. The hearing mechanism will be made available to the manufacturers to resolve discrepancies where no agreement has been reached after 60 days.

In some cases, past due and unresolved disputes have been forwarded to the Office of Recovery Services (ORS) for collection and review with the Office of the State Attorney General. There was $1,622,743 in outstanding rebate receivables during the original OIG audit. The outstanding Accounts Receivable balance has since been reduced to $272,418. A resolution log was started in March 2006 and has been kept current. Additional staff resources have been assigned to bring these disputes current. If the hearing process is unsuccessful, any unresolved disputes will be referred to ORS for collection.

OIG Recommendations 7: Develop and follow policies and procedures to ensure that records are kept for an appropriate period of time.

Utah Department of Health Response:

The Department disagrees with this finding. The Department follows State of Utah records retention policy (FIACCT 14-06-18), which requires records to be retained for 3 years.

The Department's practice is to retain records for 5 years or longer if there are unresolved balances. However, due to human error the Department was unable to provide the auditors with original documentation for some items. We will continue to train and remind staff of the State of Utah's record retention policy. The Department plans to scan source documents and store them on CDs in the future, which will solve the problem of misplaced documentation.

OIG Recommendations 8: Develop and follow policies and procedures to establish controls over and accountability for collecting rebates on single source drugs administered by physicians.

Utah Department of Health Response:

The Department concurs with the auditors that proper policies and procedures need to be established to ensure control over the accountability of collecting rebates on single source drugs administered by physicians. At present a manual process is used to generate invoices for physician-administered drugs. A program request change has been submitted to DTS to upgrade the billing process so that we can better track invoice amounts and record payments. We plan to have this system upgrade operational before September 2008.

OIG Recommendations 9: Refund to the Federal Government by reporting $389,203 ($280,397 Federal share) in rebates for single source drugs, administered by physicians, that were collected but not reported.

Utah Department of Health Response:

We agree with the auditors' recommendation and finding. The questioned costs were repaid on the CMS 64 report for the quarter ending March 31, 2008.

If you have any questions or comments about our response, please contact me at (801) 538-6689.

Sincerely,

Michael T. Hales
Director, Division of Health Care Financing