



DEPARTMENT OF HEALTH & HUMAN SERVICES

Office of Inspector General
Office of Audit Services

JUN 06 2008

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

Report Number: A-07-07-03101

Ms. Joan Miles
Director
Montana Department of Public Health and Human Services
111 North Sanders Street
P.O. Box 4210
Helena, Montana 59604

Dear Ms. Miles:

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 Montana." 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-07-07-03101 in all correspondence.

Sincerely,

A handwritten signature in black ink, appearing to read "Patrick J. Cogley", written over a horizontal line.

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 MONTANA**



Daniel R. Levinson
Inspector General

June 2008
A-07-07-03101

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 Montana, the Department of Public Health and Human Services (the State agency) administers the Medicaid drug rebate program.

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

In our previous audit of the Montana drug rebate program (A-07-03-04020), we determined that although the State agency had adequate controls over the collections from the manufacturers, it did not have adequate controls to account for accounts receivables as required by Federal regulations; exceptions included policies and procedures for recording accounts receivable, reconciliation of Form CMS-64.9R, tracking \$0 unit rebate amounts (URA), and dispute resolution. (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 the State agency complete its accounts receivable system conversion by determining an accurate accounts receivable balance for each drug manufacturer. Without accurate receivable balances, our recommendations would not result in effective control or accountability for the drug rebate assets. Furthermore, we recommended that the State agency develop and follow policies and procedures that included:

- maintaining a general ledger accounts receivable control account;
- developing a subsidiary accounts receivable system for the drug rebate program;
- reconciling the general ledger control account to the subsidiary ledgers/records and to the Form CMS-64.9R;
- tracking \$0 URAs to ensure payment;

- adjusting URA information to ensure that accounts receivable records are accurate; and
- actively pursuing disputed drug rebates including utilization of the State agency’s hearing mechanism.

The State agency concurred with our findings and recommendations and agreed to take appropriate corrective action.

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

SUMMARY OF FINDINGS

The State agency partially corrected some of the weaknesses reported in our previous audit. Although the State agency has made positive strides in determining an accurate accounts receivable balance by working to complete its accounts receivable system conversion, this conversion remains incomplete. Therefore, the State agency is unable to maintain an accurate drug rebate accounts receivable balance, maintain an accurate general ledger accounts receivable control account or subsidiary system, or perform a complete reconciliation.

Additionally, the State agency did not implement recommendations related to:

- tracking \$0 URAs to ensure payment;
- adjusting URA information to ensure that accounts receivable records are accurate; and
- actively pursuing disputed drug rebates, including utilization of the State agency’s hearing mechanism.

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

RECOMMENDATIONS

We continue to recommend the State agency complete its accounts receivable system conversion by determining an accurate accounts receivable balance for each manufacturer. Without accurate accounts receivable balances, our recommendations will not result in effective control or accountability for the drug rebate assets.

Furthermore, we also continue to recommend that the State agency develop and follow policies and procedures that include:

- tracking \$0 URAs to ensure payment;
- adjusting URA information to ensure that accounts receivable records are accurate; and
- actively pursuing disputed drug rebates including utilization of the State agency's hearing mechanism.

STATE AGENCY COMMENTS AND OFFICE OF INSPECTOR GENERAL RESPONSE

In written comments on our draft report, the State agency concurred or partially concurred with all of our findings and recommendations. The State agency partially concurred with the findings and recommendations regarding (1) the adjustment of URA information to ensure amounts receivable records are accurate and (2) dispute resolution. The State agency's 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 Montana, the Department of Public Health and Human 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," 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.

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

In Montana, physician-administered drugs are billed to the State Medicaid program on a physician claim form or a uniform billing (UB) form. The State agency uses the CMS-1500 as the physician claim form and the UB-04 for physician claims submitted by facilities. Both the CMS-1500 and UB-04 use the procedure codes that are part of the Healthcare Common Procedure Coding System (HCPC). However, the UB-04 contains a field in which the physician can indicate the NDC of the drug used. 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 Montana drug rebate program, we determined that although the State agency had adequate controls over the collections from the manufacturers, it did not have adequate controls to account for receivables as required by Federal regulations; exceptions included policies and procedures for recording accounts receivable, reconciliation of Form CMS-64.9R, tracking \$0 URAs, and dispute resolution.³

We recommended the State agency complete its accounts receivable system conversion by determining an accurate accounts receivable balance for each drug manufacturer. Without accurate accounts receivable balances, our recommendations would not result in effective control or accountability for the drug rebate assets. Furthermore, we recommended that the State agency develop and follow policies and procedures that included:

- maintaining a general ledger accounts receivable control account;
- developing a subsidiary accounts receivable system for the drug rebate program;
- reconciling the general ledger control account to the subsidiary ledgers/records and to the Form CMS-64.9R;

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 Montana” (A-07-03-04020), issued May 13, 2003.

- tracking \$0 URAs to ensure payment;
- adjusting URA information to ensure that accounts receivable records are accurate; and
- actively pursuing disputed drug rebates, including utilization of the State agency's hearing mechanism.

The State agency concurred with our findings and recommendations and agreed to take appropriate corrective action.

Montana Drug Rebate Program

The State agency is responsible for administration and oversight of the Medicaid drug rebate program; however, it contracted with Affiliated Computer Systems (ACS) for physician-administered drug rebates. ACS's responsibilities included developing crosswalks for physician-administered drug rebates, processing quarterly claims, invoicing, monitoring payments, and handling dispute resolution related to physician-administered drug rebates. The State agency is responsible for receiving all payments.

The State agency reported an outstanding drug rebate balance of \$5,927,692 on the June 30, 2006, Form CMS-64.9R. However, \$5,812,033 of this amount related to quarterly billings and was not past due as of June 30, 2006. Of the remaining \$115,392 that was past due, \$120,567 was more than 1 year past due.⁴ For the fiscal year ended June 30, 2006, the State agency reported rebate billings of approximately \$22,484,845 and collections of \$9,831,913.

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

⁴The State agency's accounts receivable "total outstanding balance" of \$115,392 as of June 30, 2006, was less than the balance outstanding "for more than a year" of \$120,567 because the "total outstanding balance" included accounts receivable balances of (\$26,440) for the quarter ended March 31, 2006; \$2,144 for the quarter ended December 31, 2005; and \$19,121 for the quarter ended September 30, 2005; taken together, these balances account for the difference of (\$5,175).

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 and its contractor, both of which are located in Helena, Montana, during October and November 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 report concerning the drug rebate program in Montana;
- reviewed the policies and procedures related to the State agency's drug rebate accounts receivable system;
- interviewed State agency officials to determine the policies, procedures, and controls that related to the Medicaid drug rebate program;
- reviewed copies of Form CMS-64.9R for the period July 1, 2005, through June 30, 2006;
- reviewed accounts receivable records for the State fiscal year ended June 30, 2006;
- interviewed State agency officials and contractor staff 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, 2006, 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 RECOMMENDATIONS

The State agency partially corrected some of the weaknesses reported in our previous audit. Although the State agency has made positive strides in determining an accurate accounts receivable balance by working to complete its accounts receivable system conversion, this conversion remains incomplete. Therefore, the State agency is unable to maintain an accurate drug rebate accounts receivable balance, maintain an accurate general ledger accounts receivable control account or subsidiary system, or perform a complete reconciliation.

Additionally, the State agency did not implement recommendations related to:

- tracking \$0 URAs to ensure payment;
- adjusting URA information to ensure that accounts receivable records are accurate; and
- actively pursuing disputed drug rebates, including utilization of the State agency's hearing mechanism.

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

IMPLEMENTATION OF PRIOR RECOMMENDATIONS

In our previous audit of the Montana drug rebate program, we determined that although the State agency had adequate controls over the collections from the manufacturers, it did not have adequate controls to account for accounts receivables as required by Federal regulations; exceptions included policies and procedures for the proper recording of accounts receivable, reconciliation of Form CMS-64.9R, tracking \$0 URAs, and dispute resolution.

Since then, the State agency has taken actions to correct the weaknesses related to our prior finding. It has worked to complete the conversion of its drug rebates accounts receivable system conversion. However, the State agency has not completed the conversion and is unable to maintain an accurate ending drug rebate accounts receivable balance.

Accounts Receivable System Conversion

In our prior audit, we noted that the State agency did not complete the conversion of its accounts receivable system prior to implementation, thereby causing manufacturers' accounts receivable balances to be inaccurate. (The initial conversion consisted of the State agency transferring the accounts receivable information from the older version of the Drug Rebate Analysis and Management System (DRAMS) to a newer version of DRAMS. This conversion process required State agency staff to individually research and adjust each manufacturers' accounts in the system.) In its comments on our prior audit finding, the State agency concurred with our finding and stated that it had added staff to help with the data conversion, and would work to prioritize accounts that needed to be converted. During this current audit, we noted that although the State agency has made significant strides in completing the system conversion, that

conversion remains incomplete. The State agency indicated that it has not been able to devote sufficient resources to complete the conversion because of personnel issues and staff time shortages.

The State agency has identified at least six manufacturers that have not yet been converted to the new system. However, documentation provided by the State agency indicated that additional manufacturers may not yet have been converted. The State agency was unable to provide an accurate number of manufacturers' balances that remain outstanding.

The State agency has developed and followed policies and procedures for maintaining a general ledger accounts receivable control account and subsidiary accounts receivable system. Additionally, the State agency has developed sufficient policies and procedures for reconciling the drug rebate control account to the subsidiary ledgers and to the Form CMS-64.9R. However, because the State agency did not complete its system conversion, the State agency's accounts receivable balance remained inaccurate and could not be verified. In the absence of such verification, the accuracy of both the general ledger control account and the subsidiary ledger was called into question, and the necessary reconciliations of the drug rebate program remained incomplete.

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

Without completing the conversion of the drug rebate accounts receivable system, the State agency's ending accounts receivable balance for drug rebates is inaccurate. The State agency is unable to maintain an accurate drug rebate accounts receivable balance until it completes the conversion of its accounts receivable system with respect to all relevant manufacturers.

Tracking \$0 Unit Rebate Amounts and Adjusting Unit Rebate Amount Information

In our prior audit, we noted that the State agency did not adequately record adjustments to ensure that payments representing recalculated URAs were properly adjusted or that \$0 URAs were calculated and remitted as required.⁵ In its comments on our prior audit finding, the State agency concurred with our finding and stated that it would implement additional procedures to more effectively track \$0 URAs to ensure an amount was calculated and remitted by the manufacturers. During this current audit, we noted that the State agency had not developed sufficient policies and procedures for tracking \$0 URAs to ensure that manufacturers had made payment. Additionally, the State agency had not developed sufficient policies and procedures for adjusting \$0 URA information after payment had been made by the manufacturer and a rate had been included on the CMS quarterly data tape.

⁵The term “\$0 URAs” refers to drugs included on CMS's quarterly Medicaid drug data tape, distributed to the States, that lack pricing information.

The State agency creates a report that tracks payments made by manufacturers; however, the State agency does not track \$0 URAs that were unpaid by manufacturers. Additionally, the State agency does not immediately follow up with manufacturers that do not pay on \$0 URAs, nor does it send out invoices or follow up with manufacturers once the CMS quarterly Medicaid drug tape has updated a \$0 URA. The State agency did not make any subsidiary accounts receivable adjustments when payments were received on invoiced \$0 URAs. The State agency did not update its subsidiary ledger accounts receivable balance for \$0 URAs it collected until CMS updated the URA on the CMS tape, and even then, the State agency did not promptly follow up with manufacturers.

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

Without sufficient policies and procedures for following up on \$0 URAs, it is likely that the State agency did not receive all drug rebate payments due from manufacturers. Moreover, without sufficient policies and procedures for adjusting the drug rebates accounts receivable balance for payments on \$0 URAs, the State agency is understating its drug rebate accounts receivable balance.

Dispute Resolution

In our prior audit, we noted that although the State agency was successful in actively pursuing disputed drug rebates when those disputes first became known, it did not adequately follow up on disputes that were not immediately resolved to ensure resolution within 60 days. Additionally, the State agency did not offer manufacturers the option to utilize the State hearing mechanism for resolving disputes as required by the rebate agreement. In its comments on our prior audit finding, the State agency concurred with our finding and stated that it would implement additional policies and procedures that would provide for an adequate follow-up on disputes with manufacturers. However, during this current audit we noted that the State agency did not develop and implement adequate policies and procedures outlining and documenting the process it uses for handling dispute resolution and it did not establish procedures to incorporate the State’s hearing mechanism into its dispute resolution process.

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”

Although the State agency continued to pursue disputed drug rebates by working directly with the manufacturers to resolve disputes, it did not sufficiently document its procedures for doing so. Additionally, the State agency explained that it did not incorporate the State’s hearing

mechanism into its procedure because it feels that the State's hearing process is more tailored for provider and client issues and does not specifically address Medicaid drug rebates.

PHYSICIAN-ADMINISTERED SINGLE SOURCE DRUGS

The State agency established controls over collecting rebates for single source drugs administered by physicians as required by the DRA. The State agency paid \$1,550,334 in claims for physician-administered drugs during the January through June 2006 time period and billed manufacturers for rebates totaling \$679,850.

RECOMMENDATIONS

We continue to recommend the State agency complete its accounts receivable system conversion by determining an accurate accounts receivable balance for each manufacturer. Without accurate accounts receivable balances, our recommendations will not result in effective control or accountability for the drug rebate assets.

Furthermore, we also continue to recommend that the State agency develop and follow policies and procedures that include:

- tracking \$0 URAs to ensure payment;
- adjusting URA information to ensure that accounts receivable records are accurate; and
- actively pursuing disputed drug rebates including utilization of the State agency's hearing mechanism.

STATE AGENCY COMMENTS

In written comments on our draft report, the State agency concurred or partially concurred with all of our findings and recommendations. The State agency partially concurred with the findings and recommendations regarding (1) the adjustment of URA information to ensure amounts receivable records are accurate and (2) dispute resolution. The State agency comments included a discussion of implementation and corrective action proposed for all of the findings and recommendations.

The State agency commented on the finding and recommendation regarding the adjustment of URA information, stating that it has ensured the adequacy of its system processing and operating procedures and is “. . . comfortable that [its] business process estimates the general ledger receivable appropriately . . .” and has “. . . adequate controls over Medicaid funds.” Regarding the finding and recommendation for dispute resolution, the State agency commented that it “. . . will continue working towards documentation of existing procedures” for dispute resolution and will pursue “. . . an administrative rule change . . . in order to provide hearing rights to pharmaceutical manufacturers . . .”

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. With respect to the finding and recommendation for the adjustment of URA information, we reiterate that without sufficient policies and procedures for adjusting the drug rebates accounts receivable balance for payments on \$0 URAs, the State agency is understating its drug rebate accounts receivable balance. Regarding the finding and recommendation for dispute resolution, notwithstanding the fact that the State agency is pursuing an administrative rule change to provide hearing rights to pharmaceutical manufacturers, the State agency's corrective actions do not address incorporating the State's hearing mechanism into its dispute resolution process.

APPENDIX

DEPARTMENT OF
PUBLIC HEALTH AND HUMAN SERVICES



BRIAN SCHWEITZER
GOVERNOR

JOAN MILES
DIRECTOR

STATE OF MONTANA

www.dphhs.mt.gov

PO Box 4210
HELENA, MT 59604-4210

April 25, 2008

Department of Health & Human Services
Office of Inspector General, Offices of Audit Services
Region VII
Attn: Daniel R. Levinson
601 East 12th St, Room 284A
Kansas City, MO 64106

Re: A-07-07-03101

Dear Mr. Levinson:

Thank you for your letter dated February 25, 2008, regarding the audit of the Medicaid Drug Rebate program in Montana. Department personnel have worked diligently to complete the required system changes in order to strengthen the internal control weaknesses identified in the audit as stated in your findings and recommendations.

As requested, below are our responses and corrective actions plans for: Accounts Receivable System Conversion, Tracking and Adjusting URAs and URA information and Dispute Resolution.

Accounts Receivable System Conversion:

We continue to recommend the state agency complete its accounts receivable system conversion by determining an accurate accounts receivable balance for each manufacturer.

Response:

The Department concurs with this recommendation.

Actions to Date:

The conversion from the old rebate system into the new system, DRAMS (Drug Rebate Analysis and Management System), was completed in February 2006. This conversion consisted of entering old checks from all the manufacturers by NDC level into DRAMS from 1991 through first quarter 1999.

The rebate staff has worked to verify and reconcile the accounts receivable system in DRAMS for each manufacturer. The reconciliation for the majority of manufacturers is complete; however, two issues have consistently delayed the process. The first issue is timely receipt of manufacturers documentation required to complete this task. Manufacturer's site such issues as off-site documentation storage as the main reason they have not honored our requests. Currently two manufacturers, each with multiple labels to reconcile, have yet to respond to documentation requests.

The second issue is the significant amount of time required to reconcile the discrepancies. The documentation consists of data from the old method where manufacturers paid by invoice vs. per NDC. All remaining unreconciled items are a result of activity relating to transactions prior to the implementation of the now standard Reconciliation Of State Invoice (ROSI) and Prior Quarters

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Adjustment Statement (PQAS) forms. The process takes a significant amount of time and limits the amount of resources available for current Drug Rebate Program operations. The unreconciled items are not related to any current system or procedural weaknesses.

Continued Corrective Action Plan:

We appreciate the auditor's recognition of the significant strides State staff had made in completing this process. The Department will continue to work towards full reconciliation of prior quarter discrepancies.

Tracking \$0 URAs to ensure payment:

We ...continue to recommend that the State agency develop and follow policies and procedures that include tracking \$0 URA's to ensure payment.

Response:

The Department concurs with this recommendation.

Actions to Date:

The Department has implemented appropriate procedures to fully address this finding. All \$0 URA's are followed up with the manufacturer or the provider as appropriate.

Adjusting URA information to ensure accounts receivable records are accurate

We ...continue to recommend that the State agency develop and follow policies and procedures that include adjusting URA information to ensure that accounts receivable records are accurate.

Response:

The Department partially concurs with this recommendation.

Actions to Date:

The Department has ensured adequate system processing and operating procedures exist for both 1) adjusting \$0 URA information after a rate has been included on the CMS tape and 2) following up on all unpaid \$0 URA's.

We have reviewed our procedures for adjusting subsidiary accounts receivable records when payments are received on \$0 URA's. While we recognize the timing delays caused by waiting for CMS to provide the official URA, we are comfortable that our business process estimates the general ledger receivable appropriately and when combined with the above mentioned \$0 URA tracking procedures ensures adequate controls over Medicaid funds.

Dispute resolutions:

We ...continue to recommend that the State agency develop and follow policies and procedures that include actively pursuing disputed drug rebates including utilization of the State agency's hearing mechanism.

Response:

The Department partially concurs with this recommendation.

Actions to Date:

As noted by the auditors the Department has continued to pursue disputed drug rebates by working directly with the manufacturers.

Continued Corrective Action Plan:

The Department will continue working towards documentation of existing procedures. An administrative rule change will be pursued in order to provide hearing rights to pharmaceutical manufacturers as the current hearing mechanism is client and provider specific.

Summary:

The Department will continue to work toward implementing the corrective actions resulting from the 2007 OIG Audit (A-07-07-03101). Should you have any questions regarding this response please contact Dan Peterson at (406) 444-4144.

Sincerely,



Joan Miles
Director

Cc: John Chappuis
Mary Dalton
Marie Matthews
Rebecca Beckert-Graham
Dan Peterson
Betty DeVaney
Michaelanne Fagnan

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