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

December 12, 2003

Report Number A-07-03-04020

Ms. Gail Gray, Director
Montana Department of Public Health and Human Services
111 Sanders St.
Helena, MT 59604

Dear Ms. Gray:

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

The audit objective was to evaluate whether the Montana Department of Public Health and Human Services (Department) had established adequate accountability and internal controls over the Medicaid drug rebate program.

We determined that although the Department had adequate controls over the collections of drug rebates from the manufacturers, they did not have adequate controls to account for receivables as required by Federal regulations.

These issues occurred because the Department did not develop or follow adequate policies and procedures with regard to the Medicaid drug rebate program and also because they did not devote sufficient resources to complete a system conversion prior to implementation.

Specifically, Federal regulations require effective control over and accountability for all funds, property and other assets.

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

We recommend that the Department develop and follow policies and procedures that include:

- 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 URA's to ensure payment.
- Adjusting URA information to ensure that accounts receivable records are accurate.
- Actively pursuing disputed drug rebates including the utilization of the State's hearing mechanism.

The Department concurred with our findings and recommendations and agreed to take appropriate corrective actions.

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

In accordance with the principles of the Freedom of Information Act, 5 U.S.C. 552, as amended by Public Law 104-231, Office of Inspector General, OAS reports issued to the Department's grantees and contractors are made available to members of the press and general public to the extent information contained therein is not subject to exemptions in the Act. (See 45 CFR Part 5.) As such, within 10 business days after the final report is issued, it will be posted on the worldwide web at *http://oig.hhs.gov*. To facilitate identification, please refer to Report Number A-07-03-04020 in all correspondence relating to this report.

Sincerely,

James P. Aasmundstad
Regional Inspector General
for Audit Services

HHS ACTION OFFICIAL

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

Department of Health and Human Services

OFFICE OF INSPECTOR GENERAL

AUDIT OF THE MEDICAID DRUG REBATE PROGRAM IN MONTANA

DECEMBER 2003
A-07-03-04020

Office of Inspector General

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OAS FINDINGS AND OPINIONS

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

EXECUTIVE SUMMARY

OBJECTIVE

Our audit objective was to evaluate whether the Montana Department of Public Health and Human Services (Department) had established adequate accountability and internal controls over the Medicaid drug rebate program.

FINDINGS

We determined that although the Department had adequate controls over the collections of drug rebates from the manufacturers, they did not have adequate controls to account for receivables as required by Federal regulations. We identified internal control weaknesses in the following areas:

- Recording Accounts Receivable.
- Reconciliation of Form CMS 64.9R.
- Tracking $0 unit rebate amounts (URA's).
- Dispute Resolution.

These issues occurred because the Department did not develop or follow adequate policies and procedures with regard to the Medicaid drug rebate program and also because they did not devote sufficient resources to complete a system conversion prior to implementation. Federal regulations require effective control over and accountability for all funds, property and other assets. Also, the rebate agreement between the States and the drug manufacturers require States to offer the use of their hearing mechanism to resolve disputes.

Our review showed that drug rebate receivables were perpetually understated and it was likely that the Department did not receive all rebate payments due from manufacturers. Moreover, the lack of sufficient internal controls increased the risk for fraud, waste, or abuse of drug rebate program funds.

RECOMMENDATIONS

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

Furthermore, we recommend that the Department develop and follow policies and procedures that include:

- 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 URA's to ensure payment.
- Adjusting URA information to ensure that accounts receivable records are accurate.
- Actively pursuing disputed drug rebates including utilization of the State's hearing mechanism.

INTRODUCTION

BACKGROUND

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

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

The CMS provides the URA information to the State agency on a quarterly computer tape. However, the CMS tape may contain a $0 URA if the pricing information was not provided timely, or if the computed URA has a 50 percent variance from the previous quarter. In instances of a $0 URA, the State agency is instructed to invoice the units and the manufacturer is required to calculate the URA and remit the appropriate amount to the State agency. In addition, the manufacturers can change any URA based on updated pricing information, and submit this information to the State agency in a Prior Quarter Adjustment Statement.

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

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

received during the current quarter, and uncollected rebate balances for the current and prior quarters on the Form CMS 64.9R.

The Department reported an uncollected rebate balance of $3,150,182 on the CMS 64.9R for the quarter ending June 30, 2002. The Department reported that the State owed manufacturers $554,815 for drug rebates older than 90 days. The average collections during the audit period were $3,245,399 per quarter.

OBJECTIVE, SCOPE AND METHODOLOGY

Objectives

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

Scope

The drug rebate program was effective January 1, 1991. We concentrated our review on the current policies, procedures and controls of the Department. We also interviewed Department staff to understand how the Medicaid drug rebate program has operated there since 1991.

Methodology

To accomplish our objective, we reviewed the applicable Federal laws, regulations, and requirements including sections 1903 and 1927 of the Social Security Act, the Omnibus Budget Reconciliation Act of 1990 and the Office of Management and Budget Circular A-87.

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

Our fieldwork was conducted at the Department's office in Helena, Montana during August 2003, and continued in the Office of Audit Services field office in Denver, Colorado through October 2003.

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

FINDINGS AND RECOMMENDATIONS

We determined that although the Department had adequate controls over the collections of drug rebates from the manufacturers, they did not have adequate controls to account

for receivables as required by Federal regulations. We identified internal control weaknesses in the following areas:

- Recording Accounts Receivable.
- Reconciliation of Form CMS 64.9R.
- Tracking $0 unit rebate amounts (URA's).
- Dispute Resolution.

INTERNAL CONTROLS

Recording Accounts Receivable

The State did not maintain a general ledger accounts receivable control account or a detailed subsidiary ledger to account for uncollected rebate balances as required. Drug rebates are "other assets" to the State that should be accounted for properly.

Title 45 sec. 74.21 paragraph (b)(3) of the Code of Federal Regulations requires that financial management systems provide for "Effective control over and accountability for all funds, property and other assets. Recipients shall adequately safeguard all such assets and assure they are used solely for authorized purposes." Additionally, generally accepted accounting principles (GAAP) require the use of a general ledger. The National Council on Governmental Accounting (NCGA)[1] issued *Statement 1, Governmental Accounting and Financial Reporting Principles*. It states in part,

> **"A governmental accounting system must make it possible both: (a) to present fairly and with full disclosure the financial position and results of financial operations of the funds and account groups of the governmental unit in conformity with generally accepted accounting principles; and (b) to determine and demonstrate compliance with finance-related legal and contractual provisions."**

The State had a general ledger account for receivables on their official accounting system. However, the recorded balance was an estimate based on drug rebate collections made during the fourth quarter of each fiscal year. The estimate was made at the beginning of each fiscal year and an entry was then made to update the drug rebate receivable balance.

The Department recorded and tracked uncollected rebates as running balances in a system known as the Drug Rebate Analysis and Management System (DRAMS). That system was also used to prepare quarterly invoices that were sent to manufacturers and to track

[1] The Governmental Accounting Standards Board (GASB) establishes standards for activities and transactions of State and local governmental entities. Its pronouncements are authoritative for State and local governmental entities. Following the jurisdictional approach discussed in the GASB Codification of Governmental Accounting and Financial Reporting Standards, the hierarchy of GAAP for governmental entities begins with GASB pronouncements and all pronouncements of the NCGA acknowledged as applicable by the GASB

payments received. However, the DRAMS included incorrect balances and could not be relied upon.

We obtained two DRAMS reports in an attempt to determine the current uncollected rebate balance. The first receivable report indicated the State owed manufacturers $765,345. The second report indicated manufacturers owed the State over $21 million. Neither balance appeared reasonable or accurate.

We determined that the incorrect balances in the DRAMS were a result of the conversion from the old system. The conversion process required staff to individually research and adjust each account. The Department did not devote sufficient resources to complete the conversion system-wide prior to implementation. Instead, conversions were made as needed to resolve disputes or when an accurate balance was deemed necessary. At the time of our review, approximately 75 of the 500 accounts have been converted or are in the process of being converted.

Because the general ledger rebate balance was an estimate and the subsidiary accounts receivable ledgers were inaccurate, the State agency did not have reasonable assurance that receivable balances reported to CMS were accurate. As a result of these accounting weaknesses, rebate funds were subject to potential waste, fraud, and abuse.

CMS 64.9R Reconciliation

The Department did not perform a reconciliation to verify the accuracy of the uncollected rebate balance reported on the Form CMS 64.9R as required by Federal regulations. They did, however, routinely reconcile the cash collections recorded in the DRAMS to amounts reported in the State's accounting system.

Title 45 Sec. 74.21 paragraph (b)(3) of the Code of Federal Regulations requires that financial management systems provide for "Effective control over and accountability for all funds, property and other assets. Recipients shall adequately safeguard all such assets and assure they are used solely for authorized purposes."

The Department did not reconcile the Form CMS 64.9R to the general ledger account balance or to the detailed subsidiary accounts receivable records because they did not adequately maintain a general ledger control account. As a result, the Department did not have reasonable assurance that drug rebate program activity reported to CMS was accurate.

This condition was further demonstrated when the Department reported an uncollected rebate balance in excess of $1.5 billion for the quarters ended June 30, 2001 and September 30, 2001. Although the reported balance was due to erroneous URA information provided by CMS, a routine reconciliation could have alerted Department officials that the balance was abnormal.

URA Adjustments

The Department did not adequately record adjustments to ensure that payments representing recalculated URA's were properly adjusted or that $0 URA's were calculated and remitted as required.

The Code of Federal Regulations, Title 45 Sec. 74.21 paragraph (b)(3) requires states to adequately safeguard assets. Manufacturers were allowed to adjust URA information based on current pricing information and remit a corrected amount. If the URA is $0, the manufacturer is required to calculate the URA when billed and remit payment. Therefore, the Department should accept URA's recalculated by the manufacturer and make appropriate adjustments to the subsidiary ledger.

According to CMS Medicaid Drug Rebate Program Release #33, States are required to include $0 URA's on the quarterly invoices sent to the manufacturers. In many cases, the manufacturer does not remit payment as required, forcing the Department to track those invoices until payment is made in order to adequately safeguard assets.

The Department did not adequately track $0 URA's to ensure an amount was calculated and remitted by the manufacturer. In cases where a manufacturer did not recalculate and remit payment for $0 URA's as required, the Department did not initiate action to notify the manufacturer that payment was due. Instead, the Department waited until an actual URA was received from CMS, that information was then updated to the DRAMS and resulted in an adjusted balance. The Department did not pursue those adjusted balances because there was no tracking procedures in place to make them aware that $0 URA's had been adjusted. A proper tracking mechanism would keep the Department apprised of unpaid URA's that were not disputed items.

At a minimum, the Department should maintain a list of all the $0 URA's that were not calculated and paid by the manufacturer as required in order to facilitate follow-up inquiries and to identify items that are subject to interest penalties. As a result, the drug rebate receivables were perpetually understated and it is likely that the Department did not receive all drug rebate payments due from manufacturers.

Dispute Resolution

The Department was successful in actively pursuing disputed drug rebates when those disputes first became known. However, they did not adequately follow-up on disputes that were not immediately resolved to ensure resolution within 60 days. According to State officials, this was due to inadequate staff assigned to the drug rebate program. Furthermore, they did not offer manufacturers the option to utilize the State hearing mechanism for resolving disputes as required by the rebate agreement.

Specifically, the agreement requires that the States and drug manufacturers resolve rebate discrepancies within 60 days of receipt of notification of a dispute. It further states, "In the event that the State and the manufacturer are not able to resolve a discrepancy within

60 days, CMS shall require the State to make available to the manufacturer the State's hearing mechanism available under the Medicaid program."

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

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

RECOMMENDATIONS

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

Furthermore, we recommend that the Department develop and follow policies and procedures that include:

- 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 URA's to ensure payment.
- Adjusting URA information to ensure that accounts receivable records are accurate.
- Actively pursuing disputed drug rebates including utilization of the State's hearing mechanism.

AUDITEE RESPONSE

The Department provided a written response to our draft report. Their response is included in its entirety as Appendix A. The Department concurred with our findings and recommendations and agreed to take appropriate corrective actions.

Appendix

DEPARTMENT OF PUBLIC HEALTH AND HUMAN SERVICES

JUDY MARTZ
GOVERNOR

GAIL GRAY
DIRECTOR

STATE OF MONTANA

www.dphhs.state.mt.us

PO Box 4210
HELENA, MT 59604-4210

December 3, 2003

James P. Aasmundstad
Regional Inspector General for Audit Services
Department of Health and Human Services, Region VII
601 East 12th Street, Room 284A
Kansas City, MO 64106

Re: Audit of the Medicaid Drug Rebate Program in Montana (A-07-03-04020)

Dear Mr. Aamundstad:

We have reviewed the copy of the U.S. Department of Health and Human Services, Office of Inspector General, Office of Audit Service's draft report entitled "Audit of the Medicaid Drug Rebate Program in Montana", dated November 4, 2003.

The Department found the report to be helpful and has recognized there is areas of the Medicaid Drug Rebate program that need additional attention. While the audit report provides recommendations that will improve the accounting of accounts receivables for rebates, the report may lead the reader to incorrect conclusions regarding the State's management of the drug rebate program. The Department believes our management of the Drug Rebate program and controls over the collections and reconciliation of rebates provide effective control over and accountability for funds. We also believe that we provide sufficient internal controls over the program to assure the State of Montana and CMS an accurate accounting of rebates received to minimize the risk for fraud, waste, or abuse of the drug rebate program.

The OIG report specifically identified internal control weaknesses in the following areas:

- Recording Accounts Receivable
- Reconciliation of Form CMS 64.9R
- Tracking $0 unit rebate amounts (URA's)
- Dispute Resolution

Based upon our review of the findings and recommendations we concur with the audit and would like to offer additional comments regarding the findings and recommendations:

Recording Accounts Receivable

The OIG report states that the Department did not maintain a general ledger accounts receivable control account or a detailed subsidiary ledger to account for uncollected rebate balances as required. Drug rebates are "other assets" to the State that should be accounted for properly. The report identifies issues regarding data conversion of labeler information in our drug rebate system, DRAMS, and the inability to obtain reasonable or accurate reports from DRAMS regarding receivable balances. The Department concurs with this finding.

The Department implemented a new drug rebate analysis and management system (DRAMS) in the fall of 1999. Prior to this time the Department accounted for rebates using a database and spreadsheets to account for rebate information at the labeler level. DRAMS provides the ability to more accurately account for rebates at the NDC level. However, as noted by the audit report, the Department has historical rebate information (1991-1999) that needs to be converted in DRAMS, to the NDC level. As noted in the audit report, the Department has converted some labeler information. The fact that we have been unable to complete the full conversion of information does impact the reliability of accounts receivable information.

The Department has added additional staff to help with data conversion of prior year labeler information and will make every effort to complete the conversion of this information in DRAMS. A workgroup has met and will continue to meet to prioritize accounts that need to be converted into DRAMS. In addition, we have been working closely with ACS State Healthcare, our fiscal intermediary, to enhance the capabilities of DRAMS. When the historical data is entered, the information in DRAMS will show the current balance of each manufacturer. In addition, personnel from the drug rebate program and fiscal services division are evaluating possible alternatives for maintaining a control account and subsidiary accounts receivable ledgers and will implement the most cost effective solution.

The Department would like to take this opportunity to comment on the difficulty of maintaining a control account and subsidiary accounts receivable ledgers. The accounts receivable system for drug rebate does not fit well into a traditional accounts receivable system because the State does not have any control over the rebate amounts. Rebate amounts are based upon units dispensed and a multiplier called "Unit Rebate Amount" (URA) as determined by CMS. The URA is calculated by CMS based upon information provided by manufactures. The problem with the accounts receivable accounting for rebates is that units can change when claims are adjusted by pharmacies and the URA amount can change. The State does have not control over unit changes and URA changes. In addition, reconciliation of rebates with manufacturers is based upon settling units, not dollar amounts. The accounts receivable balance is determined by multiplying the outstanding units by the most recent URA as determined by CMS. The accounts receivable balance is also adjusted by paid units times the difference in URA changes as reported by CMS for prior quarters.

The major difficulty with accounting for accounts receivable has been our inability to control changes to the URA. CMS allows labelers to retroactively change the amount they will pay on rebates. CMS also allows labelers the ability to change the amount they will pay states on rebates as far back as 1991. In many instances, the State may not have rebates records that far back. Retroactive changes that lower a previously

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paid URA create balances that are applied to current rebates. The State remains at a disadvantage and will incur significant administrative burdens to maintain accounts receivable systems as recommended by this OIG audit report as long as there are no regulations in place for controlling retroactive changes in URA's. The State must weigh the cost benefit of implementing administrative measurers to record the multitude of changes in receivable balances that are the result unit changes and URA changes for over 500 manufacturers and thousands of NDC's.

CMS 64.9R Reconciliation

The OIG report states that the Department did not perform a reconciliation to verify the accuracy of the uncollected rebate balance reported on the Form CMS 64.9R as required by Federal regulations. However, the Department does routinely reconcile the cash collections recorded in the DRAMS to amounts reported in the State's accounting system. Specifically, the Department did not reconcile the CMS 64.9R to the general ledger account balance or to the detailed subsidiary accounts receivable records because they did not adequately maintain a general ledger control account. The Department concurs with this finding.

After the Department implements the solution mentioned above, reconciliation of the rebate program and the CMS 64.9R will be attained. We appreciate the recognition of the OIG audit regarding our detailed reconciliation of cash collections between DRAMS and the State's accounting system. We believe that our internal controls in this area adequately safeguard all cash assets and assure they are used solely for authorized purposes.

Noted in the findings by OIG report was an uncollected rebate balance in excess of $1.5 billion for the quarter ended June 30, 2001. The Department was aware of the erroneous URA amount we received from CMS and this was noted on the CMS 64.9R by quarter and by labeler. The quarter ended September 30, 2001 reflects the corrected URA amount we received from CMS. An error like this could have been avoided if CMS had properly used their 50/50 edit report and rejected the erroneous rate information from the manufacturer. The 50/50 report explanation is shown in the CMS Medicaid Drug Rebate Operation Training Guide on page G10: "This report lists all NDC's that have a URA for the current quarter that calculates as being more than 50%(+ or -) different from the prior quarter."

URA Adjustments

The OIG report states that the Department did not adequately record adjustments to ensure that payments representing recalculated URA's were properly adjusted or that $0 URA's were calculated and remitted as required. Specifically, manufacturers are allowed to adjust URA information based upon current pricing information and remit a corrected amount. Therefore, the Department should accept URA's recalculated by the manufacturer and make appropriate adjustments to the subsidiary ledger. At a minimum, the Department should maintain a list of all the $0 URA's that were not calculated and paid by the manufacturer as required in order to facilitate follow-up inquiries and to identify items that are subject to interest penalties. As a result, the drug rebate receivables were perpetually understated and it is likely that the Department did not receive all drug rebate payments due from manufacturers. The Department concurs with this finding.

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Our current procedures include allocation of checks where the manufacturer will either supply a URA and pay the rebate or dispute that NDC as either an invalid or terminated NDC (dispute codes O or N). If it is disputed, the Department will contact the pharmacy to confirm the NDC dispensed and require documentation of an invoice or a copy of the drug label. If the pharmacy cannot confirm the NDC dispensed, they are required to adjust the claim, reversing the units. The units for $0 URA's are then reversed and no rebate is owed. If the manufacturer pays a rebate and supplies the Department with a URA on a $0 dollar URA, a code "B" is entered on the ROSI.

The Department will implement additional procedures to more adequately track $0 URA's to ensure an amount was calculated and remitted by the manufacturer. The Department will run a report by NDC on dispute code "B" and all $0 URA's at the end of a quarter. This report will be sent to CMS requesting updated URA calculations and the respective manufacturer requesting payment of rebates or updated pricing information to CMS so that URA's can be calculated.

Dispute Resolution

The OIG report states that the Department did not adequately follow-up on disputes that were not immediately resolved to ensure resolution within 60 days. Specifically, the rebate agreement requires that the States and drug manufacturers resolve rebate discrepancies within 60 days of receipt of notification of a dispute. It further states, "In the event that the State and the manufacturer are not able to resolve a discrepancy within 60 days, CMS shall require the State to make available to the manufacturer the State's hearing mechanism available under the Medicaid program." The Department concurs with this finding.

The Department appreciates the note in the audit report regarding our successful application of dispute resolution with manufacturers when the disputes first become known. Manufacturers will often contact Department staff immediately after receiving invoices to inquire about certain NDC's that may be in dispute. Our drug rebate system, DRAMS, provides immediate access to rebate information that is useful in resolving disputes. In addition, when rebate information is posted from the ROSI, Department staff is afforded the opportunity to investigate disputes made by manufacturers in an attempt to resolve disputes immediately. DRAMS has the ability to provide an audit trail of unit changes based upon discussion and documentation between the Department and the manufacturer.

For the disputed units that cannot be resolved immediately the Department will implement additional policies and procedures that will adequately follow-up on disputes with manufacturers.

The Department would like to take this opportunity to comment on this recommendation given the guidance we have received from CMS. We acknowledge that the rebate agreement CMS has with manufacturers requires that States and drug manufacturers resolve discrepancies within 60 days of receipt of notification of a dispute. However, based upon guidance by CMS, this requirement was never enforced by CMS, nor were we encouraged by CMS to utilize this avenue. States were encouraged by CMS to utilize the Dispute Resolution Project (DRP) meetings conducted by CMS. Montana has attended these meetings and found them to be very useful in resolving disputes

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with manufacturers. In addition, the DRP meetings have been useful as a mechanism to share information with other States to improve processes for management of the drug rebate program.

Summary

In conclusion, the State concurs with the findings by the OIG audit and will work on changing policies and procedures to enhance our ability to maintain internal controls over the drug rebate program to adequately safeguard assets. While this audit report has been helpful to the Montana Drug Rebate program, there is much more work that needs done both at the state and federal level regarding the drug rebate program.

It is our understanding that the OIG has recommendations for CMS regarding the administration of the drug rebate program at the federal level and we would be interested in receiving a copy of that report. In addition, it is important to note for the readers of this audit report that CMS has not published rules or regulations for the administration of the Medicaid Drug Rebate program that was implemented in 1991. To date, two proposed rules were drafted by CMS and never finalized. The drug rebate program would be enhanced by publication of rules and/or regulations guiding the program administration. The administration of this program is strictly based upon provisions contained in OBRA 90; CMS program memorandums; and best practices.

Thank you for the opportunity to comment on the draft audit report. Should you have any questions regarding this response, please contact Jeff Buska at (406) 444-4145 or Duane Preshinger at (406) 444-4144.

Sincerely,

Gail Gray

Gail Gray
Director

C John Chappuis
Chuck Hunter
Jeff Buska
Duane Preshinger
Marie Matthews
Betty DeVaney