DEPARTMENT OF HEALTH & HUMAN SERVICES OFFICE OF INSPECTOR GENERAL

Region IX
Office of Audit Services
50 United Nations Plaza, Room 171
San Francisco, CA 94102

October 20, 2003

Report Number A-10-03-00008

Mr. David Rogers
Division Administrator
Idaho Department of Health and Welfare
Division of Medicaid
P.O. Box 83720
Boise, Idaho 83720-0036

Dear Mr. Rogers:

Enclosed are two copies of the Department of Health and Human Services (HHS), Office of Inspector General (OIG) Report entitled, "Audit of the Medicaid Drug Rebate Program in Idaho."

Final determination as to actions taken on all matters reported will be made by the HHS action official named on page 2 of this transmittal letter. 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), OIG 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 which the Department chooses to exercise. (See 45 CFR Part 5.) As such, within 10 business days after the final report is issued, it will be posted on the Internet at *http://oig.hhs.gov.*

To facilitate identification, please refer to report number A-10-03-00008 in all correspondence relating to this report. If you have any questions or need additional information, please contact Doug Preussler at (415) 437-8309 or Juliet Lo at (415) 437-8350.

Sincerely,

Lori A. Ahlstrand
Regional Inspector General
for Audit Services

Direct Reply to HHS Action Official:

Ms. Linda A. Ruiz
Centers for Medicare & Medicaid Services
Regional Administrator, Region X
2201 Sixth Avenue, MS-40
Seattle, WA 98121

Enclosures – As stated

Department of Health and Human Services

OFFICE OF
INSPECTOR GENERAL

AUDIT OF THE MEDICAID DRUG REBATE PROGRAM IN IDAHO

OCTOBER 2003
A-10-03-00008

Office of Inspector General

http://oig.hhs.gov/

The mission of the Office of Inspector General (OIG), as mandated by Public Law 95-452, as amended, is to protect the integrity of the Department of Health and Human Services (HHS) programs, as well as the health and welfare of beneficiaries served by those programs. This statutory mission is carried out through a nationwide network of audits, investigations, and inspections conducted by the following operating components:

Office of Audit Services

The OIG's Office of Audit Services (OAS) provides all auditing services for HHS, either by conducting audits with its own audit resources or by overseeing audit work done by others. Audits examine the performance of HHS programs and/or its grantees and contractors in carrying out their respective responsibilities and are intended to provide independent assessments of HHS programs and operations in order to reduce waste, abuse, and mismanagement and to promote economy and efficiency throughout the Department.

Office of Evaluation and Inspections

The OIG's Office of Evaluation and Inspections (OEI) conducts short-term management and program evaluations (called inspections) that focus on issues of concern to the Department, the Congress, and the public. The findings and recommendations contained in the inspections reports generate rapid, accurate, and up-to-date information on the efficiency, vulnerability, and effectiveness of departmental programs.

Office of Investigations

The OIG's Office of Investigations (OI) conducts criminal, civil, and administrative investigations of allegations of wrongdoing in HHS programs or to HHS beneficiaries and of unjust enrichment by providers. The investigative efforts of OI lead to criminal convictions, administrative sanctions, or civil monetary penalties. The OI also oversees State Medicaid fraud control units, which investigate and prosecute fraud and patient abuse in the Medicaid program.

Office of Counsel to the Inspector General

The Office of Counsel to the Inspector General (OCIG) provides general legal services to OIG, rendering advice and opinions on HHS programs and operations and providing all legal support in OIG's internal operations. The OCIG imposes program exclusions and civil monetary penalties on health care providers and litigates those actions within the Department. The OCIG also represents OIG in the global settlement of cases arising under the Civil False Claims Act, develops and monitors corporate integrity agreements, develops model compliance plans, renders advisory opinions on OIG sanctions to the health care community, and issues fraud alerts and other industry guidance.

Notices

THIS REPORT IS AVAILABLE TO THE PUBLIC
at http://oig.hhs.gov/

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

OAS FINDINGS AND OPINIONS

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

DEPARTMENT OF HEALTH & HUMAN SERVICES

Office of Inspector General

Region IX
Office of Audit Services
50 United Nations Plaza
Room 171
San Francisco, CA 94102

October 20, 2003

Report Number A-10-03-00008

Mr. David Rogers
Division Administrator
Idaho Department of Health and Welfare
Division of Medicaid
P.O. Box 83720
Boise, Idaho 83720-0036

Dear Mr. Rogers:

This report provides you with the results of our "Audit of the Medicaid Drug Rebate Program in Idaho." The Medicaid drug rebate program was established to allow Medicaid to receive pricing benefits commensurate with its position as a high-volume purchaser of prescription drugs.

EXECUTIVE SUMMARY

OBJECTIVE

The objective of our review was to evaluate whether the State of Idaho's Department of Health and Welfare (State Agency) had established adequate accountability and internal controls over the Medicaid drug rebate program.

SUMMARY OF FINDINGS

Although the State Agency had policies and procedures for the drug rebate program, it did not revise the policies and procedures to reflect current practices. In addition, the State Agency had not established adequate internal controls over the Medicaid drug rebate program as required by 45 Code of Federal Regulations (CFR) Part 74.21. As a result, the State Agency did not properly report drug rebate information to the Centers for Medicare & Medicaid Services (CMS). We identified weaknesses in the following areas:

- **Quarterly Reporting** - The 64.9R report filed by the State Agency to CMS was inaccurate because prior quarter adjustments were not applied to the appropriate quarter. Additionally, the State Agency did not reconcile the uncollected rebate balance reported to CMS to its subsidiary ledger system (the supporting receivable account).

- **Accounts Receivable System** - The State Agency did not maintain a general ledger accounts receivable control account nor a sufficiently detailed subsidiary accounts receivable system to provide adequate accountability over its drug rebate activity.

- **Adjustments, Dismissals, and Write-offs** - Management review was not required by the State Agency for adjustments, dismissals, and write-offs of drug rebate funds.

- **Segregation of Duties** - The State Agency did not properly segregate duties between the drug rebate billing and collection functions.

- **Dispute Resolution** - The State Agency and its' contractor, Electronic Data Systems (Contractor), did not actively work to resolve the backlog of manufacturer drug rebate disputes. In addition, the State Agency had not used the State hearing process to resolve long-standing disputes with manufacturers as suggested by CMS.

RECOMMENDATIONS

We recommend that the State Agency:

(1) revise the policies and procedures to reflect current practices for its Medicaid drug rebate program; and

(2) establish internal controls to:

- accurately report drug rebate receivables to CMS and reconcile the ending balance of uncollected rebates to the receivable account;

- create a general ledger accounts receivable control account and a sufficiently detailed subsidiary accounts receivable system;

- provide management oversight for adjustments, dismissals, and write-offs;

- provide for segregation of duties between the drug rebate billing and collection functions; and

- actively work to resolve manufacturer disputes and, when appropriate, use the State hearing mechanism to resolve long-standing disputes.

STATE AGENCY COMMENTS

In written comments to our draft report, the State Agency generally agreed with most of the findings and recommendations. The State Agency disagreed with the findings regarding its

quarterly reporting and accounts receivable system. The complete text of the State Agency's comments is included as an appendix to this report.

For quarterly reporting, the State Agency believed the uncollected rebate balances reported to CMS in total were accurate and stated that it reconciled the uncollected balance to the receivable account. For accounts receivable system, the State Agency felt its present general and subsidiary ledger systems were adequate and that reconciliation of drug rebates to the National Drug Code (NDC) level was not required by Federal regulations.

OFFICE OF INSPECTOR GENERAL (OIG) RESPONSE

In regard to quarterly reporting, the receivable balances reported to CMS were not accurate and the reported ending balances were not reconciled to the receivable account. The receivable balances reported to CMS were not accurate because all activity was applied to the current quarter rather than the period for which the activity pertained. It is essential to track drug rebate activity to the appropriate quarter and NDC in order to properly review and resolve disputes. In addition, because the subsidiary ledger was not maintained by NDC and all activity was posted to the current quarter, a reconciliation could not be performed to the level of detail necessary for this complex program.

For the accounts receivable system, we agree that reconciliation of drug rebates to the NDC level may not be specifically required by Federal regulations. However, the complexity of the Medicaid drug rebate program requires tracking activity to the NDC level to ensure adequate accountability.

INTRODUCTION

BACKGROUND

On November 5, 1990, Congress enacted the Omnibus Budget Reconciliation Act of 1990 legislation (OBRA '90), which established the Medicaid drug rebate program that became effective January 1, 1991. The Medicaid drug rebate program was established to allow Medicaid to receive pricing benefits commensurate with its position as a high-volume purchaser of prescription drugs. Responsibility for the rebate program was shared among the drug manufacturers, CMS, and participating States. Throughout the program, CMS issued memoranda to State agencies and manufacturers to provide guidance on numerous issues related to the Medicaid drug rebate program.

The OBRA '90 required a drug manufacturer to enter into, and have in effect, a rebate agreement with CMS in order to have its products covered under the Medicaid program. After a rebate agreement was signed, the manufacturer was required to submit to CMS a listing of all covered outpatient drugs, including the average manufacturer price and best price information for each drug. A covered outpatient drug is one of approximately 56,000 drugs listed in the NDC listing. Approximately 550 pharmaceutical companies participated in the program nationally.

Based on the information received from the manufacturers, CMS calculated and provided the unit rebate amount (URA) for each covered drug to the States quarterly on a computer tape. However, the CMS tape may have contained a $0 URA if the pricing information was not provided timely by a manufacturer or if the computed URA had a 50 percent variance from the previous quarter. In instances of $0 URAs, States were instructed to invoice the units and the manufacturers were required to calculate the URAs and remit the appropriate amounts to the State. In addition, the manufacturers could change any URA based on updated pricing information, and submit this information to States.

Each State was required to maintain, by manufacturer, the number of units dispensed for each covered drug. That number was applied to the URA to determine the actual rebate amount due from each manufacturer. States were required to provide drug utilization data to the manufacturers and CMS on a quarterly basis.

From the date an invoice was postmarked, each manufacturer had 38 days to remit the drug rebate amount owed to the State before interest started to accrue. The manufacturers were to provide the State with a Reconciliation of State Invoice detailing its rebate payment by NDC. A manufacturer could dispute utilization data it believed to be erroneous, but was required to pay the undisputed portion of the rebate by the due date. If the manufacturer and the State could not, in good faith, resolve the discrepancy, the manufacturer was required to provide written notification of the dispute to the State by the due date. The manufacturer was required to calculate and remit interest for disputed rebates when settlement was made in favor of the State. If the State and manufacturer were not able to resolve the discrepancy within 60 days, the State was required to make available a hearing mechanism under the State's Medicaid program for the manufacturer to resolve the dispute. In addition, States had the option to attend conferences, such as the Dispute Resolution Project sponsored by CMS, to resolve disputes with manufacturers.

States were required to report, on a quarterly basis, rebate collections on the CMS 64.9R report. Specifically, States were required to report rebates invoiced in the current quarter, adjustments and rebates received during the current quarter, and uncollected rebate balances for the current and prior quarters. The CMS 64.9R report was part of the CMS 64 report, which summarized actual Medicaid expenditures for each quarter and was used by CMS to reimburse the Federal share of these expenditures.

The State Agency reported (1) an average of $4.9 million in billings and $5.8 million in collections per quarter during the 1-year period ending June 30, 2002, and (2) $5.5 million as the outstanding receivable balance as of June 30, 2002. According to its accounting records, the State Agency's outstanding receivable balance as of June 30, 2002 was $6.3 million. Of this $6.3 million, $924,000 had been outstanding for 90 days or longer.

The Idaho drug rebate program was established on January 1, 1991. The State Agency was responsible for all of the functions of the drug rebate program from January 1991 through September 1995. Effective October 1995, the State Agency contracted with a private company, to perform the day-to-day management of the rebate program. The Contractor's responsibility

included the invoicing, rebate collections, adjustment, dispute resolution, and record keeping processes. The State Agency continued to perform the quarterly reporting function.

OBJECTIVE, SCOPE, AND METHODOLOGY

Objective

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

Scope

We focused our audit on the current policies, procedures, and internal controls established by the State Agency and Contractor for the Medicaid drug rebate program. We also reviewed accounts receivable information related to prior periods and interviewed State Agency and Contractor staff to gain an understanding of how the Medicaid drug rebate program had operated since the State Agency began working with the Contractor in October 1995.

Methodology

Our audit was performed in accordance with generally accepted government auditing standards. To accomplish our objectives, we interviewed State Agency and Contractor officials to determine the policies, procedures and internal controls that existed with regard to the Medicaid drug rebate program. We interviewed State Agency and Contractor employees that performed functions related to the drug rebate program, to understand their roles in the invoicing and dispute resolution processes. In addition, we reviewed the drug rebate accounts receivable balance reported in the State Agency's subsidiary ledger system and compared the data to the CMS 64.9R report for the quarter ending June 30, 2002.

Our fieldwork was conducted during the period April 2003 through July 2003, and included a site visit to State Agency and Contractor offices in Boise, Idaho.

FINDINGS AND RECOMMENDATIONS

We found that the State Agency had not revised its policies and procedures to reflect current practices for the Medicaid drug rebate program. In addition, the State Agency had not established adequate internal controls as required by 45 CFR Part 74.21. As a result, the State Agency did not properly report drug rebate information to CMS. We identified weaknesses in the following areas:

- Quarterly Reporting
- Accounts Receivable System
- Adjustments, Dismissals, and Write-Offs
- Segregation of Duties
- Dispute Resolution

FORMAL POLICIES AND PROCEDURES

The State Agency did not maintain current formal written policies and procedures over the Medicaid drug rebate program. The State Agency approved policies and procedures developed by the Contractor for the day-to-day management of the drug rebate program. However, the most recent policies and procedures approved by the State Agency was in 1997.

INTERNAL CONTROLS AND ACCOUNTABILITY

Quarterly Reporting

The uncollected rebate balances reported to CMS by the State Agency were inaccurate. This was partially due to the fact that the State Agency did not ensure that the Contractor applied prior quarter adjustments received from manufacturers to the quarter in which the rebate was claimed. The manufacturers submitted prior quarter adjustments along with their payments for current period rebate billings and adjustments. The Contractor processed the current period payments in a timely manner but incorrectly applied prior quarter adjustments to the current quarter. Therefore, the reported amounts did not match the revenues to the appropriate period.

In addition, the State Agency did not maintain documentation to support the amounts reported on the CMS 64.9R report and did not reconcile the total uncollected balance reported to the subsidiary ledger.

Accounts Receivable System

The State Agency did not maintain a general ledger accounts receivable control account nor maintain its subsidiary accounts receivable system at a sufficiently detailed level to accurately account for drug rebate activity. The State Agency's general ledger system only maintained drug rebate collections in the aggregate whereas the State Agency's subsidiary accounts receivable system tracked drug rebate activity by quarter and year for each labeler number but did not track activity by NDC. Since the State Agency did not maintain a general ledger accounts receivable control account nor a sufficiently detailed subsidiary accounts receivable system, the State Agency could not reconcile the amount of uncollected rebates between the two systems nor adequately account for the complex NDC level transactions that made up the drug rebate program.

The drug rebate program was complex with rebates calculated quarterly by CMS for approximately 56,000 NDCs. The complexity was further increased by $0 URAs and URA adjustments.

The quarterly URA tapes provided by CMS contained many $0 URAs. In those instances, the States were instructed to prepare an invoice for the manufacturer to calculate the URA and remit the appropriate rebate to the State. As a result of $0 URAs, the original invoiced amount recorded as a receivable was understated and should have been adjusted when the manufacturer remitted payment.

Additionally, because of updated pricing information, manufacturers were required by CMS to adjust URAs for updated pricing information. Adjustments in URAs were common and, if not posted or otherwise accounted for by States, the receivable balance was inaccurate.

Adjustments, Dismissals, and Write-Offs

The State Agency did not provide adequate management oversight over adjustments, dismissals, and write-offs. One Contractor employee was responsible for initiating the adjustments, dismissals, and write-offs and for processing the transaction. As a result, large outstanding balances were adjusted, dismissed, and written-off without management review or approval. Since the establishment of its drug rebate program in 1991, the State Agency had made a total of $42 million in adjustments, dismissals and write-offs without requiring management approval. The lack of management oversight and review increased the potential risk for fraud, waste, and abuse of drug rebate program funds.

Segregation of Duties

The State Agency did not adequately segregate duties for rebate billings and collections. The same Contractor employee performed the billing function of preparing rebate invoices as well as the collection functions of updating receivables, dispute resolution, adjustments, dismissals, and write-offs. The lack of segregation of duties between the billing and collection functions increased the potential risk for fraud, waste, and abuse of drug rebate program funds.

Dispute Resolution

The State Agency and Contractor had not actively worked to resolve long-standing disputes with manufacturers over drug rebate amounts. In addition, the State Agency did not utilize the State hearing mechanism to resolve long-standing disputes with manufacturers.

The State Agency was responsible for resolving amounts disputed from January 1991 through September 1995 while the Contractor was responsible for amounts disputed from October 1995 to the present. Both the State Agency and Contractor had a backlog of long-standing dispute cases. Upon receipt of a dispute notification, the Contractor would send a letter of acknowledgement to the manufacturer when it was in agreement with the manufacturer that a dispute existed. However, except for this initial contact by the Contractor, neither the State Agency nor Contractor had continued to actively work to resolve its backlog of long-standing cases.

In addition, the State Agency did not utilize the State hearing mechanism to resolve long-standing disputes with manufacturers. The drug rebate agreement between CMS and manufacturers required the States and manufacturers to use their best efforts to resolve rebate discrepancies within 60 days of receipt of a dispute notification. However, in the event that the State and manufacturer were unable to resolve a discrepancy, CMS required the State to make available to the manufacturer a State hearing mechanism under the Medicaid Program. CMS Program Release #44 issued to the State Medicaid Directors, indicated that CMS believed the

State hearing process was the appropriate mechanism for both the manufacturers and States to resolve disputes.

As of April 2003, the State Agency and Contractor had an outstanding disputed rebate balance of $1 million. This outstanding disputed rebate balance included some long-standing disputes. The State hearing mechanism is an appropriate method to resolve the long-standing portion of these disputes, which may result in increased rebate collections.

RECOMMENDATIONS

We recommend that the State Agency:

(1) revise the policies and procedures to reflect current practices for its Medicaid drug rebate program; and

(2) establish internal controls to:

- accurately report drug rebate receivables to CMS and reconcile the ending balance of uncollected rebates to the receivable account;
- create a general ledger accounts receivable control account and a sufficiently detailed subsidiary accounts receivable system to account for all drug rebate activity;
- provide management oversight for adjustments, dismissals, and write-offs;
- provide for segregation of duties between the rebate billing and collection functions; and
- actively work to resolve manufacturer disputes and, when appropriate, use the State hearing mechanism to resolve long-standing disputes.

STATE AGENCY COMMENTS

In written response to our draft report, the State Agency concurred with our finding and recommendation regarding updating its policies and procedures to reflect current practices. The State Agency disagreed with our recommendations regarding its quarterly reporting and accounts receivable system. The State Agency generally concurred with our findings and recommendations regarding management oversight for adjustments, dismissals, and write-offs; segregation of duties; and dispute resolution. The complete text of the State Agency's comments is included as an appendix to this report.

For quarterly reporting, the State Agency believed the uncollected rebate balance reported to CMS in total were accurate and stated that it reconciled the uncollected balance to the receivable

accounts. State Agency officials believed the recommended changes were not cost effective nor feasible due to limited resources.

For the accounts receivable system, State Agency officials indicated the present general and subsidiary ledger systems were adequate and that reconciliation of drug rebates to the NDC level was not required by Federal regulations. They stated that the total accounts receivable balance is reported at State fiscal year end on its Comprehensive Annual Financial Report and believed the current subsidiary ledger system ensured adequate accountability for the drug rebate program. In addition, the State Agency believed that the costs required to implement a subsidiary ledger system to track drug rebate activity to the NDC level outweighed any benefits, and that this level of tracking and reconciliation was not required by Federal regulations.

For adjustments, dismissals, and write-offs, State Agency officials concurred that enhanced management oversight would be appropriate and indicated they plan to conduct random samples to review and confirm adjustments, dismissals and write-offs in the future.

For segregation of duties and dispute resolution, State Agency officials stated they may hire additional staff to further segregate duties and resolve drug rebate disputes more quickly.

OIG RESPONSE

In regard to quarterly reporting, the receivable balances reported to CMS were not accurate and the reported ending balances were not reconciled to the receivable account. The receivable balances reported to CMS were not accurate because all activity was applied to the current quarter rather than the period for which the activity pertained. It is essential to track drug rebate activity to the appropriate quarter and NDC in order to properly review and resolve disputes. In addition, because the subsidiary ledger was not maintained by NDC and all activity was posted to the current quarter, a reconciliation could not be performed to the level of detail necessary for this complex program.

For the accounts receivable system, reporting the total uncollected receivables to the State Agency's annual financial report is not adequate. This balance was taken from the 64.9R report to CMS and was not an independent verification of the accuracy of the subsidiary ledger. In addition, although reconciliation of drug rebates to the NDC level may not be specifically required by Federal regulations, the complexity of the Medicaid drug rebate program requires tracking activity to the NDC level to ensure adequate accountability.

For dispute resolution, although the State Agency may hire additional drug rebate staff, it should also consider using the State hearing process to resolve any long-standing disputes with manufacturers, when appropriate.

* * * * * * *

In accordance with the principles of the Freedom of Information Act (5 U.S.C. 552, as amended by Public Law 104-231), OIG 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 which the Department chooses to exercise. (See 45 CFR, part 5.)

To facilitate identification, please refer to report number A-10-03-00008 in all correspondence relating to this report.

Sincerely,

Lori A. Ahlstrand
Regional Inspector General
for Audit Services

Enclosure

APPENDIX

IDAHO DEPARTMENT OF
HEALTH & WELFARE

DIRK KEMPTHORNE - Governor
KARL B. KURTZ - Director

DAVID A. ROGERS - Administrator
DIVISION OF MEDICAID
P.O. Box 83720
Boise, ID 83720-0036
PHONE 208-334-5747
FAX 208-364-1811

October 2, 2003

Lori A. Ahlstrand
Regional Inspector General
for Audit Services
Office of Inspector General
Department of Health and Human Services
Region IX, Office of Audit Services
50 United Nations Plaza, Room 171
San Francisco, CA 94102

Dear Ms. Ahlstrand:

Enclosed are the Department's written comments in response to the draft report entitled "Audit of the Medicaid Drug Rebate Program in Idaho," identified as report number A-10-03-00008.

We look forward to receipt of the final report in the near future.

Sincerely,

DAVID A. ROGERS
Administrator

Enc.

DAR/lpw

Response to
Audit of the Medicaid Drug Rebate Program in Idaho
Report Number A-10-03-00008

Recommendation:
Revise the policies and procedures to reflect current practices for its Medicaid drug rebate program.

Response:
The Department concurs that the procedure manual should reflect current practices. We anticipate this manual to be completed updated prior to year end.

Recommendation:
Establish internal controls to:

1. Accurately report drug rebate receivables to CMS and reconcile the ending balance of uncollected rebates to the receivable account;
2. Create a general ledger accounts receivable control account and a sufficiently detailed subsidiary accounts receivable system to account for all drug rebate activity.
3. Provide management oversight over adjustments, dismissals and write-offs;
4. Provide for segregation of duties between the rebate billing and collection functions; and
5. Actively work to resolve manufacturer disputes and, when appropriate, use the State hearing mechanism to resolve long-standing disputes.

Response:

1. The Department's current MMIS system does not accurately report the uncollected rebates in the proper quarter because of the receipt posting process. Recommended changes to this process would require staff resources and funds, which are not available at this time. The uncollected balances shown on each quarterly 64.9R are accurate in total. There is documentation to support the amounts reported on the 64.9R, and the uncollected balance is reconciled to the subsidiary ledger. The recommended change would not increase the rebate amounts, and would have no effect on the total uncollected balance.

2. The Department believes the present systems are adequate. Costs to change the systems would be significant. The Department reports the accounts receivable amount in the

annual CAFR at the end of each State fiscal year. This balances with the amount reported on the 64.9R and the detailed subsidiary system. The subsidiary maintained in our MMIS is our detailed subsidiary account receivable system and ensures adequate accountability for our program.

45 CFR Part 74.21 does not appear to require reconciliation of drug rebates at the NDC level. Our understanding is that this CMS does not interpret the regulation to require this level of reconciliation. The expense to fund the system changes and staff to receipt rebates at the NDC level outweigh any benefit to the Department.

Zero dollar URAs are handled in the reconciliation process. Zero dollar URAs are identified on invoices and reviewed for payment. Invoices are not considered paid until all zero dollar URAs are addressed. The Department believes the follow-up process is adequate.

3. The Department believes the appropriate limit of authority is in place for write-offs. Rebate amounts are estimates; therefore, adjustments are often necessary. All adjustments and dismissals are documented. Write-offs for disputed rebates are properly limited. The Department concurs that enhanced management review would be appropriate and in the future we plan to conduct random samples to review and confirm these activities.

4. The contracted employee who administers drug rebate activities (invoices and reconciliation) does not handle the rebate checks. The current process is deemed adequate by the Department. A proposal from the contractor to increase drug rebate staff is under consideration by the Department. If accepted, we may further require segregation of invoice and reconciliation functions.

5. The Department has a State hearing process in place. We will continue to work closely with manufacturers to resolve disputes quickly. As noted previously, a proposal from the Department's contractor to increase drug rebate staff is under consideration. Increased staffing will help to resolve disputes more quickly.