DEPARTMENT OF HEALTH & HUMAN SERVICES

Office of Inspector General

Office of Audit Services
1100 Commerce, Room 632
Dallas, TX 75242

April 30, 2003

Common Identification Number: A-06-03-00012

Ms. Carolyn Ingram
Medicaid Director
Human Services Department/Medical Assistance Division
P.O. Box 2348
Santa Fe, New Mexico 87504-2348

Dear Ms. Ingram:

Enclosed are two copies of the Department of Health and Human Services (HHS), Office of Inspector General (OIG), Office of Audit Services' (OAS) report entitled "Review of Medicaid Drug Rebate Collections-State of New Mexico." A copy of this report will be forwarded to the action official noted below for his/her review and any action deemed necessary.

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

To facilitate identification, please refer to Common Identification Number A-06-03-00012 in all correspondence relating to this report.

Sincerely yours,

Gordon L. Sato

Gordon L. Sato
Regional Inspector General
for Audit Services

Enclosures - as stated

Direct Reply to HHS Action Official:
Dr. James R. Farris, M.D.
Regional Administrator
Centers for Medicare and Medicaid Services
1301 Young Street, Suite 714
Dallas, TX 75202

Department of Health and Human Services

OFFICE OF INSPECTOR GENERAL

REVIEW OF MEDICAID DRUG REBATE COLLECTIONS STATE OF NEW MEXICO

JANET REHNQUIST
Inspector General

APRIL 2003
A-06-03-00012

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.

EXECUTIVE SUMMARY

OBJECTIVE

The audit objective was to evaluate whether the New Mexico Human Services Department (NMHSD) had established adequate accountability and internal controls over the Medicaid drug rebate program.

FINDINGS

The NMHSD had not established adequate controls over the drug rebate program as required by federal rules and regulations. Areas that lacked sufficient controls included:

- accounts receivable system,
- segregation of duties,
- interest accrual and collection,
- dispute resolution, and
- Form CMS 64.9R reconciliation.

Federal regulations require that financial management systems provide for effective control over and accountability for all funds, property, and other assets. In addition, the rebate agreements between the Centers for Medicare and Medicaid Services (CMS) and the drug manufacturer(s) require the payment of interest on all disputed, late, and unpaid drug rebates.

In our opinion, the control weaknesses occurred because the NMHSD had not established formal policies and procedures. The NMHSD officials stated that written policies and procedures were not developed for the drug rebate program. Additionally, we believe that the NMHSD has not devoted adequate resources to the drug rebate program.

As a result, the NMHSD had not provided effective control over and accountability for drug rebate collections. Specifically, there was no reasonable assurance as to the accuracy of the $5.8 million that NMHSD reported as its outstanding balance as of June 30, 2002. Also, the lack of segregation of duties resulted in a potential risk for waste, fraud, or abuse of the drug rebate program funds. In addition, there was no assurance that NMHSD was collecting all of the interest payments for late, unpaid, or disputed rebates.

RECOMMENDATIONS

The NMHSD reported a balance of $5.8 million in uncollected drug rebates as of June 30, 2002. Because of the weaknesses that exist in the current accounting system, this amount could even be greater. We believe that the NMHSD has the opportunity to significantly increase the amount of revenue that is realized from drug rebates. Therefore, we recommend that the NMHSD develop formal policies, procedures, and controls that, at a minimum, would:

1) Create a sufficiently detailed subsidiary accounts receivable with a corresponding control account for accounts receivable,
2) Provide for the proper segregation of duties for receipt of cash,
3) Account for the interest related to late or disputed rebate payments,
4) Monitor disputed rebate amounts, including appropriate use of the hearing mechanism prescribed in the rebate agreement between CMS and the manufacturer(s), and
5) Accurately report drug rebate collections on Form CMS 64.9R.

In addition, we recommend that the NMHSD consider devoting more resources to the drug rebate program.

The NMHSD responded to our draft report in a letter dated April 18, 2003. The NMHSD generally agreed with the findings of our review, except for segregation of duties for the receipt of cash. The complete text of the NMHSD's response is included as **Appendix 1**.

INTRODUCTION

BACKGROUND

On November 5, 1990, Congress enacted the Omnibus Budget Reconciliation Act (OBRA) of 1990 legislation, which among other provisions established the Medicaid drug rebate program. Responsibility for the rebate program is shared among the drug manufacturer(s), the Centers for Medicare and Medicaid Services (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 on numerous issues related to the Medicaid drug rebate program.

A drug manufacturer is required 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 is signed, 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 unit rebate amount (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 pricing information has a 50 percent variance from the previous quarter. In instances of $0 URAs, the state agency is instructed to invoice the units and the manufacturer should pay the rebate based on the manufacturer's information. In addition, the manufacturers often change the URA based on updated pricing information, and submit this information to the state agency in the Prior Quarter Adjustment Statement (PQAS).

Each state agency is required to maintain the number of units dispensed, by manufacturer, for each covered drug. Approximately 56,000 National Drug Code (NDC) are available under the program. Each state agency uses the URA from CMS and the utilization for each drug to determine the actual rebate amounts due from the manufacturer. The CMS requires each state agency to provide drug utilization data to the manufacturer.

The manufacturer has 38 days from the day a state agency sends an invoice to pay the rebate to avoid interest. The manufacturers submit to the state agency a Reconciliation of State Invoice (ROSI) that details the current quarter's payment by NDC. A manufacturer can dispute utilization data that it believes is erroneous, but the manufacturer is required to pay the undisputed portion by the due date. If the manufacturer and the state agency cannot in good faith resolve the discrepancy, the manufacturer must provide written notification to the state agency by the due date. If the state agency and the manufacturer are not able to resolve the discrepancy within 60 days, the state agency must make a hearing mechanism available under the Medicaid program to the manufacturer in order to resolve the dispute.

Each state agency reports, on a quarterly basis, outpatient drug expenditures and 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. The NMHSD reported to CMS an average of $4.3 million in billings per quarter and collections of $2.8 million per quarter during the 1-year period ending June 30, 2002. The NMHSD reported $5,833,793 on the CMS 64.9R as the outstanding balance as of June 30, 2002.

The NMHSD contracted with its fiscal intermediary to prepare and mail the invoices to manufacturers, but performed all other functions of the drug rebate program. One pharmacist was responsible for monitoring and working on drug rebate accounts receivable, including resolving disputes, researching utilization data to resolve errors, communicating with manufacturers, and monitoring outstanding balances. Staff in other departments separately performed the functions of depositing funds, posting payments to the general ledger, and preparing the CMS 64 reports.

OBJECTIVE, SCOPE, AND METHODOLOGY

Objective

The audit objective was to evaluate whether the NMHSD 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 NMHSD as of June 30, 2002. We also reviewed accounts receivable information related to prior periods and interviewed NMHSD staff to understand how the Medicaid drug rebate program has operated since 1993.

Methodology

To accomplish our objectives, we interviewed NMHSD officials to determine the policies, procedures and controls that existed with regard to the Medicaid drug rebate program. Also, we interviewed staff members that performed functions related to the drug rebate program, and we interviewed the fiscal intermediary staff to determine its role in the invoicing process. In addition, we obtained and reviewed drug rebate accounts receivable records and compared this data to the Form CMS 64.9R report for June 30, 2002.

Field work was performed at the NMHSD's office in Santa Fe, New Mexico during November 2002 and January 2003, and continued in the Little Rock, Arkansas field office through February 2003. Our audit was performed in accordance with generally accepted government auditing standards.

FINDINGS AND RECOMMENDATIONS

The NMHSD had not established adequate controls over the drug rebate program as required by federal rules and regulations. Areas that lacked sufficient controls included:

- accounts receivable system,
- segregation of duties,
- interest accrual and collection,
- dispute resolution, and
- Form CMS 64.9R reconciliation.

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. In addition, the rebate agreements between CMS and the drug manufacturer(s) require the payment of interest on all disputed, late, and unpaid drug rebates.

Accounts Receivable System

The NMHSD did not maintain a general ledger accounts receivable control account nor were the subsidiary accounts receivable maintained at a sufficiently detailed level to accurately account for drug rebate collections. The NMHSD maintained two separate accounts receivable systems, one by the Fiscal Management Bureau (FMB) and another by the pharmacist in the Benefit Services Bureau (BSB). Neither of the systems was a control account nor was either sufficiently detailed to accurately monitor rebate collections.

The drug rebate program is complex as rebates are calculated quarterly for approximately 56,000 drugs. The complexity is made even greater by $0 URAs and URA adjustments. The quarterly URA tape provided by CMS contains many $0 amounts. In those instances the state agency is instructed to invoice the units and the manufacturer is required to calculate the URA and remit the appropriate payment to the state agency. As a result of $0 URAs, the original invoiced amount that is recorded as a receivable is understated and should be adjusted when the manufacturer remits the payment. Additionally, because of updated pricing information, manufacturers are required by CMS to adjust URAs. Adjustments in URAs are common and if not posted or otherwise accounted for, the receivable balance is inaccurate.

Both of the accounts receivable systems were maintained at the manufacturer level with only invoice totals and payment totals posted. None of the URA adjustments, including those for drugs that were billed with a $0 URA, were posted to either system. Without the posting of adjustments, neither system provided an accurate measure of drug rebates receivable.

As a result, the NMHSD had not provided effective control over and accountability for drug rebate collections. Although the NMHSD reported an outstanding balance of $5.8

million as of June 30, 2002, we do not have reasonable assurance as to the accuracy of the amount.

Segregation Of Duties

The NMHSD did not have a proper segregation of duties for the receipt of drug rebate funds. Only one staff member was involved in the receipt of mail containing drug rebate checks. This staff member then prepared copies of the checks and accompanying documentation for distribution, and forwarded the checks to another department for deposit. In addition, there were no procedures available for us to document this process.

The lack of segregation of duties resulted in a potential risk for waste, fraud, or abuse of the drug rebate program funds.

Interest on Late, Disputed, and Unpaid Rebates

The NMHSD did not have adequate controls to accrue interest for late or disputed rebate payments. The NMHSD did not accrue, track, or verify whether interest payments received from manufacturers were correct.

According to the rebate agreements between the manufacturers and CMS, required by Section 1927 of the Social Security Act, manufacturers are required to pay interest on late, disputed, or unpaid rebates. Section V, paragraph (b) of the rebate agreement states:

> *(b) If the Manufacturer in good faith believes the State Medicaid Agency's Medicaid Utilization Information is erroneous, the Manufacturer shall pay the State Medicaid Agency that portion of the rebate amount claimed which is not disputed within the required due date in II (b). The balance due, if any, plus a reasonable rate of interest as set forth in section 1903(d)(5) of the Act, will be paid or credited by the Manufacturer or the State by the due date of the next quarterly payment in II(b) after resolution of the dispute.*

According to CMS Medicaid Drug Rebate Program Release #65, it is the manufacturers' responsibility to calculate and pay interest for applicable rebate invoices and the State's responsibility to track collections and report those amounts to CMS. In addition, Program Release #29 requires that interest must be collected and cannot be disregarded as part of the dispute resolution process by either the manufacturer or the State. As the methodology is prescribed in the regulations, a reasonable estimate could have been made and booked as an accrual for all applicable billings, and interest payments received could have been verified.

Because NMHSD was not accruing or verifying interest, there was no assurance that NMHSD was collecting all of the interest payments for late, unpaid, or disputed rebates.

Dispute Resolution

The NMHSD lacked adequate policies and procedures for resolving disputes with manufacturers. Disputes occur frequently due to the complexity of the program, the large number of manufacturers and drugs, and the large volume of dispensed drugs.

The NMHSD identified disputes when the manufacturers sent the ROSI to the State with the rebate payment, or when the manufacturer contacted the pharmacist in the BSB. However, the pharmacist who was responsible for resolving disputes stated that there was not a formal system of monitoring outstanding disputes. The pharmacist stated that she worked on disputes as she had time, and did document an example of a resolved dispute. However, she estimated that only 30 percent of her time was devoted to drug rebates in the past 2 years.

CMS 64.9R Reconciliation

The NMHSD did not perform a reconciliation to verify the accuracy of the uncollected rebate balance reported on the Form CMS 64.9R. The CMS 64.9R report is used by the states to report the results of the Medicaid drug rebate program. 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, the 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 Form CMS 64.9R was prepared by the Administrative Services Division of the NMHSD, based on reported totals of invoiced amounts and cash receipts from the FMB. The ending balance of the prior quarter was rolled forward to become the beginning balance for the current quarter. New rebates invoiced during the current quarter were added and rebates received during the current quarter were subtracted to calculate the ending balance. However, adjustments to account balances were not made in the subsidiary ledgers and thus were not reported on the CMS 64.9R. Additionally, the NMHSD did not reconcile the rebate figures reported to CMS to either of the accounts receivable systems.

In our opinion, each of the control weaknesses noted above occurred because the NMHSD had not established formal policies and procedures. The NMHSD officials stated that written policies and procedures were not developed for the drug rebate program. In fact, neither the FMB Chief nor the BSB Chief was aware of the functions performed by the other Bureau. Additionally, we believe that the NMHSD has not devoted adequate resources to the drug rebate program, as evidenced by the limited staff assigned to the drug rebate program.

RECOMMENDATIONS

The NMHSD reported a balance of $5.8 million in uncollected drug rebates as of June 30, 2002. Because of the weaknesses that exist in the current accounting system, this amount could even be greater. We believe that the NMHSD has the opportunity to significantly increase the amount of revenue that is realized from drug rebates. Therefore we recommend that the NMHSD develop formal policies, procedures, and controls that, at a minimum, would:

1) Create a sufficiently detailed subsidiary accounts receivable with a corresponding control account for accounts receivable,
2) Provide for the proper segregation of duties for receipt of cash,
3) Account for the interest related to late or disputed rebate payments,
4) Monitor disputed rebate amounts, including appropriate use of the hearing mechanism prescribed in the rebate agreement between CMS and the manufacturer(s), and
5) Accurately report drug rebate collections on Form CMS 64.9R.

In addition, we recommend that the NMHSD consider devoting more resources to the drug rebate program.

AUDITEE'S COMMENTS

The NMHSD responded to our draft report in a letter dated April 18, 2003. The NMHSD generally agreed with our findings and recommendations, except for segregation of duties for the receipt of cash. The NMHSD's comments for each recommendation are summarized below and included in their entirety as **Appendix 1**.

1) Create a sufficiently detailed subsidiary accounts receivable with a corresponding control account for accounts receivable.

The NMHSD disagreed with our characterization of its accounts receivable system, but did acknowledge that the records were fragmented and should be fully developed into an accounts receivable system. The NMHSD also stated that it will convene work groups to develop improved methods of tracking financial activity for the drug rebate program.

2) Provide for the proper segregation of duties for receipt of cash.

The NMHSD disagreed that duties were not properly segregated for the receipt of cash. The NMHSD's response described the entire process for receipt and deposit of drug rebate checks, which included multiple staff members.

3) Account for the interest related to late or disputed rebate payments.

The NMHSD agreed and stated that it will ensure there are procedures in place to account for the interest related to late or disputed rebate payments.

4) Monitor disputed rebate amounts, including appropriate use of the hearing mechanism prescribed in the rebate agreement between CMS and the manufacturer(s). Also consider devoting more resources to the drug rebate program.

The NMHSD agreed, and stated that devoting more resources so that dispute resolution can be performed adequately has been discussed. Also, NMHSD indicated changes already have been made to identify disputes by NDC.

5) Accurately report drug rebate collections on Form CMS 64.9R.

The NMHSD concurred that accurate federal reporting is desirable, and is reviewing the processes to ensure that the amounts reported on the CMS 64.9R are complete and accurate.

OIG RESPONSE

Concerning the segregation of duties, we agree that there were several staff members in multiple departments that processed the payment receipt and deposit cycle. However, we disagree that duties were properly segregated for the receipt of mail containing rebate checks. We believe it is a prudent business practice to have more than one staff member involved at the time of receipt in order to establish proper control of the check and decrease the risk of fraud, waste or abuse.

NEW MEXICO HUMAN SERVICES DEPARTMENT
P.O Box 2348 Santa Fe, NM 87504-2348
Medical Assistance Division
Phone: 505-827-3100

Bill Richardson
Governor

Pamela S. Hyde, J.D.
Secretary

April 18, 2003

Gordon L. Sato
Regional Inspector General for Audit Services
Office of the Inspector General
Office of Audit Services
1100 Commerce, Room 632
Dallas, Texas 75242

Dear Mr. Sato:

Enclosed please find our response to the draft audit report entitled "Review of Medicaid Drug Rebate Collections-State of New Mexico". The New Mexico response document has been formatted to include the findings and recommendations detailed in the draft report, followed by our response.

We look forward to receiving the final report from your office and appreciate the opportunity to improve the New Mexico Drug Rebate program. If you have any questions, please contact Georgia Cleverley, Benefits Bureau Chief, at (505) 827-3134.

Sincerely:

C. Ingram

Carolyn Ingram
Director

Enclosures

Recognized for Leadership and Excellence

FINDINGS AND RECOMMENDATIONS

The NMHSD has not established adequate controls over the drug rebate program required by federal rules and regulations. Areas that lacked sufficient controls included:

- Accounts receivable system,
- Segregation of duties,
- Interest accrual and collection,
- Dispute resolution, and
- Form CMS 64.9R reconciliation.

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. In addition, the rebate agreements between CMS and the drug manufacturer(s) require the payment of interest on all disputed, late, and unpaid drug rebates.

FINDING
Accounts Receivable System

The NMHSD did not maintain a general ledger accounts receivable control account nor were the subsidiary accounts receivable maintained at a sufficiently detailed level to accurately account for drug rebate collections. The NMHSD maintained two separate accounts receivable systems, one by the Fiscal Management Bureau (FMB) and another by the pharmacist in the Benefit Services Bureau (BSB). Neither of the systems was a control account nor was either sufficiently detailed to accurately monitor rebate collections.

The drug rebate program is complex as rebates are calculated quarterly for approximately 56,000 drugs. The complexity is made even greater by $0 URAs and URA adjustments. The quarterly URA tape provided by CMS contains many $0 amounts. In those instances the state agency is instructed to invoice the units and the manufacturer is required to calculate the URA and remit the appropriate payment to the state agency. As a result of $0 URAs, the original invoiced amount that is recorded as a receivable is understated and should be adjusted when the manufacturer remits the payment. Additionally, because of updated pricing information, manufacturers are required by CMS to adjust URAs. Adjustments in URAs are common and if not posted or otherwise accounted for, the receivable balance is inaccurate.

Both of the accounts receivable systems were maintained at the manufacturer level with only invoice totals and payment total posted. None of the URA adjustments, including those for drugs that were billed with a $0 URA, were posted to either system. Without the posting of adjustments, neither system provided an accurate measure of drug rebates receivable.

As a result, the NMHSD had not provided effective control over and accountability for drug rebate collections. Although the NMHSD reported an outstanding balance of $5.8

million as of June 30, 2002 we do not have reasonable assurance as to the accuracy of the amount.

RECOMMENDATION
Accounts Receivable System

Create a sufficiently detailed subsidiary accounts receivable with a corresponding control account for accounts receivable.

Department Response

The New Mexico Human Services Department (HSD) disagrees that there are "two separate accounts receivable systems" as identified above in the draft audit findings. As discussed with the federal auditor, the accounts receivable system for HSD is maintained at the Administrative Services Division (ASD). The "two separate accounts receivable systems" are actually sub-systems that are maintained in the Medical Assistance Division (MAD) Benefits Bureau (BB) and Fiscal Management Bureau (FMB) for Drug Rebate program tracking purposes.

The Department agrees that records pertaining to the Drug Rebate program have been fragmented into three different areas of responsibility, the BB, FMB, and ASD, and need to be fully developed into an accounts receivable system and integrated into the ASD general ledger system.

HSD also agrees that it is desirable to create formal accounts receivable documentation for the Medicaid Drug Rebate program, and protocols and procedures should be created to define related processing activities and responsibilities. This issue was noted in the Executive Summary of the draft audit findings. HSD uses the term "protocol" because "policies" under New Mexico Medicaid are required to be promulgated. It takes approximately three months to promulgate a policy and involves a public hearing process. Protocol for dispute resolution already exists and was provided to the auditor.

HSD will convene appropriate work groups within ASD and MAD to develop improved methods of tracking financial activity for the Drug Rebate program, including coordination of the sub-systems in MAD with ASD's official accounts receivable records. The workgroups will also expand existing protocol for the Drug Rebate program dispute resolution activities, and develop protocol for the accounts receivable responsibilities.

FINDING
Segregation Of Duties

The NMHSD did not have a proper segregation of duties for the receipt of drug rebate funds. Only one staff member was involved in the receipt of mail containing drug rebate checks. This staff member then prepared copies of the checks and accompanying documentation for distribution, and forwarded the checks to another department for deposit. In addition, there were no procedures available for us to document this process.

The lack of segregation of duties resulted in a potential risk for waste, fraud, or abuse of the drug rebate program funds.

RECOMMENDATION
Segregation Of Duties

Provide for the proper segregation of duties for receipt of cash,

Department Response

HSD disagrees with this finding as verbally expressed to the auditor during the site visit. There are numerous staff members involved in the processing of Drug Rebate checks. The first person receiving the checks is in FMB, where the checks are date stamped and prepared for deposit. The FMB staff member assembles a standard HSD "cash receipts" packet, containing a "Human Services Department Standard Deposit Form", which identifies the receipts and accounting codes to be used. The packet further contains a "Warrant Transmittal" listing the particulars of the cash receipts. The packet finally contains the actual checks, along with appropriate supporting documentation.

The FMB staff member preparing the packet submits the packet to her supervisor for review and approval. When approved, the "cash receipts" packet is hand delivered to the ASD's Financial Operations Bureau, where additional individuals review the cash receipts and perform the actions of formally depositing them with the State Treasurer's Office. ASD is a division within HSD, not a separate department.

The procedures for processing these checks are the same as those followed for all cash receipts and comply with departmental procedures which are, in turn, in compliance with statutory requirements affecting cash receipts. The checks, typically for hundreds of thousands of dollars, are payable to the "Human Services Department, Medical Assistance Division". Such checks would be virtually impossible for any individual to fraudulently convert. Further, the checks are promptly processed as described above, by multiple staff members, whose duties are segregated across divisional and departmental lines.

FINDING
Interest on Late, Disputed, and Unpaid Rebates

The NMHSD did not have adequate controls to accrue interest for late or disputed rebate payments. The NMHSD did not accrue, track, or verify whether interest payments received from manufacturers were correct.

According to the rebate agreements between the manufacturers and CMS, required by Section 1927 of the Social Security Act, manufacturers are required to pay interest on late, disputed, or unpaid rebates. Section V, paragraph (b) of the rebate agreement states:

(b) If the Manufacturer in good faith believes the State Medicaid Agency's Medicaid Utilization Information is erroneous, the Manufacturer shall pay the State Medicaid Agency that portion of the rebate amount claimed which is not disputed within the required due date in ii (b). The balance due, if any, plus a reasonable rate of interest as set forth in section 1903 (d) (5) of the Act, will be paid or credited by the Manufacturer or the State by the due date of the next quarterly payment in II (b) after resolution of the dispute.

According to CMS Medicaid Drug Rebate Program Release #65, it is the manufacturers' responsibility to calculate and pay interest for applicable rebate invoices and the State's responsibility to track collections and report those amounts to CMS. In addition, Program Release #29 requires that interest must be collected and cannot be disregarded as part of the dispute resolution process by either the manufacturer or the State. As the methodology is prescribed in the regulations, a reasonable estimate could have been made and booked as an accrual for all applicable billings, and interest payments received could have been verified.

Because NMHSD was not accruing or verifying interest, there was no assurance that NMHSD was collecting all of the interest payments for late, unpaid, or disputed rebates.

RECOMMENDATION
Interest on Late, Disputed, and Unpaid Rebates

Account for the interest related to late or disputed rebate payments

Department Response

HSD agrees with this finding and will ensure there are procedures in place to account for the interest related to late or disputed rebate payments.

FINDING
Dispute Resolution

The NMHSD lacked adequate policies and procedures for resolving disputes with manufacturers. Disputes occur frequently due to the complexity of the program, the large number of manufacturers and drugs, and the large volume of dispensed drugs.

The NMHSD identified disputes when the manufacturers sent the ROSI to the State with the rebate payment, or when the manufacturer contacted the pharmacist in the BSB. However, the pharmacist who was responsible for resolving disputes stated that there was not a formal system of monitoring outstanding disputes. The pharmacist stated that she worked on disputes as she had time, and did document an example of a resolved dispute. However, she estimated that only 30 percent of her time was devoted to drug rebates in the past 2 years.

RECOMMENDATIONS
Dispute Resolution

Monitor disputed rebate amounts, including appropriate use of the hearing mechanism prescribed in the rebate agreement between CMS and the manufacturer(s).

NMHSD consider devoting more resources to the Drug Rebate program.

Department Response

HSD agrees with this finding. Current years dispute resolutions have occurred, but there are outstanding years that have not been disputed and collected. The one employee devoted to dispute resolutions is a pharmacist who has been detailed to handle other duties within MAD. This has greatly limited her ability to attend to outstanding disputes, and caused her to focus only on current disputes. The Department is under new administration and there has already been some discussion regarding devoting more resources to the Drug Rebate program so that dispute resolution can be performed adequately.

HSD has already made changes in the Drug Rebate program to begin identifying disputes by National Drug Code (NDC).

HSD has a policy governing fair hearings and a Hearings Bureau within ASD. The drug manufacturers have access to this fair hearings process

FINDING
CMS 64.9R Reconciliation

The NMHSD did not perform a reconciliation to verify the accuracy of the uncollected rebate balance reported on the Form CMS 64.9R. The CMS 64.9R report is used by the states to report the results of the Medicaid drug rebate program. This report is part of the Form CMS64 report, which summarizes actual Medicaid expenditures for each quarter and is used by CMS to reimburse the federal share of these expenditures. Specifically, the 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 Form CMS 64.9R was prepared by the Administrative Services Division of the NMHSD, based on reported totals of invoiced amounts and cash receipts from the FMB. The ending balance of the prior quarter was rolled forward to become the beginning balance for the current quarter. New rebates invoiced during the current quarter were added and rebates received during the current quarter were subtracted to calculate the ending balance. However, adjustments to account balances were not made in the subsidiary ledgers and thus were not reported on the CMS 64.9R. Additionally, the NMHSD did not reconcile the rebate figures reported to CMS to either of the accounts receivable systems.

In our opinion, each of the control weaknesses noted above occurred because the NMHSD had not established formal policies and procedures. The NMHSD officials stated that written policies and procedures were not developed for the drug rebate program. In fact, neither the FMB Chief nor the BSB Chief was aware of the functions performed by the other Bureau. Additionally, we believe that the NMHSD has not devoted adequate resources to the drug rebate program, as evidenced by the limited staff assigned to the drug rebate program.

RECOMMENDATION
CMS 64.9R Reconciliation

Accurately report drug rebate collections on Form CMS 64.9R.

Department Response

HSD concurs that accurate federal reporting is desirable. We are currently reviewing the processes and sources of the information to ensure that the amounts reported on the CMS 64.9R report are complete and accurate. We are working on enhancing the processes to ensure that the information is properly transmitted and recorded on HSD's general ledger system to properly support the amounts reported.

HSD agrees that additional staff is needed to better operate the drug rebate program and will work interdivisionally to develop protocol, procedures, and an improved structure for the Drug Rebate program. Additional staff resources will be requested to accomplish the desired improvements in the program's operations. Internal meetings have already occurred to begin these processes.