

**Department of Health and Human Services**

**OFFICE OF  
INSPECTOR GENERAL**

**REVIEW OF MEDICAID  
DRUG REBATE COLLECTIONS  
STATE OF LOUISIANA**



**JANET REHNQUIST**  
Inspector General

**APRIL 2003**  
**A-06-03-00011**

# ***Office of Inspector General***

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April 7, 2003

Common Identification Number: A-06-03-00011

Ben Bearden, Medicaid Director  
Louisiana Department of Health and Hospitals  
Post Office Box 91030  
Baton Rouge, Louisiana 70821

Dear Mr. Bearden:

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 Louisiana." 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-06-03-00011 in all correspondence relating to this report.

Sincerely yours,

A handwritten signature in black ink that reads "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

## EXECUTIVE SUMMARY

### OBJECTIVE

The audit objective was to evaluate whether the Louisiana Department of Health and Hospitals (DHH) had established adequate accountability over the Medicaid drug rebate program.

### FINDINGS

Generally, the DHH had established adequate controls over the Medicaid drug rebate program as required by federal rules and regulations. The DHH had extensive policies and procedures in place that enabled it to keep detailed and accurate records. However, improvement in two areas could enhance the DHH's accountability over drug rebates. Specifically, the DHH had not: (1) reconciled the outstanding balance of drug rebate accounts receivable reported on the Centers for Medicare and Medicaid Services (CMS) 64.9R report to the supporting books and records, and (2) utilized the hearing mechanism available under the Medicaid program to resolve disputes with drug manufacturers as prescribed in the rebate agreement between the CMS and the manufacturer(s).

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.

The reconciliation did not occur because the DHH had not developed a procedure requiring reconciliation of the CMS 64.9R to the supporting books and records. The DHH had not utilized the hearing mechanism because it believed disputes had been resolved adequately and hearings had not been necessary.

As a result of not reconciling the CMS 64.9R to the supporting books and records, DHH overstated its Medicaid drug rebates accounts receivables as of June 30, 2002 by \$33.8 million. Also, the DHH's records showed \$2.9 million in uncollected drug rebates from 1991 through 1995. We believe that the hearing mechanism prescribed in the rebate agreement between CMS and the manufacturer(s) could provide a viable method to resolve these outdated disputes.

During the course of the audit, DHH was able to identify the errors that led to the overstatement. The DHH officials stated that they intended to correct the overstatement on the next quarterly report to CMS. They also stated that they would implement new controls over the reporting process.

## **RECOMMENDATIONS**

We recommend that DHH:

- Ensure that a control is implemented requiring the outstanding rebate amount reported to CMS to be reconciled with the supporting books and records, and
- Consider appropriate use of the hearing mechanism prescribed in the rebate agreement between CMS and the manufacturer(s) as a method to resolve older disputed rebate amounts.

The DHH responded to our draft report in a letter dated March 21, 2003. The DHH was pleased with the findings of our review and had already implemented a requirement to reconcile the 64.9R to the supporting books and records. The DHH also noted that \$2.9 million in uncollected rebates was related to rate changes rather than disputes and did not warrant the use of hearings. The complete text of the DHH's response is included in **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 states 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 rebate 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, a manufacturer can change the URA based on updated pricing information, and submit this information to the state agency in the Prior Quarter Adjustment Statement.

Each state agency is required to maintain the number of units dispensed, by manufacturer, for each covered outpatient drug. Approximately 56,000 National Drug Codes (NDCs) are available under the rebate program. Each state agency uses the URA from CMS and the utilization data 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.

A manufacturer has 38 days from the day the state agency sends an invoice to pay the rebate to avoid interest. A manufacturer submits to the State agency a Reconciliation of State Invoice 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 DHH reported to CMS an average of \$29.9 million in billings per quarter and collections of \$26.1 million per quarter during the 1-year period ending June 30, 2002. The drug rebate accounts receivable balance as of June 30, 2002 was \$30,834,415.

The DHH contracted with The University of New Orleans (UNO) to administer most of the day-to-day operations drug rebate program. The UNO had five full-time employees, as well as part-time student employees, working with the drug rebate program who were responsible for invoicing, posting and reconciling payments, and communicating with drug manufacturers to resolve disputes.

The DHH converted to a new information system in August 2001. The new system is used to track the invoicing and collection of rebates from pharmaceutical manufacturers. As manufacturers make payments to DHH, the new system provides for the allocation and reconciliation of those payments on a NDC by NDC basis. It is also used to log calls and track and resolve manufacturer disputed units.

## **OBJECTIVE, SCOPE AND METHODOLOGY**

### ***Objective***

The audit objective was to evaluate whether the DHH had established adequate accountability over the Medicaid drug rebate program.

### ***Scope***

The Medicaid drug rebate program was effective January 1, 1991. We concentrated our review on the current policies, procedures and controls of DHH. We also reviewed accounts receivable information related to prior periods and interviewed DHH staff to understand how the Medicaid drug rebate program had operated since 1991.

### ***Methodology***

To accomplish our objectives, we interviewed DHH 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. 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.

Fieldwork was performed at DHH's office in Baton Rouge, Louisiana during October 2002, and continued in our Baton Rouge, Louisiana field office through January 2003.

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

## **FINDINGS AND RECOMMENDATIONS**

Generally, the DHH had established adequate controls over the Medicaid drug rebate program as required by federal rules and regulations. The DHH had extensive policies and procedures in place that enabled it to keep detailed and accurate records. However, improvement in two areas could enhance the DHH's accountability over drug rebates. Specifically, the DHH had not: (1) reconciled the outstanding balance of drug rebate accounts receivable reported on the CMS 64.9R report to the supporting books and records, and (2) utilized the hearing mechanism available under the Medicaid program to resolve disputes with drug manufacturers as prescribed in the rebate agreement between CMS and the manufacturer(s).

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.

### **Adequate Controls Established**

As part of the DHH's controls over the Medicaid drug rebate program, the UNO contract employees kept detailed and accurate records by (1) recording all transactions at the NDC level, (2) reconciling payments to the original invoices, and (3) recording all contact with the manufacturers in the information system. By keeping such a detailed information system, DHH could accurately monitor accounts receivable and effectively pursue collection of outstanding balances from drug manufacturers.

The DHH also had policies and procedures in place to resolve disputes with manufacturers. Before the invoices were sent out, UNO staff reviewed the number of units dispensed for reasonableness. If errors were found, UNO staff contacted the pharmacies to have the claims that were in error reversed and re-billed. After the invoices were sent and the payments received, UNO staff identified disputed units during the posting of payments from the manufacturers. When a dispute was found, an auditor was assigned to contact the manufacturer and work to resolve the dispute.

### **CMS 64.9R Reconciliation**

The DHH had not reconciled the outstanding balance of drug rebate accounts receivable reported to CMS to the supporting books and records. 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 CMS 64.9R report was prepared by DHH staff without comparing the ending balance to the detailed accounting records that were maintained by the UNO staff. However, errors occurred during the conversion to the new information system that were not discovered because the DHH had not developed a procedure to reconcile the outstanding balance reported to CMS to the detailed accounting records.

As a result, the DHH overstated the Medicaid drug rebate accounts receivable balance as of June 30, 2002 on the CMS 64.9R report by \$33.8 million.

During the course of our audit, DHH identified the errors that led to the overstatement. The DHH officials stated that they intended to correct the overstatement on the next quarterly report to CMS. They also stated that they would implement new controls over the reporting process.

### **Dispute Resolution**

The DHH had not utilized the hearing mechanism prescribed in the rebate agreement between CMS and the manufacturer(s). An official of DHH stated that the hearing mechanism had not been utilized because it believed disputes had been resolved adequately and hearings had not been necessary.

However, \$2.9 million of uncollected drug rebates were for balances from 1991 through 1995, according to detailed accounting records provided by UNO staff. We believe that the hearing mechanism prescribed in the rebate agreement between CMS and the manufacturer(s) could be an appropriate method to resolve these disputes.

### **RECOMMENDATIONS**

We recommend that DHH:

- Ensure that a control is implemented requiring the outstanding rebate amount reported to CMS to be reconciled with the supporting books and records, and
- Consider appropriate use of the hearing mechanism prescribed in the rebate agreement between CMS and the manufacturer(s) as a method to resolve older disputed rebate amounts.

### **AUDITEE RESPONSE**

The DHH responded to our draft report in a letter dated March 21, 2003. The DHH was pleased with the findings of our review and had already implemented a requirement to reconcile the 64.9R to the supporting books and records. The DHH also noted that \$2.9 million in uncollected rebates was related to rate changes rather than disputes and did not warrant the use of hearings. The complete text of the DHH's response is included in **Appendix 1**.



M. J. "Mike" Foster, Jr.  
GOVERNOR

**STATE OF LOUISIANA**  
**DEPARTMENT OF HEALTH AND HOSPITALS**



David W. Hood  
SECRETARY

March 21, 2003

Common Identification Number: A-06-03-00011

Gordon L. Sato  
Regional Inspector General for Audit Services  
Department of Health and Human Services  
Office of Inspector General  
Office of Audit Services  
1100 Commerce, Room 632  
Dallas, TX 75242

Dear Mr. Sato:

Please consider this as the State of Louisiana's formal response to your offices draft report entitled "Review of Medicaid Drug Rebate Collections-State of Louisiana." As stated in your letter, the "audit objective was to evaluate whether the Louisiana Department of Health and Hospitals had established adequate accountability and internal controls over the Medicaid drug rebate program."

The review made two recommendations for improvement to the program. These are listed below along with our response to each item.

- 1) Ensure that a control is implemented requiring the outstanding rebate amount reported to CMS to be reconciled with the supporting books and records.

*We have modified our CMS 64 procedures to insure reconciliation between the CMS 64 and the supporting books and records. A complete detail of our plan for correction (which was implemented with the 9/30/02 CMS 64 submission) along with our current procedure is attached to substantiate this statement.*

- 2) Consider appropriate use of the hearing mechanism prescribed in the rebate agreement between CMS and the manufacturer(s) as a method to resolve older disputed rebate amounts.

*The review reported that we had net 2.9 million outstanding of old disputes covering invoice years 1991 to 1995 and that we should use the hearing process prescribed by CMS to resolve these amounts. We have reviewed the outstanding amounts at the invoice item level, and more than 2.9 million of this is due to rate errors. As of March 20, 2003, these errors have either been corrected with rate changes sent on the quarterly CMS tape or they are rates pending correction. We would submit that at any given point in time, there will be amounts reported as outstanding that are not in fact collectible by the state because of this rate issue. The only way this cycle will end is if CMS puts a time limit on how far back a labeler can resubmit their pricing data and therefore change their rates. The majority of the 2.9 million listed in the review was not in fact collectible. Since we*

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1201 CAPITOL ACCESS ROAD § P. O. BOX 91030 § BATON ROUGE, LA 70821-9030  
PHONE #: 225/342-3956 OR 225/342-5774 § FAX #: 225/342-3893  
"AN EQUAL OPPORTUNITY EMPLOYER"

*must report the rates as they come from CMS, these amounts must be reported on our books. Additionally, it should be noted that the outstanding balances which include these rate issue are reported on the quarterly CMS 64 report. This report will continually be processed with these types of issues.*

*We have enclosed, in electronic form, a spreadsheet showing the detail supporting our statement that 2.9 million of the amount due is in fact due to rate errors and is not collectible. It contains the labeler/year/qtr data from the 6/30/02 accounts receivable report (that makes up the 2.9 million outstanding as reported in the review) along with a 3/20/03 accounts receivable report covering the same invoice years and quarters. By comparing the two reports, you will see that many of the labeler's rate errors have been corrected. For the remaining items that have not been corrected, we have commented how we support that these are rate and/or unit type change errors and are clearly not collectible balances.*

*For this reason, we feel that there are not enough valid disputes on our books from the 91-95 time periods to warrant considering the appropriate use of the hearing mechanism as recommended by the Department's draft report.*

We are pleased with the findings of your review, and feel that we have fully addressed the issues identified by the Department. Please contact M.J. Terrebonne, Pharmacy Director at 225-342-1590 if you have any questions regarding the Louisiana Medicaid pharmacy rebate program or this formal response to your draft report.

Thank you for the opportunity to respond to your recommendations.

Sincerely,



Ben Bearden  
Medicaid Director  
Louisiana Department of Health and Hospitals

Enclosures – as stated

### **SUMMARY OF CMS64 RESTATEMENT**

Just prior to the OIG arrival in October 2002, we realized that line 6 of CMS 64 had been overstated.

After research, we determined the overstatement was due to three things:

- 1) 10 million dollar data entry error we had entered into LAPRIMS during conversion. The data entry error was taken from beginning balances that were returned from the 5<sup>th</sup> floor accounting department in error
- 2) The fact that we had a methodology change during the conversion process that was not taken into account at the time of conversion. In the old rebate system, adjustments to invoices were made via a 9Flag field. Since these adjustments were not entered uniformly in the old system, we could not convert that data to the new system automatically
- 3) An error in the coding logic of line 2 of the Generate HCFA64 process in LAPRIMS

To remedy this situation, we have done the following:

- 1) Corrected the coding logic for the Generate HCFA 64 process
- 2) Corrected the beginning balance error for 9/30/2001 from the 5<sup>th</sup> floor

The process for restatement includes:

State side:

- 1) Rerun the CMS64s starting from 9/30/2001 to 6/30/2002 for the 5<sup>th</sup> floor using the corrected logic and corrected beginning balances. Supporting detail for all the line 5 figures resides in the CMS 64 Reports folder on the server.
- 2) For 9/30/2002, we are adjusting the CMS 64 calculation process according to instructions from Bob Cowan (meeting 11/20/2002). We will now exclude interest from line 5 of the CMS 64 and include supplemental rebates established and paid. The attached CMS 64 Report Detail, Report Specifications document outlines how we will support the correct figures.
- 3) We have given the 5<sup>th</sup> floor a tentative 9/30/02 restated CMS 64. When we are comfortable with the restated CMS 64's from 9/30/2001 to 6/30/2002, we will delete that data from our LAPRIMS tables and hand enter from the backend, the actual CMS64's that were submitted to CMS from 9/30/01 to 6/30/02. This is because CMS does not allow the state to retroactively restate CMS 64's, so all the adjustments to correct the errors noted above have to be made in the current quarter, which is 9/30/02.
- 4) We will amend the Generate HCFA64 process in LAPRIMS to calculate for all Program types.

Federal Side

- 1) We will reflect all adjustments from 9/30/01 to 9/30/02 in the 9/30/02 CMS 64.
- 2) Starting with 9/30/2002 CMS 64 report, we will correctly report interest and supplemental data as directed by Bob Cowan. Interest collected will not be shown on Line 5 of the HCFA 64, but will instead be shown on "line 5 other" on the CMS 64 Summary page. Supplemental Rebates Established will be reflected in line 3 of the CMS 64 and their Principal payments will be reflected in line 5. They will be broken out on line 7A1(Federal) and 7A2(State Supplemental) of the CMS 64.9 Base Report.

All of the above were performed and the new CMS 64 process is generated using the LAPRIMS system and all logic has been coded into detail labeler/year/qtr reports that support all CMS 64 figures. This process reconciles the CMS 64 to the outstanding balances totals in LAPRIMS and on our detail reports.

### CMS64 Creation Cycle – Internal Procedures (Amended Fall 2002)

Beginning the first quarter of Federal fiscal year 1994, all state are required to submit to Health Care Financing Administration (HCFA) now Center for Medicare and Medicaid Services (CMS) summary information on pending drug rebates at the beginning of the quarter, the amounts of drug rebates computed for all drug labelers, amounts written off, other adjustments, remaining pending drug rebates and amount collected, and received. The CMS 64 report is basically a cash flow statement for the rebate program.

These reports are submitted to Department of Health and Hospitals, Division of Fiscal Management, Revenue Management Unit, which generates the CMS 64 that accounts for Medicaid spending, and must be received by the Revenue Management Unit no later than 45 days following the end of the quarter.

<u>Quarter Ended</u>	<u>Reporting Due Date</u>
September 30	October 15
December 31	January 15
March 31	April 15
June 30	July 15

#### **CMS 64 Reporting Procedure**

The data is generated by populating SQL tables from the LAPRIMS system. The supporting reports are generated by Crystal Report v.8.

1) Approximately 1 week after the close of the quarter, run the **CMS 64 Unreconciled Items Report**.

**Location:** L:\Reports\CMS(HCFA) Reports

**Parameters =** CMS 64 Reporting quarter

If the report returns items, let the pharmacy rebate section know that they must reconcile all payments with a deposit date within the reporting quarter ASAP. The CMS 64 cannot be generated if there are any unreconciled payments.

2) Once the CMS 64 Unreconciled Items report returns 0 records, a rebate manager must open the LAPRIMS system.

From the LAPRIMS Billing Menu, choose "Create HCFA 64."

Enter the report year and report quarter and press the "Create HCFA 64" button.

It will take approximately 5 minutes to generate the data. When it is complete, a box will come up indicating that the process is complete.

3) Run the following reports to create labeler detail support for each line of the CMS 64

1) **HCFA 64**

**Location:** L:\Reports\CMS(HCFA) Reports\HCFA64

**Parameters =** Report Year and Report Quarter

2) **CMS 64 Record of Remittance**

**Location:** L:\Reports\CMS(HCFA) Reports\ARAB09 – Record of Remittance

**Parameters =** Date Deposit From = 7/1/2002, Date Deposit To = 9/30/2002, PIV

# = check set to null.

**Special Note:** enter the first day of the quarter with the time = 12:00:00 AM and the last day of the quarter = 11:59:59 PM.

3) **CMS 64 Line 3 Detail**

**Location:** L:\Reports\CMS(HCFA) Reports\CMS 64 Line 3 Detail

**Parameters = Report Year and Report Quarter**

4) **CMS 64 Line 6 Detail**

**Location:** L:\Reports\CMS(HCFA) Reports\CMS 64 Line 6 Detail

**Parameters = Report Year and Report Quarter**

5) **CMS 64 Top 10 List**

**Location:** L:\Reports\CMS(HCFA) Reports\CMS 64 Top 10 List

**Parameters = Report Year and Report Quarter**

4) Verify the figures on the HCFA 64 report to the supporting reports and the Fiscal Management Receipt Data for the quarter.

Line	Description
Line 1	Represents the balance as of the beginning of the quarter. This figure is derived from the previously submitted quarterly report on line 6.
Line 2	Represents adjustments to the reported balances in Line 1. These adjustments can be from labelers and the state.
Line 3	Rebates established this quarter. Invoices we created this quarter
Line 4	Subtotal (line 1 + Line 2 + Line 3). This totals the adjusted balance due before payments received during the reporting quarter were applied.
Line 5	Principal payments received during the reporting quarter
Line 6	Balance due as of the end of this quarter after payments received during the reporting quarter have been applied. (This will be line 1 for the following reporting quarter)

5) Save all the Crystal Reports you have run as Read Only in the CMS 64 History Folder located at L:\ CMS (HCFA) Reports folder under the appropriate Year/Qtr.

6) Draft Memorandum to be signed by Medicaid Director

7) Submit to the Department of Health and Hospitals, Division of Fiscal Management, Revenue Management Unit.