



DEPARTMENT OF HEALTH & HUMAN SERVICES

Office of Inspector General

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

Report Number: A-06-08-00028

August 6, 2008

Mr. Albert Hawkins  
Executive Commissioner  
Health and Human Services Commission  
4900 North Lamar Boulevard  
Austin, Texas 78751

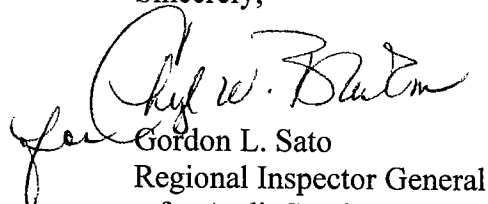
Dear Mr. Hawkins:

Enclosed is the U.S. Department of Health and Human Services (HHS) Office of Inspector General (OIG), final report entitled "Follow-Up Audit of the Medicaid Drug Rebate Program in Texas." We will forward a copy of this report to the HHS action official noted below.

Pursuant to the principles of the Freedom of Information Act, 5 U.S.C. § 552, as amended by Public Law 104-231, OIG reports generally are made available to the public to the extent the information is not subject to exemptions in the Act (45 CFR part 5). Accordingly, this report will be posted on the Internet at <http://oig.hhs.gov>.

If you have any questions or comments about this report, please direct them to the HHS action official. Please refer to report number A-06-08-00028 in all correspondence.

Sincerely,

  
Gordon L. Sato  
Regional Inspector General  
for Audit Services

Enclosure

**HHS Action Official:**

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Department of Health and Human Services

**OFFICE OF  
INSPECTOR GENERAL**

**FOLLOW-UP AUDIT OF THE  
MEDICAID DRUG REBATE  
PROGRAM IN TEXAS**



Daniel R. Levinson  
Inspector General

August 2008  
A-06-08-00028

# *Office of Inspector General*

<http://oig.hhs.gov>

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Pursuant to the principles of the Freedom of Information Act, 5 U.S.C. § 552, as amended by Public Law 104-231, Office of Inspector General reports generally are made available to the public to the extent the information is not subject to exemptions in the Act (45 CFR part 5).

## **OFFICE OF AUDIT SERVICES FINDINGS AND OPINIONS**

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

## EXECUTIVE SUMMARY

### BACKGROUND

The Medicaid drug rebate program, which began in 1991, is set forth in section 1927 of the Social Security Act. For a manufacturer's covered outpatient drugs to be eligible for Federal Medicaid funding under the program, the manufacturer must enter into a rebate agreement with the Centers for Medicare & Medicaid Services (CMS) and pay quarterly rebates to the States. CMS, the States, and drug manufacturers each undertake certain functions in connection with the drug rebate program. In Texas, the Health and Human Services Commission (the State agency) administers the Medicaid drug rebate program.

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

In the previous audit of the Texas drug rebate program, the Texas State Auditor (State Auditor) determined that the State agency had poor controls and inconsistent procedures. Areas with poor controls and inconsistent procedures included (1) the accounts receivable system, (2) calculating and tracking interest, (3) segregation of duties, (4) dispute resolution and adjustments, and (5) CMS Form-64.9R reporting. The State Auditor recommended that the State agency:

- convert accounts receivable data that were maintained in both hardcopies and electronic spreadsheets outside of the automated system from January 1991 through June 1995 to the automated system and identify and correct transaction posting errors that resulted from not reconciling invoiced amounts to payment details;
- calculate, track, and actively pursue interest on late or disputed rebate amounts and determine the accuracy of prior interest payments;
- segregate duties for rebate billing, payment, and adjustment;
- prioritize dispute resolution efforts using the age of the unpaid balance as a factor, ensure staff follow Federal guidelines when resolving disputes, and develop standard criteria for dispute resolution; and
- ensure that Federal reports (i.e., CMS Form-64.9R) correctly account for invoiced, paid, and outstanding rebate amounts.

The State agency agreed with the State Auditor's findings and recommendations.

This current review of Texas is part of a nationwide series of reviews conducted to determine whether States have addressed the weaknesses in accountability for and internal controls over their drug rebate programs found in the previous reviews. Additionally, because the Deficit Reduction Act of 2005 required States as of January 2006 to begin collecting rebates on single source drugs administered by physicians, this series of reviews will also determine whether States have complied with the new requirement.

## **OBJECTIVES**

Our objectives were to determine whether the State agency had (1) implemented certain recommendations made in the State Auditor's report on the Texas drug rebate program and (2) established controls over collecting rebates on single source drugs administered by physicians.

## **SUMMARY OF FINDINGS**

The State agency implemented the recommendations from the prior audit related to (1) the accounts receivable system, (2) calculating and tracking interest, (3) segregation of duties, (4) dispute resolution and adjustments, and (5) CMS Form-64.9R reporting. The State agency established controls over collecting rebates for single source drugs administered by physicians. Therefore, we do not offer any recommendations.

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## INTRODUCTION

### BACKGROUND

Pursuant to Title XIX of the Social Security Act (the Act), the Medicaid program provides medical assistance to certain low-income individuals and individuals with disabilities. The Federal and State Governments jointly fund and administer the Medicaid program. At the Federal level, the Centers for Medicare & Medicaid Services (CMS) administers the program. Each State administers its Medicaid program in accordance with a CMS-approved State plan. Although the State has considerable flexibility in designing and operating its Medicaid program, it must comply with applicable Federal requirements.

### Drug Rebate Program

The Medicaid drug rebate program, which began in 1991, is set forth in section 1927 of the Act. For a manufacturer's covered outpatient drugs to be eligible for Federal Medicaid funding under the program, the manufacturer must enter into a rebate agreement with CMS and pay quarterly rebates to the States. CMS, the States, and drug manufacturers each undertake certain functions in connection with the drug rebate program. In Texas, the Health and Human Services Commission (the State agency) is responsible for the drug rebate program.

Pursuant to section II of the rebate agreement and section 1927(b) of the Act, manufacturers are required to submit a list to CMS of all covered outpatient drugs and to report each drug's average manufacturer price and, where applicable, best price. Based on this information, CMS calculates a unit rebate amount for each covered outpatient drug and provides the amounts to States quarterly.

Section 1927(b)(2)(A) of the Act requires States to maintain drug utilization data that identifies, by National Drug Code (NDC), the number of units of each covered outpatient drug for which the States reimbursed providers. The number of units is applied to the unit rebate amount to determine the actual rebate amount due from each manufacturer. Section 1927(b)(2) of the Act requires States to provide the drug utilization data to CMS and the manufacturer. States also report drug rebate accounts receivable data on Form CMS-64.9R. This is part of Form CMS-64, "Quarterly Medicaid Statement of Expenditures for the Medical Assistance Program," which summarizes actual Medicaid expenditures for each quarter and is used by CMS to reimburse States for the Federal share of Medicaid expenditures.

### Physician-Administered Drugs

Section 6002(a) of the Deficit Reduction Act of 2005 (DRA) amends section 1927 of the Act and requires States, as of January 1, 2006, to collect and submit utilization data for single source drugs administered by physicians so that States may obtain rebates for the drugs.<sup>1</sup> Single source drugs are commonly referred to as "brand name drugs" and do not have generic equivalents.

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<sup>1</sup>This provision of the DRA expanded the requirement to certain multiple source drugs administered by physicians after January 1, 2008.



In Texas, physician-administered drugs are billed to the State Medicaid program on a physician claim form using procedure codes that are part of the Healthcare Common Procedure Coding System. The NDC was not included on the physician claim form until January 1, 2008, when the DRA expanded the requirement to collect rebates for certain multiple source drugs. The procedure code identifies a drug by its active ingredient(s) and identifies the number of drug units (billing units) allowed per reimbursement for that procedure code. Because rebates are calculated and paid based on NDCs, each procedure code must be converted to an NDC. Additionally, the billing units for a procedure code may differ from the units used for rebate purposes (e.g., grams versus liters). Therefore, to determine rebates, the procedure codes must be converted into NDCs for single source drugs, and procedure code billing units must be converted into equivalent NDC billing units.

### **Prior Office of Inspector General and Texas State Auditor Reports**

In 2005, we issued a report on the results of audits of the Medicaid drug rebate programs in 49 States and the District of Columbia.<sup>2</sup> Those audits found that only four States had no weaknesses in accountability for and internal controls over their drug rebate programs. As a result of the weaknesses, we concluded that States lacked adequate assurance that all of the drug rebates due to the States were properly recorded and collected. Additionally, CMS did not have reliable information from the States to properly monitor the drug rebate program.

In the previous audit of the Texas drug rebate program, the Texas State Auditor (State Auditor) determined that the State agency had poor controls and inconsistent procedures.<sup>3</sup> Areas with poor controls and inconsistent procedures included (1) the accounts receivable system, (2) calculating and tracking interest, (3) segregation of duties, (4) dispute resolution and adjustments, and (5) CMS Form-64.9R reporting. The State Auditor recommended that the State agency:

- convert accounts receivable data that were maintained in both hardcopies and electronic spreadsheets outside of the automated system from January 1991 through June 1995 to the automated system and identify and correct transaction posting errors that resulted from not reconciling invoiced amounts to payment details;
- calculate, track, and actively pursue interest on late or disputed rebate amounts and determine the accuracy of prior interest payments;
- segregate duties for rebate billing, payment, and adjustment;
- prioritize dispute resolution efforts using the age of the unpaid balance as a factor, ensure staff follow Federal guidelines when resolving disputes, and develop standard criteria for dispute resolution; and

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<sup>2</sup>“Multistate Review of Medicaid Drug Rebate Programs” (A-06-03-00048), issued July 6, 2005; Arizona was not included because it did not operate a drug rebate program.

<sup>3</sup>“An Audit Report on The Health and Human Services Commission’s Prescription Drug Rebate Program” (report number 03-029), issued April 2003. Available online at <http://www.sao.state.tx.us> Accessed June 20, 2008.

- ensure that Federal reports (i.e., CMS Form-64.9R) correctly account for invoiced, paid, and outstanding rebate amounts.

The State agency agreed with the State Auditor's findings and recommendations.

### **Texas Drug Rebate Program**

The State agency contracted with First Health Services Corporation (First Health) to perform all drug rebate program functions, effective January 1, 2006, other than receiving drug rebate funds. During the conversion, all historical accounts receivable records were transferred to First Health's accounts receivable system.

The State agency reported an outstanding drug rebate balance of \$191,727,422 on the June 30, 2006, Form CMS-64.9R. However, \$43,155,985 of this amount related to quarterly billings and was not past due as of June 30, 2006. Of the remaining \$148,571,437 that was past due, \$125,923,039 was more than 1 year old. For the fiscal year ended June 30, 2006, the State agency reported rebate billings of approximately \$671.1 million and collections of \$804.2 million.

This current review of the Texas drug rebate program is part of a nationwide series of reviews conducted to determine whether States have addressed the weaknesses in accountability for and internal controls over their drug rebate programs found in the previous reviews. Additionally, because the DRA required States as of January 2006 to begin collecting rebates on single source drugs administered by physicians, this series of reviews will also determine whether States have complied with the new requirement.

## **OBJECTIVES, SCOPE, AND METHODOLOGY**

### **Objectives**

Our objectives were to determine whether the State agency had (1) implemented certain recommendations made in the State Auditor's report on the Texas drug rebate program and (2) established controls over collecting rebates on single source drugs administered by physicians.

### **Scope**

We reviewed the State agency's current policies, procedures, and controls over the drug rebate program. We reviewed the accounts receivable data reported on Form CMS-64.9R as of June 30, 2006. The State Auditor's report included 42 specific recommendations. We limited our review to the recommendations listed in this report. We performed our fieldwork at the State agency in Austin, Texas, in April and May 2008.

## **Methodology**

To accomplish our objectives, we

- reviewed section 1927 of the Act, section 6002(a) of the DRA, CMS guidance issued to State Medicaid directors and other information pertaining to the Medicaid drug rebate program;
- reviewed the State Auditor's report on the State agency's drug rebate program (report number 03-029);
- analyzed the 42 recommendations listed in the State Auditor's report and identified recommendations on which to follow up;
- reviewed the policies and procedures related to First Health's drug rebate accounts receivable system;
- interviewed (1) State agency officials to gain an understanding of what was done to address the State Auditor's recommendations prior to the transition to First Health and (2) First Health officials to determine the policies, procedures, and controls that related to the Medicaid drug rebate program;
- reviewed copies of Form CMS-64.9R for the period July 1, 2005, through June 30, 2006;
- reviewed policies and procedures for converting physician services claims data into drug rebate data related to single source drugs administered by physicians; and
- reviewed rebate billings and reimbursements for procedure codes related to single source drugs administered by physicians for the period January 1 through June 30, 2006.

We conducted this performance audit in accordance with generally accepted government auditing standards. Those standards require that we plan and perform the audit to obtain sufficient, appropriate evidence to provide a reasonable basis for our findings and conclusions based on our audit objectives. We believe that the evidence obtained provides a reasonable basis for our findings and conclusions based on our audit objectives.

## **RESULTS OF AUDIT**

The State agency implemented the recommendations from the prior audit related to (1) the accounts receivable system, (2) calculating and tracking interest, (3) segregation of duties, (4) dispute resolution and adjustments, and (5) CMS Form-64.9R reporting. The State agency established controls over collecting rebates for single source drugs administered by physicians. Therefore, we do not offer any recommendations.

## **IMPLEMENTATION OF PRIOR RECOMMENDATIONS**

In the prior audit of the Texas drug rebate program, the State Auditor determined that the State agency did not:

- properly account for all outstanding rebate revenue;
- collect or account for all interest;
- properly segregate duties for rebate billings, payments, and adjustments;
- establish adequate procedures for dispute resolution and adjustments; and
- report accurate information on Form CMS-64.9R.

### **Accounting for Outstanding Rebate Revenue**

In the prior audit, the State Auditor found that the State agency had not properly accounted for all outstanding rebate revenue. Specifically, the State agency had not converted electronic spreadsheets maintained outside of the Pharmacy Rebate Information Management System (PRIMS) and hard copy records for the period prior to June 1995 into PRIMS files. Additionally, control weaknesses related to the PRIMS affected the reliability of data within the PRIMS. Since the prior audit, the State agency has undertaken a payment posting project in which the nonautomated records were entered into the PRIMS. As part of the project, the State agency also corrected transaction posting errors identified by the State Auditor. Also, the State agency transferred all accounts receivable data and drug rebate functions, except for receiving drug rebate funds, to First Health in January 2006. First Health had controls in place to account for outstanding rebate revenue.

### **Interest Accounting and Collection**

In the prior audit, the State Auditor found that the State agency did not verify interest payments from manufacturers and did not have a record of interest owed for the period prior to June 1995. Since the prior audit, the State agency, as part of the payment posting project, has calculated interest due on unpaid balances. In addition, First Health's procedures included a comparison of interest payments made to the amount of interest owed.

### **Segregation of Duties**

In the prior audit, the State Auditor found that all rebate staff could add, modify, or delete any type of record in the PRIMS and that the structure of the PRIMS database did not allow for the segregation of rebate collection and adjustment duties. Since the prior audit, the State agency has transferred drug rebate operations to First Health, and duties have been properly segregated in its accounts receivable system.

### **Dispute Resolution and Adjustments**

In the prior audit, the State Auditor found that the State agency lacked standardized procedures and criteria for adjusting drug pricing (unit rebate amounts) and utilization data, and thus could not verify the accuracy of rebate adjustments staff had made. Also, the State agency did not

prioritize collection activities by the age of accounts receivable balances. Since the prior audit, the State agency has transferred drug rebate operations to First Health which (1) had dispute resolution policies and procedures that were in accordance with CMS guidance and (2) created detailed reports on the ages of accounts receivable balances.

### **Form CMS-64.9R Reporting**

In the prior audit, the State Auditor found that the State agency did not comply with the requirement to summarize drug rebate accounts receivable billing and collection information (on CMS Form-64.9R). Specifically, amounts related to the electronic spreadsheets maintained outside of PRIMS and hard copy records for the period prior to June 1995 were not included on CMS Form-64.9R. As detailed above, the State agency entered those nonautomated records into PRIMS and transferred all data to First Health, which summarized the amounts from its accounts receivable system and provided the summaries to the State agency to include in its Form CMS-64.9R report.

### **PHYSICIAN-ADMINISTERED SINGLE SOURCE DRUGS**

The State agency established controls over collecting rebates for single source drugs administered by physicians as required by the DRA. The State agency paid \$17,684,901 in claims for single source physician-administered drugs during the January through June 2006 time period and billed manufacturers for rebates totaling \$8,701,182.