Office of Audit Services
Region I
John F. Kennedy Federal Building
Boston, MA 02203
(617) 565-2684

JUN 12 2008

Report Number: A-01-08-00002

Mr. Michael P. Starkowski
Commissioner
Department of Social Services
25 Sigourney Street
Hartford, Connecticut 06106

Dear Mr. Starkowski:

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 Connecticut." We will forward a copy of this report to the HHS action official noted on the following page for review and any action deemed necessary.

The HHS action official will make final determination as to actions taken on all matters reported. We request that you respond to this 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.

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 do not hesitate to call me, or contact Curtis Roy, Audit Manager, at (617) 565-9281 or through e-mail at Curtis.Roy@oig.hhs.gov. Please refer to report number A-01-08-00002 in all correspondence.

Sincerely,

Michael J. Armstrong
Regional Inspector General
for Audit Services

Enclosure

Department of Health and Human Services

OFFICE OF INSPECTOR GENERAL

FOLLOW-UP AUDIT OF THE MEDICAID DRUG REBATE PROGRAM IN CONNECTICUT

Daniel R. Levinson
Inspector General

June 2008
A-01-08-00002

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 Connecticut, the Department of Social Services (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 our previous audit of the Connecticut drug rebate program, we determined that the State agency's controls were generally in place to record and track the collection of drug rebates (A-01-03-00003). In addition, the Federal share of drug rebate amounts was properly offset from Federal Medicaid reimbursement. However, the State agency had not established procedures for reporting its pending drug rebate amounts on the Form CMS-64.9R report. As a result, the amount reported for the quarter that ended June 30, 2002, was inaccurate. Based on the results of our review, the pending balance was understated by about $14 million (Federal share). We recommended that the State agency establish procedures to provide accurate pending rebate amounts and properly present an aging schedule of its drug rebate receivables in its quarterly reports to CMS.

This current review of Connecticut is part of a nationwide series of reviews conducted to determine whether States have addressed the weaknesses found in the previous reviews in accountability for and internal controls over their drug rebate programs. 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 the recommendation made in our previous audit of the Connecticut drug rebate program and (2) established controls over collecting rebates on single source drugs administered by physicians.

SUMMARY OF FINDINGS

The State agency had not implemented the recommendation from our prior audit to establish procedures to provide accurate pending rebate amounts and properly present an aging schedule of its drug rebate receivables in its quarterly reports to CMS.

Regarding the second objective, the State agency had established controls over collecting rebates on single source drugs administered by physicians.

RECOMMENDATION

We reiterate our recommendation that the State agency establish procedures to provide accurate pending rebate amounts and properly present an aging schedule of its drug rebate receivables in its quarterly reports to CMS.

DEPARTMENT OF SOCIAL SERVICES COMMENTS

In its written comments on our draft report, the State agency agreed with our finding and recommendation.

The State agency's comments are included in their entirety as the Appendix.

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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 Connecticut, the Department of Social Services (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 identify, 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.[1] Single source drugs are commonly referred to as "brand name drugs" and do not have generic equivalents.

[1]This provision of the DRA expands the requirements to certain multiple source drugs administered by physicians after January 1, 2008.

In Connecticut, physician-administered drugs are billed to the State Medicaid program on a physician claim form. Beginning March 1, 2005, the State agency required claim forms to include not only procedure codes that are part of the Healthcare Common Procedure Coding System but also the corresponding NDCs for single source physician-administered 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. Rebates are calculated and paid based on NDCs rather than on procedure codes. In addition, the billing units for a procedure code may differ from the units used for rebate purposes (e.g., grams versus liters). Thus, before rebates can be determined, procedure codes must be converted to NDCs for single source drugs, and procedure code billing units must be converted into equivalent NDC billing units.

Prior Office of Inspector General 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.[2] 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 our previous audit of the Connecticut drug rebate program, we determined that the State agency's controls were generally in place to record and track the collection of drug rebates (A-01-03-00003). In addition, the Federal share of drug rebate amounts was properly offset from Federal Medicaid reimbursement. However, the State agency had not established procedures for reporting its pending drug rebate amounts on the Form CMS-64.9R report. As a result, the amount reported for the quarter that ended June 30, 2002, was inaccurate. Based on the results of our review, the pending balance was understated by about $14 million (Federal share). We recommended that the State agency establish procedures to provide accurate pending rebate amounts and properly present an aging schedule of its drug rebate receivables in its quarterly reports to CMS.

The State agency agreed with our finding and recommendation.

Connecticut Drug Rebate Program

The State agency contracted with its fiscal agent, Electronic Data Systems, to perform all drug rebate program functions other than preparing and submitting the Form CMS-64.9R. The fiscal agent's responsibilities included preparing and mailing invoices to manufacturers, receiving and posting payments, resolving disputes, and accounting for rebates on single source drugs administered by physicians. The fiscal agent also converted the procedure code billing units into equivalent NDC billing units.

[2]"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.

For the fiscal year ending June 30, 2006, the State agency reported rebate billings of approximately $76.3 million and collections of approximately $135.9 million on its Forms CMS-64.9R.

This current review of the Connecticut drug rebate program is part of a nationwide series of reviews conducted to determine whether States have addressed the weaknesses found in the previous reviews in accountability for and internal controls over their drug rebate programs. 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 the recommendation made in our previous audit of the Connecticut 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 and the accounts receivable data reported on Form CMS-64.9R as of June 30, 2006.

We performed our fieldwork at the State agency in Hartford, Connecticut, from October 2007 through April 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 policies and procedures related to the fiscal agent's drug rebate accounts receivable system;

- reviewed the previous Office of Inspector General audit report on the drug rebate program in Connecticut;

- interviewed State agency officials and fiscal agent staff 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 supporting documentation for rebates invoiced, adjustments, and rebates collected for the four quarters that ended June 30, 2006, (July 1, 2005, through June 30, 2006); and

- interviewed fiscal agent staff to determine the processes used in converting physician services claims data into drug rebate data related to single source drugs administered by physicians.

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 finding and conclusions based on our audit objectives. We believe that the evidence obtained provides a reasonable basis for our finding and conclusions based on our audit objectives.

FINDING AND RECOMMENDATION

The State agency had not implemented the recommendation from our prior audit to establish procedures to provide accurate pending rebate amounts and properly present an aging schedule of its drug rebate receivables in its quarterly reports to CMS. As a result, the State agency did not submit accurate Forms CMS-64.9R.

Regarding the second objective, the State agency had established controls over collecting rebates on single source drugs administered by physicians.

IMPLEMENTATION OF PRIOR RECOMMENDATION

In our prior audit of the Connecticut drug rebate program, we determined that the State agency had not established procedures for reporting its pending drug rebate amounts and properly presenting an aging schedule of its drug rebate receivables on the Form CMS-64.9R.

Section 2500.6(B) of the CMS State Medicaid Manual, requires the State agency to " . . . submit to HCFA [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 amounts collected, and reduce your claim for Federal reimbursement by the Federal share of amounts received. All pending drug rebates must be aged by comparing the dates the pending rebate was established with the ending date of the period shown on the . . . . Form [CMS]-64 . . . . "

Our current review found that the State agency had not developed policies and procedures to report to CMS accurate pending drug rebate amounts and properly present an aging schedule, as we had recommended and as CMS requires. As a result, the State agency's Forms CMS-64.9R for the four quarters that ended June 30, 2006, were inaccurate. Specifically, the State agency reported a negative balance of $167,088,100 as the ending balance for drug rebate receivables for the quarter that ended June 30, 2006. This negative balance occurred in large part because the State agency did not fully record the rebate amounts reported by the fiscal agent. For example:

- The fiscal agent billed manufacturers $130.7 million for the four quarters that ended June 30, 2006, but the State agency reported rebate billings of only $76.3 million during this period because it reported billings for only two of the four quarters.

- The fiscal agent reported negative adjustments to previously reported rebates from manufacturers totaling $5.6 million for the quarters that ended on or before March 31, 2006. However, the State agency reported no adjustments for these prior quarters.

Because an accurate aging schedule is the result of reporting accurate rebate billings, adjustments, and rebates collected, the State agency's failure to fully record the rebate amounts reported by the fiscal agent also contributed to its inaccurate presentation of an aging schedule. The State agency further compromised the accuracy of this schedule by reporting drug rebates collected during the quarter that ended June 30, 2006, as having been invoiced during this quarter rather than in the quarters in which they were actually invoiced.

The State agency needs to correct the reporting of pending rebates to provide CMS with an accurate measure of what needs to be collected. Corrective action will also allow for the proper aging of outstanding rebates and provide a management tool for determining the likelihood of collecting all outstanding rebates.

PHYSICIAN-ADMINISTERED SINGLE SOURCE DRUGS

The State agency had established controls over collecting rebates on single source drugs administered by physicians, as the DRA requires. The State agency paid $3,254,784 in claims for physician-administered drugs during January through June 2006 and billed manufacturers for rebates totaling $1,612,039.

RECOMMENDATION

We reiterate our recommendation that the State agency establish procedures to provide accurate pending rebate amounts and properly present an aging schedule of its drug rebate receivables in its quarterly reports to CMS.

DEPARTMENT OF SOCIAL SERVICES COMMENTS

In its written comments on our draft report, the State agency agreed with our finding and recommendation and said that it would take corrective action.

The State agency's comments are included in their entirety as the Appendix.

APPENDIX

MICHAEL P. STARKOWSKI
Commissioner

STATE OF CONNECTICUT

DEPARTMENT OF SOCIAL SERVICES

OFFICE OF THE COMMISSIONER

TELEPHONE
(860) 424-5053
TDD/TTY
1-800-842-4524
FAX
(860) 424-5057
EMAIL
commjs.dss@ct.gov

June 4, 2008

Mr. Michael J. Armstrong, Regional Inspector General for Audit Services
Department of Health & Human Services
Office of Inspector General
John F. Kennedy Federal Building
Boston, Massachusetts 02203

Subject: Audit Number: A-01-08-00002
Follow-Up Audit of the Medicaid Drug Rebate Program

Dear Mr. Armstrong:

I have received your letter dated May 5, 2008 requesting written comments concerning the subject draft audit report.

The Department has reviewed the audit findings and the recommendations and is in agreement. As indicated in the report, the Department has established controls for collecting rebates on single source drugs administered by physicians.

Concerning the issue of inaccurate accounts receivable data on the Form CMS-64.9R, the Department will be taking corrective action. The Department is working with EDS to develop procedures to provide accurate pending rebate amounts and to present an aging schedule of its drug rebate receivables in its quarterly reports to CMS. With the implementation of our Department's new MMIS (interChange), functionality to provide such reporting will be made available and supported.

If you have any questions or need any additional information, please call Mr. James Wietrak, Director of Quality Assurance at (860) 424-5903.

Sincerely

Michael P. Starkowski
Commissioner

MPS:jw
Attachment

cc: Amalia Vazquez Bzdyra, Deputy Commissioner of Administration
David Parrella, Director, Medical Care Administration
Evelyn Dudley, Manager, Medical Administration Operations
Lee Voghel, Director, Office of Financial Management & Analysis
James Wietrak, Director, Quality Assurance