DEPARTMENT OF HEALTH & HUMAN SERVICES

Office of Inspector General

Region IX
Office of Audit Services
90 – 7th Street, Suite 3-650
San Francisco, CA 94103

APR 15 2008

Report Number: A-09-07-00064

Ms. Leslie Clement
Administrator of Division of Medicaid
State of Idaho
3232 Elder Street
Boise, Idaho 83705

Dear Ms. Clement:

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 Idaho." 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.

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If you have any questions or comments about this report, please do not hesitate to call me, or contact Alice Norwood, Audit Manager, at (415) 437-8360 or through e-mail at Alice.Norwood@oig.hhs.gov. Please refer to report number A-09-07-00064 in all correspondence.

Sincerely,

Lori A. Ahlstrand
Regional Inspector General
for Audit Services

Enclosure

Direct Reply to HHS Action Official:

Ms. Jackie Garner, Consortium Administrator
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cc:
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Acting Associate Regional Administrator
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Department of Health and Human Services

OFFICE OF INSPECTOR GENERAL

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

Daniel R. Levinson
Inspector General

April 2008
A-09-07-00064

Office of Inspector General

http://oig.hhs.gov

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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. States report drug rebate accounts receivable data on Form CMS-64.9R, "Medicaid Drug Rebate Schedule." In Idaho, the Department of Health and Welfare (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 Idaho drug rebate program, we determined that although the State agency had policies and procedures for the program, it did not revise its policies and procedures to reflect current practices (A-10-03-00008). We also identified internal control and accountability weaknesses in the following areas: (1) quarterly reporting; (2) the accounts receivable system; (3) adjustments, dismissals, and writeoffs of drug rebate funds; (4) segregation of duties; and (5) dispute resolution. We recommended that the State agency (1) revise its policies and procedures to reflect current practices for the drug rebate program and (2) establish internal controls to:

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

The State agency disagreed with the findings and recommendations regarding quarterly reporting and the accounts receivable system. However, the State agency generally agreed with the remaining findings and recommendations.

This current review of Idaho 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 the recommendations made in our previous audit of the Idaho drug rebate program and (2) established controls over collecting rebates on single source drugs administered by physicians.

SUMMARY OF FINDINGS

Regarding the first objective, the State agency implemented the recommendations from our prior audit that related to its policies and procedures, segregation of duties, and dispute resolution. Although the State agency did not implement the recommendation related to the accounts receivable system, the State agency demonstrated that it maintained a subsidiary accounts receivable system at a sufficiently detailed level. In addition, the State agency did not implement the recommendation related to quarterly reporting and did not fully implement the recommendation related to management oversight for adjustments, dismissals, and writeoffs.

- **Quarterly Reporting**. The State agency did not maintain sufficient documentation to support amounts reported on Form CMS-64.9R. As a result, there was no assurance that the amounts reported were accurate, except for rebates collected.

- **Adjustments, Dismissals, and Writeoffs**. Although the State agency provided adequate management oversight for writeoffs of drug rebate funds, it did not provide adequate management oversight for adjustments and dismissals of those funds. This lack of oversight increased the potential risk for fraud, waste, and abuse.

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

RECOMMENDATIONS

We recommend that the State agency implement internal controls to:

- maintain sufficient documentation to support the amounts reported on Form CMS-64.9R and

- provide management oversight for adjustments and dismissals of drug rebate funds.

STATE AGENCY COMMENTS

In its comments on our draft report (included in their entirety as the Appendix), the State agency concurred with our recommendations. The State agency commented that it anticipated being able to develop internal controls related to maintaining sufficient documentation to support amounts reported on Form CMS-64.9R effective for the quarter ended March 31, 2008. The State agency also commented that it had implemented procedures to provide for management review and approval of adjustments and dismissals.

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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 Idaho, the Department of Health and Welfare (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, "Medicaid Drug Rebate Schedule." 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 requirement to certain multiple source drugs administered by physicians after January 1, 2008.

In Idaho, the State agency collects rebates on both single source and multiple source drugs administered by physicians. Physician-administered drugs are billed to the State Medicaid program on either a physician claim form or an outpatient hospital claim form. The State agency requires claim forms to include not only procedure codes that are part of the Healthcare Common Procedure Coding System but also the corresponding NDCs for all 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. 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. The State agency relies on physicians to perform these conversions.

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 Idaho drug rebate program, we determined that although the State agency had policies and procedures for the program, it did not revise its policies and procedures to reflect current practices.[3] We also identified internal control and accountability weaknesses in the following areas: (1) quarterly reporting; (2) the accounts receivable system; (3) adjustments, dismissals, and writeoffs of drug rebate funds; (4) segregation of duties; and (5) dispute resolution. We recommended that the State agency (1) revise its policies and procedures to reflect current practices for the drug rebate program and (2) establish internal controls to:

- accurately report drug rebate receivables to CMS and reconcile the ending balance of uncollected rebates to the receivable account;
- create a general ledger accounts receivable control account and a sufficiently detailed subsidiary accounts receivable system;
- provide management oversight for adjustments, dismissals, and writeoffs;
- provide for segregation of duties between the drug rebate billing and collection functions; and

[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.

[3]"Audit of the Medicaid Drug Rebate Program in Idaho," (A-10-03-00008), issued October 20, 2003.

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

The State agency disagreed with the findings and recommendations regarding quarterly reporting and the accounts receivable system. However, the State agency generally agreed with the remaining findings and recommendations.

Idaho Drug Rebate Program

The State agency is responsible for the drug rebate program and contracts with its fiscal agent, Electronic Data Systems Corporation, to perform all drug rebate program functions other than quarterly reporting. Specifically, the fiscal agent's responsibilities include invoicing, rebate collections, accounts receivable adjustments, dispute resolution, and recordkeeping processes.

The State agency reported an outstanding drug rebate balance of $3,623,859 on the June 30, 2006, Form CMS-64.9R. However, $3,447,052 of this amount related to quarterly billings and was not past due as of June 30, 2006. Of the remaining $176,807 that was past due, $95,201 was more than 1 year old. For the fiscal year ended June 30, 2006, the State agency reported rebate billings of approximately $40.7 million and collections of approximately $44.9 million.

This current review of the Idaho 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 the recommendations made in our previous audit of the Idaho 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, which included visits to the State agency and its fiscal agent offices in Boise, Idaho, from May 2007 through February 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 agency's policies and procedures related to the drug rebate accounts receivable system;

- 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 disputes for the quarter ended June 30, 2006;

- interviewed State agency officials to determine whether our prior recommendations were implemented;

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

- reviewed rebate billings and reimbursements for procedure codes related to 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.

FINDINGS AND RECOMMENDATIONS

Regarding the first objective, the State agency implemented the recommendations from our prior audit that related to its policies and procedures, segregation of duties, and dispute resolution. Although the State agency did not implement the recommendation related to the accounts receivable system, the State agency demonstrated that it maintained a subsidiary accounts receivable system at a sufficiently detailed level. In addition, the State agency did not implement the recommendation related to quarterly reporting and did not fully implement the recommendation related to management oversight for adjustments, dismissals, and writeoffs. Regarding the second objective, the State agency established controls over collecting rebates on single source drugs administered by physicians.

IMPLEMENTATION OF PRIOR RECOMMENDATIONS

The State agency did not implement the recommendation related to the accounts receivable system. However, the State agency demonstrated that its current subsidiary accounts receivable system was sufficiently detailed to allow the fiscal agent to reconstruct drug rebate activity by quarter and identify and resolve disputes. In addition, the State agency did not implement the recommendation related to quarterly reporting and did not fully implement the recommendation related to management oversight for adjustments, dismissals, and writeoffs.

Federal Regulations

Pursuant to 42 CFR § 433.32(a), States are required to "[m]aintain an accounting system and supporting fiscal records to assure that claims for Federal funds are in accord with applicable Federal requirements."

Quarterly Reporting

In our prior audit, we determined that the uncollected rebate balances reported to CMS by the State agency were inaccurate. In addition, we determined that the State agency did not maintain documentation to support the amounts reported on Form CMS-64.9R and did not reconcile the total uncollected balance to the subsidiary ledgers.

Since our prior audit, the subsidiary ledgers that the State agency used to report the uncollected rebate balances continued to be inaccurate by quarter; however, CMS informed us that it was satisfied with the State agency's efforts to report rebate amounts in the proper period. In addition, the State agency maintained sufficient documentation to support amounts reported for rebates collected. However, as of the end of our fieldwork, the State agency had not maintained sufficient documentation to support the other amounts reported on Form CMS-64.9R.

To report the amount of rebates collected, the State agency used actual drug rebate cash receipts data from its accounting system. According to the State agency, it calculated all other amounts on Form CMS-64.9R, including rebates invoiced and adjustments, based on the uncollected rebate balances derived from the State agency's subsidiary ledgers. However, the State agency could not support that the uncollected rebate balances reconciled to the subsidiary ledgers, because the State agency did not maintain historical subsidiary ledgers and other source documentation from its subsidiary accounts receivable system. As a result, there was no assurance that the amounts reported on Form CMS-64.9R were accurate, except for rebates collected.

Adjustments, Dismissals, and Writeoffs

In our prior audit, we determined that the State agency did not provide adequate management oversight for adjustments, dismissals, and writeoffs of drug rebate funds. Since our prior audit, the State agency provided adequate management oversight for writeoffs. However, as of the end of our fieldwork, the State agency had not provided adequate oversight for adjustments and dismissals.

For the quarter ended June 30, 2006, of the $13.3 million in drug rebates billed, the fiscal agent initiated, processed, and tracked more than $6.2 million in adjustments and dismissals. The State agency did not require the fiscal agent to obtain prior approval of or provide detailed information related to the adjustments and dismissals. For example, the fiscal agent made an adjustment of over $1 million to drug rebates due from one manufacturer without management review or approval.

The State agency indicated that it planned to conduct random samples of transactions related to the fiscal agent's adjustments and dismissals in an effort to enhance management oversight. However, as of the end of our fieldwork, the State agency was not conducting these samples and could not provide documentation of other types of management review or approval. The lack of management oversight for adjustments and dismissals increased the potential risk for fraud, waste, and abuse of drug rebate funds.

PHYSICIAN-ADMINISTERED SINGLE SOURCE DRUGS

The State agency established controls over collecting rebates on single source drugs administered by physicians as required by the DRA.[4] The controls include automated system edits that require physicians to provide valid NDCs, valid units of measure, and NDC quantities greater than zero when filing claims with specific procedure codes. Because this information is used to bill manufacturers for rebates, the fiscal agent relies on physicians to correctly convert procedure code units into NDC units. Therefore, to identify physician conversion errors, the fiscal agent initiated a process to manually scan invoices for unusual NDC billing quantities. For the 6-month period ended June 30, 2006, net adjustments due to conversion errors totaled over 85 percent of the billed amount for rebates on physician-administered drugs.

The State agency paid $2,402,729 in claims for both single source and multiple source physician-administered drugs from January through June 2006 and billed manufacturers for rebates totaling $9,623,151.[5] After the fiscal agent adjusted for physician conversion errors, rebates billed to manufacturers totaled $1,358,553.

RECOMMENDATIONS

We recommend that the State agency implement internal controls to:

- maintain sufficient documentation to support the amounts reported on Form CMS-64.9R and

- provide management oversight for adjustments and dismissals of drug rebate funds.

[4]The controls established by the State agency related to both single source and multiple source drugs.

[5]The State agency could not provide data that differentiated between single source and multiple source drugs.

STATE AGENCY COMMENTS

In its comments on our draft report (included in their entirety as the Appendix), the State agency concurred with our recommendations. The State agency commented that it anticipated being able to develop internal controls related to maintaining sufficient documentation to support amounts reported on Form CMS-64.9R effective for the quarter ended March 31, 2008. The State agency also commented that it had implemented procedures to provide for management review and approval of adjustments and dismissals.

APPENDIX

IDAHO DEPARTMENT OF
HEALTH & WELFARE

C.L. "BUTCH" OTTER - GOVERNOR
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March 21, 2008

Lori A. Ashland
Regional Inspector General for Audit Services
Office of Inspector General
Department of Health and Human Services
Region IX, Office of Audit Services
90 – 7th Street, Suite 3-650
San Francisco, CA 94103

Dear Ms. Ashland:

Enclosed are the Department's written comments in response to the draft audit report entitled "Follow-Up Audit of the Medicaid Drug Rebate Program in Idaho," Identified as report numberA-09-07-00064.

We look forward to receipt of the final report in the near future. If you have questions, please contact Larry Tisdale, Bureau Chief of Medicaid Financial Operations at (208) 287-1141.

Sincerely,

LESLIE M. CLEMENT
Administrator

Enc.

LMC/ksl

Response to
Follow-Up Audit of the Medicaid Drug Rebate Program in Idaho
Report Number A-09-07-00064

Recommendation:
Implement internal controls to maintain sufficient documentation to support the amounts reported on form CMS-64.9R.

Response:
The Department concurs that internal controls should be in place to maintain sufficient documentation to support amounts reported on Form CMS_64.9R. The Department anticipates that it will be able to develop acceptable internal controls when creating the CMS-64.9R for the second federal fiscal quarter. This report is due before the end of April 2008.

Recommendation:
Implement internal controls to provide management oversight for adjustments and dismissals of drug rebate funds.

Response:
The Department concurs that internal controls should be in place to provide management oversight for adjustments and dismissals of drug rebate funds. The Department has put in place procedures to ensure that justification is provided to the Department, by its drug rebate vendor, and that approval for adjustments and dismissals are received from the Department prior to their occurrence. These procedures will be reviewed for compliance during the regularly conducted contract monitoring of the vendor.