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

Report Number: A-09-07-00084

February 27, 2008

Ms. Sandra Shewry
Director
California Department of Health Care Services
1501 Capital Avenue, MS 0000
P.O. Box 997413
Sacramento, California 95899-7413

Dear Ms. Shewry:

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 California." 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 contact me at (415) 437-8360 or through e-mail at Lori.Ahlstrand@oig.hhs.gov, or contact Jerry McGee, Audit Manager, at (301) 261-7218, extension 603, or through e-mail at Jerry.Mcgee@oig.hhs.gov. Please refer to report number A-09-07-00084 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
Consortium for Medicaid and Children's Health Operations
Centers for Medicare & Medicaid Services
233 North Michigan Avenue, Suite 600
Chicago, Illinois 60601

Department of Health and Human Services

OFFICE OF INSPECTOR GENERAL

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

Daniel R. Levinson
Inspector General

February 2008
A-09-07-00084

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 (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 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 California, the Department of Health Care Services (the State agency) administers the Medicaid drug rebate program.

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."

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 California drug rebate program, we determined that the State agency had an adequate system to track receivables for drug rebates by NDC and had established formal policies and procedures for the drug rebate program (A-09-03-00038). However, we identified weaknesses related to quarterly reporting and dispute resolution. We recommended that the State agency establish internal controls to:

- implement a system capable of providing documentation to support rebate amounts reported to CMS, and reconcile the ending balance of uncollected rebates to the receivable account, and

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

The State agency agreed with these findings and recommendations.

This current review of California 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 California 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 recommendation from our prior audit related to dispute resolution and partly implemented the recommendation related to quarterly reporting. Specifically, the State agency uses the rebate accounting system to prepare Form CMS-64.9R; however, this system does not maintain a historical record of the summary amounts used to prepare the CMS-64.9R. We determined that reconciliation is no longer needed because the reported amounts are based on summarized claim records. In June 2007, the State agency submitted a system change to maintain a record of the amounts used for quarterly reporting to CMS. The system change is scheduled for implementation in April 2008.

In addition, the State agency established controls over collecting rebates on 81 single source drugs administered by physicians. In July 2007, the State agency initiated a request for a claims system change that would require physicians to include NDCs when submitting claims for drugs they administer. The system change is targeted for implementation in June 2009.

RECOMMENDATION

We recommend that the State agency ensure that the system change scheduled for implementation in April 2008 provides documentation to support rebate amounts reported to CMS.

STATE AGENCY'S COMMENTS

In written comments on the draft report (included in their entirety as the Appendix), the State agency addressed our recommendation by stating that it is working on a system change that will enable it to capture and document the data to support rebate amounts reported to CMS quarterly. The change is scheduled to be implemented by July 15, 2008.

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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 California, the Department of Health Care 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 identifies, by National Drug Code (NDC), the number of units of each covered outpatient drug for which they 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) amended 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.

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

In California, 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 is not included on the physician claim form. 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 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 California drug rebate program, we determined that the State agency had an adequate system to track receivables for drug rebates by NDC and had established formal policies and procedures for the drug rebate program.[3] However, we identified weaknesses related to quarterly reporting and dispute resolution. We recommended that the State agency establish internal controls to:

- implement a system capable of providing documentation to support rebate amounts reported quarterly to CMS, and reconcile the ending balance of uncollected rebates to the receivable account, and

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

The State agency agreed with these findings and recommendations.

California State Auditor Reports

The Bureau of State Audits (BSA) issued two reports after our previous audit that related to the State agency's drug rebate program. Our review of these reports identified one finding that pertained to the objectives of our current review: "Health Services Has Not Yet Reconciled All

[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 California" (A-09-03-00038), issued December 23, 2003.

Its Older Rebate Disputes and Its Backlog of Current Disputes Is Growing."[4] The State agency indicated that rebate disputes from January 1991 through December 2001 had decreased; however, current disputes had increased. The State agency attributed the increasing backlog to the difficulty of retaining personnel for dispute resolutions.

After the BSA reports were issued, the State legislature directed the State agency to resolve the older disputed rebates and converted 11 limited-term (3-year) positions to 7 permanent positions. The State agency also developed a comprehensive rebate training manual, which includes procedures for using the State hearing mechanism.

California Drug Rebate Program

The State agency is responsible for the drug rebate program and contracts with its fiscal agent, Electronic Data Systems Corporation, to process and maintain claim data for the program. Other program functions are performed by the State agency.

The State agency reported an outstanding drug rebate balance of $835,328,219 on the June 30, 2006, Form CMS-64.9R. However, $304,941,633 of this amount related to quarterly billings and was not past due as of June 30, 2006. Of the remaining $530,386,586 that was past due, $459,032,125 was more than 1 year old. For the fiscal year ended June 30, 2006, the State agency reported rebate billings of approximately $2.0 billion and collections of approximately $2.2 billion.

This current review of the California 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 California 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.

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[4]BSA's Letter Report 2007-501, issued June 2007, page 9.

We excluded from our review the recommendation from the previous audit related to establishing a general ledger accounts receivable control account, because the CMS action official agreed with the State agency's nonconcurrence with the recommendation. CMS did not require the State agency to implement the recommendation.

We performed our fieldwork at the State agency and its fiscal agent, both of which are located in Sacramento, California, from July through October 2007.

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 drug rebate accounts receivable system;

- interviewed State agency officials and fiscal agent staff to determine the policies, procedures, controls, and any other audits 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 accounts receivable records as of June 30, 2006, and interest payments received for the quarter ended June 30, 2006;

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

- reviewed rebate listings of 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.

FINDINGS AND RECOMMENDATION

The State agency implemented the recommendation from our prior audit related to dispute resolution and partly implemented the recommendation related to quarterly reporting. In addition, the State agency established controls over collecting rebates on 81 single source drugs administered by physicians.

IMPLEMENTATION OF PRIOR RECOMMENDATIONS

In our prior audit, we determined that the State agency did not provide documentation to support the $1.34 billion in uncollected rebates reported on Form CMS-64.9R as of June 30, 2002. In addition, the State agency did not reconcile this balance to its subsidiary ledger system. As a result, it did not assure the accuracy of the balance reported on the CMS-64.9R. Since our prior audit, the State agency reported to CMS that it had investigated why the CMS-64.9R was incorrect, corrected this report, and submitted the corrections.

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." In our current review, we determined that the State agency uses the rebate accounting system to prepare Form CMS-64.9R; however, this system does not maintain a historical record of the summary amounts used to prepare the CMS-64.9R. We determined that reconciliation is no longer needed because the reported amounts are based on summarized claim records.

In June 2007, the State agency submitted a system change to its fiscal agent to maintain a historical record of amounts reported on Form CMS-64.9R. The system change is scheduled for implementation in April 2008.

PHYSICIAN-ADMINISTERED SINGLE SOURCE DRUGS

The State agency established controls over collecting rebates for 81 single source drugs administered by physicians as required by the DRA. For 81 procedure codes, the State agency paid $64,896,157 in claims for physician-administered drugs from January through June 2006 and billed manufacturers for rebates totaling $14,747,175.

According to California's "Drug Rebate Section Training Manual," the State agency began submitting rebate invoices to manufacturers for the quarter ending December 1996. The State agency has continued to invoice for physician-administered drugs that can be identified by a single NDC. As of September 2007, the State agency had identified 81 NDCs for procedure codes associated with single source drugs administered by physicians and had converted the billing units into units used for the rebate program.

In July 2007, the State agency initiated a request for a claims system change that would require physicians to include NDCs when submitting claims for drugs they administer. The system change is targeted for implementation in June 2009.

RECOMMENDATION

We recommend that the State agency ensure that the system change scheduled for implementation in April 2008 provides documentation to support rebate amounts reported to CMS.

STATE AGENCY'S COMMENTS

In written comments on the draft report (included in their entirety as the Appendix), the State agency addressed our recommendation by stating that it is working on a system change that will enable it to capture and document the data to support rebate amounts reported to CMS quarterly. The change is scheduled to be implemented by July 15, 2008.

APPENDIX

DHCS
SANDRA SHEWRY
Director

State of California—Health and Human Services Agency
Department of Health Care Services

ARNOLD SCHWARZENEGGER
Governor

FEB 19 2008

Lori A. Ahlstrand
Regional Inspector General for Audit Services
Office of Inspector General
90 7th Street, Suite 3-650
San Francisco, CA 94103

Dear Ms. Ahlstrand:

The California Department of Health Care Services (DHCS) has prepared its response to the Office of Inspector General's (OIG) draft report entitled "Follow-Up Audit of the Medicaid Drug Rebate Program in California" (A-09-07-00084). The DHCS appreciates the work performed by the OIG and the opportunity to respond to the draft report.

Please contact Pilar Williams, Chief, Pharmacy Benefits Division, at (916) 552-9500 if you have any questions.

Sincerely,

Stan Rosenstein
Chief Deputy Director
Health Care Programs

cc: See next page

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FEB 19 2008

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California Department of Health Care Services' Response to the
Office of Inspector General's Draft Report Entitled

Follow-Up Audit of the Medicaid Drug Rebate Program in California

Recommendation:	We recommend that the State agency ensure that the system change scheduled for implementation in April 2008 provides documentation to support rebate amounts reported to the Centers for Medicare & Medicaid Services (CMS).
Response:	The Department of Health Care Services is currently working on System Development Notice 07001 which is scheduled to implement by July 15, 2008. With the implementation of this system modification, the Rebate Accounting and Information Subsystem (RAIS) will be able to capture and document the data to support rebate amounts that are reported on a quarterly basis to CMS on the Drug Rebate CMS 64.