

DEPARTMENT OF HEALTH AND HUMAN SERVICES

OFFICE OF AUDIT SERVICES 233 NORTH MICHIGAN AVENUE CHICAGO, ILLINOIS 60601

REGION V OFFICE OF INSPECTOR GENERAL

September 18, 2008

Report Number: A-05-08-00058

Mr. Cal Ludeman Commissioner Department of Human Services 540 Cedar Street St. Paul, Minnesota 55155

Dear Mr. Ludeman:

Enclosed is the U.S. Department of Health and Human Services (HHS), Office of Inspector General (OIG), final report entitled "Review of Minnesota's Drug Rebate Accounts Receivable Balance Reported on the Form CMS-64." 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 Lynn Barker, Audit Manager, at (317) 226-7833 extension 21 or through e-mail at Lynn.Barker@oig.hhs.gov. Please refer to report number A-05-08-00058 in all correspondence.

Sincerely,

Marc Gystafson

Regional Inspector General

for Audit Services

Enclosure

Page 2 – Mr. Cal Ludeman

cc:

Ms. Christine Bronson, Medicaid Director Department of Human Services 540 Cedar Street St. Paul, Minnesota 55155

Mr. David Ehrhardt, Internal Audit Director Department of Human Services 444 Lafayette Road St. Paul, Minnesota 55155

Department of Health and Human Services

OFFICE OF INSPECTOR GENERAL

REVIEW OF MINNESOTA'S DRUG REBATE ACCOUNTS RECEIVABLE BALANCE REPORTED ON THE FORM CMS-64



Daniel R. Levinson Inspector General

September 2008 A-05-08-00058

Office of Inspector General

http://oig.hhs.gov

The mission of the Office of Inspector General (OIG), as mandated by Public Law 95-452, as amended, is to protect the integrity of the Department of Health and Human Services (HHS) programs, as well as the health and welfare of beneficiaries served by those programs. This statutory mission is carried out through a nationwide network of audits, investigations, and inspections conducted by the following operating components:

Office of Audit Services

The Office of Audit Services (OAS) provides auditing services for HHS, either by conducting audits with its own audit resources or by overseeing audit work done by others. Audits examine the performance of HHS programs and/or its grantees and contractors in carrying out their respective responsibilities and are intended to provide independent assessments of HHS programs and operations. These assessments help reduce waste, abuse, and mismanagement and promote economy and efficiency throughout HHS.

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The Office of Evaluation and Inspections (OEI) conducts national evaluations to provide HHS, Congress, and the public with timely, useful, and reliable information on significant issues. These evaluations focus on preventing fraud, waste, or abuse and promoting economy, efficiency, and effectiveness of departmental programs. To promote impact, OEI reports also present practical recommendations for improving program operations.

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Notices

THIS REPORT IS AVAILABLE TO THE PUBLIC at http://oig.hhs.gov

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 Minnesota, the Department of Human Services (the State agency) administers the Medicaid drug rebate program.

The Medicaid program requires States to present a complete, accurate, and full disclosure of all pending drug rebates and collections, including interest. States report drug rebate accounts receivable data on Form CMS-64.9R. The Form CMS-64.9R 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.

Federal regulations (42 CFR § 433.32) require State agencies to maintain an accounting system and supporting fiscal records to assure that claims for Federal funds comply with applicable Federal requirements. Without routine reconciliations, the State agency does not have reasonable assurance that drug rebate information reported to CMS is accurate.

OBJECTIVE

Our objective was to determine whether the State agency accurately reported the accounts receivable balances for drug rebates on the Form CMS-64.9R.

SUMMARY OF FINDINGS

The State agency did not accurately report the accounts receivable balance for drug rebates on the Form CMS-64.9R. The State agency did not accurately report required adjustments, current billings and collections of interest on the Form CMS-64.9R and implement procedures to ensure reported accounts receivable balances were reconciled to and supported by accounting records. As a result, the State agency understated the reported accounts receivable balance by approximately \$31.4 million and reported a credit balance of \$10.2 million on the CMS-64.9R as of June 30, 2006.

RECOMMENDATIONS

We recommend the State agency:

- correct the outstanding accounts receivable balance reported to CMS and
- implement procedures to ensure that the accounts receivable balance for drug rebates reported on the Form CMS-64.9R is reconciled to and supported by accounting records.

STATE AGENCY COMMENTS

In its comments on our draft report, the State agency provided information on steps it had taken to implement the recommendations. The State agency's comments are included in their entirety as the Appendix.

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STATE AGENCY COMMENTS

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.

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.

Federal Requirements for Reporting Drug Rebate Accounts Receivables

The Medicaid program requires States to present a complete, accurate, and full disclosure of all pending drug rebates and collections, including interest. States report drug rebate accounts receivable data on Form CMS-64.9R. The Form CMS-64.9R 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.

Federal regulations (42 CFR § 433.32) require State agencies to maintain an accounting system and supporting fiscal records to assure that claims for Federal funds comply with applicable Federal requirements. Without routine reconciliations, the State agency does not have reasonable assurance that drug rebate information reported to CMS is accurate.

Minnesota Drug Rebate Program

In Minnesota, the Department of Human Services (the State agency) is responsible for the drug rebate program. For the fiscal year ended June 30, 2006, the State agency reported rebate billings of approximately \$123.1 million and collections of \$139.5 million.

OBJECTIVE, SCOPE, AND METHODOLOGY

Objective

Our objective was to determine whether the State agency accurately reported the accounts receivable balances for drug rebates on the Form CMS-64.9R.

Scope

We reviewed the State agency's current policies, procedures, and controls over the drug rebate program and the reporting of accounts receivable data on Form CMS-64.9R as of June 30, 2006.

We performed our fieldwork at the State agency in St. Paul, Minnesota, from October 2007 through June 2008.

Methodology

To accomplish our objective, we

- reviewed section 1927 of the Act and CMS guidance issued to State Medicaid directors and other information pertaining to the Medicaid drug rebate program;
- reviewed the State agency policies and procedures related to the drug rebate accounts receivable system;
- interviewed State agency officials to determine the policies, procedures, and controls related to the Medicaid drug rebate program; and
- reconciled the Form CMS-64.9R to the State agency accounting records for the four quarters ended 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 objective. We believe that the evidence obtained provides a reasonable basis for our findings and conclusions based on our audit objective.

FINDING AND RECOMMENDATIONS

The State agency did not accurately report the accounts receivable balance for drug rebates on the Form CMS-64.9R. The State agency did not accurately report required adjustments, current billings and collections of interest on the Form CMS-64.9R and implement procedures to ensure reported accounts receivable balances were reconciled to and supported by accounting records. As a result, the State agency understated the reported accounts receivable balance by approximately \$31.4 million and reported a credit balance of \$10.2 million on the CMS-64.9R as of June 30, 2006.

ACCOUNTS RECEIVABLE BALANCE

The State agency did not accurately report the accounts receivable balance for drug rebates on the Form CMS-64.9R.

Federal Requirements

Pursuant to 42 CFR § 433.32(a), State agencies are required to maintain an accounting system and supporting fiscal records to assure that claims for Federal funds comply with applicable Federal requirements. Section (V)(b) of the rebate agreement between CMS and manufacturers requires manufacturers to pay interest on late rebate payments, and CMS program release 29 requires interest to be collected.¹

Reconciliation of Reported Accounts Receivables to Supporting Records

As of June 30, 2006, the State agency reported the accounts receivable balance for drug rebates on the Form CMS-64.9R as a credit (negative) \$10.2 million while the accounting records indicated the balance was \$21.2 million.

Table: Accounts Receivable (A/R) Balances

	A/R Balance for 6/30/2006 Quarter	A/R Balance 3/31/2006 Quarter	A/R Balance 12/31/2005 Quarter	A/R Balance 9/30/2005 Quarter	A/R Balance over 1 year	Total A/R Balance
State Agency Accounting Records	\$16,951,897	\$3,531,553	\$(735,098)	\$(146,111)	\$1,551,396	\$21,153,637
Reported on Form CMS- 64.9R	\$16,951,897	\$3,531,552	\$(714,978)	\$(140,468)	\$(29,838,993)	\$(10,210,990)
Difference	-	\$1	\$(20,120)	\$(5,643)	\$31,390,389	\$31,364,627

The differences for the accounts receivable quarterly balances, the balance over 1 year and the total balance occurred because required adjustments, interest, and current billings were not

¹CMS issued drug rebate program guidance to State Medicaid directors and posted the program releases on its Web site at http://www.cms.hhs.gov/MedicaidDrugRebateProgram/02 StateReleases.asp. Accessed March 19, 2008.

accurately reported on the Form CMS-64.9R. Additionally, the State agency did not implement procedures to ensure accounts receivable balances for rebates reported on the Form CMS-64.9R were reconciled to and supported by accounting records. Consequently, the State agency understated the accounts receivable balance by approximately \$31.4 million and reported a credit balance of \$10.2 million as of June 30, 2006.

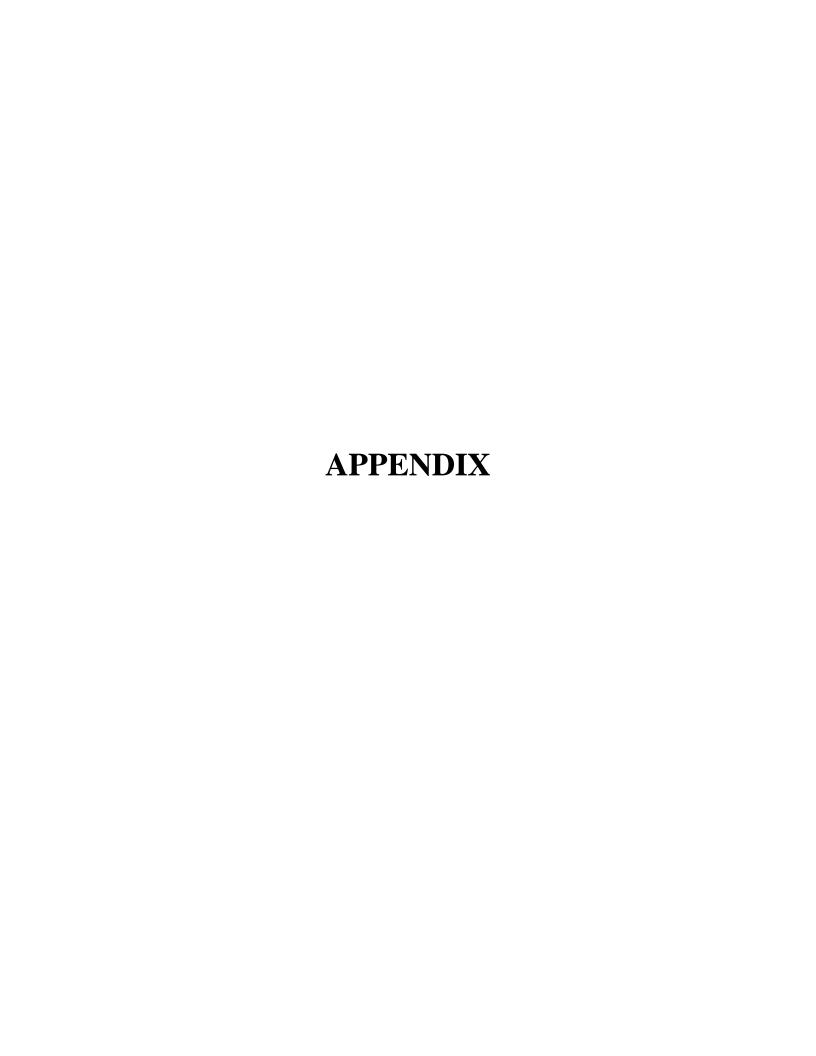
RECOMMENDATIONS

We recommend the State agency:

- correct the outstanding accounts receivable balance reported to CMS and
- implement procedures to ensure that the accounts receivable balance for drug rebates reported on the Form CMS-64.9R is reconciled to and supported by accounting records.

STATE AGENCY COMMENTS

In its comments on our draft report, the State agency provided information on steps it had taken to implement our recommendations. The State agency's comments are included in their entirety as the Appendix.



Minnesota Department of Human Services -

September 10, 2008

Marc Gustafson
Regional Inspector General
for Audit Services
Department of Health and Human Services
Office of the Inspector General for Audit Services
233 North Michigan Avenue, Suite 1360
Chicago, Illinois 60601

RE: Review of State of Minnesota's Accounts Receivable Balance Reported on the Form CMS-64 for the State Fiscal Year ending June 30, 2006

Audit Report Number A-05-08-00058

Dear Mr. Gustafson:

Thank you for the opportunity to review and comment on your report covering our reporting of drug rebate accounts receivable balances on the CMS-64 form for the state fiscal year ending June 30, 2006. It is our understanding that our response will be published in the Office of the Inspector General's final audit report. We appreciated the effort of your staff in keeping the department informed of their progress during the audit. The report contained the following recommendations

Recommendation #1: Correct the outstanding accounts receivable balance reported to CMS.

Response: The state worked with the local CMS official to make Line 2 adjustments to the Drug Rebate Schedule so the CMS-64.9R accounts receivable balance reconciles to the states accounting records. These adjustments were made to the CMS-64 Report for the quarter ending 9/30/07.

<u>Recommendation #2</u>: Implement procedures to ensure that the accounts receivable balance for drug rebates reported on the Form CMS-64.9R is reconciled to and supported by accounting records.

Response: In October of 2007, the state added an additional control to ensure that future accounts receivable balances reported on the CMS-64 reconciled to state accounting records. Specifically, the program accountant responsible for entering data into the CMS-64.9R page now sends the Drug Rebate Coordinator a copy of the CMS-64.9R page for verification and concurrence prior to submission to CMS.

Marc Gustafson Page 2 September 10, 2008

If you have any further questions, please contact David Ehrhardt, Internal Audit Director, at (651) 431 3619.

Sincerely,

Cal R. Ludeman Commissioner

cc: Lynn Barker, HHS OIG