



DEPARTMENT OF HEALTH AND HUMAN SERVICES
OFFICE OF AUDIT SERVICES
233 NORTH MICHIGAN AVENUE
CHICAGO, ILLINOIS 60601

REGION V
OFFICE OF
INSPECTOR GENERAL

July 8, 2008

Report Number: A-05-08-00014

Ms. Janet Olszewski
Director
Michigan Department of Community Health
Medical Services Administration
Capital View Building
201 Townsend Street
Lansing, Michigan 48913

Dear Ms. Olszewski:


Enclosed is the U.S. Department of Health and Human Services, Office of Inspector General (OIG), final report entitled "Follow-Up Review of the Medicaid Drug Rebate Program in Michigan." 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 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-05-08-00014 in all correspondence.

Sincerely,


Marc Gustafson
Regional Inspector General
for Audit Services

Enclosure

Direct Reply to HHS Action Official:

Jackie Garner, Consortium Administrator
Consortium for Medicaid and Children's Health Operations
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233 North Michigan Avenue, Suite 600
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cc:

Mr. Paul Reinhart, Senior Deputy Director.
Michigan Department of Community Health
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Department of Health and Human Services

**OFFICE OF
INSPECTOR GENERAL**

**FOLLOW-UP REVIEW OF THE
MEDICAID DRUG REBATE
PROGRAM IN MICHIGAN**



Daniel R. Levinson
Inspector General

July 2008
A-05-08-00014

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. In Michigan, the Department of Community Health (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 Michigan drug rebate program (A-05-03-00047), we determined that the State agency had adequate controls over its drug rebate program, with one exception: It did not reconcile the outstanding drug rebate balance reported to CMS to its supporting records. We recommended that the State agency develop policies, procedures and controls to ensure that the outstanding rebate amount reported to CMS is reconciled to supporting records. The State agency agreed with our finding and recommendation.

The current review of Michigan 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 Michigan drug rebate program and (2) established controls over collecting rebates on single source drugs administered by physicians.

SUMMARY OF FINDINGS

The State agency did not implement our prior audit recommendation to develop policies, procedures and controls to ensure that the outstanding rebate amount reported to CMS was reconciled to supporting records. As a result, the State agency understated the accounts

receivable balance by \$84.5 million on the Form CMS-64.9R as of June 30, 2006. The State agency made an adjustment on the September 30, 2007 Form CMS-64.9R to correct the understated accounts receivable balance.

The State agency established controls over collecting rebates on single source drugs administered by physicians.

RECOMMENDATION

We reiterate our recommendation that the State agency develop policies, procedures and controls to ensure that the outstanding rebate amount reported to CMS is reconciled with the supporting records.

STATE AGENCY COMMENTS

In written comments on our draft report, the State agency agreed with the 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 Michigan, the Department of Community Health (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 to CMS a list 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) amended section 1927 of the Act and required 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.

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

In Michigan, physician-administered drugs are billed to the State Medicaid program on a physician claim form using the 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 Michigan drug rebate program, we determined that generally the State agency had adequate controls over its drug rebate program. However, improvement in one area could enhance accountability over drug rebates. Specifically, the State agency had not reconciled the outstanding balance of drug rebate accounts receivable reported on the Form CMS-64.9R to supporting records. We recommended that the State agency develop policies, procedures, and controls to ensure that the outstanding rebate amount reported to CMS is reconciled with the supporting records.³

The State agency agreed with our findings and recommendations.

Michigan Drug Rebate Program

The State agency contracts with First Health Services Corporation (First Health), to perform all drug rebate program functions other than receiving rebate funds. First Health's responsibilities included verifying interest payments and accounting for rebates on single source drugs administered by physicians. First Health also converted the procedure code billing units into equivalent NDC billing units.

The State agency's supporting records showed an outstanding drug rebate balance of \$18,390,783 as of June 30, 2006.⁴ However, \$6,575,045 of this amount related to quarterly

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"Review of Medicaid Drug Rebate Program - State of Michigan" (A-05-03-00047), issued September 19, 2003.

⁴The State agency reported an outstanding drug rebate balance of negative \$66,073,333 as of the June 30, 2006 Form CMS-64.9R.

billings and was not past due as of June 30, 2006. Of the remaining \$11,815,738 that was past due, \$11,135,203 was more than 1 year old. For the fiscal year ended June 30, 2006, the State agency reported rebate billings of approximately \$287.7 million and collections of \$327.8 million.

The current review of the Michigan 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 Michigan 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 Lansing, Michigan.

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 First Health's drug rebate accounts receivable system;
- interviewed State agency 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 and compared to supporting documentation;
- compared subsidiary schedules to accounts receivable detail for quarters ending March 31, 2006 and June 30, 2006;

- reviewed copies of Form CMS-64 for quarters ending June 30, 2003; 2004; and 2005; and compared rebate reported amounts to supporting records;
- interviewed State agency officials 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 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 did not implement our prior audit recommendation to develop policies, procedures and controls to ensure that the outstanding rebate amount reported to CMS was reconciled with the supporting records. The State agency established controls over collecting rebates on single source drugs administered by physicians.

IMPLEMENTATION OF PRIOR RECOMMENDATION

Since our prior audit, the State agency has implemented procedures to (1) compare First Health receipts to the State agency's receipt records on both a weekly and monthly basis and (2) reconcile First Health's 64.9R schedules to supporting documents maintained by both the State agency and First Health. However, the State agency did not reconcile First Health's 64.9R schedules with the outstanding rebate amount reported on the Form CMS-64.9R.

Pursuant to 42 CFR § 433.32(a), State agencies 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.”

The State agency verified the accuracy of First Health's 64.9R schedules; however the State agency did not reconcile First Health's 64.9R schedules with the outstanding rebate amount reported to CMS on the Form CMS-64.9R. As a result, the State agency understated the accounts receivable balance by \$84.5 million on the Form CMS-64.9R as of June 30, 2006. The State agency made an adjustment on the September 30, 2007 Form CMS-64.9R to correct the understated accounts receivable balance.

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 \$50,169,230 in claims for physician-administered drugs during the January through June 2006 time period and billed manufacturers for rebates totaling \$6,420,576.

RECOMMENDATION

We reiterate our recommendation that the State agency develop policies, procedures and controls to ensure that the outstanding rebate amount reported to CMS is reconciled with the supporting records.

STATE AGENCY COMMENTS

In written comments on our draft report, the State agency agreed with the recommendation. The State agency's comments are included in their entirety as the Appendix.

APPENDIX



JENNIFER M. GRANHOLM
GOVERNOR

STATE OF MICHIGAN
DEPARTMENT OF COMMUNITY HEALTH
LANSING

JANET OLSZEWSKI
DIRECTOR

June 18, 2008

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

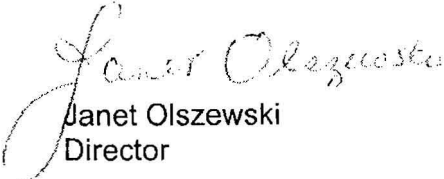
Re: Report Number (A-05-08-00014)

Dear Mr. Gustafson:

Enclosed is the Michigan Department of Community Health's response to the draft report entitled "Follow-Up Review of the Medicaid Drug Rebate Program in Michigan" that covered the period July 1, 2005 through June 30, 2006.

We appreciate the opportunity to review and comment on the report before it is released. If you have any questions regarding this response, please refer them to Pam Myers at (517) 373-1508.

Sincerely,


Janet Olszewski
Director

JO:kk

Enclosure

cc: Paul Reinhart
Sue Moran
Nick Lyon
Pam Myers

MICHIGAN DEPT. OF COMMUNITY HEALTH'S RESPONSE TO HHS OIG AUDIT
REPORT A-05-08-00014 REGARDING MICHIGAN MEDICAID'S DRUG REBATE PROGRAM

HHS OIG Recommendation

We reiterate our recommendation that the State agency develop policies, procedures and controls to ensure that the outstanding rebate amount reported to CMS is reconciled with the supporting records.

DCH (Department of Community Health) Response

As a result of the prior audit recommendation, DCH implemented policies, procedures and controls to reconcile the outstanding rebate amount reported to CMS with the supporting records. However, the Department acknowledges these did not ensure the reconciliation was performed each quarter.

DCH agrees with the recommendation and has revised its policies, procedures and controls to ensure this reconciliation is performed each quarter.

The audit report indicates that DCH understated the accounts receivable balance on the Form CMS-64.9R as of June 30, 2006. It is of note that DCH identified the understated balance and processed an adjustment to correct it, prior to OIG beginning the follow-up audit.