

Office of Inspector General Offices of Audit Services

Region VII 601 East 12th Street Room 284A Kansas City, Missouri 64106

APR 0 3 2008

Report Number: A-07-07-03094

Mr. Kevin W. Concannon Director Iowa Department of Human Services Hoover State Office Building, 5th Floor 1305 East Walnut Street Des Moines, Iowa 50309-0114

Dear Mr. Concannon:

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 Iowa." 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 Greg Tambke, Audit Manager, at (573) 893-8338, extension 30, or through e-mail at <u>Greg.Tambke@oig.hhs.gov</u>. Please refer to report number A-07-07-03094 in all correspondence.

Sincerely,

Patrick J. Cogley 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 IOWA



Daniel R. Levinson Inspector General

> April 2008 A-07-07-03094

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 drug 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 Iowa, the Department of Human 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 Iowa drug rebate program (A-07-03-04014), we determined that the State agency lacked sufficient controls over its Medicaid drug rebate program. Areas that lacked sufficient internal controls included: (1) recording accounts receivable, (2) Form CMS-64.9R and general ledger reconciliation, (3) reporting rebates received, (4) dispute resolution, (5) interest accrual, collection and reporting, and (6) record retention. We recommended that the State agency develop and follow policies and procedures that included:

- establishing a general ledger accounts receivable account for drug rebates;
- reconciling the general ledger account to the subsidiary ledgers/records and to the Form CMS-64.9R;
- reconciling quarterly the drug rebate collections on the cash receipts log to collections on the Form CMS-64.9R;
- reporting rebate collections in the proper time period;
- making use of the State's hearing mechanism to resolve disputes after 60 days;
- estimating and accruing interest on all overdue rebate balances;
- properly reporting interest collections on the Form CMS-64 Summary Sheet; and
- ensuring that records are kept for an appropriate period of time.

The State agency agreed with our findings and recommendations related to developing and following policies and procedures to properly report interest collections. However, the State agency did not agree with our other findings and recommendations.

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

SUMMARY OF FINDINGS

The State agency generally corrected the control weaknesses identified in our previous audit that related to: (1) recording accounts receivable, (2) Form CMS-64.9R and general ledger reconciliation, (3) reporting rebates received, (4) interest accrual and collection, and (5) record retention.

However, the State agency did not develop adequate policies and procedures to offer the State's hearing mechanism for disputes that were 60 days old. The State agency also did not develop adequate policies and procedures to ensure that interest collections were properly and accurately reported. As a result, the State agency did not report interest totaling \$873 that was collected during our audit period. Additionally, the State agency established controls over and accountability for collecting rebates on single source drugs administered by physicians.

RECOMMENDATIONS

We recommend that the State agency:

- develop and follow policies and procedures to offer use of the State's hearing mechanism to resolve disputes after 60 days;
- develop and follow policies and procedures to properly report interest collections on the Form CMS-64 Summary Sheet; and
- report interest of \$873 that was collected, but not reported, during the audit period.

STATE AGENCY'S COMMENTS AND OFFICE OF INSPECTOR GENERAL'S RESPONSE

In written comments on our draft report, the State agency concurred with the first finding and recommendation and concurred in part with the remaining findings and recommendations. In additional comments regarding the first recommendation, the State agency expressed concern that there is a conflict between the rebate agreements and CMS's Best Practices. Additionally, the State agency provided additional documentation to support its response regarding reporting interest.

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

After reviewing the State agency's comments, we continue to support our findings and recommendations. Although we continue to support our recommendation that the State should develop policies and procedures to make a State hearing mechanism available to manufacturers in an effort to resolve disputes, we also believe that the State agency should pursue discussions with CMS on the possible conflict between the drug rebate agreement and CMS's Best Practices guidelines.

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STATE AGENCY'S COMMENTS

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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 drug 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 Iowa, the Department of Human Services (the State agency) is responsible for the 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, its best price. Based on this information, CMS calculates a unit rebate amount for each covered outpatient drug and provides the amounts to States on a quarterly basis.

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 have 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 requires States, as of January 1, 2006, to collect and submit utilization 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 expands the requirement to certain multiple source drugs administered by physicians after January 1, 2008.

In Iowa, 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 Iowa drug rebate program, we determined that the State agency lacked sufficient controls over its program. Areas that lacked sufficient internal controls included: (1) recording accounts receivable, (2) Form CMS-64.9R and general ledger reconciliation, (3) reporting rebates received, (4) dispute resolution, (5) interest accrual, collection and reporting, and (6) record retention.³

We recommended that the State agency develop and follow policies and procedures that included:

- establishing a general ledger accounts receivable account for drug rebates;
- reconciling the general ledger account to the subsidiary ledgers/records and to the Form CMS-64.9R;
- reconciling quarterly the drug rebate collections on the cash receipts log to collections on the Form CMS-64.9R;
- reporting rebate collections in the proper time period;
- making use of the State's hearing mechanism to resolve disputes after 60 days;
- estimating and accruing interest on all overdue rebate balances;

²"Multistate Review of Medicaid Drug Rebate Programs" (A-06-03-00048), issued July 6, 2005; Arizona was not included as it did not operate a drug rebate program.

³"Audit of the Medicaid Drug Rebate Program in Iowa" (A-07-03-04014), issued June 24, 2003.

- properly reporting interest collections on the Form CMS-64 Summary Sheet; and
- ensuring that records are kept for an appropriate period of time.

The State agency agreed with our findings and recommendations related to developing and following policies and procedures to properly report interest collections. However, the State agency did not agree with our other findings and recommendations.

Iowa Drug Rebate Program

The State agency contracted with Goold Health Systems Data Management of Maine (GHS) to operate the pharmacy point-of-sale for all of the drug rebate program functions, except for mailing the invoices to the manufacturers, physical receipt of rebate payments, and completing the Form CMS-64.9R. GHS became the State agency's point-of-sale contractor on July 1, 2005.

The State agency reported an outstanding drug rebate balance of \$25,646,858 on the June 30, 2006, Form CMS-64.9R. However, \$15,827,665 of this amount related to quarterly billings and was not past due as of June 30, 2006. Of the remaining \$9,819,193 that was past due, \$7,595,885 was more than 1 year past due. For the fiscal year ended June 30, 2006, the State agency reported rebate billings of approximately \$132.6 million and collections of approximately \$137.8 million.

This current review of the Iowa 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 Iowa 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 conducted fieldwork at the State agency, located in Des Moines, Iowa, from June through August 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 previous Office of Inspector General audit report over the drug rebate program in Iowa;
- reviewed the policies and procedures related to the fiscal agent's 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 accounts receivable records of interest payments received for the quarter ended June 30, 2006;
- 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; 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 RECOMMENDATIONS

The State agency generally corrected the control weaknesses identified in our previous audit that related to: (1) recording accounts receivable, (2) Form CMS-64.9R and general ledger reconciliation, (3) reporting rebates received, (4) interest accrual and collection, and (5) record retention.

However, the State agency did not develop adequate policies and procedures to offer the State's hearing mechanism for disputes that were 60 days old. The State agency also did not develop adequate policies and procedures to ensure that interest collections were properly and accurately reported. As a result, the State agency did not report interest totaling \$873 that was collected

during our audit period. Additionally, the State agency established controls over and accountability for collecting rebates on single source drugs administered by physicians.

IMPLEMENTATION OF PRIOR RECOMMENDATIONS

In our previous audit of the Iowa drug rebate program, we determined that the State agency lacked sufficient controls over its program. Areas that lacked sufficient internal controls included: (1) recording accounts receivable, (2) Form CMS-64.9R and general ledger reconciliation, (3) reporting rebates received, (4) dispute resolution, (5) interest accrual, collection and reporting, and (6) record retention.⁴

Since our prior audit, the State agency has developed and followed policies and procedures to:

- maintain a general ledger accounts receivable control account;
- perform reconciliations to verify the accuracy of the uncollected rebate balances reported on Form CMS-64.9R;
- perform reconciliations to verify the accuracy of the collections reported on its Form CMS-64.9R;
- report its Medicaid drug rebate collections on the Form CMS-64.9R accurately and timely,
- estimate and accrue interest on all overdue rebate balances; and
- retain records for an appropriate period of time.

However, as of the end of our fieldwork, the State agency had not implemented policies and procedures to (1) offer the State's hearing mechanism to resolve disputes after 60 days, and (2) ensure interest collections were properly and accurately reported.

State Hearing Mechanism

The State agency did not develop and follow policies and procedures to offer use of the State's hearing mechanism to resolve disputes after 60 days. In its comments on our prior audit finding, the State agency stated that a hearing process was not required for dispute resolution because the States were not direct parties to the rebate agreement. The State agency added that it was unaware of any authoritative requirement that it use hearings to solve disputes. Furthermore, the State agency said that the use of a hearing mechanism would require it to provide documentation of every prescription related to the dispute – a requirement that might not be cost effective.

However, CMS's drug rebate agreement with the manufacturers states that in the event that the State and the manufacturer are not able to resolve a discrepancy within 60 days, CMS shall

⁴"Audit of the Medicaid Drug Rebate Program in Iowa" (A-07-03-04014), issued June 24, 2003.

require the State to make available to the manufacturer the State's hearing mechanism available under the Medicaid program.

During our review of dispute resolution procedures, we found that the State agency's contractor did contact manufacturers directly to resolve disputes. However, the State agency's policies and procedures deviated from the rebate agreements in two respects: they allowed for 240 days of negotiations by the contractor before the dispute would be referred to the State agency, and they did not require the State agency to offer the hearing mechanism after 60 days.

Interest Reporting

The State agency did not develop and follow policies and procedures to properly report interest collections on the Form CMS-64 Summary Sheet. In its comments on our prior audit finding, the State agency indicated that it concurred with our finding, had implemented procedures to separate the interest portion of collections, and had begun reporting that amount on the Form CMS-64 Summary Sheet. However, the procedures implemented by the State agency did not ensure that interest collections were accurately reported.

The State agency reported interest received on drug rebates on its Form CMS-64 Summary sheet starting with the quarter ended March 31, 2006. However, the amounts reported on the Form CMS-64 Summary sheet were not accurate for that quarter, or for the following quarter.

For the quarter ended March 31, 2006, the interest reported on Line 5 of the Form CMS-64 Summary sheet was incorrectly reported as a negative number and did not take into account the interest for the month of February. For the quarter ended June 30, 2006, Line 5 of the Form CMS-64 Summary sheet included an adjustment to correct the prior quarter's negative amount. However, this adjustment did not compensate for the erroneous exclusion of February's interest from the prior quarter's report. Additionally, Line 5 of the Form CMS-64 Summary sheet for the quarter ended June 30, 2006 did not include the interest collected for the months of April and June.

As a result, the State agency did not report interest totaling \$873 that was collected during our audit period.

PHYSICIAN-ADMINISTERED SINGLE SOURCE DRUGS

The State agency established controls over and accountability for collecting rebates for single source drugs administered by physicians as required by the DRA. The State agency paid \$1,357,112 in claims for physician-administered drugs during the January through June 2006 time period and billed manufacturers for rebates totaling \$225,880.

RECOMMENDATIONS

We recommend that the State agency:

- develop and follow policies and procedures to offer use of the State's hearing mechanism to resolve disputes after 60 days;
- develop and follow policies and procedures to properly report interest collections on the Form CMS-64 Summary Sheet; and
- report interest of \$873 that was collected, but not reported, during the audit period.

STATE AGENCY'S COMMENTS

In written comments on our draft report, the State agency concurred, either wholly or in part, with all of our findings and recommendations. In all cases, though, the State agency offered comments to clarify its positions.

Although the State agency concurred with our finding and recommendation regarding the State hearing mechanism, it stated that the rebate agreements appear to conflict with the guidelines contained within CMS's Dispute Resolution Program Best Practices. The State agency stated that those guidelines "include five steps, and holding a state administrative hearing is only suggested when all other options have been exhausted." In light of this perspective, the State agency offered an alternative procedure for dispute resolution and indicated that it ". . . would welcome the opportunity for discussion with CMS" about the conflict between the Drug Rebate Agreements and CMS's Best Practices guidelines, "in regard to the timeframe in which to provide for the State hearing mechanism."

The State agency concurred in part with our second recommendation, and stated that it has "... documented procedures that have been implemented since November 2005 for recording receivables on the general ledger and for reporting these receivables on the CMS-64 Expenditure Report. These procedures will be updated to more clearly include the process for reporting drug rebate interest collections."

The State agency also concurred in part with our third recommendation, and acknowledged that it did not report the interest collections on the CMS-64. Instead, the interest was reported as a drug rebate collection on the Form CMS-64.9R. The State agency provided additional documentation to support this clarification.

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

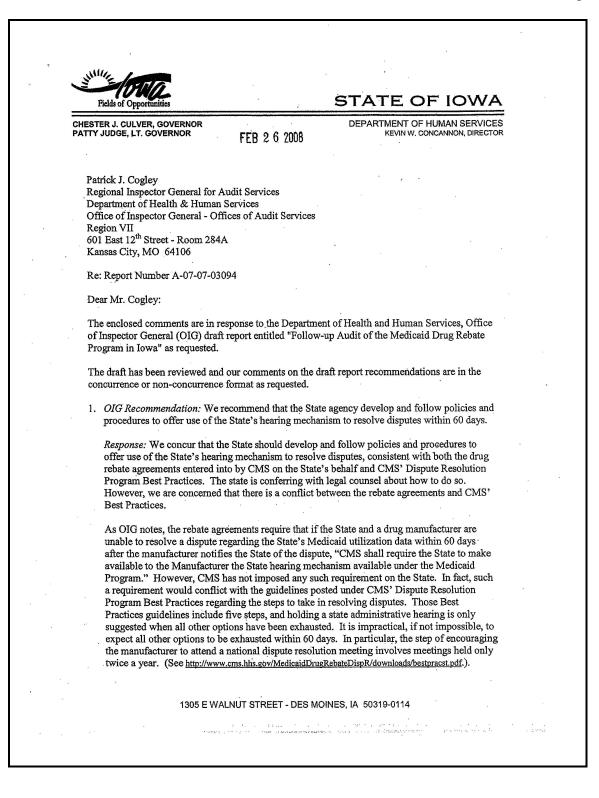
OFFICE OF INSPECTOR GENERAL'S RESPONSE

After reviewing the State agency's comments, we continue to support our findings and recommendations. Although we continue to support our recommendation that the State should develop policies and procedures to make a State hearing mechanism available to manufacturers

in an effort to resolve disputes, we also believe that the State agency should pursue discussions with CMS on the possible conflict between the drug rebate agreement and CMS's Best Practices guidelines.

With respect to our third recommendation, we reviewed the additional documentation that the State agency provided on its interest reporting, and determined that the State agency reported February and April 2006 interest as drug rebate collections on the Form CMS-64.9R instead of reporting these amounts as interest on the Form CMS-64 Summary. However, we determined that the State agency did not report interest collections for June 2006. Based on the additional documentation and our analysis of it, we have adjusted our report to reflect the amounts that the State agency actually reported to CMS.

APPENDIX



Patrick J. Cogley Office of Inspector General Re: Report Number A-07-07-03094 Page 2

The ability to resolve disputes within 60 days after the manufacturer notifies the State of the dispute is impractical as noted by the guidelines and time limits provided by CMS in the Stages of the Dispute Resolution Process printed in the Medicaid Drug Rebate Program State Release #45 and the Medicaid Drug Rebate Program Manufacturer Release #14.

In light of the conflict between the rebate agreements and CMS' Best Practices, we propose to provide for use of the State's hearing mechanism to resolve disputes within 60 days after the State receives notice from the CMS Central Office that it has been unable to resolve a dispute, pursuant to CMS' Best Practices. This means the State has been unable to resolve the dispute with the manufacturer directly, through the National Dispute Resolution Meetings, or through contacts with the CMS Regional and Central Office Dispute Resolution Coordinators.

We would welcome the opportunity for discussion with CMS on the conflict between the Drug Rebate Agreements and CMS' Best Practices guidelines, in regard to the timeframe in which to provide for the State hearing mechanism.

2. *OIG Recommendation:* We recommend that the State agency develop and follow policies and procedures to properly report interest collections on the Form CMS-64 Summary Sheet.

Response: We concur in part with this recommendation with the following clarification. The State has documented procedures that have been implemented since November 2005 for recording receivables on the general ledger and for reporting these receivables on the CMS-64 Expenditure Report. These procedures will be updated to more clearly include the process for reporting drug rebate interest collections. The updated procedures will be used on a quarterly basis to insure the proper reporting of drug rebate interest on the Form CMS-64 Summary Sheet.

We have verified that drug rebate interest collections have been properly reported on every quarterly CMS-64 submission since the audit period reviewed.

 OIG Recommendation: We recommend that the State agency report interest of \$10,562 that was collected, but not reported, during the audit period.

Response: We concur in part with this recommendation with the following clarification. Of the \$10,562 or \$6,718 Federal dollars identified by OIG, only \$873 or \$555 Federal dollars were not reported during the audit period. The remaining \$9,689 or \$6,163 Federal dollars were reported on the CMS-64 as a drug rebate rather than drug rebate interest. Additional documentation is available upon request, which verifies our calculations and reporting.

The State agency will work with CMS to ensure the necessary adjustments are made to properly report this interest.

Thank you for the opportunity to respond to the draft report and provide additional information regarding the OIG's recommendations for the Medicaid Drug Rebate Program.

APPENDIX Page 3 of 3

Patrick J. Cogley Office of Inspector General Re: Report Number A-07-07-03094 Page 3 Questions about this DHS response should be addressed to: Ken Tigges, Executive Officer Iowa Department of Human Services - Div. of Fiscal Mgmt Hoover State Office Building, 1st Floor South Des Moines, IA 50319-0114 Phone: (515) 281-6027 Sincerely, Kein W Kevin W. Concannon Director KWC/slp cc: Kellie McNulty, Auditor DHHS/OIG/OAS 210 Walnut Street, Room 593B Federal Office Building Des Moines, IA 50309