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

JAN 22 2009

Report Number: A-09-08-00051

Mr. William Streur
Deputy Commissioner
Department of Health and Social Services
Division of Health Care Services
4501 Business Park Boulevard
Anchorage, Alaska 99503-7167

Dear Mr. Streur:

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 Alaska." 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 at (415) 437-8360, or contact Doug Preussler, Audit Manager, at (415) 437-8360 or through e-mail at Doug.Preussler@oig.hhs.gov. Please refer to report number A-09-08-00051 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 ALASKA

Daniel R. Levinson
Inspector General

January 2009
A-09-08-00051

Office of Inspector General

http://oig.hhs.gov

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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 (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 Alaska, the Department of Health and Social 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 Alaska drug rebate program, we determined that the State agency had not established adequate policies, procedures, and internal controls over the Medicaid drug rebate program (A-10-03-00006). Specifically, we identified weaknesses in the following areas: (1) quarterly reporting, (2) accounts receivable system, (3) segregation of duties, (4) interest accrual and collection, and (5) dispute resolution. We recommended that the State agency correct the reported balance of uncollected rebates to accurately reflect the State agency's drug rebate activity and ending balance. In addition, we recommended that the State agency establish policies, procedures, and internal controls to:

- reconcile the ending balance of uncollected rebates to the State agency's supporting receivable account, and ensure the accuracy of the data reported to CMS;

- create a general ledger accounts receivable control account and a sufficiently detailed subsidiary accounts receivable system;

- provide for the proper segregation of duties within and between the rebate billing, collection, and accounting functions;

- calculate simple interest on disputed, late, and unpaid rebate payments, and verify the accuracy of interest payments received; and

- make use of the State hearing mechanism when appropriate.

The State agency generally concurred with our findings and recommendations but expressed concerns regarding the use of the State hearing mechanism.

This current review of Alaska 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 Alaska 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 segregation of duties and dispute resolution. The State agency did not implement the recommendation related to quarterly reporting. The State agency partly implemented the recommendations related to the accounts receivable system and interest accrual and collection.

- **Quarterly Reporting.** The State agency has continued to report inaccurate amounts to CMS on the quarterly Form CMS-64.9R. These amounts do not reconcile to its subsidiary ledger system.

- **Accounts Receivable System.** The State agency did not create a sufficiently detailed subsidiary accounts receivable system to track drug rebate activity before October 1, 2003, by NDC.

- **Interest Accrual and Collection.** The State agency accounted for interest due on disputed, late, and unpaid rebate payments. However, it did not verify the accuracy of interest collections received. As a result, the State agency could not assure that it collected all of the interest owed on disputed, late, and unpaid balances.

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 policies, procedures, and internal controls to:

- ensure the accuracy of Form CMS-64.9R by reconciling the reported amounts to its subsidiary ledger system;
- create a sufficiently detailed subsidiary accounts receivable system to track drug rebate activity before October 1, 2003, by NDC; and
- verify the accuracy of interest collections received.

STATE AGENCY COMMENTS

In comments on the draft report (included as the Appendix), the State agency concurred with the recommendations related to quarterly reporting and interest accrual and collection. However, the State agency did not concur with the recommendation related to the accounts receivable system, stating that the recommendation could not be implemented. The State agency commented that, prior to October 1, 2003, its Medicaid Management Information System was not programmed with enough detail to account for drug rebate funds at the NDC level. The State agency indicated that, in its opinion, the outstanding balances from first quarter 1991 through third quarter 2003 should be written off as uncollectible because the balances are not available at the NDC level.

OFFICE OF INSPECTOR GENERAL RESPONSE

We continue to recommend that the State agency create a sufficiently detailed subsidiary accounts receivable system to track drug rebate activity before October 1, 2003, by NDC, unless CMS agrees that these outstanding balances are uncollectible and can be written off.

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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 Alaska, the Department of Health and Social 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 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.

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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 Alaska, physician-administered drugs are billed to the State Medicaid program on either a physician claim form or an outpatient hospital claim form. Before April 1, 2008, physician-administered drugs were billed on the claim forms using procedure codes that are part of the Healthcare Common Procedure Coding System. 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, a crosswalk is needed to convert procedure codes into NDCs for single source drugs and to convert procedure code billing units into equivalent NDC billing units.

Effective April 1, 2008, the State agency required claim forms to include the NDCs and NDC billing units for all physician-administered drugs.

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 Alaska drug rebate program, we determined that the State agency had not established adequate policies, procedures, and internal controls over the Medicaid drug rebate program.[3] Specifically, we identified weaknesses in the following areas: (1) quarterly reporting, (2) accounts receivable system, (3) segregation of duties, (4) interest accrual and collection, and (5) dispute resolution. We recommended that the State agency correct the reported balance of uncollected rebates to accurately reflect the State agency's drug rebate activity and ending balance. In addition, we recommended that the State agency establish policies, procedures, and internal controls to:

- reconcile the ending balance of uncollected rebates to the State agency's supporting receivable account, and ensure the accuracy of the data reported to CMS;

- create a general ledger accounts receivable control account and a sufficiently detailed subsidiary accounts receivable system;

- provide for the proper segregation of duties within and between the rebate billing, collection, and accounting functions;

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[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 Medicaid Drug Rebate Program in Alaska" (A-10-03-00006), issued July 23, 2003.

- calculate simple interest on disputed, late, and unpaid rebate payments, and verify the accuracy of interest payments received; and

- make use of the State hearing mechanism when appropriate.

The State agency generally concurred with our findings and recommendations but expressed concerns regarding the use of the State hearing mechanism.

Alaska Drug Rebate Program

The State agency contracted with its fiscal agent, First Health Services Corporation, to perform all drug rebate program functions other than receiving rebate funds and quarterly reporting. The fiscal agent's responsibilities included preparing and mailing invoices to manufacturers, managing dispute resolution procedures, and accounting for rebates on single source drugs administered by physicians. Before April 1, 2008, the fiscal agent also converted procedure codes into NDCs for single source drugs and converted procedure code billing units into equivalent NDC billing units.

The State agency reported an outstanding drug rebate balance of $21,947,886 on the June 30, 2006, Form CMS-64.9R. For the fiscal year ended June 30, 2006, the State agency reported rebate billings of approximately $32.8 million and collections of approximately $32.0 million.

This current review of the Alaska 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 Alaska 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 Anchorage, Alaska, in August and September 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 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 supporting documentation for rebates invoiced, adjustments, and rebate and 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 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 RECOMMENDATIONS

Regarding the first objective, the State agency implemented the recommendations from our prior audit that related to segregation of duties and dispute resolution. The State agency did not implement the recommendation related to quarterly reporting. The State agency partly implemented the recommendations related to the accounts receivable system and interest accrual and collection.

- **Quarterly Reporting.** The State agency has continued to report inaccurate amounts to CMS on the quarterly Form CMS-64.9R. These amounts do not reconcile to its subsidiary ledger system.

- **Accounts Receivable System.** The State agency did not create a sufficiently detailed subsidiary accounts receivable system to track drug rebate activity before October 1, 2003, by NDC.

- **Interest Accrual and Collection.** The State agency accounted for interest due on disputed, late, and unpaid rebate payments. However, it did not verify the accuracy of interest collections received. As a result, the State agency could not assure that it collected all of the interest owed on disputed, late, and unpaid balances.

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

IMPLEMENTATION OF PRIOR RECOMMENDATIONS

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 State agency understated by $3.3 million the June 30, 2002, balance of uncollected rebates reported to CMS. The understatement was due in part to the State agency not reconciling its CMS quarterly reports to its subsidiary ledger system. Without the proper reconciliation, the State agency omitted prior quarter adjustments and incorrectly reported quarterly Form CMS-64.9R ending balances.

Since our prior audit, the State agency has continued to report inaccurate amounts related to its drug rebate activity and ending balances on Form CMS-64.9R. Our review of quarterly Form CMS-64.9Rs for the period July 1, 2005, through June 30, 2006, revealed discrepancies with the State agency's subsidiary ledger system. For example, for the quarter ended March 31, 2006, line 2 ("Adjustments To Previously Reported Rebates From Drug Labelers Included In Line 1"), column (F), of Form CMS-64.9R erroneously showed a positive amount of $21,159,518, whereas the subsidiary ledger showed a negative amount of $418,249. For the quarter ended June 30, 2006, line 2 showed a positive amount of $576,025, whereas the subsidiary ledger showed a negative amount of $576,025. These deficiencies, as well as other clerical errors, were caused by the State agency's lack of written policies and procedures for preparing Form CMS-64.9R and reconciling the reported amounts to its subsidiary ledger system.

Accounts Receivable System

In our prior audit, we determined that the State agency did not maintain its subsidiary accounts receivable system at a sufficiently detailed level to accurately account for drug rebate activity.

Since our prior audit, the State agency still has not created a sufficiently detailed subsidiary accounts receivable system to track drug rebate activity for drug rebate balances before October 1, 2003. Although the subsidiary accounts receivable system tracked drug rebate activity beginning October 1, 2003, and for later periods by NDC, the system tracked activity before October 1, 2003, only by quarter and year for each manufacturer.

Interest Accrual and Collection

In our prior audit, we determined that the State agency did not have adequate controls in place to accurately account for interest due on disputed, late, and unpaid rebate payments nor to ensure that interest collections received from manufacturers were accurate.

Since our prior audit, the State agency has accounted for interest due on disputed, late, and unpaid rebate payments. However, as of the end of our fieldwork, the State agency still had not implemented a procedure to verify the accuracy of interest collections received from manufacturers.

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.[4] Neither the State agency nor its fiscal agent verified the accuracy of interest payments received from manufacturers. The fiscal agent believed that it was the manufacturers' responsibility to accurately calculate and pay the interest owed. However, without verification that interest paid by manufacturers was accurate, the State agency could not assure that it collected all of the interest owed on disputed, late, and unpaid balances.

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. For the procedure codes on the crosswalk, the State agency paid $523,874 in claims for physician-administered drugs from January through June 2006 and billed manufacturers for rebates totaling $190,681.

RECOMMENDATIONS

We recommend that the State agency implement policies, procedures, and internal controls to:

- ensure the accuracy of Form CMS-64.9R by reconciling the reported amounts to its subsidiary ledger system;
- create a sufficiently detailed subsidiary accounts receivable system to track drug rebate activity before October 1, 2003, by NDC; and
- verify the accuracy of interest collections received.

[4]CMS has issued guidance to State Medicaid directors pertaining to the drug rebate program and posts the program releases on its Web site at http://www.cms.hhs.gov/MedicaidDrugRebateProgram/02_StateReleases.asp. Accessed September 25, 2008.

STATE AGENCY COMMENTS

In comments on the draft report (included as the Appendix), the State agency concurred with the recommendations related to quarterly reporting and interest accrual and collection. However, the State agency did not concur with the recommendation related to the accounts receivable system, stating that the recommendation could not be implemented. The State agency commented that, prior to October 1, 2003, its Medicaid Management Information System was not programmed with enough detail to account for drug rebate funds at the NDC level. The State agency indicated that, in its opinion, the outstanding balances from first quarter 1991 through third quarter 2003 should be written off as uncollectible because the balances are not available at the NDC level.

OFFICE OF INSPECTOR GENERAL RESPONSE

We continue to recommend that the State agency create a sufficiently detailed subsidiary accounts receivable system to track drug rebate activity before October 1, 2003, by NDC, unless CMS agrees that these outstanding balances are uncollectible and can be written off.

APPENDIX

STATE OF ALASKA
DEPT. OF HEALTH AND SOCIAL SERVICES
DIVISION OF HEALTH CARE SERVICES

SARAH PALIN, GOVERNOR

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December 23, 2008

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

Re: Report Number A-09-08-00051

Dear Ms. Ahlstrand,

The Department of Health and Social Services, Division of Health Care Services, offers the following comments to the Office of Inspector General report dated November 24, 2008 on the Alaska Drug Rebate program:

Quarterly Reporting

The Department concurs with the Office of the Inspector General on this finding. It made the $20 million correction (see pg. 5) on the QE 9-30-08 CMS 64.9R and footnoted it. The Budget and Revenue sections of the Department of Health and Social Services will work with the Division of Health Care Services to create written policies and procedures after fiscal reporting changes with the drug rebate fiscal agent (First Health Services Corporation) have been established. These changes will permit improved and timelier financial drug rebate reconciliations between the State and its fiscal agent.

Accounts Receivable System

The Department does not concur with the Office of the Inspector General on this finding. Since the balances prior to 10/1/2003 were not tracked by National Drug Code (NDC) level, this request is not a solution that can be implemented. It is our opinion that the CMS threshold for balances from 1Q1991 through 3Q2003 with reason of "uncollectible because balances are not at NDC level as required by CMS" be applied to this timeframe. The drug rebate fiscal agent can accomplish this task.

The current Accounts Receivable system works very well and sufficiently details all invoiced, received and disputed money at the NDC level. However, prior to October 1, 2003 the State of Alaska Medicaid Management Information System (MMIS) was not programmed with enough detail to account for funds at the NDC level. In addition, at the time of its design and implementation it may not have been cost effective to program the current MMIS at such a highly detailed level. The new Drug Rebate system (First Rebate) that was implemented on October 1, 2003 is not a mainframe system and was implemented with reasonable cost considerations.

Interest Accrual and Collection

The Department concurs with the Office of the Inspector General on this finding. Until the June 2008 release of the Data guide that replaced the CMS Operational Manual, CMS had the interest calculation in

the ownership of the manufacturers. States were required to track the interest. This is done by estimating the calculation for manufacturer delivery. Through our fiscal agent, we are now in compliance with the CMS guidelines on the calculation of interest but it is not applied daily. It is applied on a quarterly cycle. Until CMS releases a more substantial program wide mandate, our fiscal agent, FHSC, will continue to track interest as it does today.

If you have any questions concerning these comments, please contact me at the above address.

Sincerely,

William Streur
Deputy Commissioner

Cc: [redacted]

Office of Inspector General Note: Names and titles shown in the State agency's comments have been redacted to safeguard against the release of personally identifiable information.