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Dear Dr. Bigby:

Enclosed is the U.S. Department of Health and Human Services (HHS), Office of Inspector General (OIG), final report entitled "Audit of Controls Over Collecting Rebates on Single Source Drugs Administered by Physicians in Massachusetts." We will forward a copy of this report to the HHS action official noted below.

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 direct them to the HHS action official. Please refer to report number A-01-08-00005 in all correspondence.

Sincerely,

A handwritten signature in cursive script that reads "Michael J. Armstrong".

Michael J. Armstrong
Regional Inspector General
for Audit Services

Enclosure

HHS Action Official:

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Department of Health and Human Services

**OFFICE OF
INSPECTOR GENERAL**

**AUDIT OF CONTROLS OVER
COLLECTING REBATES ON
SINGLE SOURCE DRUGS
ADMINISTERED BY PHYSICIANS
IN MASSACHUSETTS**



Daniel R. Levinson
Inspector General

October 2008
A-01-08-00005

Office of Inspector General

<http://oig.hhs.gov>

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THIS REPORT IS AVAILABLE TO THE PUBLIC
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OFFICE OF AUDIT SERVICES FINDINGS AND OPINIONS

The designation of financial or management practices as questionable, a recommendation for the disallowance of costs incurred or claimed, and any other conclusions and recommendations in this report represent the findings and opinions of OAS. Authorized officials of the HHS operating divisions will make final determination on these matters.

EXECUTIVE SUMMARY

BACKGROUND

The Medicaid drug rebate program, which began in 1991, is set forth in section 1927 of the Social Security Act (the Act). For a manufacturer's covered outpatient drugs to be eligible for Federal Medicaid funding under the program, the manufacturer must enter into a rebate agreement with the Centers for Medicare & Medicaid Services (CMS) and pay quarterly rebates to the States. CMS, the States, and drug manufacturers each undertake certain functions in connection with the drug rebate program. In Massachusetts, the Executive Office of Health and Human Services, Office of Medicaid (the State agency), is responsible for the drug rebate program.

Section 6002(a) of the Deficit Reduction Act of 2005 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. Single source drugs are commonly referred to as "brand name drugs" and do not have generic equivalents. This current review of the controls over collecting rebates on single source drugs administered by physicians is part of a nationwide series of reviews conducted to determine whether States have complied with the new requirement.

OBJECTIVE

Our objective was to determine whether the State agency had established controls over collecting rebates on single source drugs administered by physicians.

RESULTS OF AUDIT

The State agency had established controls over collecting rebates on single source drugs administered by physicians. Thus we have no recommendations.

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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 Massachusetts, the Executive Office of Health and Human Services, Office of Medicaid (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 identify, 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) 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.

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

In Massachusetts, 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. During our audit period, the NDC was 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. Rebates are calculated and paid based on NDCs rather than on procedure codes. In addition, the billing units for a procedure code may differ from the units used for rebate purposes (e.g., grams versus liters). Thus, before rebates can be determined, procedure codes must be converted into NDCs for single source drugs, and procedure code billing units must be converted into equivalent NDC billing units.

Massachusetts Drug Rebate Program

The State agency contracts with the University of Massachusetts Medical School (UMass) and its Medicaid claim processor, Affiliated Computer Services, Inc. (ACS). UMass is responsible for converting procedure code billing units into equivalent NDC billing units for physician-administered drugs. ACS's responsibilities include processing the drug rebate tape with the unit rebate amounts from CMS, preparing and mailing invoices to manufacturers, and collecting and depositing drug rebate payments.

For the fiscal year ending June 30, 2006, the State agency reported rebate billings of approximately \$252.6 million and collections of approximately \$279.6 million on its Forms CMS-64.9R.

The DRA requires States as of January 2006 to begin collecting rebates on single source drugs administered by physicians. This current review of the State agency's controls over collecting rebates on physician-administered single source drugs is part of a nationwide series of reviews conducted to determine whether States have complied with the new requirement.

OBJECTIVE, SCOPE, AND METHODOLOGY

Objective

Our objective was to determine whether the State agency had 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.

We performed our fieldwork at the State agency and at UMass's offices in Boston, Massachusetts, from July to 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;
- interviewed State agency, UMass, and ACS officials to determine the policies, procedures, and controls related to the Medicaid drug rebate program;
- interviewed UMass and ACS 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.

RESULTS OF AUDIT

The State agency had established controls over collecting rebates on single source drugs administered by physicians, as the DRA requires. Thus we have no recommendations.