



DEPARTMENT OF HEALTH & HUMAN SERVICES  
OFFICE OF INSPECTOR GENERAL  
OFFICE OF AUDIT SERVICES  
150 S. INDEPENDENCE MALL WEST  
SUITE 316  
PHILADELPHIA, PENNSYLVANIA 19106-3499

**FEB 27 2008**

Report Number: A-03-08-00201

Mr. Theodore Dallas, Executive Deputy Secretary  
Department of Public Welfare  
Health and Welfare Building  
Commonwealth Avenue and Forster Street  
P.O. Box 2675  
Harrisburg, Pennsylvania 17105

Dear Mr. Dallas:

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 Pennsylvania." We will forward a copy of this report to the HHS action official noted below.

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, within 10 business day after this report is issued, it 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-03-08-00201 in all correspondence.

Sincerely,

A handwritten signature in black ink, appearing to read "Stephen Virbitsky".

Stephen Virbitsky  
Regional Inspector General  
for Audit Services

Enclosure

**HHS Action Official**

Jackie Garner, Consortium Administrator  
Consortium for Medicaid and Children's Health Operations, Region III  
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  
PENNSYLVANIA**



Daniel R. Levinson  
Inspector General

February 2008  
A-03-08-00201

# *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 all 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.

## *Office of Evaluation and Inspections*

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. Specifically, these evaluations focus on preventing fraud, waste, or abuse and promoting economy, efficiency, and effectiveness in departmental programs. To promote impact, the reports also present practical recommendations for improving program operations.

## *Office of Investigations*

The Office of Investigations (OI) conducts criminal, civil, and administrative investigations of allegations of wrongdoing in HHS programs or to HHS beneficiaries and of unjust enrichment by providers. The investigative efforts of OI lead to criminal convictions, administrative sanctions, or civil monetary penalties.

## *Office of Counsel to the Inspector General*

The Office of Counsel to the Inspector General (OCIG) provides general legal services to OIG, rendering advice and opinions on HHS programs and operations and providing all legal support in OIG's internal operations. OCIG imposes program exclusions and civil monetary penalties on health care providers and litigates those actions within HHS. OCIG also represents OIG in the global settlement of cases arising under the Civil False Claims Act, develops and monitors corporate integrity agreements, develops compliance program guidances, renders advisory opinions on OIG sanctions to the health care community, and issues fraud alerts and other industry guidance.

# *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 Pennsylvania, the Department of Public Welfare (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 Pennsylvania drug rebate program, we determined that the State agency needed to establish controls over its drug rebate program. It did not: (1) reconcile rebates received from drug manufacturers with the invoices submitted for payment by the National Drug Codes (NDC) or age its outstanding drug rebate accounts receivable; (2) keep accurate records of outstanding disputed amounts for each manufacturer; (3) review quarterly payments received from drug manufacturers to determine if interest was owed when payment was received 38 days after the due date and verify the accuracy of interest payments on disputes either when received from or owed to drug manufacturers; (4) reconcile the Form CMS-64.9R outstanding balances in the drug rebate program to State agency's accounting records; and (5) maintain all prior years' information since the inception of the program that is needed for input to the new PROMISE (Provider Reimbursement and Operations Management Information System) system (A-03-03-00201).

We recommended that the State agency:

- ensure that the PROMISE system contains adequate policies, procedures and controls that sufficiently detail accounts receivable to accurately monitor and collect receivables, record disputes, and provide information for the Form CMS-64.9R prior periods;
- age the accounts receivable and write off any amount deemed uncollectible. The State agency should follow CMS guidelines for write-offs;
- monitor interest accruals and payments for accuracy; and
- move the transition to the PROMISE system earlier than March 2004 and keep CMS advised periodically of the transition.

The State agency disagreed with our findings and recommendations.

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

## **RESULTS OF REVIEW**

Although the State agency did not concur with our findings, it did implement the recommendations made in our previous audit. The State agency introduced a new Medicaid Management Information System, the PROMISe System, which corrected the weaknesses noted in our prior review. In addition, the State agency established controls over collecting rebates on single source drugs administered by physicians. Accordingly we have no recommendations at this time.

## TABLE OF CONTENTS

	<b><u>Page</u></b>
<b>INTRODUCTION</b> .....	1
<b>BACKGROUND</b> .....	1
Drug Rebate Program .....	1
Physician-Administered Drugs .....	1
Prior Office of Inspector General Reports .....	2
Pennsylvania Drug Rebate Program .....	3
<b>OBJECTIVES, SCOPE, AND METHODOLOGY</b> .....	3
Objectives .....	3
Scope.....	3
Methodology .....	3
<b>RESULTS OF REVIEW</b> .....	4
<b>IMPLEMENTATION OF PRIOR RECOMMENDATION</b> .....	4
<b>PHYSICIAN-ADMINISTERED SINGLE SOURCE DRUGS</b> .....	5

## 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 manufacturers 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 Pennsylvania, the Department of Public Welfare (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. 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.<sup>1</sup> Single source drugs are commonly referred to as "brand name drugs" and do not have a generic equivalent.

---

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

In Pennsylvania, all claims must be submitted by NDC. The State does not differentiate between physician-administered drugs and other drugs submitted for reimbursement.

### **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.<sup>2</sup> 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 Pennsylvania drug rebate program, we determined that the State agency needed to establish controls over its drug rebate program. It did not: (1) reconcile rebates received from drug manufacturers with the invoices submitted for payment by the NDC or age its outstanding drug rebate accounts receivable; (2) keep accurate records of outstanding disputed amounts for each manufacturer; (3) review quarterly payments received from drug manufacturers to determine if interest was owed when payment was received 38 days after the due date and verify the accuracy of interest payments on disputes either when received from or owed to drug manufacturers; (4) reconcile the Form CMS-64.9R outstanding balances in the drug rebate program to State agency accounting records; and (5) maintain all prior years' information since the inception of the program that is needed for input to the new PROMISe (Provider Reimbursement and Operations Management Information System) system.<sup>3</sup>

We recommended that the State agency:

- ensure that the PROMISe system contains adequate policies, procedures and controls that sufficiently detail accounts receivable to accurately monitor and collect receivables, record disputes, and provide information for the Form CMS-64.9R prior periods;
- age the accounts receivable and write off any amount deemed uncollectible. The State agency should follow CMS guidelines for write-offs;
- monitor interest accruals and payments for accuracy; and
- move the transition to the PROMISe system earlier than March 2004 and keep CMS advised periodically of the transition.

The State agency disagreed with our findings and recommendations.

---

<sup>2</sup>“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.

<sup>3</sup>“Review of the Commonwealth of Pennsylvania Medicaid Drug Rebate Program” (A-03-03-00201), issued July 2, 2003.

## **Pennsylvania Drug Rebate Program**

The State agency contracts with two fiscal agents. Unisys handles the regular drug rebate program and Provider Synergies handles the supplemental drug rebate program. The two fiscal agents perform all drug rebate program functions other than receiving rebate funds. The fiscal agents' responsibilities include verifying interest payments, billing and reconciliation of all accounts, dispute resolution and reporting all quarterly figures to the appropriate State agency.

The State agency reported an outstanding drug rebate balance of \$35,201,741 on the June 30, 2006, Form CMS-64.9R. However, \$34,701,949 of this amount related to quarterly billings and was not past due as of June 30, 2006. Of the remaining \$499,792 that was past due; however, no past due amount was more than a year old. For the fiscal year ended June 30, 2006, the State agency reported rebate billings of \$40.9 million and collections of \$55 million.

This current review of the Pennsylvania 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 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 Pennsylvania 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 located in Harrisburg, Pennsylvania in October 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 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 to ensure the fiscal agents were reconciling at the NDC;
- reviewed Form CMS-64 for June 30, 2006, to verify that the State agency made the recommended adjustments; and
- 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.

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 conclusion based on our audit objectives.

## **RESULTS OF REVIEW**

Although the State agency did not concur with our findings, it did implement the recommendations made in our previous audit. The State agency introduced a new Medicaid Management Information System (MMIS), the PROMISe System, which corrected the weaknesses noted in our prior review. In addition, the State agency established controls over collecting rebates on single source drugs administered by physicians. Accordingly, we have no recommendations at this time.

## **IMPLEMENTATION OF PRIOR RECOMMENDATIONS**

In our previous audit of the Pennsylvania drug rebate program, we determined that the State agency had not established adequate controls over its drug rebate program.

Although the State agency commented they did not concur with our findings, they did implement all our recommendations. Subsequent to that audit, the State agency hired Unisys to implement a new MMIS called PROMISe. Once implemented, the PROMISe system addressed and resolved all our prior recommendations.

The State agency currently contracts with two fiscal agents. Unisys handles the regular drug rebate program and Provider Synergies handles the supplemental drug rebate program. The two fiscal agents perform all drug rebate program functions other than receiving rebate funds. The fiscal agents' responsibilities include verifying interest payments, billing and reconciliation of all accounts, dispute resolution and reporting all quarterly figures to the appropriate State agency. With the hiring of these two contractors, the State established accountability and controls over its Medicaid Drug Rebate Program. There were no exceptions noted.

### **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. Outpatient medication claims submitted by the dispensing prescriber must be provided electronically to the Pennsylvania Medicaid Program using the NDC corresponding to the drug dispensed to the patient. All claims for pharmacy products, regardless of whether submitted by the dispensing prescriber or a pharmacy, are reported as outpatient medication claims and included in the rebate calculation. Accordingly, we have no recommendations at this time.