October 21, 2010

TO: Mary Wakefield, Ph.D., R.N.
Administrator
Health Resources and Services Administration

FROM: /George M. Reeb/
Acting Deputy Inspector General for Audit Services

SUBJECT: Review of Ryan White Title II AIDS Drug Assistance Program Funding in New Jersey (A-02-08-02007)

Attached, for your information, is an advance copy of our final report on Ryan White Title II AIDS Drug Assistance Program funding in New Jersey. We will issue this report to the New Jersey Department of Health and Senior Services within 5 business days.

If you have any questions or comments about this report, please do not hesitate to call me, or your staff may contact Lori S. Pilcher, Assistant Inspector General for Grants, Internal Activities, and Information Technology Audits, at (202) 619-1175 or through email at Lori.Pilcher@oig.hhs.gov or James P. Edert, Regional Inspector General for Audit Services, Region II, at (212) 264-4620 or through email at James.Edert@oig.hhs.gov. Please refer to report number A-02-08-02007.

Attachment

DEPARTMENT OF HEALTH & HUMAN SERVICES **Office of Inspector General**

Office of Audit Services
Jacob Javits Federal Building
26 Federal Plaza, Room 3900
New York, NY 10278

October 26, 2010

Report Number: A-02-08-02007

Poonam Alaigh, M.D., M.S.H.C.P.M., F.A.C.P.
Commissioner
New Jersey Department of Health and Senior Services
P.O. Box 360
Trenton, NJ 08625-0360

Dear Dr. Alaigh:

Enclosed is the U.S. Department of Health & Human Services (HHS), Office of Inspector General (OIG), final report entitled *Review of Ryan White Title II AIDS Drug Assistance Program Funding in New Jersey*. 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.

Section 8L of the Inspector General Act, 5 U.S.C. App., requires that OIG post its publicly available reports on the OIG Web site. Accordingly, this report will be posted at http://oig.hhs.gov.

If you have any questions or comments about this report, please do not hesitate to call me, or contact John J. Madigan, Audit Manager, at (518) 437-9390, extension 224, or through email at John.Madigan@oig.hhs.gov. Please refer to report number A-02-08-02007 in all correspondence.

Sincerely,

/James P. Edert/
Regional Inspector General
for Audit Services

Enclosure

Direct Reply to HHS Action Official:

Team Leader, Compliance Team, OFAM/DFI
Health Resources and Services Administration
Parklawn Building, Room 11A-55
5600 Fishers Lane
Rockville, MD 20857

Department of Health & Human Services

OFFICE OF INSPECTOR GENERAL

REVIEW OF RYAN WHITE TITLE II AIDS DRUG ASSISTANCE PROGRAM FUNDING IN NEW JERSEY

Daniel R. Levinson
Inspector General

October 2010
A-02-08-02007

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 & 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:

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The Office of Audit Services (OAS) provides 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.

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

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The Office of Investigations (OI) conducts criminal, civil, and administrative investigations of fraud and misconduct related to HHS programs, operations, and beneficiaries. With investigators working in all 50 States and the District of Columbia, OI utilizes its resources by actively coordinating with the Department of Justice and other Federal, State, and local law enforcement authorities. The investigative efforts of OI often lead to criminal convictions, administrative sanctions, and/or civil monetary penalties.

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Notices

THIS REPORT IS AVAILABLE TO THE PUBLIC

at http://oig.hhs.gov

Section 8L of the Inspector General Act, 5 U.S.C. App., requires that OIG post its publicly available reports on the OIG Web site.

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 Ryan White Comprehensive AIDS Resources Emergency (CARE) Act of 1990, P.L. No. 101-381, funds health care and support services for people who have HIV/AIDS and who have no health insurance or are underinsured. As the Federal Government's largest source of funding specifically for people with HIV/AIDS, the CARE Act assists more than 500,000 individuals each year. Within the U.S. Department of Health & Human Services, the Health Resources and Services Administration administers the CARE Act.

Title II of the CARE Act, sections 2611–2631 of the Public Health Service Act, provides grants to States and territories to fund the purchase of medications through AIDS Drug Assistance Programs (ADAP) and other health and support services. Title II grant funds may be used only for individuals determined to meet medical and financial eligibility requirements. Additionally, pursuant to 42 U.S.C. § 300ff-27(b)(6)(F), these grant funds may not be used to pay for items or services that are eligible for coverage by other Federal, State, or private health insurance. This provision is commonly referred to as the "payer of last resort" requirement.

During our audit period (April 1, 2003, through March 31, 2006), the New Jersey Department of Health and Senior Services (the health department) claimed Title II drug expenditures totaling $195,404,000.

OBJECTIVES

Our objectives were to determine, for grant years 2003–2005, whether the health department:

- complied with the Title II payer-of-last-resort requirement that funds not be used to pay for drugs that are eligible for coverage by other Federal, State, or private health insurance and

- used the Title II funds only for clients whose files contained the documentation needed to determine eligibility for the ADAP.

SUMMARY OF FINDING

For the 99 claims that we sampled, the health department (1) generally complied with the Title II payer-of-last-resort requirement that funds not be used to pay for drugs that are eligible for coverage by other Federal, State, or private health insurance and (2) generally complied with ADAP eligibility requirements. However, for a portion of our audit period (April 1, 2003, through June 30, 2004), the health department billed $2,498,819 to Title II for ADAP clients who were covered by the Medicaid program. Because we did not contact private insurers to determine whether ADAP clients had private insurance coverage, we would not have identified any instances in which ADAP clients had such coverage but had not informed the health department.

RECOMMENDATION

We recommend that the health department refund $2,498,819 to the Federal Government.

HEALTH DEPARTMENT COMMENTS

In written comments on our draft report, the health department described actions that it had taken to address the issue we identified. The health department did not directly address our recommendation. The health department's comments are included in their entirety as the Appendix.

OFFICE OF INSPECTOR GENERAL RESPONSE

After reviewing the health department's comments, we maintain that the health department should refund $2,498,819 to the Federal Government.

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INTRODUCTION

BACKGROUND

The Ryan White Comprehensive AIDS Resources Emergency (CARE) Act of 1990, P.L. No. 101-381, funds health care and support services for people who have HIV/AIDS and who have no health insurance or are underinsured. As the Federal Government's largest source of funding specifically for people with HIV/AIDS, the CARE Act assists more than 500,000 individuals each year. Within the U.S. Department of Health & Human Services (HHS), the Health Resources and Services Administration (HRSA) administers the CARE Act.

Title II Grant Funds

Title II of the CARE Act, sections 2611–2631 of the Public Health Service Act, provides grants to States and territories to fund the purchase of medications through AIDS Drug Assistance Programs (ADAP) and other HIV/AIDS health and support services, such as outpatient care, home and hospice care, and case management. Pursuant to section 2616(b) of the Public Health Service Act (42 U.S.C. § 300ff-26(b)), to be eligible to receive assistance from a State under Title II of the CARE Act, an individual must "(1) have a medical diagnosis of HIV disease; and (2) be a low-income individual, as defined by the State."

In New Jersey, the Department of Health and Senior Services (the health department) administers the Title II program. During our audit period (April 1, 2003, through March 31, 2006), the health department claimed Title II drug expenditures totaling $195,404,000.

Payer-of-Last-Resort Requirement

Title II of the CARE Act stipulates that grant funds not be used to pay for items or services that are eligible for coverage by other Federal, State, or private health insurance. This provision is commonly referred to as the "payer of last resort" requirement. Specifically, section 2617(b)(6)(F) of the Public Health Service Act (42 U.S.C. § 300ff-27(b)(6)(F)) states:

> [T]he State will ensure that grant funds are not utilized to make payments for any item or service to the extent that payment has been made, or can reasonably be expected to be made, with respect to that item or service –
>
> > (i) under any State compensation program, under an insurance policy, or under any Federal or State health benefits program; or
> > (ii) by an entity that provides health services on a prepaid basis.[1]

[1] Subsequent to our audit period, the Ryan White HIV/AIDS Treatment Modernization Act of 2006, §§ 204(c)(1)(A) and (c)(3), P.L. No. 109-415 (Dec. 19, 2006), redesignated this provision as section 2617(b)(7)(F) (42 U.S.C. § 300ff-27(b)(7)(F)) and amended subparagraph (ii) to prohibit the State from using these grant funds for any item or service that should be paid for "by an entity that provides health services on a prepaid basis (except for a program administered by or providing the services of the Indian Health Service)."

In addition, HRSA Program Policy No. 97-02, issued February 1, 1997, and reissued as DSS[2] Program Policy Guidance No. 2 on June 1, 2000 (and included in section IV of HRSA's *CARE Act Title II Manual* (2003)), reiterates the statutory requirement that "funds received … will not be utilized to make payments for any item or service to the extent that payment has been made, or can reasonably be expected to be made …" by sources other than Title II funds. The guidance then provides: "At the individual client level, this means that grantees and/or their subcontractors are expected to make reasonable efforts to secure other funding instead of CARE Act funds whenever possible." Furthermore, in situations in which a client is eligible under ADAP but later becomes retroactively eligible for Medicaid, HRSA's *ADAP Manual*, section II, chapter 3, page 3 (2003), provides that the State "should back-bill Medicaid for ADAP funds expended during the retroactive coverage period."

New Jersey's AIDS Drug Assistance Program

New Jersey's ADAP, the AIDS Drug Distribution Program, is operated under an agreement between the health department and the State Medicaid agency, the Department of Human Services. The health department determines patient eligibility and drug formulary decisions. The State Medicaid agency pays drug claims to pharmacies, reports expenditure data, and collects rebates from pharmaceutical manufacturers.[3] The health department reimburses the State Medicaid agency for prescription claims and processing costs. The health department subsequently receives Federal reimbursement for these costs through HHS's Payment Management System and details these expenditures on its annual financial status reports to HRSA.

To ensure that the ADAP is the payer of last resort, the health department screens ADAP clients on a monthly basis against a State Medicaid agency database of individuals enrolled in Medicaid or the State's drug assistance program.[4] On an annual basis, the health department reviews and determines whether clients are still eligible for ADAP. In addition, the State Medicaid agency contracts with Health Management Systems (HMS) to identify ADAP clients who have third-party liability coverage.[5]

[2] DSS is the Division of Service Systems, a component of HRSA's HIV/AIDS Bureau.

[3] New Jersey has an "open" formulary that covers most U.S. Food and Drug Administration-approved medications.

[4] The State's Pharmaceutical Assistance to the Aged and Disabled program provides coverage for prescription drugs, insulin, and insulin supplies for eligible beneficiaries.

[5] HMS matches ADAP clients against a database that includes government plans, commercial insurance, casualty insurance, and other third-party payors and initiates recovery payments from these third parties.

OBJECTIVES, SCOPE, AND METHODOLOGY

Objectives

Our objectives were to determine, for grant years 2003–2005, whether the health department:

- complied with the Title II payer-of-last-resort requirement that funds not be used to pay for drugs that are eligible for coverage by other Federal, State, or private health insurance and

- used the Title II funds only for clients whose files contained the documentation needed to determine eligibility for the ADAP.

Scope

Our review covered the period April 1, 2003, through March 31, 2006 (grant years 2003–2005). On its Federal financial status reports for that period, the health department claimed expenditures totaling $103,708,030 for ADAP drugs dispensed.[6]

We did not assess the health department's or the State Medicaid agency's overall internal controls for administering Title II funds. Rather, we limited our review to gaining an understanding of those significant controls related to the claiming of drug costs. Because of concerns about protecting program clients' personally identifiable information, we did not contact private health insurance companies to determine whether clients had private health insurance coverage. We conducted our fieldwork at the health department's offices in Mercerville, New Jersey, and at 12 pharmacies throughout the State.

Methodology

To accomplish our objective, we:

- reviewed applicable Federal laws, regulations, and guidance;

- reviewed documentation provided by the health department for grant years 2003–2005, including notices of grant award, financial status reports and supporting accounting records, and the ADAP's drug formulary (a list of drugs authorized for purchase by the program);

- held discussions with health department officials to identify policies, procedures, and guidance used to identify other insurance coverage and to bill ADAP drugs to other Federal, State, or private health insurance plans;

[6] The State's ADAP uses funds from the Ryan White Title II program, pharmaceutical rebates, and third-party recoveries to fund drug costs and uses the Medicaid system to process and pay pharmaceutical bills.

- held discussions with HMS officials to develop an understanding of HMS procedures used to recover drug costs from third parties liable for coverage;

- reviewed HMS documentation for contracts and recoveries for grant years 2003–2005;

- analyzed the health department's procedures for accounting for and dispensing drugs to ADAP clients;

- visited a judgmentally selected sample of 12 pharmacies that distributed ADAP drugs to determine how the pharmacies dispensed and claimed ADAP drugs;

- obtained a file from the health department of 688,019 ADAP claims totaling $195,404,000 (including both Federal- and State-funded ADAP drugs);

- eliminated from the file 8,613 claims totaling $2,498,819 that the health department potentially should have retroactively billed to the State Medicaid agency;

- eliminated from the file 335,070 claims totaling $14,536,944 that had individual claim values below the average cost of $140.66;

- identified a sampling frame of 344,336 claims totaling $178,368,237 (including both Federal- and State-funded ADAP drugs);

- selected a simple random sample of 99 claims[7] from the 344,336 claims and, for each of the sampled claims:

    - reviewed the State Medicaid agency's database to determine whether clients were enrolled in Medicaid,

    - reviewed the health department's and HMS's files to determine whether clients were enrolled in other health insurance plans,

    - reviewed ADAP eligibility records, and

    - reviewed the health department's payment invoices to identify the cost of dispensed drugs; and

- obtained from the health department and validated a file of ADAP drug claims made on behalf of clients who had applied for and were later determined to be eligible for Medicaid.

[7] We initially selected a simple random sample of 100 claims. We subsequently eliminated one sampled claim that was not in our population of interest.

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 finding and conclusions based on our audit objectives.

FINDING AND RECOMMENDATION

For the 99 claims that we sampled, the health department (1) generally complied with the Title II payer-of-last-resort requirement that funds not be used to pay for drugs that are eligible for coverage by other Federal, State, or private health insurance and (2) generally complied with ADAP eligibility requirements.[8] However, for a portion of our audit period (April 1, 2003, through June 30, 2004), the health department billed $2,498,819 to Title II for ADAP clients who were covered by the Medicaid program. Because we did not contact private insurers to determine whether ADAP clients had private insurance coverage, we would not have identified any instances in which ADAP clients had such coverage but had not informed the health department.

IMPROPER TITLE II CLAIMS FOR MEDICAID BENEFICIARIES

The payer-of-last-resort requirement set forth in section 2617(b)(6)(F) of the Public Health Service Act provides that Title II funds not be used to pay for items or services that are eligible for coverage under other Federal, State, or private health insurance. Furthermore, in situations in which a client is eligible under ADAP but later becomes retroactively eligible for Medicaid, HRSA's *ADAP Manual* provides that the State should retroactively bill Medicaid for ADAP funds expended during the retroactive coverage period.

Contrary to Federal requirements, for the period April 1, 2003, through June 30, 2004, the health department billed 8,613 claims totaling $2,498,819 to Title II for ADAP clients who were covered by the Medicaid program. These ADAP clients received drugs while they awaited a determination from the State Medicaid agency regarding their Medicaid applications. Once these individuals were determined eligible for the Medicaid program, the health department should have retroactively billed the State Medicaid agency for ADAP drug costs incurred since the dates of the individuals' Medicaid applications.

Beginning in July 2004, the health department implemented a procedure to retroactively bill the State Medicaid agency for ADAP claims paid on behalf of ADAP clients also enrolled in Medicaid.[9] To identify these claims, the State Medicaid agency provides the health department with a monthly computer-generated list of ADAP drug claims made on behalf of individuals enrolled in the Medicaid program. However, the health department did not retroactively bill the

[8] The health department did not comply with the Title II payer-of-last resort requirement for 2 of the 99 sampled claims. For one other sampled claim, the client was not eligible for ADAP benefits. The value of these three claims was immaterial; therefore, we are not seeking a refund for the claims.

[9] In New Jersey, if an individual is determined eligible for the Medicaid program, the individual's eligibility period is retroactive to the date of the individual's application for Medicaid benefits.

State Medicaid agency for similar ADAP claims submitted before July 2004. As a result, the health department did not retroactively bill the State Medicaid agency for 8,613 ADAP claims totaling $2,498,819 that were made on behalf of ADAP clients also enrolled in Medicaid.

RECOMMENDATION

We recommend that the health department refund $2,498,819 to the Federal Government.

HEALTH DEPARTMENT COMMENTS

In written comments on our draft report, the health department described actions that it had taken to address the issue we identified. The health department did not directly address our recommendation. The health department's comments are included in their entirety as the Appendix.

OFFICE OF INSPECTOR GENERAL RESPONSE

After reviewing the health department's comments, we maintain that the health department should refund $2,498,819 to the Federal Government.

APPENDIX

APPENDIX: HEALTH DEPARTMENT COMMENTS

State of New Jersey
DEPARTMENT OF HEALTH AND SENIOR SERVICES
PO BOX 360
TRENTON, N.J. 08625-0360
www.nj.gov/health

CHRIS CHRISTIE
Governor

KIM GUADAGNO
Lt. Governor

July 20, 2010

POONAM ALAIGH, MD, MSHCPM, FACP
Commissioner

Mr. James P. Edert
Regional Inspector General
for Audit Services
Department of Health and Human Services
Office of Inspector General
Office of Audit Services
Region II
Jacob Javits Federal Building
26 Federal Plaza – Room 3900
New York, New York 10278

Dear Mr. Edert:

The Department of Health and Senior Services acknowledges the receipt of the audit of the AIDS Drug Distribution Program (ADDP) for Ryan White fiscal years 2003-2005. For FY 2003, a total of $2,498,819 was identified as having been paid by ADDP for claims that should have been charged to Medicaid.

The Department of Health and Senior Services has contacted the New Jersey Department of Human Services, Division of Medical Assistance, to ascertain whether funds were inappropriately charged during the period of the audit. It should be noted that beginning in State fiscal year 2005, a State Appropriation in a dedicated line item was provided for the State share of Medicaid claims, so the State has taken the necessary steps to assure that this issue will not arise again. On the issue of recoupment, the State expended $10.7 million in resources in State fiscal year 2005, which we believe covers the timeframe in question.

Thank you for your assistance with this matter. We will contact you once more information becomes available.

Sincerely,

Poonam Alaigh, MD, MSHCPM, FACP
Commissioner