Region IX
Office of Audit Services
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Mark B. Horton, M.D., M.S.P.H.
Director
California Department of Public Health
1615 Capitol Avenue, MS 0500
Sacramento, California 95899-7377

Dear Dr. Horton:

Enclosed is the U.S. Department of Health and Human Services (HHS), Office of Inspector General (OIG), final report entitled "Review of the California Department of Public Health's Compliance With the Ryan White CARE Act Payer-of-Last-Resort Requirement." We will forward a copy of this report to the HHS action official noted below.

Pursuant to the Freedom of Information Act, 5 U.S.C. § 552, OIG reports generally are made available to the public to the extent that information in the report is not subject to exemptions in the Act. 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-09-09-00037 in all correspondence.

Sincerely,

Lori A. Ahlstrand
Regional Inspector General
for Audit Services

Enclosure

HHS Action Official:

Team Leader, Compliance Team, OFAM/DFI
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Department of Health and Human Services

OFFICE OF INSPECTOR GENERAL

REVIEW OF THE CALIFORNIA DEPARTMENT OF PUBLIC HEALTH'S COMPLIANCE WITH THE RYAN WHITE CARE ACT PAYER-OF-LAST-RESORT REQUIREMENT

Daniel R. Levinson
Inspector General

April 2009
A-09-09-00037

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:

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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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Pursuant to the Freedom of Information Act, 5 U.S.C. § 552, Office of Inspector General reports generally are made available to the public to the extent that information in the report is not subject to exemptions in the Act.

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, Public Law 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 and 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 and other health care and support services. 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 June 30, 2006), the California Department of Public Health (the Department) claimed Title II drug expenditures totaling $305,356,447.

OBJECTIVE

Our objective was to determine whether the 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.

SUMMARY OF RESULTS

Based on our limited review, the 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. Of the 100 prescriptions we sampled, all were correctly claimed under the Title II program for clients without other health care coverage for HIV/AIDS drugs. Consequently, our report contains no recommendations.

TABLE OF CONTENTS

INTRODUCTION

BACKGROUND

The Ryan White Comprehensive AIDS Resources Emergency (CARE) Act of 1990, Public Law 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 and Human Services, 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.

In California, the Department of Public Health (the Department), Office of AIDS, administers the Title II program.[1] The majority of California's Title II program funds are designated for drugs to treat HIV/AIDS through the ADAP. For example, ADAP drug expenditures in each of the three grant years accounted for about 55 percent of Title II expenditures.

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
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> (ii) by an entity that provides health services on a prepaid basis.[2]

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[1]In California, administration of ADAP is contracted to the pharmacy benefits manager (PBM). The PBM subcontracts with over 200 enrollment sites, which handle "intake" activities, such as processing initial applications and renewals and verifying eligibility. As part of this process, enrollment-site workers are required to screen all clients for current or potential Medicaid eligibility and document the status in the clients' files.

[2]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 (December 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[3] Program Policy Guidance No. 2 on June 1, 2000, 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."

OBJECTIVE, SCOPE, AND METHODOLOGY

Objective

Our objective was to determine whether the 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.

Scope

Our review covered the period April 1, 2003, through June 30, 2006.[4] On its financial status reports for that period, the Department claimed ADAP expenditures totaling $305,356,447 for HIV/AIDS drugs dispensed at over 3,400 pharmacies.

We did not assess the Department'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 HIV/AIDS drug costs. Because of concerns regarding the protection of program clients' personally identifiable identification, we did not contact private health insurance companies to confirm health insurance coverage.

We conducted our fieldwork at the Office of AIDS in Sacramento, the office of the PBM in Oakland, and 47 different enrollment sites throughout California.

Methodology

To accomplish our objective, we:

- reviewed applicable Federal laws, regulations, and guidance, as well as State guidance;

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

[4]Although the HRSA grant year is April 1 through March 31, the Department reported prescription costs on the financial status report based on the State's fiscal year, July 1 through June 30. For grant year 2005, the Department included costs from April, May, and June 2006. Therefore, the Department included prescriptions for the 39-month period April 1, 2003, through June 30, 2006.

- reviewed documentation provided by the Department for the period April 1, 2003, through June 30, 2006, including Title II grant applications, notices of grant award, financial status reports and supporting accounting records, and the ADAP drug formulary (a list of drugs authorized for purchase by the program);

- held discussions with Department officials to identify policies, procedures, and guidance for billing HIV/AIDS drugs to other Federal or State programs and private insurance plans;

- analyzed the Department's procedures for accounting for and dispensing drugs to Title II clients;

- identified a sampling frame of 1,253,939 HIV/AIDS prescriptions of $100 or more that were included in claims during the audit period;

- selected a simple random sample of 100 prescriptions from the sampling frame; and

- visited 47 enrollment sites to review eligibility and enrollment information for the clients who received the 100 HIV/AIDS drug prescriptions selected for review.

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 objective.

RESULTS OF REVIEW

Based on our limited review, the 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. Of the 100 prescriptions we sampled, all were correctly claimed under the Title II program for clients without other health care coverage for HIV/AIDS drugs. Consequently, our report contains no recommendations.