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October 5, 2004

Report Number: A-09-03-01016

Ms. Sandra Shewry, Director
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Dear Ms. Shewry:

Enclosed are two copies of the U.S. Department of Health and Human Services (HHS), Office of Inspector General report entitled "Review of Title II of the Ryan White Comprehensive AIDS Resources Emergency Act at the California Department of Health Services." If you have any questions or comments concerning the matters presented in this report, please direct them to the HHS official named below.

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Please refer to report number A-09-03-01016 in all correspondence.

Sincerely,

Lori A. Ahlstrand
Regional Inspector General
for Audit Services

Enclosures – as stated

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Department of Health and Human Services

**OFFICE OF
INSPECTOR GENERAL**

**REVIEW OF TITLE II
OF THE RYAN WHITE
COMPREHENSIVE AIDS RESOURCES
EMERGENCY ACT AT THE
CALIFORNIA DEPARTMENT
OF HEALTH SERVICES**



OCTOBER 2004

A-09-03-01016

Office of Inspector General

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OAS FINDINGS AND OPINIONS

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



EXECUTIVE SUMMARY

BACKGROUND

Under the Ryan White Comprehensive AIDS Resources Emergency Act, Title II (CARE Act Title II), the Health Resources and Services Administration (HRSA) makes grants to all U.S. States and territories for HIV/AIDS programs to fund (1) drug therapies under the AIDS Drug Assistance Program (ADAP) and (2) comprehensive treatment services, including outpatient care, home and hospice care, and case management.

Aimed at people living with HIV or AIDS who have no other source of health care or have limited insurance coverage, each CARE Act Title II-funded program is the “payor of last resort” and fills gaps that are not covered by other resources. CARE Act Title II and the Public Health Services (PHS) Grants Policy Statement requires grantees to:

- establish key service-delivery performance goals
- comply with certain program requirements, such as providing non-Federal matching funds and spending within established limits
- use cost-saving strategies in their drug purchasing programs
- meet Federal requirements issued by the Office of Management and Budget

The Senate Committee on Finance requested a review of CARE Act Title II program activities and use of funds. In response to this request, we audited the California Department of Health Services (State agency), Office of AIDS implementation of CARE Act Title II for the grant year April 1, 2001 to March 31, 2002. During that grant year, the State agency administered the nation’s second largest CARE Act Title II program, with Federal funding totaling almost \$110 million.

OBJECTIVES

Our objectives were to determine whether the State agency:

- met key service-delivery performance goals and complied with program requirements
- followed applicable cost requirements in the expenditure of CARE Act Title II funds
- purchased prescription drugs at the lowest prices available for ADAP

RESULTS OF AUDIT

The State agency operated its CARE Act Title II program in accordance with the CARE Act and Federal regulations. Specifically, the State agency:

- met its key service-delivery performance goals and complied with program requirements
- complied with cost requirements in the expenditure of CARE Act Title II funds
- purchased prescription drugs at discounted prices

Although the State agency purchased prescription drugs at discounted prices, it did not fully use all the rebates received from manufacturers to expand CARE Act Title II program services and activities in a timely manner, as required by section VII of the ADAP Manual. The State agency took corrective action and used \$66.8 million of rebate funds for ADAP in State fiscal year (SFY) 2005. It also established monitoring procedures to ensure that future rebate funds are identified and used for the program in a timely manner. The results of our audit were discussed with State agency officials.

INTRODUCTION

BACKGROUND

Ryan White CARE Act Title II

Within the U.S. Department of Health and Human Services (HHS), HRSA administers the CARE Act, enacted in 1990 and reauthorized in 1996 and 2000. The objective of CARE Act Title II is to improve access to comprehensive, high-quality, community-based primary medical care and support services for people with HIV/AIDS who have no other source of health care or have limited insurance coverage. Each CARE Act Title II program is the “payor of last resort” and fills gaps that are not covered by other resources, such as Medicaid and private insurance.

HRSA awards CARE Act Title II grants to all U.S. States and territories. States are allowed program flexibility to ensure a basic standard of care across their diverse service areas. The majority of CARE Act Title II program funds, however, are earmarked for medications to treat HIV through States’ ADAPs. In California, for example, ADAP expenditures for the grant year ended March 31, 2002 accounted for approximately 84 percent of the Federal share of CARE Act Title II expenditures.

Section 340B—Drug Discount Program

State ADAPs can purchase discounted drugs through a provision in section 340B of the PHS Act. This law requires drug manufacturers to provide discounts to covered entities, such as the State Medicaid program, for covered drugs.

In June 1998, HRSA authorized a rebate option for ADAPs as an alternative method of accessing the section 340B drug discount program. California elected to use the rebate option and reimbursed the contracted pharmacy benefits manager at a discounted rate. ADAP also received additional discounts by billing manufacturers for rebates. The State agency also purchased drugs through 22 PHS pharmacies, which qualify to purchase ADAP drugs under the Federal Drug Pricing Program at discounted rates.

California—Second Largest Funded Program

For the grant year ended March 31, 2002, HRSA awarded the State agency \$109,966,418 in CARE Act Title II funding, making California the second largest State or territory in the program. The State agency centralized the administration of ADAP under a contract with a pharmacy benefits management corporation, which acted as a fiscal intermediary between the State agency and approximately 3,000 pharmacies. The fiscal intermediary provided point-of-service pharmacy billing, which enabled statewide dispensing of drugs to clients. In addition, the State agency contracted with 59 organizations to provide HIV-related services.

OBJECTIVES, SCOPE, AND METHODOLOGY

Objectives

In response to a request from the Senate Committee on Finance to review CARE Act Title II program activities and use of funds, we audited the State agency's implementation of CARE Act Title II. Our objectives were to determine whether the State agency:

- met key service-delivery performance goals and complied with program requirements
- followed applicable cost requirements in the expenditure of CARE Act Title II funds
- purchased prescription drugs at the lowest prices available for ADAP

Scope

Our audit covered the grant year April 1, 2001 to March 31, 2002. During this period, the State agency was awarded Federal funding totaling \$109,966,418. During our review, we noted that actual drug rebate collections exceeded rebates used. Therefore, we expanded our review of rebate balances for the 7-year period ending June 30, 2004 to evaluate rebates collected and budgeted for the program.

We did not have access to the full PHS schedule of 340B drug prices to determine whether the State agency received the lowest possible prices for ADAP. However, we did have access to 340B prices for a limited number of high-volume drugs prescribed under California's CARE Act Title II program, which we used to evaluate ADAP prices.

We limited our review of internal controls at the State agency to the procedures needed to accomplish our audit objectives. We performed our fieldwork at the State agency's office and the California Bureau of State Audits office in Sacramento, CA, and at the State agency Audits Section office in Oakland, CA, from June 2003 through March 2004. We performed additional fieldwork at the State agency's office in August 2004.

Methodology

To accomplish our objectives, we:

- interviewed State agency officials responsible for tracking and reporting performance goals
- reviewed and verified program performance reports and supporting documentation provided by State agency officials
- reviewed the State agency's cost-savings strategies for purchasing drugs

- reviewed the State agency's procedures and documentation for billing, collection, and use of manufacturers' rebates
- reviewed the State agency's policies and procedures for claiming costs and performed limited testing of compliance with Federal requirements
- compared available 340B prices for a limited number of high-volume drugs prescribed under California's CARE Act Title II program with the prices the State agency paid, after discounts and rebates
- reviewed and relied on the State agency Audits Section audit report and working papers, which covered the ADAP contract between the State agency and the fiscal intermediary for the period March 19, 2001 to June 30, 2002
- reviewed and relied on the California Bureau of State Audits audit report and working papers for its statewide audit for the SFY ended June 30, 2002, which included a financial and compliance review of CARE funds for the grant year ended March 31, 2002

We performed our review in accordance with generally accepted government auditing standards.

RESULTS OF AUDIT

The State agency operated its CARE Act Title II program in accordance with the CARE Act and Federal regulations. Specifically, the State agency:

- met its key service-delivery performance goals and complied with program requirements
- complied with cost requirements in the expenditure of CARE Act Title II funds
- purchased prescription drugs at discounted prices

Although the State agency purchased prescription drugs at discounted prices, it did not fully use all the rebates received from manufacturers to expand CARE Act Title II program services and activities in a timely manner, as required by section VII of the ADAP Manual. The State agency took corrective action and used \$66.8 million of rebate funds for ADAP in SFY 2005. It also established monitoring procedures to ensure that future rebate funds are identified and used for the program in a timely manner. The results of our audit were discussed with State agency officials.

STATE AGENCY MET ITS KEY PERFORMANCE GOALS AND PROGRAM REQUIREMENTS

The State agency met its key service-delivery performance goals and complied with program requirements.

CARE Act Title II Grantees Required To Establish Program Performance Goals and Meet Program Requirements

CARE Act Title II requires grantees to establish program performance goals and meet program requirements:

- **Performance Goals:** Section 2617 of the CARE Act requires that a grantee's application for CARE Act Title II funds contain performance goals for the number of eligible HIV clients to be served with these funds. Goals are to be based on historical and actuarial data.
- **Program Requirements:** Sections 2617 and 2618 of the CARE Act require States to comply with certain program requirements. Specifically, a State must provide non-Federal matching funds; exceed its previous year's program expenditures; spend within the limits established for administrative, planning, and evaluation activities; and adequately include the public in the planning process. HRSA incorporates each State's requirements into the Notice of Grant Award each year.

Key Goals and Requirements Met

For the grant year ended March 31, 2002, the State agency met its key performance goals for CARE Act Title II. For example, the State agency:

- increased the number of drugs on its ADAP formulary from 145 to 146 and continued to provide ADAP clients with uninterrupted access to the formulary
- provided services to 35,124 clients, exceeding the goal to serve 34,295 clients

The State agency complied with program requirements, such as providing the required non-Federal matching funds of \$55 million. Specifically, the State agency:

- exceeded its required non-Federal matching funds by \$21.8 million
- exceeded its previous year's reported program expenditures by \$1 million
- claimed costs for administration, planning, and evaluation activities within the established limits
- included persons living with HIV and representatives of grantees, providers, and public agencies in the Care Act Title II planning process

STATE AGENCY COMPLIED WITH FEDERAL COST REQUIREMENTS

The State agency complied with Federal cost requirements in the expenditure of CARE Act Title II funds.

States Must Follow Federal Requirements in Charging Costs to the CARE Act Title II Program

The PHS Grants Policy Statement requires that grantees, such as the State agency, employ sound management practices to ensure that grantees meet program objectives and properly spend project funds. The State has the responsibility to meet Federal cost requirements issued by the Office of Management and Budget. Recipients of Federal funds are required to establish financial management systems to provide for (1) records that adequately identify the source and use of funds for federally sponsored activities and (2) written procedures for determining the reasonableness, allocability, and allowability of costs.

State Agency CARE Act Title II Charges Complied With Federal Requirements

Based on our review of and reliance on the work of the California Bureau of State Audits, the State agency complied with Federal cost requirements in the expenditure of CARE Act Title II funds.

The California Bureau of State Audits sampled selected items to test for allowable costs for program expenditures. Based on these tests, the bureau found no instances of material noncompliance. Its opinion on compliance stated, "...[State agency] complied, in all material respects, with the requirements that are applicable to the program...for the [State fiscal] year ended June 30, 2002."

STATE AGENCY PURCHASED PRESCRIPTION DRUGS AT DISCOUNTED PRICES

The State agency purchased prescription drugs at discounted prices. However, it did not fully use all the rebates received from manufacturers to expand CARE Act Title II program services and activities in a timely manner, as required by section VII of the ADAP Manual.

HRSA Policy Requires ADAPs To Adopt Cost-Saving Strategies

CARE Act Title II requires States to use cost-saving strategies in their drug purchasing programs. In June 1998, HRSA introduced a rebate option for ADAPs as a method of accessing the section 340B drug discount program. The rebate option allows ADAPs to use a local network of pharmacies to achieve cost savings.

In policy guidance issued in June 2000, HRSA reinforced cost-saving expectations it had previously communicated in letters to CARE Act Title II grantees. The policy, "Division of Service Systems Program Policy Guidance No. 6," emphasizes that both HHS and

Congress expect States to use every means possible to secure the best prices available for the products on their ADAP formularies to achieve maximum results with the grant funds. Although section 340B does not discuss an appropriate use for drug savings, the legislative history indicates that savings should be used to serve more eligible patients and provide more comprehensive services.

The State agency had an informal understanding with the State of California that allowed drug rebates collected from manufacturers to be used for CARE Act Title II program services and activities. At the time of our initial fieldwork, a trailer bill to the budget for the year ending June 30, 2005 had been proposed that would establish a special fund for AIDS drug assistance. The bill, which became law on August 16, 2004, states:

SEC. 4. Section 120956 is added to the Health and Safety Code, to read: 120956. (a) The AIDS Drug Assistance Program Rebate Fund is hereby created as a special fund in the State Treasury. (b) All rebates collected from drug manufacturers on drugs purchased through the AIDS Drugs Assistance Program (ADAP) implemented pursuant to this chapter and, notwithstanding Section 16305.7 of the Government Code, interest earned on these moneys shall be deposited in the fund exclusively to cover costs related to the purchase of drugs and services provided through ADAP. (c) Notwithstanding Section 13340 of the Government Code, moneys in the fund shall be continuously appropriated without regard to fiscal year to State Department of Health Services [State agency] and available for expenditure for those purposes specified under this section.

ADAP Drugs Purchased at Discounted Prices

The State agency used a combination of strategies to purchase prescription drugs at discounted prices:

- The State agency reimbursed the contracted pharmacy benefits manager at a discounted rate and also received additional discounts by billing manufacturers for rebates.
- The State agency purchased drugs through 22 PHS pharmacies, which qualify to purchase ADAP drugs under the Federal Drug Pricing Program at discounted rates.

Our analysis of the prices that the State agency paid for a limited number of high-volume drugs after discounts and rebates showed that the net prices approximated those available through section 340B. However, the rebate funds received from manufacturers accumulated faster than the State agency used the funds. As of June 30, 2003, there was an unused balance of \$48.2 million, and the fund balance continued to increase. This balance accumulated because the State agency did not adequately monitor rebate revenue to identify accumulated surpluses.

The State agency took corrective action and used \$66.8 million of rebate funds for ADAP in SFY 2005, leaving a fund balance of \$13.7 million as of August 2004. The State agency also established monitoring procedures to ensure that future rebate funds are identified and used for the program in a timely manner. Based on the State agency's corrective action, we have no recommendations.