



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Office of Inspector General
Office of Audit Services

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REGION IV
61 Forsyth Street, S.W., Suite 3T41
Atlanta, Georgia 30303

Report Number: A-04-03-08014

John O. Agwunobi, M.D., M.B.A.
Secretary of Health
Florida Department of Health
4052 Bald Cypress Way
Tallahassee, Florida 32399

Dear Dr. Agwunobi:

Enclosed are two copies of the U.S. Department of Health and Human Services (HHS) Office of Inspector General (OIG) final report entitled *Review of Title II of the Ryan White Comprehensive AIDS Resources Emergency Act at the Florida Department of Health*. The audit covered the grant year April 1, 2001 through March 31, 2002, in which the Florida Department of Health received an award of \$90,621,274. Should you have any questions or comments concerning the matters discussed in this report, please direct them to the HHS official named below.

In accordance with the principles of the Freedom of Information Act (5 U.S.C. 552, as amended by Public Law 104-231), OIG reports issued to HHS grantees and contractors are made available to members of the press and general public to the extent information contained therein is not subject to exemptions in the Act that the Department chooses to exercise. (See 45 CFR Part 5.)

To facilitate identification, please refer to Report Number A-04-03-08014 in all correspondence relating to this report.

Sincerely,

A handwritten signature in cursive script that reads "Charles J. Curtis".

Charles J. Curtis
Regional Inspector General
for Audit Services, Region IV

Enclosures – as stated

Direct Reply to HHS Action Official:

Nancy J. McGinness, Director
Office of Financial Policy and Oversight
Health Resources and Services Administration
Room 11A55, Parklawn Building
5600 Fishers Lane
Rockville, MD 20857

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 FLORIDA DEPARTMENT OF
HEALTH**



Inspector General

**June 2004
A-04-03-08014**

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 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. The OCIG imposes program exclusions and civil monetary penalties on health care providers and litigates those actions within the department. The OCIG also represents OIG in the global settlement of cases arising under the Civil False Claims Act, develops and monitors corporate integrity agreements, develops model compliance plans, renders advisory opinions on OIG sanctions to the health care community, and issues fraud alerts and other industry guidance.

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 the HIV/AIDS programs to fund:

- comprehensive treatment services including outpatient care, home and hospice care, and case management
- drug therapies under the AIDS Drug Assistance Program (ADAP)

Aimed at people living with HIV or AIDS who have no other source of healthcare or have only limited coverage, CARE Act Title II funded programs are the “payors of last resort” intended to fill gaps that are not covered by other resources.

In Florida, the Department of Health (Health Department) has primary responsibility and oversight of the CARE Act Title II program. To carry out the program, the Health Department entered into agreements with 14 organizations to serve as either service delivery contractors or administrative agencies. Service delivery contractors provided HIV/AIDS related services directly to eligible clients or subcontracted with other organizations to provide these services, while administrative agencies served to monitor program operations. For the period April 1, 2001 through March 31, 2002, Florida received CARE Act Title II grant funding of \$90,621,274.

OBJECTIVES

Stemming from a request from the U. S. Senate Committee on Finance to review CARE Act Title II program activities and use of funds, we conducted audits at a number of States, including Florida, the nation’s third largest funded program. Our objectives were to determine if the Health Department:

1. met key service delivery performance goals and complied with applicable program and cost requirements
2. used cost-savings strategies when purchasing ADAP drugs

SUMMARY OF FINDINGS

The Health Department exceeded its service delivery performance goals in terms of the number of clients served; complied with program requirements regarding non-Federal matching funds, previous year’s expenditures, spending caps, and public involvement; and used cost-savings strategies to purchase ADAP drugs at discounted prices.

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, the focus of this report, is to improve access to a comprehensive continuum of high-quality community-based primary medical care and support services. Aimed at people living with HIV/AIDS who have no other source of healthcare or have limited coverage, CARE Act Title II funded programs are the “payors of last resort” intended to fill 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 Florida, for example, ADAP expenditures for the grant year ended March 31, 2002 accounted for approximately 73 percent of total CARE Act Title II expenditures.

As a cost saving measure, State ADAPs can purchase discounted drugs under a provision in Section 340B of the Public Health Service Act. This law requires drug manufacturers to provide discounts to covered entities for certain drugs. Under the 340B program, manufacturers may not charge covered entities more than the 340B ceiling price, which is based on the Medicaid drug rebate amount.

There are two ways of participating in the 340B program, the direct purchase option and the rebate option. Under the direct purchase option, which Florida has adopted, State ADAPs purchase drugs directly from a manufacturer or wholesaler. Under the rebate option ADAPs reimburse pharmacies for their costs in filling prescriptions for eligible clients.

Florida —The Nation’s Third Largest Funded Program

For the grant year April 1, 2001 through March 31, 2002, HRSA awarded the Health Department \$90,621,274 in CARE Act Title II funding, making Florida the third largest State in the CARE Act Title II program.

The Health Department has primary responsibility and oversight for the CARE Act Title II grant but delegated much of the responsibility for day-to-day program operations to the 14 organizations that served as service delivery contractors or administrative agencies. Service delivery contractors provided HIV-related services directly to eligible clients or subcontracted with other organizations to provide these services, while administrative agencies served to monitor program operations.

OBJECTIVES, SCOPE, AND METHODOLOGY

Objectives

Stemming from a request from the Senate Committee on Finance, we audited the Health Department's CARE Act Title II program activities and use of funds to determine whether the Health Department:

1. met key service delivery performance goals and complied with applicable program requirements
2. used cost-savings strategies when purchasing ADAP drugs

Scope

We audited Florida's CARE Act Title II program for the period April 1, 2001 through March 31, 2002, for which the Health Department claimed reimbursement of \$90,621,274 from HRSA.

We did not review the overall internal control structure of the Health Department or its contractors, as our assessment of internal controls was limited to those considered necessary to accomplish our objectives. For example, we documented key controls related to client eligibility and operation of the ADAP program.

Our fieldwork was performed during the period June 2003 through February 2004 at the Health Department's offices in Tallahassee, FL. We also visited five service delivery contractors and administrative agencies located in Ft. Myers, Gainesville, Miami, Riviera Beach and Tampa, FL.

Methodology

To accomplish our audit objectives, we:

- compared key grant performance goals established by the Health Department in its grant application to actual performance results reported to HRSA and traced selected performance measures back to supporting documentation
- interviewed cognizant officials, reviewed policies and procedures, and tested selected transactions charged to the CARE Act Title II program for compliance with program requirements related to matching, earmarking, and level of effort
- reconciled CARE Act Title II expenditures reported by the Health Department in its final cost report to its supporting books and records
- reviewed the Health Department's procedures for purchasing drugs at discounted prices

At each of the five service delivery contractors and administrative agencies visited, we met with organization officials to ensure a proper understanding of program operations, verified that amounts billed to the program were supported by accounting records, traced program payments and discussed corrective actions taken on any findings identified in previous audits performed under Office of Management and Budget Circular A-133.

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

FINDINGS AND RECOMMENDATIONS

FLORIDA EXCEEDED SERVICE GOALS AND MET PROGRAM REQUIREMENTS

The Health Department exceeded its performance goals in terms of the number of clients served and complied with program requirements regarding non-Federal matching funds, previous year's expenditures, spending caps, and public involvement.

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

CARE Act Title II grantees are required to establish performance goals and meet certain program requirements, as follows:

- **Performance Goals:** Section 2617 of the CARE Act requires that grantees establish performance goals concerning the number of eligible HIV clients to be served with CARE Act Title II funds. These goals are based on historical data.
- **Program Requirements:** Sections 2617 and 2618 of the CARE Act require States to comply with certain program requirements. Specifically, States are to: provide non-Federal matching funds, meet or exceed previous year's State expenditures for HIV-related activities, spend within the cap 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.

In addition, the Health Department must ensure that its sub-recipients are properly carrying-out the program to ensure that program objectives are met and that project funds are properly spent.

Health Department Exceeded Performance Goals and Met Program Requirements

As shown in the following table, the Health Department reported that it had met and exceeded its performance goals specified in its grant application for the year April 1, 2001 through March 31, 2002 in terms of the numbers of clients served.

| Health Department's Key Performance Goals for Grant Year 2001 | | | |
|--|------------------------|-------------------------------------|---|
| Service Objective | Service Measure | Goal (Per Grant Application) | Actual (Per Final Progress Report) |
| Comprehensive Services | Clients Served | 32,689 | 45,484 |
| ADAP | Clients Served | 12,000 | 13,046 |
| Provide Continuation of Health Insurance (AICP) | Premiums Paid | 1,700 | 1,882 |

The Health Department also complied with program requirements. Our audit showed that the Health Department had:

- matched Federal funds with non-Federal funds at a rate of 35 percent, as required by the final Notice of Grant Award
- exceeded the previous year's program expenditures for HIV-related activities by approximately \$44 million
- limited combined administrative, planning, and evaluation costs to approximately \$5.9 million, or 6.5 percent of the award amount--well below the cap of 15 percent
- included persons living with HIV and representatives of grantees, providers, and public agencies in the CARE Act Title II planning process

Finally, the Health Department established procedures to monitor the fiscal and programmatic activities of its 14 service delivery contractors and administrative agencies.

FLORIDA USED COST SAVING STRATEGIES TO PURCHASE ADAP DRUGS

The Health Department used cost-savings strategies, as required by HRSA policy, to obtain ADAP drugs at discounted prices.

CARE Act Title II Grantees Required to Adopt Cost-Saving Strategies for ADAPs

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 the Congress expect States to use every means possible to secure the best price available for the products on their ADAP formularies in order to achieve maximum results with the funds. Specifically, the policy requires that States adopt cost-saving strategies equal to or greater than the cost savings realized by using the 340B drug discount program.

Florida ADAP Adopted The 340B Direct Purchase Option as a Cost Saving Strategy

There are two ways of participating in the 340B Program, the direct purchase option and the rebate option. Under the direct purchase option, used by Florida, ADAPs purchase drugs directly from a manufacturer or wholesaler. Under the rebate option ADAPs reimburse pharmacies for prescriptions filled.

The Health Department purchased prescription drugs at discounted prices through a contract with a prime vendor. Through its central pharmacy, the Health Department then distributed the ADAP pharmaceuticals to county health departments that filled prescriptions for eligible patients. The Health Department also operated a mail order option, under which prescriptions are sent to the central pharmacy and pharmaceuticals are sent to the patients on a monthly basis.