



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

January 14, 2010

Report Number: A-02-08-02003

Lorenzo González Feliciano, M.D.  
Secretary  
Puerto Rico Department of Health  
P.O. Box 70184  
San Juan, Puerto Rico 00936-8184

Dear Dr. González Feliciano:

Enclosed is the U.S. Department of Health and Human Services (HHS), Office of Inspector General (OIG), final report entitled "Review of the Puerto Rico AIDS Drug Assistance Program's Controls for Accounting for and Safeguarding Drugs." 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 James C. Cox, Audit Manager, at (518) 437-9390, extension 222 or through email at [James.Cox@oig.hhs.gov](mailto:James.Cox@oig.hhs.gov). Please refer to report number A-02-08-02003 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, Maryland 20857

**Department of Health and Human Services**

**OFFICE OF  
INSPECTOR GENERAL**

**REVIEW OF THE PUERTO RICO  
AIDS DRUG ASSISTANCE  
PROGRAM'S CONTROLS FOR  
ACCOUNTING FOR AND  
SAFEGUARDING DRUGS**



**Daniel R. Levinson  
Inspector General**

**January 2010  
A-02-08-02003**

# *Office of Inspector General*

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## **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, Pub. 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 and Human Services, the Health Resources and Services Administration (HRSA) administers the CARE Act. In the Commonwealth of Puerto Rico, the Puerto Rico Department of Health (Health Department) administers CARE Act funding.

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 its AIDS Drug Assistance Program (ADAP) and other health care and support services.

Commonwealth laws require that prescription drugs be dispensed by a pharmacist or a pharmacy technician under the direct supervision of a pharmacist. In addition, Federal regulations require grantees to account for grant funds in accordance with Federal and State laws and procedures to establish that such funds have not been used in violation of the restrictions and prohibitions of applicable statutes. Federal regulations also require that grantees maintain effective controls and accountability for adequately safeguarding and assuring that grant funds are used solely for authorized purposes. Further, Health Department policies and procedures require that drug inventory controls be enforced to account for and safeguard grant funds.

During the period April 1, 2004, through March 31, 2007 (grant years 2004–2006), the Health Department claimed ADAP drug expenditures totaling \$75,332,082.

### **OBJECTIVE**

Our objective was to determine whether the Health Department complied with Federal and Commonwealth requirements for dispensing, accounting for, and safeguarding ADAP drugs.

### **SUMMARY OF FINDINGS**

Contrary to Federal and Commonwealth requirements, the Health Department did not ensure that:

- ADAP drugs were dispensed by a licensed pharmacist or by a pharmacy technician under the direct supervision of a licensed pharmacist;
- the Pharmacy Distribution Center and three treatment clinics maintained an adequate ADAP drug inventory system; and
- expired ADAP drugs were properly disposed.

In addition, contrary to its policies, the Health Department did not always take advantage of the opportunity to return expired drugs to their manufacturer for credit.

These issues occurred because the Health Department did not have adequate controls to dispense, account for, and safeguard its ADAP drugs. As a result, HIV/AIDS patients may have been exposed to health risks associated with the dispensing of drugs by unlicensed personnel. In addition, the Health Department could not ensure that it did not claim Federal reimbursement for ADAP drugs that were lost, stolen, or expired. There is also a potential risk that ADAP-eligible patients may have been dispensed expired drugs.

## **RECOMMENDATIONS**

We recommend that the Health Department:

- ensure that ADAP drugs are dispensed by a licensed pharmacist or by a pharmacy technician under the direct supervision of a licensed pharmacist,
- implement procedures to adequately account for ADAP drug inventories, and
- implement procedures to properly dispose of expired ADAP drugs, and, if possible, request credit or exchange from manufacturers for eligible expired drugs.

## **HEALTH DEPARTMENT COMMENTS**

In written comments on our draft report, the Health Department generally concurred with our findings and it has taken, or plans to take, to address our recommendations. The Health Department's comments appear in their entirety as the appendix.

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## INTRODUCTION

### BACKGROUND

#### **AIDS Drug Assistance Program**

The Ryan White Comprehensive AIDS Resources Emergency (CARE) Act of 1990, Pub. 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. 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 care and support services.

Within the U.S. Department of Health and Human Services, the Health Resources and Services Administration (HRSA) administers the CARE Act. In the Commonwealth of Puerto Rico, the Puerto Rico Department of Health (Health Department) oversees CARE Act funding. The Health Department's Pharmacy Distribution Center stores ADAP drugs for dispensing by the Health Department's eight treatment clinics throughout the Commonwealth. During the period April 1, 2004, through March 31, 2007 (grant years 2004–2006), the Health Department claimed ADAP drug expenditures totaling \$75,332,082.

#### **Federal and State Requirements**

Commonwealth law (The Pharmacy Act, Puerto Rico P.L. 247 §§ 2.02-2.04 (enacted Sept. 3, 2004)) requires that prescription drugs be dispensed by a pharmacist or a pharmacy technician under the direct supervision of a pharmacist.

Pursuant to 45 CFR § 74.21(b)(3), grantees must maintain effective controls and accountability to adequately safeguard and assure that CARE Act funds are used solely for authorized purposes.

Health Department policies require that drug inventory controls be enforced to account for and safeguard grant funds and to ensure that expired drugs be returned to the manufacturers for credit or exchange or be appropriately disposed of. According to officials from HRSA's Office of Pharmacy Affairs, it would be a sound management practice for the Health Department to coordinate credit or exchange of expired drugs with manufacturers.

### OBJECTIVE, SCOPE, AND METHODOLOGY

#### **Objective**

Our objective was to determine whether the Health Department complied with Federal and Commonwealth requirements for dispensing, accounting for, and safeguarding ADAP drugs.

## Scope

Our audit period covered grant years 2004–2006. We did not review the overall internal control structure of the Health Department. Rather, we limited our internal control review to the objective of our audit.

We conducted fieldwork at the Health Department’s Pharmacy Distribution Center in San Juan, Puerto Rico, and at three treatment clinics, in Arecibo, Caguas, and San Juan, Puerto Rico.

## Methodology

To accomplish our objective, we:

- reviewed applicable Federal and Commonwealth laws and regulations, as well as the Health Department’s Policies and Procedures Manual for the Distribution of Drugs;
- interviewed Health Department officials to gain an understanding of Health Department policies and procedures for accounting for and safeguarding ADAP drugs;
- reviewed the ADAP drug inventory process and drug safeguards at the Pharmacy Distribution Center, and at three treatment clinics throughout Puerto Rico;
- reviewed licensing credentials for pharmacy staff at the three treatment clinics;
- judgmentally selected 60 of 306 ADAP drug requisition forms from the three clinics visited to test for compliance with the provisions of the Manual;
- reviewed Health Department procedures for disposing of expired ADAP drugs;
- reviewed disposal records for all ADAP drugs discarded during grant years 2004 and 2005 by the Pharmacy Distribution Center;<sup>1</sup>
- evaluated Health Department’s inventory records to identify the cost of expired ADAP drugs that could have been eligible for credit or replacement; and
- discussed with HRSA officials the potential effect of dispensing expired ADAP drugs;

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 objective. We believe that the evidence obtained provides a reasonable basis for our findings and conclusions based on our audit objective.

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<sup>1</sup> There were no disposal records available for the calendar year 2006.

## FINDINGS AND RECOMMENDATIONS

Contrary to Federal and Commonwealth requirements, the Health Department did not ensure that:

- ADAP drugs were dispensed by a licensed pharmacist or by a pharmacy technician under the direct supervision of a licensed pharmacist;
- the Pharmacy Distribution Center and three treatment clinics maintained an adequate ADAP drug inventory system; and
- expired ADAP drugs were properly disposed.

In addition, contrary to its policies, the Health Department did not always take advantage of the opportunity to return expired drugs to their manufacturer for credit.

These issues occurred because the Health Department did not have adequate controls to dispense, account for, and safeguard its ADAP drugs. As a result, HIV/AIDS patients may have been exposed to health risks associated with the dispensing of drugs by unlicensed personnel. There is also a potential risk that ADAP-eligible patients may have been dispensed expired drugs.

### UNSUPERVISED DRUG DISPENSING

Pursuant to section 2.02 of the Puerto Rico Pharmacy Law (Law Number 247, approved September 3, 2004), a pharmacist shall dispense drugs and devices by prescription, a function that includes completing pharmaceutical records, preparing drugs, verifying and delivering prescriptions, offering advice to patients, and supervising technical and administrative functions delegated to pharmacy technicians. Pursuant to section 2.03 of the Puerto Rico Pharmacy Law, a pharmacy technician “shall always be under supervision of an authorized pharmacist.” In addition, pursuant to section 2.04 of the Puerto Rico Pharmacy Law, a pharmacy technician shall not verify prescriptions against medications to identify potential drug-related problems, advise patients on prescribed drugs, or perform any other pharmacist functions.<sup>2</sup>

Contrary to these Commonwealth requirements, pharmacy technicians not under the supervision of a pharmacist dispensed prescriptions for ADAP drugs at the three Health Department treatment clinics we reviewed. One clinic had no pharmacist during our 3-year audit period. At the other two clinics, pharmacy technicians dispensed ADAP drugs when the on-staff pharmacist was absent (e.g. out sick or on vacation). In these two clinics, we observed pharmacy technicians dispensing drugs and providing guidance to patients without the supervision of a pharmacist, thereby exposing these patients to unnecessary risks. As a result, HIV/AIDS patients

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<sup>2</sup>Section 2.04 of the Puerto Rico Pharmacy Law states that a pharmacy technician “may perform, under direct supervision of the pharmacist, technical or administrative functions delegated to him/her by the pharmacist regarding the dispensing of prescription drugs and devices, and which do not require the professional judgment of the pharmacist for their performance.”

may have been exposed to health risks associated with the dispensing of drugs by unlicensed personnel.

This lack of control occurred because the Health Department did not have adequate procedures to ensure that pharmacy technicians dispense drugs only when under the supervision of a pharmacist.

## **INADEQUATE DRUG INVENTORIES**

### **Perpetual and Physical Inventories**

As a cost-saving measure, the Health Department purchased discounted ADAP drugs through HRSA's 340B Drug Pricing Program.<sup>3</sup> Pursuant to section 340B of the Public Health Service Act, program enrollees must have mechanisms in place to prevent the diversion of drugs to individuals not enrolled as qualified ADAP patients. In addition, sections X.C.8-9 of the Health Department's Policies and Procedures Manual for the Distribution of Drugs requires that physical inventories for drugs be performed using an inventory system with monthly verifications to ensure that physical inventory reports are reconciled with perpetual inventory records.<sup>4</sup>

Contrary to these requirements, the Health Department did not have an effective inventory system in place to account for ADAP drugs. Specifically, the Health Department did not have an up-to-date perpetual inventory system at the center because postings to the inventory were delayed up to two years. While physical inventories of ADAP drugs at the Pharmacy Distribution Center were performed twice during our audit period (June 2004 and June 2006); the two physical inventories were inadequate because they could not be reconciled to a perpetual inventory. No inventories were performed at the three reviewed treatment clinics. As a result, the Health Department could not ensure that it did not claim Federal reimbursement for ADAP drugs that were lost, stolen, or expired.

Health Department officials stated that inventory records were not timely because of a lack of personnel and the slow submission of supporting documentation by the Pharmacy Distribution Center to the Health Department's finance division, which is responsible for manually maintaining perpetual inventory records. In addition, the use of a non-computerized perpetual inventory system may have also contributed to these delays.

### **Drug Requisition Forms**

The Health Department requires its treatment clinics to complete drug requisition forms when requesting drugs from the Pharmacy Distribution Center. Pursuant to section X.D.1 of its

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<sup>3</sup>The 340B Drug Pricing Program limits the cost of covered outpatient drugs to certain Federal grantees, including State-operated ADAPs receiving financial support under the CARE Act.

<sup>4</sup>A physical inventory records a count of inventory taken at any given time. A perpetual inventory is a system that requires a continuous record of all receipts and withdrawals of each item of inventory.

Policies and Procedures Manual for the Distribution of Drugs, requisition forms should include the date, name of the requesting clinic, a description of medication requested, dosage, amount of drugs in stock (with expiration dates), quantity requested, the signature of the requesting pharmacist and the signature of the distribution center official authorized to approve the request. The manual also states that, after the request is received at the Pharmacy Distribution Center, the pharmacy technician and supervising pharmacist who dispensed the order to the requesting clinic are required to sign the form (sections X.D.9 through X.D.11) as well as the driver who transported the drugs to the requesting clinic (section X.D.12). Upon receipt of the drugs, the requesting pharmacist is required to sign the form and return a copy of the form to the Pharmacy Distribution Center to confirm that the delivery was made (section X.D.14).

Our review of 60 judgmentally selected drug requisition forms from three Health Department treatment clinics (20 from each clinic) disclosed non-compliance with basic inventory controls, including missing signatures for approving, dispensing, delivering, and receiving ADAP drugs. All 60 forms reviewed did not contain one or more required signatures, including 35 that did not have the signature of the requesting pharmacist. As a result, there is no assurance that the corresponding drugs were actually received by the requesting clinic.

## **EXPIRED DRUGS NOT ALWAYS PROPERLY DISPOSED**

Drug manufacturers allow customers to return expired drugs for credit or exchange if the drugs are returned within one year from their expiration dates. In Puerto Rico, the Pharmacy Distribution Center is responsible for coordinating the return (or, in certain cases, the disposal) of expired drugs from Health Department treatment clinics. Officials from HRSA's Office of Pharmacy Affairs stated that, as a sound management practice and as an enrollee in the 340B Drug Pricing Program, the Health Department should return eligible expired drugs for exchange or credit. Moreover, in its ADAP grant applications, the Health Department assured HRSA that all expired drugs would be removed from stock and traded for credit or "decommissioned" accordingly.<sup>5</sup>

The Health Department also had policies requiring its pharmacies to implement a process for decommissioning expired drugs not exchanged or credited. Further, Commonwealth law (The Puerto Rico Government Accounting Act, P.L. No. 230 Article 2(e) (enacted July 23, 1974)) requires government entities to implement controls that serve as effective tools in the administration of programs.

Contrary to Federal and Commonwealth requirements, the Health Department lacked policies to ensure that its treatment clinics timely shipped all expired ADAP drugs to the Pharmacy Distribution Center for return to their manufacturers.<sup>6</sup> As a result, some ADAP drugs remained at treatment clinics well beyond their expiration dates. Other expired ADAP drugs, which were

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<sup>5</sup>CARE Act, Title II (Part B) Grant Application, section IV(A)(10), ADAP Quality Management Procedures (grant years 2004, 2005, and 2006).

<sup>6</sup>Specifically, section XII of the Health Department's policies and procedures manual states that expired drugs should be divided into "decommission boxes" and kept in a quarantine area until they are disposed of by a contracted company that also disposes of expired vaccines and biological products.

shipped to the Pharmacy Distribution Center, were returned for credit or exchange or were disposed of because they were ineligible for credit or exchange. However, the Pharmacy Distribution Center<sup>7</sup> also disposed of \$34,043 in ADAP drugs (169 units) without attempting to receive credit from the drug manufacturer. In addition, at one of the treatment centers we visited, we found \$21,932 in ADAP drugs (118 units) that were 6 to 8 years past their expiration dates, stored in a warehouse, awaiting disposal. Health Department officials indicated that these drugs were not returned to the Pharmacy Distribution Center while still eligible for credit or exchange from their manufacturer.

In addition, during our fieldwork, we observed two expired ADAP drugs (10 units), valued at \$3,865, on a dispensing shelf at one treatment clinic. The presence of these expired drugs increased the risk that they would be distributed to clients. According to HRSA officials, dispensing expired drugs to HIV/AIDS patients may also cause drug resistance and make patients' overall treatment less effective or life-threatening.

## **RECOMMENDATIONS**

We recommend that the Health Department:

- ensure that ADAP drugs are dispensed by a licensed pharmacist or by a pharmacy technician under the direct supervision of a licensed pharmacist,
- implement procedures to adequately account for ADAP drug inventories, and
- implement procedures to properly dispose of expired ADAP drugs, and, if possible, request credit or exchange from manufacturers for eligible expired drugs.

## **HEALTH DEPARTMENT COMMENTS**

In written comments on our draft report, the Health Department generally concurred with our findings and described steps it has taken, or plans to take, to address our recommendations. The Health Department's comments appear in their entirety as the appendix.

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<sup>7</sup>The Health Department provided documentation that it returned more than \$20,000 in ADAP drugs for credit or exchange. However, the documentation was incomplete and unverifiable.

**APPENDIX: HEALTH DEPARTMENT COMMENTS**



Commonwealth of Puerto Rico  
**Puerto Rico Department of Health**

October 13, 2009

James P. Edert  
Regional Inspector General  
For Audit Services  
Office of Inspector General  
Region II  
Jacob Javits Federal Building  
26 Federal Plaza – Room 3900  
New York, NY 10278

Dear Mr. Edert:

I am submitting for your consideration our response to the U.S. Department of Health and Human Services, Office of Inspector General (OIG) draft report entitled "Review of the Puerto Rico AIDS Drug Assistance Program's Controls for Accounting for and Safeguarding Drugs" (Report Number: A-02-08-02003).

I appreciate your kindness to grant us the requested additional time to answer and look forward to a continued collaboration in the future to ensure optimal services for persons living with HIV/AIDS in Puerto Rico.

Thanks for your attention to this matter.

Lorenzo González Feliciano, MD  
Secretary  
Puerto Rico Department of Health

**Finding # 1: Unsupervised Drug Dispensing. The PR Health Department did not ensure that ADAP drugs were dispensed by a licensed pharmacist or by a pharmacy technician under the direct supervision of a licensed pharmacist.**

Since early FY 2008, the PR-ADAP identified and started business negotiations with the owners of community and privately own pharmacies that were willing to offer drug dispensation services to ADAP eligible participants who received clinical services at the Arecibo and Caguas CPTETs (Spanish acronym for Centro de Prevención y Tratamiento de Enfermedades Transmisibles), and the satellite clinic in Humacao, which is under the supervision of the Medical Director from the Caguas CPTET. As a result, the following pharmacies were contracted: Farmacia Arleen in Caguas (contract was effective on May 8, 2008), Farmacia Central in Humacao (contract was effective on May 23, 2008), Farmacia Garcia in Arecibo (contract was effective on July 14, 2008).

Contracts with these pharmacies were renewed for FY 2009. Pharmacy services continued to be provided at CLETS, Ponce and Mayagüez CPTETs, with PR Health Department licensed pharmacists and pharmacy technicians under the direct supervision of a pharmacist. All contracted pharmacies comply with the Commonwealth of Puerto Rico and Federal laws to operate and dispense drugs by qualified licensed personnel. With these actions, the PR-ADAP eliminated patients' health risks associated to dispensing drugs by unlicensed personnel.

To address the absence of a licensed pharmacist due to vacations or sickness leave in any of the three CPTETs that currently have pharmacies, the PR Health Department has other licensed pharmacists available to cover their services. Pharmacy personnel vacation plans are coordinated with the head of the Pharmacy Distribution Center in order to prepare contingency arrangements to avoid unsupervised drug dispensing at any of these pharmacies.

**Finding # 2: Inadequate Drug Inventories. The PR Health Department did not ensure that the Pharmacy Distribution Center and three treatment clinics maintained an adequate ADAP drug inventory system.**

**Perpetual and Physical Inventories**

For many years, the Pharmacy Distribution Center has had in place a manual drug inventory system to manage medications purchased with Federal and

State funds. During FY 2009, Ryan White Part B Program allocated money to purchase a computerized inventory program that will be installed at the Pharmacy Distribution Center to deal more effectively and efficiently with the ADAP drug inventory administration. This computerized system will also allow for accurate and up to date information in multi-locations (interfacing with inventory data information from the CPTETs) and facilitate drugs' return and requests for credits to drug companies and other vendors. Currently, the Office of Information and Technological Advances (OIAT) is reviewing the system requirements. After this reviewing process is done, OIAT will submit a report to PR ADAP and a bidding process (Request for Proposal) will commence with the PR-Health Department Purchasing Office. At the present time, PR-ADAP has in place a monitoring guidance that addresses the drug inventory managing process and of the credits offered by the manufacturers when expired drugs are returned.

The Office of Finance at the Department of Health has implemented a working plan to update the perpetual inventory at the Drug Distribution Center and Pharmacy. The Secretariat of Administration will continue performing the physical inventory and ensure the reconciliation of both.

#### **Drug Requisitions Forms**

Since May, 2009, Island Wide, a local transportation company, is offering drug delivery services to all HIV/AIDS public and private clinics that comprise the ADAP network, including the PRDH CPTETs. This company maintains a log where the pharmacies personnel sign drug shipments that are received and also make sure that requisition forms are signed by the requesting pharmacists. This log and requisition forms are an assurance that drugs requested were actually received by the requesting pharmacy and its authorized personnel. This contract with Island Wide confirms our commitment to foster efficiency and comply with internal and external policies, procedures and regulations concerning this subject matter.

#### **Finding # 3: Expired Drugs not always properly disposed. The PR Health Department did not ensure that expired ADAP drugs were properly disposed.**

Since January, 2007, Pharmacy Distribution Center (PDC) personnel was strengthened by recruiting a pharmacist and a pharmacy technician to, among other tasks, request credit or exchange from drug companies for eligible expired drugs and process the disposal of medications without credit. Since then, the PDC has kept records of such activity. Nonetheless, it is important to point out that the PDC has had in place before 2007, procedures regarding the proper disposal of expired drugs. Specifically,

there has been an established policy to transport expired drugs from the HIV clinics to the Pharmacy Distribution Center. Actually, the PDC is in the process of obtaining an identification number as a Controlled Waste Generator for the disposal of expired medications, as required by the Environmental Quality Board (Junta de Calidad Ambiental), that is renewable every 5 years. The PDC is currently working in the calculation of credits obtained per supplier per year. The PDC also sends a monthly reminder to the above mentioned CPTETs to return medications that will expire the following month.

To ensure that credits offered by drug manufacturers are requested, the PR ADAP included a clause in the contracts signed with the aforementioned community pharmacies that serve Arecibo and Caguas CPTETs' patients, to return medications with less than 60 days left in the expiration date. This requirement was also added to the pharmacy services agreement (PSA) formalized with CLETS.

The PR ADAP is committed to continue strengthening and improving monitoring procedures in order to assure the provision of better quality services to our participants and safeguarding their health.