



GOVERNMENT OF PUERTO RICO

Department of Health
Auction Office

**PUERTO RICO DEPARTMENT OF HEALTH
AUCTION OFFICE**

*****REQUEST FOR PROPOSAL*****

**FOR A PHARMACY BENEFITS MANAGER (PBM) FOR ADAP ONLY
ELIBIBLE CLIENTS**

AND

**THE ADMINISTRATION OF
A HEALTH INSURANCE ASSISTANCE PROGRAM (HIAP)
FOR ADAP ELIGIBLE CLIENTS WITH PRIVATE HEALTH
INSURANCE WITH HIGH COINSURANCE, COPAYMENTS AND/OR
DEDUCTIBLES TO ACCESS HIV DRUGS**

TABLE OF CONTENTS

| | |
|----------------------------------------------------------|----|
| I- INTRODUCTION ----- | 3 |
| II- GENERAL INFORMATION ABOUT THE PUERTO RICO ADAP ----- | 4 |
| III- PURPOSE OF THE REQUEST FOR PROPOSAL (RFP) ----- | 6 |
| IV- DEADLINE FOR SUBMISSION ----- | 7 |
| V- APPLICATION / PROPOSAL CONTENTS AND REQUIREMENTS --- | 7 |
| A. FORMAT ----- | 7 |
| B. COVER LETTER ----- | 7 |
| C. DESCRIPTION OF THE ORGANIZATION ----- | 8 |
| D. DESCRIPTION OF SERVICES REQUIRED ----- | 8 |
| E. DATA REQUIREMENTS ----- | 16 |
| F. BUDGET / ESTIMATED COSTS ----- | 23 |
| G. IMPLEMENTATION PLAN ----- | 23 |
| H. PAYMENT METHOD ----- | 23 |
| VI- ASSESMENT CRITERIA ----- | 24 |
| VII- PERFORMANCE MEASURES ----- | 24 |
| VIII- DOCUMENTS REQUIRED ----- | 25 |
| IX- TABLE OF CONTENTS ----- | 26 |

I. INTRODUCTION

The Puerto Rico Department of Health (PRDoH) is a grantee of funds awarded under the Ryan White HIV/AIDS Treatment Extension Act of 2009 (Public Law 111-87), as amended. The United States Congress originally approved this law in 1990 to provide services to the HIV/AIDS population living in the United States, the territories and Puerto Rico. Public Law 101-381 amended by Title XXVI of the Public Service Act (42 U.S. Code 300 ff-11 et seq.) authorized funds granted under this law. This law was re-authorized in 1996, 2000, 2006 and 2009. The Division of State HIV/AIDS Programs (DSHAP) that is under the HIV/AIDS Bureau of the Health Resources and Services Administration (HRSA) is in charge of administering Part B of the Ryan White Act.

The purpose of the Ryan White funds is to provide financial assistance based in a formula to the states, territories, and Puerto Rico, to improve the quality, availability and organization of the health care and support services for individuals and families with HIV/AIDS. The law emphasizes that the care and support must be part of a continuum in which all the needs of people living with HIV / AIDS and their families are cared for.

The Part B of the Ryan White Act provides money for the coordination and delivery of health and support services to medically indigent HIV / AIDS people living in Puerto Rico. Primary and specialized medical care, medications, treatment for alcohol and substance abuse, mental health, and home health care, are some of the health services that are funded.

The AIDS Drugs Assistance Program (ADAP) is the program under Part B of the Ryan White Act that provides FDA-approved drugs to treat HIV in medically indigent persons who do not have health insurance pharmacy coverage or who have limited pharmacy coverage. This program plays an important role in health care for people living with HIV; serving approximately 300,785 people in 2020 in the United States and Puerto Rico, about 53.6% of all patients that received Ryan White services during that same year (i.e., 561,129). Specifically in Puerto Rico, the population that participates in this program is approximately 8,000 patients per year.

The ADAPs began serving clients in 1987 when the U.S. Congress approved funding to help states purchase AZT, the only anti-retroviral drug approved then. In 1990, the ADAP program was incorporated into the Title II of the then newly formed Ryan White CARE Act. This program currently operates in 57 jurisdictions that receive funds under the Part B of the Ryan White Act.

Like all programs funded with Ryan White Act monies, the ADAPs serve as the payer of last resort, i.e., drugs will be provided to eligible people living with HIV / AIDS when other sources of funds are not available.

II. GENERAL INFORMATION ABOUT THE PUERTO RICO - ADAP

The Puerto Rico AIDS Drugs Assistance Program is managed by the Ryan White Part B / ADAP Program that operates under the Puerto Rico Department of Health Central Office for AIDS Affairs and Communicable Diseases (OCASET, for its Spanish acronym). As said before, the PR-ADAP provides medications to approximately 8,000 HIV/AIDS eligible clients living in the Island. To be ADAP eligible, an HIV/AIDS client must comply with several eligibility criteria, i.e., HIV positive, low-income (net income \leq 200 Federal Poverty Level [FPL]), living in Puerto Rico and without or limited insurance coverage. The income eligibility is currently done through the PRDoH Medicaid Program. The final eligibility determination is performed by eligibility and enrollment officers based at the ADAP administrative offices.

Ninety-three (93%) percent of these clients are co-eligible to the Government of Puerto Rico Health Insurance Plan (PRHIP); another 7 percent of the ADAP eligible clients are comprised of patients without health insurance or have a private health insurance with limited pharmacy coverage; that is, with a drug cap and/or high coinsurance, co-payments and/or deductibles to access HIV/AIDS drugs.

ADAP clients access medications through one of the 45 HIV clinics in house pharmacies or private community pharmacies contracted for this purpose. Most of these pharmacies is in urban areas, but there is a significant number located in rural municipalities. Eight (8) of these clinics (Centers for Prevention and Treatment for Communicable Diseases - CPTETs) belong to the PRDoH. The rest of the clinics are mostly community based, except for two that belong to the municipalities of San Juan and Bayamón (some of them are Ryan White Part A and Part C grantees).

The ADAP Formulary contains 42 FDA approved antiretroviral drugs in a variety of dosages and presentations. There are 1 CCR5 co-receptor antagonist, 4 HIV Integrase strand transfer inhibitor and 1 Fusion Inhibitor, 5 Non-nucleoside Reverse Transcriptase Inhibitors (NNRTIs), 5 Nucleoside Reverse Transcriptase Inhibitors (NRTIs), 9 Protease Inhibitors, 1 gp120 Attachment Inhibitor, 1 Post-attachment Inhibitor/ Monoclonal antibody and 15 fixed-dose combinations. The ADAP Drug Formulary also contains other Opportunistic Infections (OIs) and general medications.

The Puerto Rico ADAP participates of the 340B Program as a hybrid jurisdiction (Direct Purchase and Rebate) to drug companies and wholesalers, as well of the ADAP Crisis Task Force negotiated prices with drug manufacturers. The medications are stored at the PRDoH Drug Distribution Center (DDC) from where are distributed to each of the 51 ADAP participating clinics through 45 pharmacies (ADAP pharmacy network). Services agreements are in place through actual PBM contracts with each pharmacy that establish program terms and conditions to handle and dispense ADAP medications. An auditing program that includes visits to these pharmacies, review of physical inventory and reports, dispensing process and clients' complaints process is in place. In 2015, an inventory management software was developed and implemented by the Ryan

White Part B/ ADAP Program. This software manages the drugs requisition process that is initiated from each of the ADAP pharmacy network and oversees ADAP drugs inventory control and movement at the PRDoH Drug Distribution Center and each of the ADAP pharmacy network. This software provides reports using PBM drugs utilization data that assists the ADAP drugs inventory control personnel to perform these roles, preventing excessive inventory.

The PRDoH has under contract a local drug courier service to manage efficiently the transportation of drugs between the DDC and the ADAP pharmacy network. The courier company reduces considerably the time of transporting medications thus improving timely access and availability to patients.

ADAP Health Insurance Assistance Program (HIAP)

In addition to the pharmacy benefits management services (PBM), the Puerto Rico ADAP is requesting with this RFP the provision of a financial assistance for eligible individuals living with HIV to maintain a continuity of treatment under a health insurance assistance program. The Health Insurance Assistance Program (HIAP) proposed includes payment of coinsurance, copayments and deductibles for those consumers who have a private health insurance with limited pharmacy coverage or no-limit pharmacy coverage with high coinsurance or co-payments.

The ADAP determined to establish the HIAP after a cost efficiency analysis was conducted and the need to strengthen and improve access to HIV medications for patients under the 200% FPL with the above-mentioned criteria. This initiative will fill a need identified about access to medications of patients with private health insurance that are low income and don't have the resources to pay for the coinsurance, co-payments, and deductibles.

The contractor will be responsible for the implementation process of the ADAP drug formulary and ADAP benefits database on an electronic system platform that will provide adequate controls of pharmacy services, utilization history, and authorization of services and claims payment. The ADAP will ensure that the coinsurance, co-payments, and deductibles will be paid to health insurers that include a formulary that is as comprehensive as the current ADAP formulary.

The Contractor and the ADAP will consider various possible measures to ensure the cost effectiveness of the partial payments that the ADAP will make through the PBM to each pharmacy under the health insurance of each patient. The Contractor will assist the Program to: 1) compare the cost of medications at 340B and ADAP prices versus the average wholesale price (AWP); 2) evaluate the current therapy for each patient and the type of drug coverage by the private health insurer; 3) evaluate the improvements in access to HIV medications; and 4) monitor HIAP operations to assure compliance through reports submitted and monitoring visits. After a cost-effectiveness evaluation, the Program will identify if the amount of money allocated for co-payments is less, equal, or greater than the cost incurred by the program at 340B and ADAP prices.

The ADAP will cover co-payments, co-insurance and/or deductibles for patients with private health insurance that have a pharmacy coverage for HIV products.

III. PURPOSE OF THE REQUEST FOR PROPOSAL (RFP)

Contractor shall provide services to the Puerto Rico Department of Health (PRDoH) AIDS Drugs Assistance Program (ADAP), as a Pharmacy Benefits Manager (PBM) for medications dispensed to low-income individuals who are determined to be eligible by the ADAP and administrator of a Health Insurance Assistance Program (HIAP) for ADAP eligible clients who have private health insurance with high coinsurance, co-payments and/or deductibles to access HIV drugs. Services will include payments of a dispensing fee to participating pharmacies of the ADAP network and the establishment of a comprehensive auditing program.

Contractor will manage the electronic transactions of HIV drugs dispensed in the ADAP pharmacy network for ADAP only eligible clients. Under the HIAP, contractor will manage and disburse coinsurance, co-payments and deductibles for HIV eligible low-income clients who have private medical insurance with pharmacy coverage for HIV drugs.

All activities shall be performed in accordance with the following:

- Request for Proposal (RFP) for Pharmacy Benefits Manager and administrator of the Health Insurance Assistance Program.
- Contractor's final objectives, implementation plan, and detailed budget, as approved by PRDoH; and
- Any written instructions given by the PRDoH to Contractor.
- Contractor must receive written approval from PRDoH before varying from applicable policies, procedures, and protocols, and must update its implementation documentation within forty-eight (48) hours of making approved changes so that staff working on activities under the contract that will be convened have knowledge of change(s).

IV. DEADLINE FOR SUBMISSION

The deadline for submitting the proposal with all required documents is no later than 4:00 PM AST of **December 16, 2022**. **No request for extensions will be granted.** The application can be delivered in person or by courier to the Puerto Rico Department of Health Auction Office located on the second floor of the PRDoH Building H, Office #223, Rio Piedras Puerto Rico.

V. APPLICATION / PROPOSAL CONTENTS AND REQUIREMENTS

A. FORMAT (2 POINTS)

The proposal must be submitted on letter size paper (8 x 11) with margins of (1) inch on all sides (top, bottom, left and right). The pages will be listed in the top right, as per the following format: 1 of 40 pages. The text should be written in Times New Roman or Arial styles, size (12), double-spaced, except for information that could be provided in tables, which can be single-spaced.

One original application must be delivered with 2 copies unbound and unstapled, and one digital copy in pdf (USB).

The proposal can be submitted either in English or in Spanish.

B. COVER LETTER (2 POINTS)

The proposal should include a cover letter that will not exceed two pages long. The letter shall: (1) identify the organization; (2) state its intention to submit an application; (3) describe briefly the proposal to be presented; (4) establish the cost of the services proposed as a PBM and as administrator of the Health Insurance Assistance Program; (5) state the ability of the organization to perform the services proposed; and (6) express the reason(s) explaining why the organization that is submitting the application is superior to other organizations offering the same service.

The cover letter should be addressed, by e-mail or regular mail to:

Denise Marrero Santana, MBA
Director
Auctions Office
Puerto Rico Department of Health
P.O. Box 70184
San Juan, PR 00936
E-mail: subastas@salud.pr.gov

C. DESCRIPTION OF THE ORGANIZATION (5 POINTS)

Please provide the following information:

1. Official name, postal and physical address of the organization, web page address (if applicable).
2. List of the Board of Directors members.
3. Phone and fax numbers, and e-mail of the Executive Director, highest official or person authorized to represent, endorse, or sign any document sent to the PRDoH.
4. The organization's previous experience in the operation, administration and provision of services that are being proposed in this application.
5. The last Annual External Audit.
6. List of the person(s) that will be responsible for implementing and managing the project in the organization.
7. A description of the operational capacity, including infrastructure systems.

D. DESCRIPTION OF SERVICES REQUIRED (30 POINTS)

1. IN GENERAL

Contractor must provide a proposal that addresses the following core program components:

- Determine client eligibility in coordination with the ADAP and PRDoH Medicaid Program.
- Register, manage and transmit electronic transactions for each medication dispensed to ADAP eligible participants.
- Establish system controls and coordination of pharmacy benefits to assure compliance with payer of last resort requirement.
- Guarantee the continuation and possible expansion of the ADAP pharmacy network.
- Generate drug utilization reports and disburse coinsurance, co-payments and/or deductibles to participating pharmacies for eligible clients who are underinsured (with limited pharmacy coverage, that is, their health insurance does not cover all ARVs, has a drugs' cap or requires high coinsurance, co-payments and/or deductibles to access medications).

Other administrative services required:

- Maintain compliance with the National Council of Prescription Drug Program's (NCPDP) standards for pharmacy drug claims and coordination of benefits (located at <http://www.ncdp.org/>).
- Provide designated PRDoH staff with electronic access to a computer system that will allow to view live claims adjudication. Contractor shall also provide training, as directed, to designated ADAP staff on the use of the system.
- Contractor shall comply with all applicable federal and state statutes and regulations, including, but not limited to:
 - Commonwealth of Puerto Rico Law # 81 of 1912, as amended.
 - Commonwealth of Puerto Rico Law # 248 of 2018, as amended.
 - Chapter 6A (Public Health Service) of Title 42 (The Public Health and Welfare) of the United States Code, as amended; <https://uscode.house.gov/view.xhtml?path=/prelim@title42/cchapter6A&edition=prelim>
- Contractor shall comply with all applicable state and federal policies, standards, and guidelines, including, but not limited to:
 - Health Information Portability and Accountability Act (HIPAA) Regulations and Standards; Public Health Law 104-191; Health Insurance and Accountability act of 1996; <http://aspe.hhs.gov/admsimp/pl104191.htm>
 - National Standards to Protect the Privacy of Health Information; <http://www.hhs.gov/ocr/hipaa/>
 - National Security standards for the security of health care information. <http://www.cms.hhs.gov/SecurityStandard/>
- Contractor is responsible for maintaining access to current laws, standards, and guidelines, along with any other applicable documents under this contract, for its employees working on activities under this Contract.
- Contractor shall fully cooperate with all programmatic performance-monitoring activities initiated by and/or on behalf of, PRDoH.
- PRDoH reserves the right, where allowed by legal authority, to redirect funds in the event of unanticipated financial

shortfalls. PRDoH ADAP Program will monitor Contractor's expenditures on a quarterly basis. If expenditures are below that projected in Contractor's total contract amount as shown in SECTION V, CLAUSE F BUDGET/ESTIMATED COSTS, Contractor's budget may be subject to a decrease for the remainder of the contract term. Vacant positions existing after ninety (90) days may result in a decrease in funds.

2. AS A PHARMACY BENEFITS MANAGER (15 POINTS)

- Definition, handling, and management of the ADAP pharmacy coverage.
 - Development of benefits package and system rules.
 - Coverage definition.
- Design, implement and maintain a program to determine eligibility through the current ADAP eligibility process.
 - Eligibility loading and storage.
 - Creation and maintenance of eligibility archives (data bank).
 - Management of eligibility data.
 - Eligibility updates in the claims processing system.
- Program prescriptions' adjudication system.
 - Claims adjudication in the ADAP pharmacy network.
 - Process all claims in accordance with the prevailing standards of the National Council of Prescription Drug Programs (NCPDP).
 - PBM will process claims submitted by participating pharmacies, including on-line edits for prior authorization regulation and other edits that may be necessary for the accurate processing of claims and according to the pharmacy benefits coverage determined by ADAP Program.
- Develop and implement a Coordination of Benefits (COB) Program integrated with the claims/ prescription's adjudication with all private health insurance companies in Puerto Rico, in which any ADAP individual is enrolled.
 - Maintenance of the system for handling online COB.
- Develop and implement a Maximum Allowable Cost (MAC) list by National Drug Code (NDC) and Generic Product Identifier (GPI)
 - Update List for MAC award in ADAP pharmacy network.
- Design a procedure to update the ADAP Drug Formulary in the claims processing system, as per request of the ADAP.
- In the event a need arises to interface with the PBM data bank contracted by the Health Insurance Administration

(ASES, for its Spanish acronym), which administers the Government of Puerto Rico Health Insurance Plan (PRHIP), the proponent must have the capability to develop procedures according to such need.

- Develop procedures to interface with the management inventory control system developed by the Ryan White Part B/ ADAP Program, to process requisition orders, obtain and reconcile inventory information from ADAP pharmacies and the PRDoH Drug Distribution Center (DDC).
- Provide support in the evaluation of new FDA approved ARV medications.
- Perform drug utilization review, analysis, and history.
- Establish a Fraud and Abuse (FWA) program, including a strong Pharmacy auditing program.
- Contractor shall issue and deliver to the ADAP Program in a monthly electronic download via an FTP file, CD and in hard copy format, a set of reports set forth and described in the Data Requirements Section of this RFP.
---Provide to ADAP Program all processed Claims data and drug utilization reports, in the media and format or in any other form mutually agreed to by the parties from time to time.
- Contractor must enter a contract with each pharmacy of the ADAP network where it comprises the terms and conditions establish by the Ryan White Part B/ ADAP Program to manage and dispense ADAP drugs, including 340B and ADAP prices regulations.
- Create and maintain a Pharmacy Support and Service center for ADAP pharmacy network (access 24-7) that will provide technical assistance.
- Establish, implement, and manage a patient help desk (access 24-7).
- Develop, implement, and manage a pre-authorization process for certain specific drugs, as instructed by the ADAP.
- Develop and implement a training program for ADAP central offices personnel and ADAP pharmacy network.
- Issue monthly reports about inappropriate Antiretroviral Regimen Components prescriptions included in the most

recent US Public Health Service Guidelines, "Antiretroviral Regimens or Components That Should Not Be Offered at Any Time" and "Antiretroviral Regimens or Components that should not be offered for treatment of Human Immunodeficiency Virus (HIV) Infection in Children".

- Pay a Dispensing Fee to the pharmacies that belong to the ADAP Pharmacy Network. This Dispensing Fee will be paid for the dispensation of medications included in the ADAP Drugs Formulary processed electronically through the PBM system to ADAP eligible patients as described below.
 - This project requires data generation and analysis, preparation of invoices and reports to be sent to ADAP, and payment of the Dispensing Fee to pharmacies. These processes will be carried out monthly by the PBM staff.
 - Payment of the Dispensing Fee will be made to the 45 pharmacies that belong to the ADAP closed network, including the CPTET pharmacies of the PRDoH.
 - Drugs eligible for this program are those processed through the PBM adjudication system for "ADAP 01, ADAP 02 and ADAP 03" patients' profiles and for ADAP drugs dispensed to PR Health Insurance Plan (PRHI) members that are not covered by this Plan or by another payer. The drugs that apply to this program are those that correspond to the following categories of the ADAP Drug Formulary:
 - a. "ADAP 01" (2327) - Provides drugs assistance to eligible ADAP clients who are uninsured or lack pharmacy coverage on their private insurance. The ADAP 01 patient profile provides access to all three categories of the ADAP Drug Formulary.
 - b. "ADAP 02" (3327) - Provides drugs assistance to eligible ADAP clients who are privately insured but whose copayments, coinsurances and deductibles are not cost-effective for HIAP assistance. The ADAP 02 patient profile provides access to Category I of the ADAP Drug Formulary (only antiretroviral drugs, ARVs).
 - c. "ADAP 03" (5527) - Provides drugs assistance to eligible ADAP clients who are privately insured with exclusions on their pharmacy coverages. The ADAP 03 patient profile provides access to all three categories of the ADAP Drug Formulary but has a pre-authorization process for all drugs to ensure compliance with payer of last resort.
 - d. "ADAP/PRHI" (MPI) - Provides drug assistance to ADAP clients who are co-eligible to the PR Health Insurance (PRHI). As payer of last resort, the ADAP/PRHI patient profile provides access to medications of the ADAP Drug Formulary excluded from the PRHI Preferred Drug List.

- Establish a PBM Auditing Program, which includes in-store review, online audits, desk or bench audits of claims processing, and services to recover drug costs to participating pharmacies and institutions (insurance companies and hospitals) because of the auditing findings and/or referrals from the ADAP, subject to the scope and requirements set forth in a future contract agreement that will be in force. This Auditing Program must be in accordance with HRSA's Monitoring Standards.

The purpose of the program will be to verify the accuracy and the appropriateness of Claims Processing; and to determine if the Participating Pharmacies are in compliance with their contractual obligations. PBM shall, in coordination with the PRDoH, take measures to avoid repetition of any errors, abuses and wrongful utilization and to recover, whenever reasonably possible, any unduly paid or appropriated amounts. In providing its services hereunder, PBM shall implement reasonable administrative practices.

The PBM shall submit to the PRDoH on a quarterly basis the Auditing Reports.

3. AS THE ADMINISTRATOR OF THE HEALTH INSURANCE ASSISTANCE PROGRAM (HIAP): DISBURSING COINSURANCE, CO-PAYMENTS AND/OR DEDUCTIBLES TO PBM PHARMACY NETWORK (15 POINTS)

- Definition, handling, and management of the pharmacy coverage.
 - Development of benefits package and system rules.
 - Coverage definition.
- Oversee implementation of the HIAP to the payment of private health insurance pharmacy coverage coinsurance, co-payments, and deductibles for Puerto Rico residents enrolled in a private health insurance with high coinsurance, co-payments and/or deductibles to access HIV drugs.
- Design, implement and maintain a program to determine eligibility through the current ADAP eligibility process.
 - Eligibility loading and storage
 - Creation and maintenance of eligibility archives (data bank).
 - Issue of identification cards with a magnetic strip.
 - Management of eligibility data.
 - Eligibility updates in the claims processing system.

- Program prescriptions' adjudication system
 - Claims adjudication in the PBM pharmacy network
 - Process all claims in accordance with the prevailing standards of the National Council of Prescription Drug Programs (NCPDP)
 - PBM will process claims submitted by participating pharmacies, including on-line edits for prior authorization regulation and other edits that may be necessary for the accurate processing of claims and according to the pharmacy benefits coverage determined by ADAP Program.

- Develop and implement a Coordination of Benefits (COB) Program integrated with the claims/ prescription's adjudication with all private health insurance companies in Puerto Rico, in which any ADAP individual is enrolled.
 - Maintenance of the system for handling on-line COB.

- Coordinate coverage and benefits with private health insurers to ensure that applicable expenditures are credited toward meeting the enrollee's pharmacy expenditure cap, if applicable. As part of this duty, Contractor shall participate in the electronic data exchange processes, which are available in the market.
 - Ensure that the HIAP does not pay for medications that are not approved by the ADAP and is not on the formulary for the specific private health insurance plan in which an individual HIAP recipient is enrolled.

- Develop and implement a program to disburse coinsurance, co-payments and/or deductibles to participating pharmacies for eligible ADAP clients who have health insurance with high coinsurance, co-payments and/or deductibles to access HIV drugs.
 - Contractor must have an amount of money available for this purpose. Contractor will then bill the PRDoH.

- Establish a Selective Pharmacy Network (SPN) that will be able to split the billing of prescription drug costs between the private health insurance plans and the HIAP. The network of pharmacies must be geographically dispersed throughout the Puerto Rico; preferably private community and commercial chain pharmacies located near the ADAP Clinics network (mostly PRDoH CPTET, Parts A and C community based clinical centers).

- Not change the primary payer status of a private health insurance plan. The HIAP will always be considered a secondary payer.

- Comply strictly with HRSA's **Policy Clarification Notice (PCN) #18-01 Clarifications Regarding the Use of Ryan White HIV/AIDS Program Funds for Health Care Coverage Premium and Cost Sharing Assistance** effective since June 20, 2018. This PCN streamlines the Health Resources and Services Administration (HRSA) HIV/AIDS Bureau (HRSA HAB) policy regarding the use of Ryan White HIV/AIDS Program (RWHAP) funds for premium and cost sharing assistance for the purchase and maintenance of private health insurance, Medicaid, and Medicare coverage. This updated PCN simplifies and replaces the following three notices: *07-05 Use of Ryan White HIV/AIDS Program Part B ADAP Funds to Purchase Health Insurance*; *13-05 Clarifications Regarding Use of Ryan White HIV/AIDS Program Funds for Premium and Cost-Sharing Assistance for Private Health Insurance*; and *13-06 Clarifications Regarding Use of Ryan White HIV/AIDS Program Funds for Premium and Cost-Sharing Assistance for Medicaid*.
- Perform coinsurance, co-payments and deductibles utilization review, analysis, and history.
 - Electronic transfers or check processing.
- Establish a Waste, Fraud, and Abuse program, including a strong Pharmacy auditing program.
- Develop and implement a training program for ADAP central offices personnel and ADAP pharmacy network.
- Maintain a data system capable of implementing and monitoring the cost containment measures (such as annual expenditure caps on client services, and client or medication prior authorizations) established by PRDoH;
- Create and maintain a help desk (access 24-7) that will provide technical assistance to pharmacies and the PRDoH HIV / HIAP staff for billing and claims system issues.
- Establish, implement, and manage a patient help desk (access 24-7).
- The Affordable Care Act (Public Act 111-148) allowed ADAPs to become True-Out-of-Pocket (TrOOP) eligible payers, which payments count towards the Medicare Part D annual out-of-pocket threshold. Medicare Part D Plan sponsors are required since then to include Ryan White HIV/AIDS Part B ADAP expenditures covered for Part D drugs towards the TrOOP limit of Medicare Part D enrollees.

ADAP clients who are Medicare Part D enrollees are to be now able to move through the coverage gap phase into the catastrophic coverage phase when Part D covered drugs are available at a nominal cost. Payments for incurred costs during the coverage gap must be for covered Part D drugs and paid for by a TrOOP eligible payer such as a Part B ADAP under Part B of Title XXVI of the Public Health Service Act. These costs must be flagged as being from ADAP to ensure they are counted for TrOOP. To ensure ADAP expenses are accurately accounted for in the TrOOP calculation, the ADAP participates in data sharing with the CMS COB contractor. In order to participate in the COB process, the ADAP signed a data sharing agreement (DSA) with CMS and submits through the PBM electronic enrollment files with specific information that is provided to the TrOOP facilitation contractor. The ADAP implemented CMS recommendation to process their Part D secondary claims in real-time at the point of sale (pharmacy). The PRDoH entered into a Data Sharing Agreement (DSA) with CMS in October 2011. The purpose of this Agreement is to establish conditions under which: (1) an ADAP Data Sharing Partner or agent, as defined in Section IV, agrees to provide prescription drug coverage data to the CMS; and (2) the CMS agree to provide the Data Sharing Partner with Medicare Part D enrollment data on enrollees for whom the ADAP Data Sharing Partner provides prescription drug coverage. Pursuant to the DSA signed with CMS, the Contractor will be the ADAP Data Sharing Partner, Agent or technical contact designated by the PRDoH for technical or other implementation coordination issues under this Agreement. The Contractor will be the point of contact for CMS for any technical questions that may arise during the term of this Agreement. This project will be conducted under the Health Insurance Assistance Program (HIAP). The contractor must have the technical capabilities to be the technical partner of the ADAP under this DSA.

E. DATA REQUIREMENTS (5 POINTS)

1. Contractor shall submit, at a minimum, all required data elements under this RFP for each client who receives services. These data elements must be provided in an electronic master file. Such reporting must be completed in accordance with this RFP, as well as any additional instructions provided by PRDoH. In addition, all services noted as supported with PRDoH funds directed through the contractor must include information on the cost of each unit of service.

---Required data elements in the master file under this RFP for each client who receives services are: Claim number, Claim Status, Rx

number, Member Name, Member Id, Social Security, New/Continuation, Sex, Age, DOB, Pregnancy, City, Member Classification, MCO, Product name, Product ID (NDC), GPI ID, Product Description, Service day (filled date), Submitted Date, Days supplied, Quantity dispense, Provider Numbers, Provider Names, Prescriber Numbers, Prescriber Names, Patient Pay, Cost Per Units, Total cost, Ingredient Cost, Dispensing Fee, HIV Flag.

2. Contractor shall also respond to special requests for data from PRDoH by the deadlines specified.

3. The reports and data collection activities shall be completed to the satisfaction of PRDoH in order for payment vouchers to be processed. Failure to meet these conditions constitutes a breach of contract.

4. Report Names, Descriptions and frequency:

ADAP Reports

a. (ADAP-1) Monthly, Quarterly and Annual Total Patients Served Report: In Excel format per pharmacy, a breakdown of new and active unduplicated patients served with ADAP medications listing how many patients have 1-2 meds, 3-4 meds and 5+ meds and its related drug costs. The monthly report is due the 20th of the following month. The quarterly report is due 20 days after the close of the quarter: (April 20, July 20, October 20, and January 20). The annual reports are due 30 days after March 31, the close of Ryan White Part B Program/ADAP year (April to March) and 30 days after December 31, the close of calendar year (January to December). Note: This report must be submitted for all ADAP co-eligible with Puerto Rico Health Insurance (PRHI) patients that receive ADAP medications and ADAP only patients.

b. (ADAP-2) Monthly, Quarterly and Annual ADAP Client Claims Detail Report: In Excel format per Claim detail including: Claim Reference number, Claim Status, Rx number, Member name, Card Id/Member ID, Social Security Number, New/Cont, Sex, Age, Date of Birth, Pregnancy Status, City, Member Classification, MCO/Plan id, Process/Submitted date, Fill date, Date Written, Product Name, Product NDC, Product GPI, Quantity, Days' supply, Ingredient Cost, Claim Unit Cost, WAC price, Member Diagnosis, Prescriber NPI Number, Prescriber Name, Pharmacy Id, Pharmacy Name. The monthly report is due the 20th of the following month. The quarterly report is due 20 days after the close of the quarter: (April 20, July 20, October 20, and January 20). The annual reports are due 30 days after March 31, the close of Ryan White Part B Program/ADAP year (April to March) and 30 days after December 31, the close of calendar year (January to December). Note: This report must be separated and submitted for all ADAP co-eligible

with PRHI patients that receive ADAP medications and ADAP only patients. The report will include claims data processed electronically of all the medications included in the ADAP Drugs Formulary.

c. (ADAP-3) Monthly, Quarterly and Annual Drug Utilization Summary Report: In Excel format for the ADAP pharmacy network providing a relation between drugs dispensed, unduplicated members served per medication, number of claims processed, units dispensed, unit cost and total drug costs. This report will also furnish a breakdown of total unduplicated clients served by ADAP (new and active), how many are receiving 1-2 drugs, 3-4 drugs or 5+ drugs per anti-retroviral therapy, and a breakdown of unduplicated clients served by age category (0-2, 3-12, 13-24, 25-44, 45-64 and 65+). The summary of patients by therapy combination and age group must be included for unduplicated pregnant women. The monthly report is due the 20th of the following month. The quarterly report is due 20 days after the close of the quarter: (April 20, July 20, October 20, and January 20). The annual reports are due 30 days after March 31, the close of Ryan White Part B Program/ADAP year (April to March) and 30 days after December 31, the close of calendar year (January to December). Note: This report must be submitted for all ADAP co-eligible with PRHI patients that receive ADAP medications and ADAP only patients.

d. (ADAP-4) Monthly, Quarterly and Annual Therapy Combination Report: In Excel format per pharmacy per month provide a summary of Brand/Generic antiretroviral drugs combination therapy for all drugs dispensed to HIV-all patients, ADAP co-eligible PRHI patients and ADAP only patients. This report must include unduplicated number of patients by combination therapy by age group and gender. For pregnant women a separate report must be provided. The monthly report is due the 20th of the following month. The quarterly report is due 20 days after the close of the quarter: (April 20, July 20, October 20, and January 20). The annual reports are due 30 days after March 31, the close of Ryan White Part B Program/ADAP year (April to March) and 30 days after December 31, the close of calendar year (January to December). Note: This report must be submitted for all ADAP only and ADAP co-eligible PRHI patients that receive ADAP medications.

e. (ADAP-5) Monthly, Quarterly and Annual All drugs Combination Report for ADAP only patients and ADAP co-eligible PRHI patients that receive ADAP medications: In Excel format provides a summary of Brand/Generic antiretroviral drugs combination therapy for all drugs dispensed to ADAP only patients and ADAP co-eligible PRHI patients that receive ADAP medications. This report must include unduplicated number of patients by age group and gender.

For pregnant women a separate report must be provided. The monthly report is due the 20th of the following month. The quarterly report is due 20 days after the close of the quarter: (April 20, July 20, October 20, and January 20). The annual reports are due 30 days after March 31, the close of Ryan White Part B Program/ADAP year (April to March) and 30 days after December 31, the close of calendar year (January to December). Note: This report must be submitted for ADAP only and ADAP co-eligible PRHI patients that receive ADAP medications.

f. (ADAP-6) Monthly Patient Non-Compliance Report: In Excel format per each pharmacy (provider number and provider name), listing client name, client ID number, prescriber number and prescriber name, of patients without claims processed during the past six (6) months. This report is due the 20th of the following month. Note: This report must be submitted for all ADAP co-eligible with PRHI patients that receive ADAP medications and ADAP only patients.

g. (ADAP-7) Monthly, Quarterly and Annual Pharmacy Summary Utilization Report: In Excel format providing a detail by each pharmacy (including its Pharmacy Identifier) of the number of claims processed, the number of clients served, cost of medications dispensed, dispensing fees paid (if applicable); and total costs. This report must also aggregate pharmacies by each of the following pharmacy types: DoH CPTET pharmacies, DoH contracted private community pharmacies, CBC in-house pharmacies and CBC contracted private community pharmacies. This report is due the 20th of the following month and must also be provided with a graphical explanation of the Distribution of claims processed, clients served, cost of medication dispensed, dispensing fees paid (if applicable) and total drug costs per Pharmacy. The quarterly report is due 20 days after the close of the quarter: (April 20, July 20, October 20, and January 20). The annual reports are due 30 days after March 31, the close of Ryan White Part B Program/ADAP year (April to March) and 30 days after December 31, the close of calendar year (January to December). Note: This report must be submitted for all ADAP co-eligible with PRHI patients that receive ADAP medications and ADAP only patients.

h. (ADAP-8) Quarterly and Annual Rejected Claims Report: A summary of rejected claims for possible Duplicate Claims for each pharmacy, rejection description, drug NDC, Brand/Generic drug name, claims, and units. This report must total the number of claims and units rejected. The quarterly report is due 20 days after the close of the quarter: (April 20, July 20, October 20, and January 20). The annual reports are due 30 days after March 31, the close of Ryan White Part B Program/ADAP year (April to March) and 30 days after December 31, the close of calendar year (January to

December). Note: This report must be submitted for ADAP co-eligible with PRHI patients that receive ADAP medications and ADAP only patients.

i. (ADAP-9) Monthly Executive Summary: In PDF format providing the following reports: i) A breakdown of the total number of claims processed and total cost for medications dispensed per each class of anti-retroviral drugs, i.e. Non-Nucleoside (NNRTIs), Nucleoside (NRTIs), Protease Inhibitors (PIs), Integrase Inhibitors, Entry Inhibitors and Post Attachment Inhibitors; ii) Claims and total drug costs per pharmacy type, i.e. DoH CPTET pharmacies, DoH contracted private community pharmacies, CBC in-house pharmacies and CBC contracted private community pharmacies; iii) Drug Utilization history per month, including the number of claims, number of clients, average cost per claim, average cost per client and total drug cost. This report is due the 20th of the following month. The report will include graphical representations, if applicable.

j. (ADAP-10) Quarterly Call Center performance indicators: As detailed quarterly report is due 20 days after the close of the quarter (April 20, July 20, October 20, and January 20).

k. (ADAP-11) Quarterly Pharmacy Audit Reports: A narrative summary of findings, corrective actions plan undertaken, and results of all pharmacy audits performed in the reporting period. This quarterly report is due 20 days after the close of the quarter: (April 20, July 20, October 20, and January 20).

l. (ADAP-12) Annual PBM Services Summary Report: A narrative account of all measures taken by PBM to implement the programs and services provided by PBM and the results achieved. This annual report is due 30 days after March 31, the close of Ryan White Part B Program/ADAP year.

m. (ADAP-13) Quarterly Possible Inappropriate Antiretroviral Regimen Components dispensed to ADAP/ HIAP beneficiaries Report: In Excel format per Component not recommended Regimen (based on The US Public Health Service Guidelines for the Use of Antiretroviral Agents in HIV-1 Infected Adults and Adolescents and the Guidelines for the Use of Antiretroviral Agents in Pediatric HIV Infection) provide the Exceptions (if apply), Member ID number, Member Last Name, Member First Name, Program (patient category: ADAP/PRHI, ADAP only or HIAP), age, member sex code, fill date I, product name I, prescriber name I, service provider ID I, fill date II, product name II, prescriber name II, service provider ID II, fill date III, product name III, prescriber name III, service provider ID III and full therapy (including other antiretroviral components covered with funds other than ADAP and

processed by the same PBM). The quarterly report is due 20 days after the close of the quarter: (April 20, July 20, October 20 and January 20). Note: This report must be submitted for ADAP co-eligible with PRHI patients that receive ADAP medications, ADAP only and HIAP patients.

n. (ADAP-14) Weekly Hepatitis C and HAV / HBV Vaccines Utilization report: In Excel format, this report includes the following data elements: fill date, claim number, member ID, member name, carrier ID, MCO, provider number, provider name, prescriber number, prescriber name, product ID, GPI, product name, PA number, PA code, PA Code Description, Total Paid and Units, Validation. This weekly report is due the following Monday of the week that is reported.

HIAP Reports

a. (HIAP-1) Monthly, Quarterly and Annual HIAP unduplicated patients Report: In Excel format per pharmacy, per gender and age category. The monthly report is due the 20th of the following month. The quarterly report is due 20 days after the close of the quarter: (April 20, July 20, October 20, and January 20). The annual reports are due 30 days after March 31, the close of Ryan White Part B Program/ADAP year (April to March) and 30 days after December 31, the close of calendar year (January to December).

b. (HIAP-2) Monthly, Quarterly and Annual Total HIAP Patients Served Report: In Excel format per pharmacy per each month, quarter and year, provide the HIAP unduplicated patients and the total drug costs per pharmacy. The monthly report is due the 20th of the following month. The quarterly report is due 20 days after the close of the quarter: (April 20, July 20, October 20, and January 20). The annual reports are due 30 days after March 31, the close of Ryan White Part B Program/ADAP year (April to March) and 30 days after December 31, the close of calendar year (January to December).

c. (HIAP-3) Monthly, Quarterly and Annual Drug HIAP Client Claims Detail Utilization Report: In Excel format per Claim detail including: Claim Reference number, Claim Status, Rx number, Member name, Card Id/Member ID, Social Security Number, New/Cont, Sex, Age, Date of Birth, Pregnancy Status, City, Member Classification, MCO/Plan id, Process/Submitted date, Fill date, Date Written, Product Name, Product NDC, Product GPI, Quantity, Days' supply, Ingredient Cost, Total Cost, Co-pays paid, Claim Unit Cost, WAC price, Member Diagnosis, Prescriber NPI Number, Prescriber Name, Pharmacy Id, Pharmacy Name. The monthly report is due the 20th of the following month. The quarterly report is

due 20 days after the close of the quarter: (April 20, July 20, October 20, and January 20). The annual reports are due 30 days after March 31, the close of Ryan White Part B Program/ADAP year (April to March) and 30 days after December 31, the close of calendar year (January to December).

d. (HIAP-4) Monthly, Quarterly and Annual HIAP Drug Utilization Summary Report: In Excel format for the ADAP pharmacy network providing a relation between drugs dispensed, unduplicated members served per medication, number of claims processed, units dispensed, unit cost and total drug costs. This report will also furnish a breakdown of total unduplicated clients served by HIAP (new and active), how many are receiving 1-2 drugs, 3-4 drugs or 5+ drugs per anti-retroviral therapy, and a breakdown of unduplicated clients served by age category (0-2, 3-12, 13-24, 25-44, 45-64 and 65+). The monthly report is due the 20th of the following month. The quarterly report is due 20 days after the close of the quarter: (April 20, July 20, October 20, and January 20). The annual reports are due 30 days after March 31, the close of Ryan White Part B Program/ADAP year (April to March) and 30 days after December 31, the close of calendar year (January to December).

e. (HIAP-5) Monthly, Quarterly and Annual HIAP Utilization Summary Report for Rebates: In Excel format by Drug Manufacturer include the number of claims, units, plan cost, ingredient cost and ingredient cost per unit for each Product Name. The monthly report is due the 20th of the following month. The quarterly report is due 20 days after the close of the quarter: (April 20, July 20, October 20, and January 20). The annual reports are due 30 days after March 31, the close of Ryan White Part B Program/ADAP year (April to March) and 30 days after December 31, the close of calendar year (January to December).

f. (HIAP-6) Member Monthly Expenditure Report: In Excel format, this report includes the following data elements: patient ID number, patient name and co-pays approved. This report is due the 20th day of the following month.

g. (HIAP-7) Member Monthly Current Balance: In Excel format, this report includes the following data elements: patient ID number, patient name, balance, and status (active or inactive). This report is due the 20th day of the following month.

F. BUDGET / ESTIMATED COST (20 POINTS)

Contractor shall present in a table format the estimated costs for the PBM implementation, system maintenance and claims processing phases. In a separate table, contractor shall also present the estimated costs for the HIAP implementation, system maintenance and claims processing phases. Costs for the implementation of payment of dispensing fees and the auditing program, must also be rendered separately.

Under the maintenance phase of each project, contractor shall specify the monthly cost of operating each project (including administration costs). In addition, under the claims processing phase of each project, contractor shall point out the cost of each transaction fee (adjudicated/ paid) and the cost of each processing fee per transaction.

The proposer shall submit a detailed cost estimate per each of the items that have been described in Section D, on Description of Services Required. The proposer shall submit a cost estimate for all the reports itemized in the Data Requirements Section.

The estimated cost must be justified through a narrative that will provide information about the staff involved in the project, the cost per hour and the number of hours it would take to perform the proposed service, the period to be deemed complete and the total in dollars and cents it would cost.

Contractor shall state the monthly and annual cost per patient, for both projects.

G. IMPLEMENTATION PLAN (30 POINTS)

Contractor must attach with the proposal an implementation (work) plan that describes the when, how, where why and who per each service requested under each of the two projects: PBM and HIAP. This plan shall include activities, cost per activity, timeline, product expected and person(s) responsible(s) of developing and implementing each activity.

H. PAYMENT METHOD

The payment method will be **cost reimbursement**, after the required and appropriate presentation of a monthly invoice.

VI. ASSESMENT CRITERIA

Each proposal received will be evaluated based on the following criteria:

| | ASSESMENT CRITERIA | TOTAL VALUE | POINTS AWARDED |
|------------------|-----------------------------------------|--------------------|-----------------------|
| A | Format | 2 | |
| B | Cover Letter | 2 | |
| C | Description of the organization | 5 | |
| D | Description of Services Required | | |
| | ---As a PBM | 15 | |
| | ---As a HIAP | 15 | |
| E | Data Requirements | 5 | |
| F | Budget/ Estimated Cost | 20 | |
| G | Implementation (Work) Plan | 30 | |
| Sec. VIII | Documents Required | 5 | |
| Sec. IX | Table of Contents | 1 | |
| | Total Points | 100 | |

VII. PERFORMANCE MEASURES

- The PRDoH may conduct periodic evaluations of PBM's compliance with the terms and conditions of the contract that will be engage, including, but not limited to, the operational functions, quality, appropriateness, timeliness, and reasonableness of cost and administrative expenses.
- The PRDoH and PBM will be responsible for monitoring contract compliance. Said program may include compliance evaluation of the following aspects:
 - a. Pharmacy Network and credentialing
 - b. Reporting and Claims Reporting System
 - c. Drug Utilization Review and Evaluation
 - d. Fraud and abuse
 - e. Financial requirements and audits
 - f. Cost of services
 - g. Information Systems
 - h. Services to beneficiaries, pharmacies and participating providers shared responsibility with Contracted Entities)
 - i. Electronic standards, security and privacy compliance as provided by HIPAA
 - j. State and Federal Rules and Regulations compliance
- The PBM shall provide the PRDoH and other authorized entities the right of access to its facilities at all reasonable times, to monitor and evaluate performance, compliance, and/or quality assurance under this contract on behalf of the PRDoH.

- Regarding the Health Insurance Assistance Program, the following performance measures will be used, in part, to assess Contractor's effectiveness in providing the services described in this Request for Proposal (RFP), without waiving the enforceability of any of the terms of the RFP. All referenced plans, policies, procedures, and schedules must be made available on a timely basis for on-site review and must be consistent with PRDoH policies.
 - Serve all ADAP-HIAP clients as provided under this contract, including paying prescriptions claims as needed each month for each recipient enrolled.
 - Submit required program data within the timeframes given in the final, approved work plan.
 - Resolve payment errors regarding private health insurance plans within the timeframes given in the final, approved work plan.
- Convene (i.e., organize and conduct), at least quarterly, a Puerto Rico ADAP Health Insurance Assistance Program/Pharmacy Benefits Manager (ADAP-HIAP/PBM) contractor conference call to discuss fiscal, programmatic, and operational issues that occurred during the previous quarter. The PBM shall submit a written summary of each call to PRDoH within two (2) weeks of the call. PRDoH may request an action plan from the PBM regarding fiscal, programmatic, and operational issues or deficiencies that were identified. Such action plans are due to PRDoH within two (2) weeks of the date they are requested. Contractor must take actions directed by PRDoH following the agency's review of the plan submitted and must do so within the timeframes directed by PRDoH. PRDoH also reserves the right to direct actions, which the Contractor must follow, to address issues/deficiencies identified during such conference calls without first requesting an action plan from the Contractor.

VIII. DOCUMENTS REQUIRED (5 POINTS)

The following documents **must** be attached with the proposal.

- A. Certifications if a Corporation or a Limited Liability Company (LLC)
 1. Certificate of Incorporation.
 2. Certificate of filing Annual Reports to the Government of Puerto Rico Department of State.
 3. Certificate of compliance with Act No. 144 of August 10, 1995, as amended, known as the "General Corporation Law of 1995" issued by the Department of State ("Good Standing").
 4. Affidavit stating that neither the Corporation nor any of its principal officers has been convicted of crimes constituting fraud, embezzlement or illegal appropriation of public funds listed in the Law No. 458 of December 29, 2000, as amended.

5. New Ban on whether the organization has a lawsuit against the commonwealth.

B. Certifications if a Society

1. Document of Society
2. Certification that the members of the Society and their spouses are not public servants, neither have they been for the past two years.
3. Affidavit stating that neither the Society nor any of its principals has been convicted of crimes constituting fraud, embezzlement or illegal appropriation of public funds listed in the Law No. 458 of December 29, 2000, as amended.

C. Copy of last annual federal and/or local state income tax return form.

D. Financial Statement.

Must submit an audited financial statement certified for a Public Accountant (CPA), whose closing date is located in the period between (15) months preceding the date of delivery of documents required for evaluation. It is required that all audited financial statement includes the following reports:

1. Cash Flow Statement
2. Statement of Revenue and Expenses
3. Financial Statement
4. Financial Statement Notes

E. Certified copy of any license required by state or federal law to operate its business in the Commonwealth of Puerto Rico.

F. The PRDoH Office of Contracts will required other documents necessary to formalize a contract with the agency.

IX. TABLE OF CONTENTS (1 POINT)

The proposal submitted must have a Table of Contents listing by pages all of the sections solicited and required in this RFP.