ALABAMA DEPARTMENT OF PUBLIC HEALTH

Bureau of Communicable Disease

Division of HIV Prevention & Care

REQUEST FOR PROPOSALS (RFP)

FOR

HIV/AIDS DIRECT CARE SERVICES

Pharmacy Benefits Management for the
AIDS Drug Assistance Program (ADAP)

U.S. Department of Health and Human Services
Health Resources and Services Administration (HRSA)
HIV/AIDS Bureau (HAB)
Division of State HIV/AIDS Programs

HIV Care Grant Program – Part B
States/Territories Formula and AIDS Drug Assistance Program
HRSA-17-036
Catalog of Federal Domestic Assistance (CFDA) No. 93.917

November 3, 2017

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ACRONYMS

1. ADAP - AIDS Drug Assistance Program
2. ADAP-Rx – ADAP Prescription Only Coverage
3. ADPH - Alabama Department of Public Health
4. ADR – ADAP Data Report
5. AIAP - Alabama Insurance Assistance Program
6. AWP - Average wholesale price
7. BCBS - Blue Cross Blue Shield
8. CMS - Centers for Medicare and Medicaid Services
9. DHPC - Division of HIV Prevention and Care
10. FDA – Food and Drug Administration
11. FIPS - Federal Information Processing Standard 140-2
12. HIPAA - Health Insurance Portability and Accountability Act of 1996
13. HiTECH - Health Information Technology for Economic and Clinical Health
14. HRSA - Health Resources and Services Administration
15. MEDCAP - Medicare Part D Client Assistance Program
16. NCHHSTP - National Center for HIV/AIDS, Viral Hepatitis, STD, and TB Prevention
17. NCPDP - National Council on Prescription Drug Programs
18. NIST - National Institute of Standards and Technology
19. PBM - Pharmacy Benefits Manager
20. PCN - Processor Control Number
21. PDP - Prescription Drug Plan
22. PLWH - People living with HIV
23. POS - Point-of-sale
24. PPACA - Patient Protection and Affordable Care Act
25. RFP - Request for Proposals
26. RWHAP - Ryan White HIV/AIDS Program
27. Rx BIN - Prescription Benefit International Number
28. TrOOP - True Out Of Pocket

INTRODUCTION

A. Background

The Alabama Department of Public Health (ADPH), Division of HIV Prevention and Care (DHPC) will utilize Ryan White HIV/AIDS Program (RWHAP) Part B Base grant funds in support of a comprehensive system of care that ensures ongoing access to high quality HIV care, treatment, and support services for people living with HIV (PLWH). Alabama has over 14,000 PLWH, with approximately 650 to 700 newly diagnosed cases reported each year. An estimated one in six (16 percent) PLWH in Alabama are unaware of their infection and, thus, are not receiving medical care to manage their disease and achieve viral suppression. Alabama's RWHAP Part B improves access to care and optimizes outcomes for qualifying PLWH, while reducing HIV-related health disparities and inequities, in support of the HIV Care Continuum Initiative and the National HIV/AIDS Strategy (NHAS) 2020 goals. Financial eligibility for Alabama's RWHAP Part B is currently set at 400 percent of the federal poverty level.

Alabama's RWHAP Part B will use grant related funds to pay for allowable services, including AIDS Drug Assistance Program (ADAP) only medication assistance, ADAP-funded health and dental insurance assistance, and Part B core medical and support services. Alabama's RWHAP Part B allocates approximately 70 percent of federal grant funds to ADAP and 20 percent to Part B core medical and support services. The remaining 10 percent of federal grant funds are allocated to administration, planning and evaluation, and clinical quality management. Overall, almost 90 percent of federal grant funds are allocated to core medical services, including ADAP and Part B core medical services, with the remaining 10 percent allocated to support services.

Alabama is not a Medicaid expansion state. In addition, there are a limited number of medical providers that provide care to HIV infected individuals, which has resulted in the creation of an HIV care and services system outside the private medical sector primarily funded by the RWHAP. Clients living in rural areas often rely on local health departments or Ryan White funded providers to meet their care and service needs.

Alabama's ADAP provides medication and insurance services for low income, uninsured or underinsured PLWH in Alabama. In addition to medication assistance, two forms of health insurance assistance are provided: (1) a Blue Cross Blue Shield (BCBS) health insurance plan purchased off the Marketplace known as the Alabama insurance assistance plan (AIAP) and (2) the Medicare Part D client assistance program (MEDCAP), which helps eligible PLWH who do not qualify for low income subsidy assistance, to pay co-pays and premiums associated with Medicare Part D. ADAP funding ensures medications from all Food and Drug Administration (FDA) approved antiretroviral drug classes are available on the ADAP Formulary, in compliance with Health Resources and Services Administration (HRSA) requirements. In addition to antiretroviral therapy, Alabama's ADAP Formulary contains medications used to treat opportunistic infections and complications of HIV disease as well as other medications.

Alabama's ADAP is registered as hybrid Direct Purchase and Rebate option, purchasing medications directly for ADAP prescription only (ADAP-Rx) clients at sub-340B

discount pricing from Alabama's contracted sole source drug wholesaler and filing for 340B rebates from drug manufactures for ADAP insurance assistance clients. ADPH currently contracts with a single, central pharmacy located in Birmingham, Alabama to provide medication ordering, dispensing, and shipping for ADAP-Rx clients. The contracted ADAP pharmacy also provides retail, non-340B medication shipments for MEDCAP insurance assistance clients enrolled in Medicare Part D prescription drug coverage plans. By utilizing this method, the possibility of 340B medications being dispensed for MEDCAP clients, and subsequent 340B discount duplication upon 340B rebate submission to drug manufactures, is eliminated. Clients enrolled in AIAP may utilize any in-network pharmacy as defined by BCBS of Alabama. Program policies prohibit those pharmacies from filling prescriptions with 340B medications. Each pharmacy claim must be accompanied by a signed statement from the pharmacy affirming that 340B medications were not used to fill AIAP prescriptions, thus avoiding duplication of 340B discounts during the rebate submission process.

As of September 2017, approximately 900 clients receive their medications from the ADAP central pharmacy. This includes 810 ADAP-Rx clients and 90 Medicare Part D insurance assistance clients. AIAP has approximately 1,800 active clients.

B. Goals and Objectives

The goal of the Pharmacy Benefits Manager (PBM) Request for Proposals (RFP) is to improve the health outcomes of low income PLWH in Alabama. This goal can be achieved and maintained through several key objectives:

1. Coordinate with DHPC staff to assure that eligible clients are able to access their medications real time, or as close to real time as possible. Currently, approximately 810 individuals receive ADAP-Rx services, but this number will fluctuate during and after the insurance marketplace open enrollment and potential programmatic changes proposed by the new federal administration.

2. Maintain a network of pharmacies for underinsured and uninsured ADAP-Rx program participants that assures equitable geographical availability of medication, as well as one or more mail order options for clients who indicate that they have challenges in accessing transportation to visit a "brick and mortar" pharmacy location.

3. Make payments to participating pharmacies for cost shares (e.g., co-payments, coinsurance payments, deductible requirements, etc.) and/or 340B direct purchase (e.g., 340B virtual conversion with pharmacy drug inventory replenished by the state contracted drug wholesaler) in a timely manner to assure continued access to services for clients and a positive network experience for pharmacies.

4. Interface with the DHPC ADAP database as close to "real time" as possible in order to facilitate timely client eligibility and access to ADAP medication services.

5. Provide DHPC on-demand access to real-time client, service, and financial data.

6. Provide client, service and financial data in an importable format in compliance with all HRSA-defined and Alabama-specific reporting requirements (e.g., annual ADR).

7. Initiate and maintain an electronic data system that allows for client eligibility information to be viewed by DHPC staff and community partners as close to "real time" as possible, in order to facilitate timely enrollment and re-certification.

C. Purpose of RFP

The purpose of this RFP is to solicit proposals from qualified proposers that provide PBM services, including claims adjudication, coordination of benefits and point-of-sale (POS) processing for its clients. The contract will begin April 1, 2018, and the annual budget will be contingent upon the availability of federal funding. Only proposals from PBM with a **minimum of ten years** proven experience providing PBM services for state and/or territorial ADAP programs will be considered.

A contract is necessary to provide PBM services to all eligible clients with coverage through ADAP, including insured, underinsured, and uninsured clients. The successful proposer will implement and maintain an efficient and cost-effective program with a comprehensive distribution network of pharmacies, including at least one mail order pharmacy option, that provides services to eligible clients residing in all 67 counties in Alabama.

II. ADMINISTRATIVE INFORMATION

A. Invitation To Propose

The ADPH, DHPC is soliciting proposals from proposers who are qualified and experienced with managing ADAP pharmacy benefit services. Proposers shall serve as the PBM to the Alabama RWHAP Part B ADAP, providing Medication Therapy Management for ADAP clients. The proposer may also serve as the virtual 340B contract pharmacy network facilitator for clients if this service option is chosen during the contract implementation.

B. Proposer Inquiries

ADPH will accept written inquiries regarding the requirements of the RFP or scope of services to be provided during the dates specified in the Acquisition Schedule. Inquiries and requests for clarification of the content of this RFP must be received via email by the PBM point of contact during the dates specified in the Acquisition Schedule.

Any and all questions deemed to require an official response will be posted during the dates specified in the Acquisition Schedule to the Grants and Proposals web link, under Frequently Asked Questions (FAQs):
http://www.alabamapublichealth.gov/hiv/grants.html.

Action taken as a result of verbal discussion shall not be binding to the department. Only written communication and clarification shall be considered binding.

C. Acquisition Schedule

Press Release	November 13, 2017
RFP Release	November 13, 2017
Letter of Intent to Propose	November 17, 2017
Written Questions Submitted	November 20-22, 2017, at 5:00 PM CST
Blackout Period Begins	November 22, 2017, at 5:00 PM CST
Answers to Written Questions Posted	November 28, 2017
Proposal Due (no exceptions)	December 8, 2017, by 5:00 PM CST
Onsite Presentations/Demonstrations	December 13 and 14, 2017
Proposal Review	December 15, 2017
Award Announcement	December 18, 2017
Contract Negotiations Begin	January 2, 2018
Contract Begins	April 1, 2018

D. RFP Addenda

In the event it becomes necessary to revise any portion of the RFP for any reason, the department shall post addenda, supplements, and/or amendments the following web address: http://www.alabamapublichealth.gov/hiv/grants.html. It is the responsibility of the proposer to check the website for addenda to the RFP, if any are necessary.

E. On Site Presentations/Demonstrations

All onsite presentations and demonstrations will be limited to one hour with an additional 30 minutes for questions and answers. All travel expenses will be the proposer's responsibility.

F. Pharmacy Benefits RFP Point of Contact

Allison R. Smith, MPH
Direct Care Services Program Director
Division of HIV Prevention and Care
Alabama Department of Public Health
201 Monroe Street, RSA Tower - Suite 1400
Montgomery, Alabama 36104

E-mail: allison.smith@adph.state.al.us
Website: http://www.alabamapublichealth.gov/hiv/

Questions must be submitted in written format to Allison Smith. All communications between proposers and other ADPH staff members concerning this RFP shall be strictly prohibited. During the blackout period, all communication shall be conducted with the blackout period point of contact (See Section IV. Proposal, I. Blackout Period). Failure to comply with these requirements shall result in proposal disqualification. This RFP is available in PDF format at the following web link: http://www.alabamapublichealth.gov/hiv/grants.html.

III. SCOPE OF WORK

A. Project Overview

This scope of work generally describes the contractor's responsibilities under the PBM contract with the ADPH. ADPH and the selected contractor will negotiate minor modifications and changes to the Scope of Work.

The result of this contract will be coordination and access to formulary medications for all eligible program participants in all 67 counties in Alabama in an effective and efficient manner. The contractor will provide PBM services, including claims adjudication, coordination of benefits and POS processing services to eligible clients. The contractor will maintain a comprehensive network of pharmacies and must provide client level data that meets the requirements of the DHPC and the Ryan White HIV/AIDS Treatment Extension Act of 2009 (Public Law 111-87, October 30, 2009). Eligibility determination services for all of the persons applying to Alabama's RWHAP Part B ADAP will be performed by a separate entity. The contractor must have or be able to develop a mechanism to electronically receive and provide eligibility information that matches the data requirements of DHPC and HRSA. Note: HRSA defines data requirements, which may change on an annual basis.

B. Deliverables

Pharmacy Network: Contractor shall create, maintain and/or expand a pharmacy distribution network within Alabama for both insured and uninsured program participants, and contract with at least one established and operational single source mail order distribution system capable of serving the needs of eligible clients in all 67 counties of the state. The contractor shall:

1. Establish and maintain a network of pharmacy locations capable of providing walk-in service to 100 percent of ADAP program participants, while ensuring communication of billing procedures, access to client eligibility information, facilitation of claims adjudication and coordination of benefits.

2. Communicate with the pharmacy network any program updates or changes via broadcast fax, email or mail, and provide copies of all pharmacy and client correspondence to the DHPC Direct Care Program Director or their designee.

3. Provide payment to retail network pharmacies on a regular basis in accordance with National Council on Prescription Drug Programs (NCPDP) Guidelines. The Contractor must also provide detailed invoice information to DHPC staff on all reimbursable charges incurred for each invoice period, such as the cost of medication, applicable copayments and deductible charges, dispensing fees, etc.

4. Not receive payment from DHPC for ineligible charges, and any payments made for ineligible charges will be reimbursed to DHPC.

5. Have an established mail order pharmacy as an option to clients that:

a. Ensures that all eligible clients receive mail order prescriptions less than five (5) working days from the time the prescription is submitted by the prescribing provider on behalf of the client to the contracted pharmacy.

b. Addresses special shipping needs of homeless and transient ADAP clients by ensuring mail order pharmacies ship prescriptions to client's preferred address.

c. Confirms delivery of medications to DHPC, to the client's preferred address, assumes responsibility for costs associated with repeat delivery events and works with DHPC on loss reduction activities.

6. Have a documented and routinely tested emergency response/preparedness plan that, once implemented, has operations of retail claims network and/or mail order pharmacy back to 95 percent within 72 hours of the conclusion of the emergency. On an annual basis, the contractor must provide the DHPC Direct Care Director or their designee with documentation of this plan and frequency of testing, as well as any contingency plans.

7. Transition clients to either mail order and/or the retail walk-in pharmacy network within 72 hours if there is an interruption of service in either distribution system that requires implementation of the emergency response/preparedness plan.

8. Enter all data into, or prepare data for import into the Alabama RWHAP Part B ADAP database (currently a home grown database, but transitioning to CAREWare, a HRSA-developed data management system). CAREWare or other ADAP database software, relevant software updates and all relevant training will be provided upon contract negotiation and execution.

Claims Processing: Contractor shall provide an efficient electronic system for POS claims adjudication and coordination of benefits; make payments to network pharmacies; coordinate with third-party payers; provide high level electronic data management; and support member services. Electronic claims processing capacity must be sufficient to allow pharmacies to do online adjudication and split billing, so that pharmacies or clients will not need to submit manual claims for secondary payment. The contractor shall:

1. Allow for coordination of primary, secondary and tertiary payers of prescription claims. Prescription claims must always pay with DHPC as final payer based on other payers' payment of claim using "lesser of" logic. Alabama's RWHAP Part B will always be the payer of last resort.

2. Retain the primary payer status of an insurance policy or Medicare Part D Prescription Drug Plan (PDP) so that Alabama's RWHAP Part B will always be considered a secondary payer.

3. Have the ability to transmit primary and/or secondary insurance information to the pharmacy.

4. Provide remote access to the contractor's claim system to include:

    a. Pharmacy locator;

    b. Real-time claim tracking/history to include retail, mail order and direct client reimbursement claims history;

    c. Drug formulary and pricing information;

    d. Client benefit level information;

    e. Client prescription history; and

    f. Prior Authorization.

5. Identify and report DHPC client enrollment in and eligibility for other third party payers, including (but not limited to) employer-based insurance and Medicare Part D.

6. Provide an automated process of ongoing screening for other prescription benefits for DHPC clients.

7. Have a detailed, mapped recoupment process for instances where other prescription coverage has been identified, so that claims can be reversed and rebilled to other payers. Facilitate and report to DHPC staff the recoupment process and progress. Utilize outside vendors and software programs as necessary to communicate with DHPC and/or the pharmacy.

8. Coordinate coverage and benefits with insurance providers, including (but not limited to) employer-based insurance, Medicare Part D, in order to assure that applicable expenditures are credited toward meeting the client's minimum/maximum out of pocket expenditure requirements.

    a. Oversee the payment of medication deductibles, coinsurance, co-payments and costs of medications during any gaps in coverage for clients enrolled in third party insurance providers.

    b. Ensure that the DHPC does not pay for a medication that is not on the formulary for the specific insurance plan in which an individual client is enrolled.

    c. Establish a network of pharmacies that will be able to split the billing of prescription drug costs between third party insurance plans and DHPC. The network of pharmacies must be geographically dispersed throughout the state of Alabama and have at least one mail order pharmacy option available to all eligible ADAP clients.

9. Coordinate coverage and benefits with Medicare Part D PDPs and ensure that

applicable expenditures are credited toward meeting the client's True Out Of Pocket (TrOOP) expenditure requirement.

a. Oversee the payment of medication deductibles, coinsurance, co-payments and costs of medications during any gaps in coverage for clients enrolled in Medicare Part D PDPs.

b. Coordinate benefits with all Medicare Part D PDPs in the state of Alabama, without discrimination, based upon the Medicare Part D PDP in which the individual is enrolled, as clarified by the Centers for Medicare and Medicaid Services (CMS) Coordination of Benefits guidelines, and any subsequent updates to these guidelines.

c. Ensure that the DHPC does not pay for a medication that is not on the formulary for the specific Medicare Part D PDP in which an individual client is enrolled.

d. Establish a network of pharmacies that will be able to split the billing of prescription drug costs between third party insurance plans including Medicare Part D PDPs and DHPC. The network of pharmacies must be geographically dispersed throughout the state of Alabama and have at least one mail order pharmacy option available to all eligible Alabama ADAP clients.

10. Participate in data share with CMS to ensure that paid claim data is captured by the CMS TrOOP Facilitation Contractor in the claim response from the payer to the pharmacy provider.

a. Coordinate coverage and benefits with CMS and the Medicare Part D PDP and ensure that applicable expenditures are credited toward meeting the enrollee's true out-of-pocket expenditure requirement. As part of this duty, the contractor shall participate in the electronic data exchange processes as specified by CMS for reporting enrollee true out-of pocket expenses to the CMS data Contractor.

b. Maintain for DHPC a unique Prescription Benefit International Number (Rx BIN) and a unique Pharmacy Benefit Processor Control Number (PCN) to code for coverage that is supplemental to Medicare Part D. The Input and Response Files used by the CMS Data Sharing Agreement program include data fields for both Rx BIN and PCN reporting. This unique coding will assure that the supplemental paid claim is captured by the CMS TrOOP Facilitation Contractor in the claim response from the payer to the pharmacy provider. The TrOOP Facilitation Rx BIN(s) or PCN(s) will be separate and distinct from a PBM's standard Rx BIN and PCN. Rx BIN(s) and/or PCN(s) may be obtained from the American National Standards Institute located at http://www.ansi.org/ or the NCPDP located at http://www.ncpdp.org/.

Drug Pricing: Contractor shall continuously maximize the cost effectiveness of DHPC through drug pricing negotiation. The contractor must:

1. Provide monthly reporting of up-to-date drug pricing to include Average Wholesale Price (AWP) and contracted AWP discounted rate.

2. Agree to biannual renegotiation of contracted AWP discount rate, as well as dispensing and transaction fees (when applicable), in order to pass along further savings to the program. This will ensure that DHPC program is able to respond to the changing needs of a program participant population that may increase or decrease significantly based on the proposed programmatic changes under the new federal administration. At a minimum, AWP discounted rate must increase by one-half (0.5%) of one percent for every year the contract remains in place.

3. Ensure a discounted rate for mail order prescriptions at least three and one-half percent (3.5%) higher than retail rate with biannual renegotiation of mail order AWP discount based on the increase in number of patients utilizing mail order delivery of medications.

Note: AmerisourceBergen is Alabama's current contracted direct purchase sole source drug wholesaler for Alabama's RWHAP Part B ADAP-Rx direct purchase option.

Technical/Customer Support: Contractor shall provide knowledgeable staff who are readily available to answer calls or emails from DHPC staff, Ryan White Part B providers, clinicians, providers, pharmacists, and clients. The contractor shall:

1. Provide technical guidance to DHPC staff and pharmacy service providers on inquiries including but not limited to access to medications supported by DHPC resources, third party coordination of benefits, claims processing for both adjudication and reimbursement, data collection systems, and billing/invoicing.

2. Maintain current contact information for network pharmacies, prescribing physicians and insurance companies.

3. Assign a designated phone number to respond to client inquiries. The individual or individuals who staff this phone line must have customer service experience, be trained and knowledgeable of the program's services, and have access to client-level information to respond to participants' inquiries regarding program enrollment and coverage information. This person or persons must also have a designated back up.

4. Maintain a toll-free client support number, which will be staffed (at a minimum) from 7:00 a.m. to 5:00 p.m. Central Time (CT) Monday through Friday, and 10:00 a.m. to 5:00 p.m. CT on Saturday, excluding federal holidays. The toll-free client support number must also be available in the event of DHPC staff furlough, government shut down, emergency evacuation or other unforeseen events.

5. Maintain a help desk that will provide technical assistance to network pharmacies for billing and claims system issues. At a minimum, the help desk staff must be readily available between the hours of 7:00 a.m. to 7:00 p.m. Central Time (CT), Monday

through Friday. In place of 24 hour access, an automated phone system must be maintained for telephone calls received after hours with response to messages occurring on the next business day.

6. Maintain, at minimum, monthly contact via in person meeting or phone call with DHPC staff to review and discuss contract objectives and program performance, share challenges and barriers to progress and propose resolutions, as well as convey general program updates and specific changes in staffing. The DHPC Direct Care Director or their designee will serve as the primary contact for communication with DHPC staff.

7. Prepare a monthly call log that documents problem calls, and include, at a minimum: date, caller, type of problem, how the problem was resolved, and when it was resolved.

Data System: Contractor shall maintain a data system that is capable of receiving and managing client eligibility information to use for claims processing, monthly invoicing, reports and billing. The contractor shall:

1. Provide and manage a data system to collect client level data on each person for whom payment was provided on behalf of DHPC. This information will be provided to DHPC no later than the 15th of each month, following the month in which services were provided. DHPC will specify the format for the download.

2. Maintain a data system capable of implementing and monitoring cost containment measures (such as annual expenditure caps on client services, medication prior authorizations, etc.) established by DHPC.

3. Provide DHPC with access to a web-based system that will allow DHPC staff to view live claims adjudication, and provide training for DHPC staff on the use of the system. The system must be compatible with Internet Explorer 11.0 or another search engine supported by ADPH information technology.

4. Provide DHPC on-demand access to downloadable real-time client, service, and financial data in one of the following formats: XML, CSV, XLSX, or ACCDB.

5. Provide DHPC on-demand access to ad hoc reporting tools through the contractor's PBM data system.

6. Provide claims level data upon request, in order to complete required reports for pharmaceutical manufacturers to achieve the collection of rebates.

Reporting: Contractor shall provide all required annual, semi-annual, quarterly, and monthly reports and exchange of data. The contractor shall:

1. Submit required program data by the deadlines set forth in the final, approved contract.

2. Provide the following deliverables within the specified timeframes, as required by HRSA or DHPC:

Report	Schedule	Description
Drug Pricing Summary	Quarterly: due to DHPC last day of the month following the end of the calendar year quarter.	Summary of all drug prices and drug price changes. Fields & format to be determined during contract negotiation.
ADAP Enrollment Status Summary	Quarterly: due to DHPC last day of the month following the end of calendar year quarter.	Individual & aggregate report on client enrollment/disenrollment for each service type. Fields & format to be determined during contract negotiation.
ADAP Program Aggregate Utilization	Monthly: Due to DHPC by 15th of following month.	Summary report on service utilization. Fields & format to be determined during contract negotiation.
ADAP Adherence Summary	Due with monthly invoices.	List of clients who were late or missed picking up refills. Fields & format to be determined during contract negotiation.

3. Capture required information for payment and analysis of program statistics, including HRSA ADAP reporting requirements and drug manufacturer rebate requests.

4. Generate the two required HRSA ADAP reports listed below.

Report	Schedule	Description
ADAP Quarterly Report	Due to DHPC the 20th of the month following the end of the calendar year quarter.	Aggregate report using HRSA's required format. (See **Attachment D** for reporting instructions.)
ADAP Data Report (includes client level data)	Due to DHPC 30 days prior to the HRSA deadline (HRSA deadline is to be decided.)	See **Attachment D** for example reporting instructions (updated by HRSA annually)

5. Ensure network pharmacies resolve payment errors made to third party insurance and Medicare Part D PDPs within 90 days.

6. Report DHPC out-of-pocket payments to the CMS TrOOP facilitator by the fifth of each month, following the month in which payments were provided.

7. Schedule, organize and conduct, at least quarterly, a DHPC/contractor conference call to discuss programmatic issues that occurred during the previous quarter. The contractor shall submit a written summary of each call to DHP within ten (10) business days of the call.

8. DHPC may request an action plan from the contractor regarding programmatic issues or deficiencies that are identified. Such action plans must be submitted to DHPC within ten (10) business days of the date they are requested. The contractor must address any corrective actions identified by DHPC staff following the review of the current issues or deficiencies, and must do so within the timeframes directed by DHPC.

Monthly Payment: The contractor must provide monthly services, employ staff, pay claims, and perform all other required work prior to receiving payment from DHPC. The contractor shall:

1. Reimburse the network pharmacies in accordance with NCPDP Guideline timeframe for prescriptions filled for eligible clients. The contractor will then also submit an invoice for review to DHPC by the 15th of each month, following the month in which services were provided. Reimbursement to the contractor will be made once the invoice review process is complete.

2. Generate and transmit invoices that include all costs for claims processed.

3. Provide by the 10th of each month, following the month in which services were provided, a data file or a complete data set that contains all of the previous month's claims in client level detail and in an electronic format that can be imported into CAREWare (or the data system selected for use by DHPC) or matched with data that already exists in the DHPC ADAP database (currently home grown, transitioning to CAREWare).

4. Add or remove specific drugs to the uninsured formulary as directed by DHPC staff. DHPC defines the formulary. The formulary includes individual drugs and whole classes of drugs.

Client Confidentiality and Data Security. The contractor must be compliant with all DHPC and Health Insurance Portability and Accountability Act (HIPAA) of 1996 Guidelines, the federal Health Information Technology for Economic and Clinical Health (HiTECH) Act of 2009, and the National Center for HIV/AIDS, Viral Hepatitis, STD, and TB Prevention's (NCHHSTP) Data Security and Confidentiality Guidelines for HIV, Viral Hepatitis, Sexually Transmitted Disease, and Tuberculosis Programs: Standards to Facilitate Sharing and Use of Surveillance Data for Public Health Action (2011). Confidential information shall include sensitive health and treatment information, as well as client personal identifiers, potentially identifying information, and any other information provided to the contractor for which confidentiality was assured when the individual or department provided the information.

Extremely stringent standards of client confidentiality must be maintained, and the Contractor should perform, or subcontract with a qualified entity to perform, routine technological and physical risk assessments. The use of client information for commercial purposes shall be prohibited. Likewise, the contractor shall not publish any

information about program participants, even in the aggregate, without DHPC review and prior written permission.

Conflict of Interest: Neither the contractor nor any subcontractors shall have ownership nor any financial interest in any pharmacies in Alabama which will participate in the provider network created or utilized under the contract awarded through this RFP.

The contractor and any subcontractors must divulge all formal or informal relationships with pharmaceutical manufacturers. These relationships must be fully disclosed to DHPC prior to the effective date of the contract and updated as appropriate.

Staffing and Organization Plan: Contractor shall provide a Staffing and Organization Plan to complete all aspects of the proposed work.

Quality Assurance/Monitoring Requirements:

1. Contractor shall produce monthly, quarterly, and annual reports to assist DHPC staff in monitoring service utilization and expenditures and to ensure that the program is being implemented and delivered as required.

2. Within ninety (90) calendar days of the contract start date, the contractor shall work collaboratively with key DHPC staff to establish a quality assurance and monitoring protocol. This protocol must include, at a minimum, a plan to internally review 5 percent of all active client records on a quarterly basis. For each of the client records reviewed, the contractor must verify the accuracy of information entered into or imported into CAREWare (or the data system selected for use by DHPC).

   The minimum data elements to verify shall include:

   a. Client profile and health insurance information;

   b. Number of services provided;

   c. Total expenditures from the beginning of each grant year and the total expenditure for each quarter; and

   d. Number of payments.

3. The contractor will also be subject to an annual in-person or virtual site visit from a cross-disciplinary DHPC monitoring and review team.

4. Contractor shall collaborate with DHPC staff to conduct annual client and provider satisfaction surveys.

5. Prior delivering services, the contractor must have a policy/protocol outlining client "Rights and Responsibilities" and have a detailed client grievance policy in effect.

Transition Plan: Contractor must have a task-specific and time-limited transition plan that will successfully implement contractor responsibilities upon initiation of the contract, and transfer contractor activities upon termination of the contract, without interrupting services to clients.

C. Fraud and Abuse

1. The contractor shall have internal controls, policies and procedures in place that are designed to prevent, detect, and report known or suspected fraud and abuse activities.

2. Such policies and procedures must be in accordance with state and federal regulations. Contractor shall have adequate staffing and resources to investigate unusual incidents and develop and implement corrective action plans to assist the contractor in preventing and detecting potential fraud and abuse activities.

D. Technical Requirements

The contractor will be required to transmit all non-proprietary data which is relevant for analytical purposes to DHPC on a regular schedule in an agreed upon format. Final determination of relevant data will be made by DHPC based on collaboration between both parties. The schedule for transmission of the data will be established by DHPC and dependent on the needs of the department related to the data being transmitted. The agreed upon file formats for this purpose will be transmitted via secure file transfer protocol to the department. Any other data or method of transmission used for this purpose must be approved via written agreement by both parties.

1. The contractor is responsible for procuring and maintaining hardware and software resources which are sufficient to successfully perform the services detailed in this RFP.

2. The contractor should adhere to state and federal regulations and guidelines as well as industry standards and best practices for systems or functions required to support the requirements of this RFP.

3. Unless explicitly stated to the contrary, the contractor is responsible for all expenses required to obtain access to DHPC systems or resources which are relevant to successful completion of the requirements of this RFP. The contractor is also responsible for expenses required for DHPC to obtain access to the contractor's systems or resources which are relevant to the successful completion of the requirements of this RFP. Such expenses are inclusive of hardware, software, network infrastructure and any licensing costs.
4. Any confidential information must be encrypted to the Federal Information Processing Standard (FIPS) 140-2 standards when at rest or in transit.

5. Contractor owned resources must be compliant with industry standard physical and procedural safeguards (National Institute of Standards and Technology (NIST) SP

800-114, NIST SP 800-66, NIST 800-53A, ISO 17788, etc.) for confidential information (HiTECH, HIPAA part 164).

6. Any contractor's use of flash drives or external hard drives for storage of DHPC data must first receive written approval from the department and upon such approval shall adhere to FIPS 140-2 hardware level encryption standards.

7. All contractor utilized computers and devices must:

a. Be protected by industry standard virus protection software which is automatically updated on a regular schedule.

b. Have installed all security patches which are relevant to the applicable operating system and any other system software.

c. Have encryption protection enabled at the Operating System level.

E. Subcontracting

1. The ADPH shall have a single prime contractor as the result of any contract negotiation, and that prime contractor shall be responsible for all deliverables specified in the RFP and proposal. This general requirement notwithstanding, proposers may enter into subcontractor arrangements, however, they should acknowledge in their proposals total responsibility for the entire contract.

2. Unless provided for in the contract with the ADPH, the prime contractor shall not contract with any other party for any of the services herein contracted without the express prior written approval of the department.

3. For subcontractor(s), before commencing work, the contractor will provide letters of agreement, contracts or other forms of commitment which demonstrate that all requirements pertaining to the contractor will be satisfied by all subcontractors through the following:

a. The subcontractor(s) will provide a written commitment to accept all contract provisions.

b. The subcontractor(s) will provide a written commitment to adhere to an established system of accounting and financial controls adequate to permit the effective administration of the contract.

F. Compliance With Civil Rights Laws

1. The contractor agrees to abide by the requirements of the following as applicable: Title VI and Title VII of the Civil Rights Act of 1964, as amended by the Equal Opportunity Act of 1972, Federal Executive Order 11246, the Federal Rehabilitation

Act of 1973, as amended, the Vietnam Era Veteran's Readjustment Assistance Act of 1974, Title IX of the Education Amendments of 1972, the Age Act of 1975, and contractor agrees to abide by the requirements of the Americans with Disabilities Act of 1990.

2. Contractor agrees not to discriminate in its employment practices, and will render services under this contract without regard to race, color, religion, sex, sexual orientation, national origin, veteran status, political affiliation, disability, or age in any matter relating to employment. Any act of discrimination committed by contractor, or failure to comply with these statutory obligations when applicable shall be grounds for termination of this contract.

G. Insurance Requirements

Insurance shall be placed with insurers with an A.M. Best's rating of no less than A-: VI. This rating requirement shall be waived for Workers' Compensation coverage only.

1. Contractor's Insurance

The contractor shall not commence work under this contract until it has obtained all insurance required herein, including but not limited to automobile liability insurance, Workers' Compensation Insurance and general liability insurance. Certificates of insurance, fully executed by officers of the insurance company shall be filed with the department for approval prior to commencement of work. The contractor shall not allow any subcontractor to commence work on his subcontract until all similar insurance required for the subcontractor has been obtained and approved. In the event of a claim or dispute of a claim, the department reserves the right to request copies of insurance policies. Said policies shall not hereafter be canceled, permitted to expire, or be changed without thirty (30) days written notice in advance to the department and consented to by the department in writing and the policies shall so provide.

2. Workers' Compensation Insurance

Before any work is commenced, the contractor shall obtain and maintain during the life of the contract, Workers' Compensation Insurance for all of the contractor's employees employed to provide services under the contract. In case any work is sublet, the contractor shall require the subcontractor similarly to provide Workers' Compensation insurance for all the latter's employees, unless such employees are covered by the protection afforded by the contractor. In case any class of employees engaged in work under the contract at the site of the project is not protected under the Workers' Compensation Statute, the contractor shall provide for any such employees, and shall further provide or cause any and all subcontractors to provide Employer's Liability Insurance for the protection of such employees not protected by the Workers' Compensation Statute.

3. Commercial General Liability Insurance

The contractor shall maintain during the life of the contract such commercial general liability insurance which shall protect contractor, the department, and any

subcontractor during the performance of work covered by the contract from claims or damages for personal injury, including accidental death, as well as for claims for property damages, which may arise from operations under the contract, whether such operations be by the contractor or by a subcontractor, or by anyone directly or indirectly employed by either of them, or in such a manner as to impose liability to the department. In the absence of specific regulations, the amount of coverage shall be as follows: Commercial general liability insurance, including bodily injury, property damage and contractual liability, with combined single limits of $1,000,000.

4. **Insurance Covering Special Hazards**
   Special hazards as determined by the department shall be covered by rider or riders in the commercial general liability insurance policy or policies herein elsewhere required to be furnished by the contractor, or by separate policies of insurance in the amounts as defined in any special conditions of the contract included therewith.

5. **Licensed and Non-Licensed Motor Vehicles**
   The contractor shall maintain during the life of the contract, automobile liability insurance in an amount not less than combined single limits of $1,000,000 per occurrence for bodily injury/property damage. Such insurance shall cover the use of any non-licensed motor vehicles engaged in operations within the terms of the contract on the site of the work to be performed thereunder, unless such coverage is included in insurance elsewhere specified.

6. **Subcontractor's Insurance**
   The contractor shall require that any and all subcontractors, which are not protected under the contractor's own insurance policies, take and maintain insurance of the same nature and in the same amounts as required of the contractor.

H. Resources Available to Contractor

The DHPC will have an assigned staff member who will be responsible for primary oversight of the contract. This individual will schedule meetings to discuss progress of activities and problems identified.

Utilization data provided by DHPC for the purpose of this RFP are estimates based on previous claims. Variation in future services, funding and utilization trends in any of the contract years will be based on the results of legislative challenges to the Patient Protection and Affordable Care Act (PPACA), and availability of federal funds for the Ryan White Care Act in the provision of Alabama's RWHAP Part B. Program participation and client service utilization could also be impacted by new guidance or requirements from federal or state administrations, and all of these variables should be considered in the proposer's calculation. Fees proposed will not be negotiated based on volume.

I. Contract Monitor

All work performed by the contractor will be monitored by the DHPC Pharmacy Benefits liaison, with support from other essential DHPC staff and supervision from the Direct Care Services Program Director or designee:

Pharmacy Benefits Liaison (position to be established)
Direct Care Services Program
Division of HIV Prevention and Care
Alabama Department of Public Health
201 Monroe Street, RSA Tower - Suite 1400
Montgomery, Alabama 36104

J. Term of Contract and Payment Terms

1. The contract resulting from this RFP shall commence on or near the date approximated in the Schedule of Events. The initial term of this contract shall be two (2) years. The initial contract can be extended for an additional three (3) years, through a two (2) year amendment and subsequent one (1) year amendment (i.e., potential contract term not to exceed five (5) years: two (2) year initial contract period, two (2) year amendment, and one (1) year amendment).

2. No contract/amendment shall be valid, nor shall the state be bound by the contract/amendment, until it has first been executed by the head of the using agency, or his designee, the contractor and signed by the Governor. The total initial contract term shall not exceed two (2) years. The continuation of this contract is contingent upon federal funding and other resources supported by the HRSA.

3. The contractor shall submit deliverables in accordance with established timelines and shall submit itemized invoices monthly or as defined in the contract terms. Payment of invoices shall be subject to approval of the PBM point of contact, Direct Care Program Director, or designee. Continuation of payment shall be dependent upon available funding.

4. Payments will be made to the contractor after written acceptance by the DHPC of the payment task and approval of an invoice. DHPC will make every reasonable effort to make payments within 45 calendar days of the approval of invoice and under a valid contract. Such payment amounts, for work performed, must be based on at least equivalent services rendered, and to the extent practical, will be connected to clearly identifiable stages of progress as reflected in electronic reports submitted with the invoices. Contractor will not be paid more than the maximum amount of the contract.

IV. PROPOSALS

A. General Information

This section outlines the provisions which govern determination of compliance of each proposer's response to the RFP. The department shall determine, at its sole discretion, whether or not the requirements have been reasonably met. Omissions of required information shall be grounds for rejection of the proposal by the department.

B. Contact After Solicitation Deadline

After the date for receipt of proposals, no proposer-initiated contact relative to the solicitation will be allowed between the proposers and ADPH until an award is made.

C. Antidiscrimination Clause

Contractor will comply with Titles IV, VI, and VII of the Civil Rights Act of 1964, the Federal Age Discrimination in Employment Act, Section 504 of the Rehabilitation Act of 1973, the Americans with Disabilities Act of 1990, and all applicable Federal and State laws, rules and regulations implementing the foregoing statutes with respect to nondiscrimination on the basis of race, creed, color, religion, national origin, age, sex, or disability, as defined in the above laws and regulations. Contractor shall not discriminate against any otherwise qualified disabled applicant for, or recipient of aid, benefits, or services or any employee or person on the basis of physical or mental disability in accordance with the Rehabilitation Act of 1973 or the Americans With Disabilities Act of 1990.

D. Rejection and Cancellation

Issuance of this solicitation does not constitute a commitment by ADPH to award a contract(s) or to enter into a contract after an award has been made. The department reserves the right to take any of the following actions that it determines to be in its best interest:

1. Reject, in whole or part, all proposals submitted in response to this solicitation.

2. Cancel this RFP.

3. Cancel or decline to enter into a contract with the successful proposer at any time after the award is made and before the contract receives final approval from the Governor.

E. Contract Award and Execution

1. The DHPC reserves the right to:

a. Make an award without presentations by proposers or further discussion of proposals received.

b. To enter into a contract without further discussion of the proposal submitted based on the initial offers received.

c. Contract for all or a partial list of services offered in the proposal.

2. The selected proposer shall be expected to enter into an ADPH contract. In no event shall a proposer submit its own standard contract terms and conditions as a response to this RFP. The proposer should submit with its proposal any exceptions or exact contract deviations that its firm wishes to negotiate. Negotiations may begin with the announcement of the selected proposer.

3. If the contract negotiation period exceeds thirty (30) calendar days or if the selected proposer fails to sign the final contract within fifteen (15) business days of delivery, the state may elect to cancel the award and award the contract to the next-highest-ranked proposer.

F. Assignments

Any assignment, pledge, joint venture, hypothecation of right or responsibility to any person, firm or corporation should be fully explained and detailed in the proposal. Information as to the experience and qualifications of proposed subcontractors or joint ventures should be included in the proposal. In addition, written commitments from any subcontractors or joint ventures should be included as part of the proposal. All assignments must be approved of by the department.

G. Determination of Responsibility

Determination of the proposer's responsibility relating to this RFP shall be made according to the standards set forth by the State of Alabama, and all applicable laws and codes. ADPH must find that the selected proposer:

1. Has adequate financial resources for performance, or has the ability to obtain such resources as required during performance.

2. Has the necessary experience, organization, technical qualifications, skills, and facilities, or has the ability to obtain them.

3. Is able to comply with the proposed or required time of delivery or performance schedule.

4. Has a satisfactory record of integrity, judgment, and performance.

5. Is otherwise qualified and eligible to receive an award under applicable laws and regulations.

Proposers should ensure that their proposals contain sufficient information for ADPH to make its determination by presenting acceptable evidence of the above to perform the contracted services.

H. Proposal and Contract Preparation Costs

The proposer assumes sole responsibility for any and all costs and incidental expenses associated with the preparation and reproduction of any proposal submitted in response to this RFP. The proposer to which the contract is awarded assumes sole responsibility for any and all costs and incidental expenses that it may incur in connection with: (1) the vendor presentation/demonstration; (2) the preparation, drafting or negotiation of the final contract; or (3) any activities that the proposer may undertake in preparation for, or in anticipation or expectation of, the performance of its work under the contract before the contract receives final approval from the ADPH. The proposer shall not include these costs or any portion thereof in the proposed contract cost. The proposer is fully

responsible for all preparation costs associated therewith even if an award is made but subsequently terminated by the department.

I. Blackout Period

The blackout period is a specified period of time during a competitive sealed procurement process in which any proposer, bidder, or its agent or representative, is prohibited from communicating with any state employee or contractor of the state involved in any step in the procurement process about the affected procurement. The blackout period applies not only to state employees, but also to any contractor of the state. "Involvement" in the procurement process includes but may not be limited to project management, design, development, implementation, procurement management, development of specifications, and evaluation of proposals for a particular procurement. All communications to and from potential proposers, bidders, vendors and/or their representatives during the blackout period must be in accordance with this solicitation's defined method of communication with the designated contact person. The blackout period begins after the submission of written questions as defined in the Acquisition Schedule and ends when the contract is awarded.

Designated contact person during blackout period:

Tijuana Tetter, Office Manager
Division of HIV Prevention and Care
Alabama Department of Public Health
201 Monroe Street, RSA Tower - Suite 1400
Montgomery, Alabama 36104

Office: 334.206.7030
E-mail: tijuana.tetter@adph.state.al.us

In those instances in which a prospective proposer is also an incumbent contractor, the State and the incumbent contractor may contact each other with respect to the existing contract only. Under no circumstances may the State and the incumbent contractor and/or its representative(s) discuss the blacked-out procurement. Any bidder, proposer, or state contractor who violates the blackout period may be liable to the State in damages and/or subject to any other remedy allowed by law. Any costs associated with cancellation or termination will be the responsibility of the proposer or bidder.

Notwithstanding the foregoing, the blackout period shall not apply to:

1. Duly noticed site visits and/or conferences for bidders or proposers.

2. Oral presentations during the evaluation process.

3. Communications regarding a particular solicitation between any person and staff of the procuring agency provided the communication is limited strictly to matters of

procedure. Procedural matters include deadlines for decisions or submission of proposals and the proper means of communicating regarding the procurement, but shall not include any substantive matter related to the particular procurement or requirements of the RFP.

J. Errors and Omissions

The department reserves the right to make corrections due to minor errors of proposer identified in proposals by the department or the proposer. The department, at its option, has the right to request clarification or additional information from proposer.

K. Ownership of Proposal

All proposals become the property of the department and will not be returned to the proposer. The department retains the right to use any and all ideas or adaptations of ideas contained in any proposal received in response to this solicitation. Selection or rejection of the offer will not affect this right. Once a contract is awarded, all proposals will become subject to the Alabama Public Records Act.

L. Resources Available To Proposer

Relevant material related to this RFP will be posted at the following web address: http://www.alabamapublichealth.gov/hiv/grants.html.

M. Proposal Submission

1. All proposals must be received by the due date and time indicated on the Acquisition Schedule. Proposals received after the due date and time will not be considered. It is the sole responsibility of each proposer to assure that its proposal is delivered at the specified location prior to the deadline. Proposals which, for any reason, are not so delivered will not be considered.

2. Proposer shall submit one original and nine hard copies via U.S. mail, courier, or hand delivery, and one electronic copy submitted via email of the entire proposal. The cost proposal and financial statements shall be submitted separately from the technical proposal; however, for mailing purposes, all packages may be shipped in one container.

3. Proposals must be submitted via U.S. mail, courier, hand delivered, and email to:

   Brenda Cummings, Communications Director
   Division of HIV Prevention and Care
   Alabama Department of Public Health
   201 Monroe Street, RSA Tower - Suite 1400
   Montgomery, Alabama 36104

   Office: (334) 206-2095
   E-mail: brenda.cummings@adph.state.al.us

N. Confidential Information, Trade Secrets, and Proprietary Information

1. All financial, statistical, personal, technical and other data and information relating to the state's operation which are designated confidential by the state and made available to the contractor in order to carry out this contract, or which become available to the contractor in carrying out this contract, shall be protected by the contractor from unauthorized use and disclosure through the observance of the same or more effective procedural requirements as are applicable to the state. The identification of all such confidential data and information as well as the State's procedural requirements for protection of such data and information from unauthorized use and disclosure shall be provided by the State in writing to the contractor. If the methods and procedures employed by the contractor for the protection of the contractor's data and information are deemed by the State to be adequate for the protection of the state's confidential information, such methods and procedures may be used, with the written consent of the State, to carry out the intent of this paragraph. The contractor shall not be required under the provisions of the paragraph to keep confidential any data or information which is or becomes publicly available, is already rightfully in the contractor's possession, is independently developed by the contractor outside the scope of the contract, or is rightfully obtained from third parties.

2. Under no circumstance shall the contractor discuss and/or release information to the media concerning this project without prior express written approval of the department.

O. Proposal Format

1. An item-by-item response to the request for proposals is requested.

2. There is no intent to limit the content of the proposals, and proposers may include any additional information deemed pertinent. Emphasis should be on simple, straightforward and concise statements of the proposer's ability to satisfy the requirements of the RFP.

P. Requested Proposal Outline

1. Introduction/Administrative Data

2. Work Plan/Project Execution

3. Relevant Corporate Experience

4. Personnel Qualifications

5. Additional Information

6. Corporate Financial Condition

7. Cost and Pricing Analysis

Q. Proposal Content

1. **Cover Letter**
   A cover letter should be submitted on the proposer's official business letterhead explaining the intent of the proposer.

2. **Table of Contents**
   The proposal should be organized in the order contained herein and include a Table of Contents.

3. **Quality And Timeliness**
   Proposals should include information that will assist the department in determining the level of quality and timeliness that may be expected. The department shall determine, at its sole discretion, whether or not the RFP provisions have been reasonably met. The proposal should describe the background and capabilities of the proposer, give details on how the services will be provided, and shall include a breakdown of proposed costs. Work samples may be included as part of the proposal.

4. **Assume Complete Responsibility**
   Proposals should address how the proposer intends to assume complete responsibility for timely performance of all contractual responsibilities in accordance with federal and state laws, regulations, policies, and procedures.

5. **Approach and Methodology**
   Proposals should define proposer's functional approach in providing services and identify the tasks necessary to meet the RFP requirements of the provision of services, as outlined in Section III. Scope of Work. Proposals should include enough information to satisfy evaluators that the proposer has the appropriate experience, knowledge and qualifications to perform the scope of services as described herein. Proposers should respond to all requested areas.

6. **Introduction/Administrative Data**

   a. The introductory section should contain summary information about the proposer's organization. This section should state the proposer's knowledge and understanding of the needs and objectives of the DHPC as related to the scope of this RFP. It should further cite its ability to satisfy provisions of the RFP.

   b. This introductory section should include a description of how the proposer's organizational components communicate and work together in both an administrative and functional capacity from the top down. This section should contain a brief summary setting out the proposer's management philosophy including, but not limited to, the role of quality control, professional practices,

supervision, distribution of work, and communication systems. This section should include an organizational chart displaying the proposer's overall structure.

c. This section should also include the following information:

- **i.** Location of administrative office with full time personnel, include all office locations (address) with full time personnel.
- **ii.** Name and address of principal officer.
- **iii.** Name and address for purpose of issuing checks and/or drafts.
- **iv.** For corporations, a statement listing name(s) and address(es) of principal owners who hold 5 percent interest or more in the corporation.
- **v.** If out-of-state proposer, give name and address of local representative; if none, so state.
- **vi.** If any of the proposer's personnel named is a current or former Alabama state employee, indicate the agency where employed, position, title, and last date of employment.
- **vii.** If the proposer was engaged by ADPH within the past twenty-four (24) months, indicate the contract number and/or any other information available to identify the engagement; if not, so state.
- **viii.** Proposer's state and federal tax identification numbers.

d. The following information ***must*** be included in the proposal:
Certification Statement: The proposer must sign and submit an original Business Associate Agreement (See **Attachment B**).

7. Work Plan/Project Execution

The proposer should articulate an understanding of, and ability to effectively implement services as outlined within Section III. Scope of Work, of the RFP. In this section the proposer should state the approach it intends to use in achieving each objective of the project as outlined, including a project work plan and schedule for implementation. In particular, the proposer should describe the plan for implementing pharmacy benefits management services, including claims adjudication, coordination of benefits and point-of-sale processing for DHPC consistent with this RFP. Please note that client eligibility determination services for ADAP clients are not included in this RFP.

The work plan should include a narrative addressing the following:

a. Describe the proposer's existing pharmacy network in Alabama or the proposer's ability and experience in developing other statewide pharmacy networks. If the proposer currently has a network of pharmacies in Alabama, please include the complete list of pharmacies.

b. Outline the ability to provide a mail order option for clients, with consideration for the special shipping needs of homeless and transient ADAP clients.

c. Describe the mechanism by which communication with in network pharmacies occurs to inform them of significant events, such as the addition or deletion of formulary medications, changes in protocol, program announcements, etc.

d. Provide documentation of the emergency response/preparedness plan and describe how all clients will be able to access alternative services in the event of an emergency.

e. Provide a written explanation of the organizational structures of both operations and program administration, and how those structures will support service implementation. Individual components should include plans for supervision, training, technical assistance, and collaboration with other organizations as appropriate.

f. Elaborate on the process by which staff with the necessary professional experience and skill sets will be hired to effectively meet the needs of consumers served.

g. Demonstrate an understanding of, and ability to implement, the various types of organizational strategies to be integrated within the day to day operations, which are critical in maximizing productivity, accuracy and cost effectiveness.

h. Describe the overall approach and strategy for project oversight and management.

i. Articulate the need for, and the ability to implement, a plan for continuous quality improvement; this includes (but is not limited to) reviewing the quality of services provided to DHPC Direct Services program participants and an assessment of staff productivity.

j. Demonstrate an understanding of and ability to implement data collection as needed.

k. Refer to specific documents and reports that can be produced as a result of completing tasks, to achieve the requested deliverables.

l. Articulate the ability to develop and implement an All Hazards Response plan in the event of an emergency event.

m. Identify all assumptions or constraints on tasks.

n. Discuss what flexibility exists within the work plan to address unanticipated problems which might develop during the contract period.

o. If the proposer intends to subcontract for portions of the work, include specific designations of the tasks to be performed by the subcontractor.

p. Document procedures to protect the confidentiality and security of patient information in DHPC or contractor databases, including patient information that may be transmitted electronically via e-mail or the Internet.

Claims Processing

Describe how the proposer will provide an electronic point-of-sale (POS) claims adjudication system, make payments to network pharmacies and coordinate with other payers. Provide a plan for achieving accurate client level data management and providing client support services.

Provide a detailed description of how the recoupment process will be performed. This should include type(s) of software used, third party vendor(s) used (if any), frequency at which tasks are performed, and how information will be communicated to and from DHPC and/or the network pharmacies.

Describe how the proposer will monitor billings to assure non-duplication and the proper split between primary, secondary and (if applicable) tertiary payers. Include an explanation of recoupment and reimbursement procedures.

Describe the proposer's ability and experience in coordinating and communicating with insurance plans, including (but not limited to) plans on and off the federally facilitated marketplace (FFM), employer-based insurance, Medicare Parts A - D, and individual plans written prior to the implementation of the PPACA.

Describe in detail the workflow process between DHPC, network pharmacies, third party payers, clients, DHPC staff and the proposer. The description should include timelines for accomplishments, as well as flowcharts or other visual presentations of the process.

a. Include how expenditures for Alabama Medicare Part D clients will be reported to the TrOOP facilitator to ensure applicable expenditures are credited toward the client's TrOOP.

b. Provide information regarding the capability to split bill and track multiple third-party payer sources including, but not limited to, Medicare Part D PDPs, private insurance plans and DHPC.

c. Describe how the process identified in item (b) above will prevent DHPC from making erroneous payments. Include how the proposer will ensure that DHPC does not pay for medications that are not on a client's insurance formulary or that are covered by the Medicare Part D PDPs.

d. Describe the process for resolving issues surrounding client billing and prescription fulfillment that occur at the point of sale between the retail pharmacy, DHPC and the insurance or Medicare Part D PDP.

e. Describe the process for obtaining credits and adjustments on behalf of DHPC for any possible overpayments that have been made. Include the timeframes or other parameters in which such adjustments and credits will be allowed and recorded.

f. Describe how the system will be able to effectively monitor an annual benefits cap for each client.

g. Provide information on the capability to pay incurred expenses on behalf of DHPC clients at the point of service and bill DHPC afterward.

Technical support
Describe the proposer's ability and experience in providing technical support to program staff, pharmacies and clients. Include a description of how the proposer ensures that there is adequate staff who are trained to provide coverage during transition times, such as when a key staff position becomes vacant.

Describe the ability to document problem resolution with both network pharmacies and clients.

Data system
Describe how the proposer will maintain a data system that is capable of receiving and managing client eligibility information to use for claims processing, monthly invoicing, reports and billing.

Describe the proposer's ability and experience to create and manage data systems that receive detailed client eligibility information from DHPC staff and interface with payment information from pharmacies. Include a description of how the proposer ensures that client eligibility information is accessible to the network pharmacies the same day in which it is received. Include information about technical resources that are available to DHPC through the proposer's systems, including but not limited to remote access, report builders and claims data review.

Describe the ability to submit a monthly electronic data file of all transactions provided to individual eligible clients, to include: the medication dispensed; amount paid for each medication; and the location where the medication was dispensed or delivered. Include a description of the type of data file to be provided and how it will be transmitted to DHPC.

Describe in detail any initial, and subsequent, network/hardware/software/system requirements that DHPC would need to have in order to electronically interface with the proposer's program/system. Include any special software or hardware that would need to be installed on ADPH servers or computers. If the interface is web-based, specify if it will be fully compatible with Windows Internet Explorer Version 11.0 or above. Include description of how the interface provide secure/encrypted data transmission in compliance with all ADPH and HIPAA Guidelines and the federal HiTECH Act of 2009.

Describe the proposer's ability and experience to create reports that describe monthly user activity and prescription drug costs. Include a description of standard reports, if any, and the ability to create custom reports.

Describe the ability to provide standardized monthly utilization and expenditure reports. Include how report will be submitted to DHPC staff and in what format (i.e., PDF, Excel, and Word).

Monthly Payment

Describe the proposer's ability and experience in providing payment upfront to the network pharmacies for the duration of a month while preparing an invoice to DHPC at the end of each month. Include a description of how the proposer ensures that payment is only requested for valid claims; include details about the claims checking processes that eliminate duplicate or invalid claims.

Describe the ability to create and provide to DHPC staff a monthly, claim-level detail file in electronic format.

Describe how the proposer would manage a closed formulary that includes specific drugs and drug classes. Include a description of how the proposer would ensure that routine FDA decisions and National Drug Code changes that affect approved formulary drugs would be noted and applied in a timely manner.

Treatment Adherence

Treatment adherence is defined as services provided to encourage, support, and enhance adherence to and compliance with treatment regimens, including related medical monitoring. Describe your current experience or ability to provide treatment adherence activities to improve access to medications, increase and support adherence to medication regiments, and/or assist clients with monitoring their progress in taking HIV-related medications.

Client Confidentiality and Data Security

Client confidentiality and data security are extremely important. The contractor must be compliant with all federal, state, and ADPH HIPAA Guidelines, the federal HiTECH Act of 2009, the NCHHSTP Data Security and Confidentiality Guidelines for HIV, Viral Hepatitis, Sexually Transmitted Disease, and Tuberculosis Programs: Standards to Facilitate Sharing and Use of Surveillance Data for Public Health Action (2011), and the current year's ADPH HIV Security and Confidentiality Policy. Confidential information shall include not only sensitive health and risk-related information, but also client personal identifiers, potentially identifying information, and any other information provided to the contractor for which confidentiality was assured when the individual or establishment provided the information. Extremely stringent standards of client security and confidentiality must be maintained and the use of client information and client level data for commercial purposes is not allowed.

Likewise, the contractor may not publish any information about program participants, even in the aggregate, without DHPC review and written permission.
Describe the proposer's ability and experience in assuring client confidentiality.
Describe in detail any security or confidentiality breaches experienced by the company in the past five years. Also, describe how the proposer protects client information from being used for commercial purposes or published, even in the aggregate, without DHPC review and written permission.

Provide a detailed description of how secure data will be transmitted between the different parties involved in pharmacy service coordination (CMS, ADPH DHPC PBM liaison, insurance plans, Medicare Part D PDPs, and contracted pharmacies), to comply with ADPH HIPAA Guidelines, federal HiTECH Act of 2009, the NCHHSTP Data Security and Confidentiality Guidelines for HIV, Viral Hepatitis, Sexually Transmitted Disease, and Tuberculosis Programs: Standards to Facilitate Sharing and Use of Surveillance Data for Public Health Action (2011) as well as satisfying industry standards and practices.

Conflict of Interest
Describe any potential conflicts of interest related to the provision of HIV treatment that the proposer, and/or any proposed sub-vendors may have.

Quality Assurance/Monitoring Requirements
Describe current quality assurance activities and measures, including the ability and timeline required to produce utilization and expenditure reports.
Describe the experience or ability to conduct client satisfaction and provider surveys. Include example of previous survey tools and outcomes as an attachment.
Provide documentation of the policy or protocol that outlines clients' "Rights and Responsibilities" as an attachment and provide a copy of the current client grievance policy as an attachment.

Transition Plan
Describe in detail the plan and the proposed timeline to successfully transition clients from the current ADPH central pharmacy service provision model to the proposer's service delivery system.

Explain how Contractor activities would be transitioned upon on termination of the contract without interrupting services to clients.

Fraud and Abuse
Describe the fiscal controls and accounting practices that assure against fraud or abuse of funds, including the fiscal accountability of any proposed sub-vendors. Include a description of how the proposer would take corrective/disciplinary action upon detection of fraud or abuse, and describe how you would notify DHPC.

8. Relevant Corporate Experience

a. The proposal should indicate the proposer's firm has a record of prior successful experience in the implementation of the services sought through this RFP. Proposers should include statements specifying the extent of responsibility on prior projects and a description of the projects scope and similarity to the projects outlined in this RFP. All experience under this section should be in sufficient detail to allow an adequate evaluation by the department. The proposer should have, within the last 24 months implemented a similar type project. Proposers should give at least two customer references for projects implemented in at least the last 24 months. References shall include the name, email address and telephone number of each contact person.

b. In this section, a statement of the proposer's involvement in litigation that could affect this work should be included. If no such litigation exists, proposer should so state.

9. Personnel Qualifications

a. The purpose of this section is to evaluate the relevant experience, resources, and qualifications of the proposed staff to be assigned to this project. The experience of proposer's personnel in implementing similar services to those to be provided under this RFP will be evaluated. The adequacy of personnel for the proposed project team will be evaluated on the basis of project tasks assigned, allocation of staff, professional skill mix, and level of involvement of personnel.

b. Proposers should state job responsibilities, workload and lines of supervision. An organizational chart identifying individuals and their job titles and major job duties should be included. The organizational chart should show lines of responsibility and authority.

c. Proposer should:

- **i.** Provide a Staffing and Organization Plan required to complete the proposed work.
- **ii.** Provide a list and overview of staffing positions needed to successfully meet the program objectives. Include business hours of operation and primary methods of contact.
- **iii.** Describe the responsibilities and qualifications of key staff. Note: Any staff replaced during the period of performance of any resulting contract must be replaced with staff with equivalent or superior qualifications.
- **iv.** Describe the responsibilities and qualifications of any sub-contractor who would likely be assigned to this contract.
- **v.** Describe how the proposer ensures that functions of the contract will be maintained in the absence of key staff. For example, if a staff member leaves unexpectedly, describe who would assume his/her duties and how quickly that would happen. The proposer should have an emergency preparedness plan in place and included in the proposal as an attachment.

vi. Describe how implementation of the Staffing and Organization Plan will be consistent with the designated contract start date and services start date, as listed in this RFP.

vii. Job descriptions, including the percentage of time allocated to the project and the number of personnel should be included and should indicate minimum education, training, experience, special skills and other qualifications for each staff position as well as specific job duties identified in the proposal. Job descriptions should indicate if the position will be filled by a subcontractor.

viii. Key personnel and the percentage of time directly assigned to the project should be identified.

ix. Resumés of all known personnel should be included. Resumes of proposed personnel should include, but not be limited to:

- Experience with proposer;
- Previous experience in projects of similar scope and size; and
- Educational background, certifications, licenses, special skills, etc.

x. If subcontractor personnel will be used, the proposer should clearly identify these persons, if known, and provide the same information requested for the proposer's personnel.

10. Additional Information

As an appendix to its proposal, if available, proposers should provide copies of any policies and procedures manuals applicable to this contract, inclusive of organizational standards or ethical standards. This appendix should also include a copy of proposer's All Hazards Response Plan, if available.

11. Corporate Financial Condition

a. The organization's financial solvency will be evaluated. The proposer's ability to demonstrate adequate financial resources for performance of the contract or the ability to obtain such resources as required during performance under this contract will be considered.

b. Proposal should include copies of financial statements for the last three years, preferably audited, including at least a balance sheet and profit and loss statement, or other appropriate documentation which would demonstrate to the department that the proposer's financial resources are sufficient to conduct the project.

12. Cost and Pricing Analysis

a. Proposer shall specify costs for performance of tasks. Proposal shall include all anticipated costs of successful implementation of all deliverables outlined.

b. Proposers shall submit the breakdown in a format similar to the attached sample cost template form (See **Attachment G**) for each year of the contract to demonstrate how cost was determined. Proposers must complete a cost proposal

in the format provided to be considered for award. Failure to complete will result in the disqualification of the proposal.

c. Proposers shall submit the per transaction and per dispensing fees for each item in **Attachment H** for the first year of the contract.

d. Proposer **shall** specify AWP discount rates for both generic and brand name drugs for both retail and mail order dispensing. Proposer **shall** submit the rates in a similar format, and are strongly encouraged to use the format in the chart below.

Retail Pharmacy Claims	
Services	**Percent**
1. Discounts from AWP for generic drugs	%
2. Discounts from AWP for brand drugs	%
Mail Order Claims	
Services	**Percent**
1. Discounts from AWP for generic drugs	%
2. Discounts from AWP for brand drugs	%

Note: For all 340B **direct** purchase ADAP medications, AmerisourceBergen is the current state contracted drug wholesaler for Alabama's RWHAP Part B ADAP program (current contract period through January 2018). Medications purchased through a 340B rebate mechanism are not under the AmerisourceBergen direct purchase 340B drug wholesaler contract.

R. Waiver of Administrative Informalities

The ADPH reserves the right, at its sole discretion, to waive minor administrative informalities contained in any proposal.

S. Withdrawal of Proposal

A proposer may withdraw a proposal that has been submitted at any time up to the date and time the proposal is due. To accomplish this, a written request signed by the authorized representative of the proposer must be submitted to the PBM Point of Contact or designated contact during blackout period identified in the RFP.

V. EVALUATION AND SELECTION

A. Evaluation Criteria

The following criteria will be used to evaluate proposals:

1. Evaluations will be conducted by a Proposal Review Committee.

2. Scoring will be based on a possible total of **100** points and the proposal with the highest total score will be recommended for award.

3. **Cost Evaluation**:

a. The proposer with the lowest total cost for all three years (from **Attachment G**) shall receive 15 points. Other proposers shall receive points for cost based upon the following formula:

Annual Fee Schedule (**Attachment G**)
CCS = (LPC/PC)* 15

CCS = Computed Cost Score (points) for proposer being evaluated
LPC = Lowest Proposal Cost of all proposers
PC = Individual Proposal Cost

b. The proposer with the lowest total weight per claim cost (from **Attachment H**) shall receive 10 points. Other proposers shall receive points for cost based upon the following formula:

Cost Table (**Attachment H**)
CCS = (LPC/PC)* 10

CCS = Computed Cost Score (points) for proposer being evaluated
LPC = Lowest Proposal Cost of all proposers
PC = Individual Proposal Cost

c. The assignment of the 25 points based on the above formula will be calculated by the issuing program in this case, the DHPC.

B. Evaluation Criteria and Assigned Weights

Proposals that pass the preliminary screening and mandatory requirements review will be evaluated based on information provided in the proposal. The evaluation will be conducted according to the following.

Evaluation Criteria	Assigned Weight
Introduction/Understanding of RFP	**5**
Work Plan/Project Execution	**30**
Corporate Experience	**15**
Qualification of Personnel	**10**
Financial Statements	**5**
Cost	**25**
ADAP PBM Experience	**10**
Total	**100**

C. Evaluation Team

The evaluation of proposals will be accomplished by an evaluation team, to be designated by the department, which will determine the proposal most advantageous to the department, taking into consideration cost and other evaluation factors set forth in the RFP.

D. Administrative and Mandatory Screening

All proposals will be reviewed to determine compliance with administrative and mandatory requirements as specified in the RFP. Proposals that are not in compliance will be excluded from further consideration.

E. Clarification of Proposals

The department reserves the right to seek clarification of any proposal for the purpose of identifying and eliminating minor irregularities or informalities, including resolving inadequate proposal content, or contradictory statements in a proposer's proposal.

F. Announcement of Award

1. The state will notify the successful proposer and proceed to negotiate terms for final contract.

2. The proposal selection memorandum, along with the list of criteria used and the weight assigned each criteria, the overall scores of each proposal considered, and a narrative justifying the selection of the successful proposer shall be made available, upon request, to all interested parties after the "Notice of Intent to Award" letter has been issued.

VI. SUCCESSFUL CONTRACTOR REQUIREMENTS

A. Confidentiality of Data

1. All financial, statistical, personal, technical and other data and information relating to the state's operation which are designated confidential by ADPH and made available to the contractor in order to carry out this contract, or which become available to the contractor in carrying out this contract, shall be protected by the contractor from unauthorized use and disclosure through the observance of the same or more effective procedural requirements as are applicable to ADPH. The identification of all such confidential data and information as well as ADPH's procedural requirements for protection of such data and information from unauthorized use and disclosure shall be provided by ADPH in writing to the contractor. If the methods and procedures employed by the contractor for the protection of the contractor's data and information are deemed by ADPH to be adequate for the protection of ADPH's confidential information, such methods and procedures may be used, with the written consent of ADPH, to carry out the intent of this paragraph. The contractor shall not be required under the provisions of the paragraph to keep confidential any data or information which is or becomes publicly available, is already rightfully in the contractor's possession, is independently developed by the contractor outside the scope of the contract, or is rightfully obtained from third parties.

2. Under no circumstance shall the contractor discuss and/or release information to the media concerning this project without prior express written approval of ADPH.

B. Taxes

Contractor is responsible for payment of all applicable taxes from the funds to be received under this contract.

C. Fund Use

Contractor agrees not to use contract proceeds to urge any elector to vote for or against any candidate or proposition on an election ballot nor shall such funds be used to lobby for or against any proposition or matter having the effect of law being considered by the Alabama Legislature or any local governing authority. This provision shall not prevent the normal dissemination of factual information relative to a proposition on any election ballot or a proposition or matter having the effect of law being considered by the Alabama Legislature or any local governing authority.

VII. CONTRACTUAL INFORMATION

The contract between ADPH and the contractor shall include the standard ADPH contract form (**Attachment A**) and Business Associate Agreement (**Attachment B**). The negotiated scope of work, RFP, amendments and addenda, and the contractor's proposal shall also be included.

VIII. ATTACHMENTS

A. ADPH Standard Contract Form, GC002 (2016 Revision)

B. ADPH Business Associate Agreement

C. Beason-Hammon Certificate of Compliance

D. Minimum Required Data Fields/Variables

1. ADR Instruction Manual and Addendum, 2016. Available for download at: https://careacttarget.org/library/adr-instruction-manual

2. ADR XML Schema Implementation Guide. Available for download at: https://careacttarget.org/library/adap-data-report-adr-xml-schema-implementation-guide-0

3. ADR Crosswalk2015_Final.docx. Available for download at: https://careacttarget.org/library/adap-data-report-adr-crosswalk

E. Vendor Disclosure Statement Information and Instructions

F. State of Alabama Vendor Disclosure Statement

G. Cost Template – Annual Fee Schedules

H. Cost Template - Claims Table

CONTRACT
BETWEEN
THE ALABAMA DEPARTMENT OF PUBLIC HEALTH
AND
(CONTRACTOR NAME - ALL CAPS AND BOLD)

This Contract entered into by and between the **Alabama Department of Public Health,** hereinafter "**Department**," and **(Contractor Name - Bold)**, hereinafter "**Contractor**," is effective **(Begin Date - Bold)** and terminates **(End Date - Bold)**.

WHEREAS, the purposes of this Contract are to (Insert GENERAL "overview" of the purposes of this Contract).

WHEREAS, funding for activities performed under this Contract was provided by the Department, (Bureau or County) through a cooperative agreement with the (Federal Grantee), being grant number (Grant Number, Grant Name) for budget period (Grant Period). The program was authorized through the following Acts: (Acts through which the program was authorized).

WHEREAS, this Contract is entered into following a request for proposal process in accordance with Code of Ala.1975, § 41-16-72.

WHEREAS, the Contractor will fully comply with the request for proposal, Contractor's proposal, Department's acceptance thereof and the plan or scope of work, which are herein incorporated by reference.

NOW THEREFORE, in consideration of the mutual covenants herein below specified and other good and valuable consideration, the receipt of which is hereby acknowledged, the parties herein agree to the following:

The Department shall:
(1…..Insert specific tasks for the Department to complete use as many bullets/numbers as needed)
(2……)
(3…….).

The Contractor shall:
(1…..Insert specific tasks for the Contractor to complete)
(2……)
(3…….).

Under no circumstances shall the maximum amount payable under this Contract exceed $ (Max Amount shall not exceed) for the Contract period.

BEASON-HAMMON ALABAMA TAXPAYER AND CITIZEN PROTECTION ACT. By signing this Contract, the contracting parties affirm, for the duration of the agreement, that they will not violate federal immigration law or knowingly employ, hire for employment, or continue to employ an unauthorized alien within the State of Alabama. Furthermore, a contracting party found to be in violation of this provision shall be deemed in breach of the agreement and shall be responsible for all damages resulting therefrom.

OFFICE OF INSPECTOR GENERAL EXCLUSION PROVISION. Section 6501 of the Patient Protection and Affordable Care Act ("PPACA") regarding exclusions from federal health care programs took effect on January 1, 2011. This Section of PPACA amends the Social Security Act to provide that State Medicaid agencies must exclude or terminate from participation any individual or entity excluded from participating in any Federal healthcare program, such that, if an individual or entity is excluded or terminated by Medicare or by Medicaid in any state, that individual or entity must be excluded from all other states' Medicaid programs.

Pursuant to that provision, if the Contractor is entering into this agreement for a federal health care program, Contractor agrees to screen all employees and subcontractors against the OIG list of excluded individuals and entities upon engagement and at least monthly. *This includes screening of former names and variations of names.*

CLOSEOUT CLAUSE. Contractor acknowledges that under the terms of the grant received by the Department from Federal sources including general Federal grants practices and procedures, the Contractor herein must submit all invoices or other demands for payment hereunder by a date which allows the Department to finalize and submit a financial status report to the granting federal agency. For purposes of this Contract, that date is (Invoice closeout date). Invoices or demands for payment received after that date for work and labor performed cannot be paid and are forfeit.

ANTI-DISCRIMINATION CLAUSE. Contractor will comply with Titles IV, VI, and VII of the Civil Rights Act of 1964, the Federal Age Discrimination in Employment Act, Section 504 of the Rehabilitation Act of 1973, the Americans with Disabilities Act of 1990, and all applicable Federal and State laws, rules and regulations implementing the foregoing statutes with respect to nondiscrimination on the basis of race, creed, color, religion, national origin, age, sex, or disability, as defined in the above laws and regulations. Contractor shall not discriminate against any otherwise qualified disabled applicant for, or recipient of aid, benefits, or services or any employee or person on the basis of physical or mental disability in accordance with the Rehabilitation Act of 1973 or the Americans With Disabilities Act of 1990.

(Insert the following clause when the total amount of Contract is $15,000 and greater: ANTI-BOYCOTT CLAUSE. Contractor represents that it is not currently engaged in, and will not engage in, the boycott of a person or an entity based in or doing business with a jurisdiction with which this state can enjoy open trade.)

GOVERNOR'S PRORATION CLAUSE. It is agreed that the Department may terminate this Contract by providing a thirty (30) day written notice to Contractor should the Governor of Alabama declare proration of the fund from which payment under this Contract is to be made. This termination for cause is supplemental to other rights the Department may have under this Contract or otherwise to terminate this Contract.

TERMINATION CLAUSE. This Contract may be terminated by either party providing a thirty (30) day written notice to the other party.

AMENDMENT CLAUSE. This Contract may be amended only by mutual agreement in writing, signed by Department and Contractor, and processed through and approved by all necessary authorities.

STANDARD OF PRACTICE CLAUSE. Contractor agrees to observe and comply at all times with all Federal and State laws and rules in effect during the term of this Contract which in any manner affect performance under this Contract. Contractor agrees to perform services consistent with customary standard of practice and ethics in the profession.

WHISTLEBLOWER PROTECTION CLAUSE. Pursuant to 41 U.S.C. § 4712, an employee of a contractor, subcontractor, or grantee may not be discharged, demoted, or otherwise discriminated against as a reprisal for whistleblowing. The statute defines whistleblowing as making a disclosure that the employee reasonably believes is evidence of:

Gross mismanagement of a Federal contract or grant;
A gross waste of Federal funds;
An abuse of authority relating to a Federal contract or grant;
A substantial and specific danger to public health or safety; or
A violation of law, rule, or regulation related to a Federal contract or grant.

To qualify under the statute, the employee's disclosure must be made to:

A Member of Congress or a representative of a Congressional committee;
An Inspector General;
The Government Accountability Office;
A federal employee responsible for contract or grant oversight or management at the relevant agency;
An official from the Department of Justice or other law enforcement agency;
A court or grand jury; or
A management official or other employee of the contractor, subcontractor, or grantee who has responsibility to investigate, discover or address misconduct.

ASSIGNMENT CLAUSE. The rights, duties, and obligations arising under the terms of this Contract shall not be assigned by any of the parties hereto without the written consent of all other parties.

ENTIRE AGREEMENT CLAUSE. This Contract contains the entire agreement of the parties and there are no other agreements, verbal or written, affecting this Contract that have not been incorporated herein or attached hereto.

SEVERABILITY CLAUSE**.** Each provision of this Contract is intended to be severable. If any term or provision of this Contract is illegal or invalid for any reason whatsoever, said illegality or invalidity shall not affect the legality or validity of the remainder of this Contract.

HEADINGS CLAUSE. Headings in this Contract are for convenient reference only and shall not be used to interpret or construe the provisions of this Contract.

DO NOT WORK CLAUSE. Contractor acknowledges and understands that this Contract is not effective until it has received all requisite State government approvals and Contractor shall not begin performing work under this Contract until notified to do so by the Department. Contractor is entitled to no compensation for work performed prior to the effective date of this Contract.

EMERGENCY CANCELLATION CLAUSE. Notwithstanding any other provision of this Contract, upon the issuance of a Declaration of Financial Necessity by the State Health Officer, this Contract may be canceled immediately upon notice of such cancellation being given in writing to the Contractor. Notwithstanding such cancellation, the Contractor shall be recompensed for work and labor performed and completed prior to the issuance of such notice on principles of quantum meruit.

FINANCIAL NECESSITY CLAUSE. All terms and conditions of this Contract notwithstanding, the parties agree that upon the issuance of a Declaration of Financial Necessity by the State Health Officer, the maximum amount payable under this Contract may be unilaterally reduced by the Department to an appropriate amount to be determined by the Department upon notice of such being given in writing to the Contractor. Notwithstanding such reduction, the Contractor shall be recompensed for work and labor performed and completed prior to the issuance of such notice on principles of quantum meruit.

DEBT OF STATE CLAUSE. It is agreed that the terms and commitments contained herein shall not be constituted as a debt of the State of Alabama in violation of Article XI, Section 213 of the Constitution of Alabama of 1901, as amended by Amendment Number 26. It is further agreed that if any provision of this Contract shall contravene any statute or Constitutional provision or amendment, either now in effect or which may, during the course of this Contract, be enacted, then that conflicting provision in the Contract shall be deemed null and void. The Contractor's sole remedy for the settlement of any and all disputes arising under the terms of this Contract shall be limited to the filing of a claim with the Board of Adjustment for the State of Alabama.

DISPUTES. For any and all disputes arising under the terms of this Contract, the parties hereto agree, in compliance with the recommendations of the Governor and

Attorney General, when considering settlement of such disputes, to utilize appropriate forms of non-binding alternative dispute resolution including, but not limited to, mediation by and through mediators approved by the State of Alabama or where appropriate, private mediators.

MERIT SYSTEM CLAUSE. Contractor shall not be entitled to receive any benefits under this Contract that merit system employees receive by virtue of their status or employment, nor may Contractor nor any of its officers, agents, servants or employees be employed as a merit system employee during the term of this Contract. Any such employment automatically voids this Contract.

HOLD HARMLESS CLAUSE. Contractor hereby indemnifies and holds harmless the State of Alabama and the Department and their officers, agents, servants, and employees from any and all claims arising out of acts or omissions committed by the Contractor or any Subcontractor, agent, servant or employee of Contractor while in performance hereunder.

FUND APPROPRIATION CLAUSE. It is agreed that the Department may terminate this Contract by providing a thirty (30) day written notice to Contractor should the Legislature of Alabama fail to appropriate funds for the continued payment of this Contract. This termination for cause is supplemental to any other rights Department may have under this Contract or otherwise to terminate this Contract.

TOBACCO SMOKE CLAUSE. Public Law 103227, Part C Environmental Tobacco Smoke, also known as the Pro Children Act of 1994, requires that smoking not be permitted in any portion of any indoor facility routinely owned or leased or contracted for by an entity and used routinely or regularly for provision of health, day care, education, or library services to children under the age of 18, if the services are funded by Federal programs either directly or through State or local governments, by Federal grant, contract, loan, or loan guarantee. The law does not apply to children's services provided in private residences, facilities funded solely by Medicare or Medicaid funds, and portions of facilities used for inpatient drug or alcohol treatment. Failure to comply with the provisions of the law may result in the imposition of a civil monetary penalty of up to one-thousand dollars ($1000) per day and/or the imposition of an administrative compliance order on the responsible entity. By signing and submitting this Contract the Contractor certifies that it will comply with the requirements of the Act.

The Contractor further agrees that it will require the language of this certification be included in any sub-awards which contain provisions for the children's services and that all Subcontractors shall certify accordingly.

LOBBYING CLAUSE. The undersigned certifies, to the best of his or her knowledge and belief, that:

(1) No Federal appropriated funds have been paid or will be paid, by or on behalf of the undersigned, to any person for influencing or attempting to influence an officer or

employee of an agency, a Member of Congress, an officer or employee of Congress, or an employee of a Member of Congress in connection with the awarding of any Federal Contract, the making of any Federal grant, the making of any Federal loan, the entering into of any cooperative agreement, and the extension, continuation, renewal, amendment, or modification of any Federal contract, grant, loan, or cooperative agreement.

(2) If any funds other than Federal appropriated funds have been paid or will be paid to any person for influencing or attempting to influence an officer or employee of any agency, a Member of Congress, an officer or employee of Congress, or an employee of a Member of Congress in connection with this Federal Contract, grant, loan, or cooperative agreement, the undersigned shall complete and submit Standard Form-LLL, "Disclosure Form to Report Lobbying," in accordance with its instructions.

(3) The undersigned shall require that the language of this certification be included in the award documents for all sub-awards at all tiers (including subcontracts, sub-grants, and contracts under grants, loans, and cooperative agreements) and that all sub-recipients shall certify and disclose accordingly. This certification is a material representation of fact upon which reliance was placed when this transaction was made or entered into. Submission of this certification is a prerequisite for making or entering into this transaction imposed by section 1352, title 31, U.S. Code. Any person who fails to file the required certification shall be subject to a civil penalty of not less than ten-thousand dollars ($10,000) and not more than one-hundred-thousand dollars ($100,000) for each such failure.

DEBARMENT, SUSPENSION CLAUSE. For the purposes of this clause, “prospective lower tier participant” or “lower tier participant” refers to the Contractor.

1. By signing and submitting this proposal, the prospective lower tier participant is providing the certification set out below.
2. The certification in this clause is a material representation of fact upon which reliance was placed when this transaction was entered into. If it is later determined that the prospective lower tier participant knowingly rendered an erroneous certification, in addition to other remedies available to the Federal Government the department or agency with which this transaction originated may pursue available remedies, including suspension and/or debarment.
3. The prospective lower tier participant shall provide immediate written notice to the person to whom this proposal is submitted if at any time the prospective lower tier participant learns that its certification was erroneous when submitted or had become erroneous by reason of changed circumstances.
4. The terms covered transaction, debarred, suspended, ineligible, lower tier covered transaction, participant, person, primary covered transaction, principal, proposal, and voluntarily excluded, as used in this clause, have the meaning set out in the Definitions and Coverage sections of rules implementing Executive Order 12549. You may contact the person to whom this proposal is submitted for assistance in obtaining a copy of those regulations.

5. The prospective lower tier participant agrees by submitting this proposal that, should the proposed covered transaction be entered into, it shall not knowingly enter into any lower tier covered transaction with a person who is proposed for debarment under 48 CFR part 9, subpart 9.4, debarred, suspended, declared ineligible, or voluntarily excluded from participation in this covered transaction, unless authorized by the department or agency with which this transaction originated.

6. The prospective lower tier participant further agrees by submitting this proposal that it will include this clause titled “Certification Regarding Debarment, Suspension, Ineligibility and Voluntary Exclusion-Lower Tier Covered Transaction," without modification, in all lower tier covered transactions and in all solicitations for lower tier covered transactions.

7. A participant in a covered transaction may rely upon a certification of a prospective participant in a lower tier covered transaction that it is not proposed for debarment under 48 CFR part 9, subpart 9.4, debarred, suspended, ineligible, or voluntarily excluded from covered transactions, unless it knows that the certification is erroneous. A participant may decide the method and frequency by which it determines the eligibility of its principals. Each participant may, but is not required to, check the List of Parties Excluded from Federal Procurement and Nonprocurement Programs.

8. Nothing contained in the foregoing shall be construed to require establishment of a system of records in order to render in good faith the certification required by this clause. The knowledge and information of a participant is not required to exceed that which is normally possessed by a prudent person in the ordinary course of business dealings.

9. Except for transactions authorized under sub-paragraph 5 above, if a participant in a covered transaction knowingly enters into a lower tier covered transaction with a person who is proposed for debarment under 48 CFR part 9, subpart 9.4, suspended, debarred, ineligible, or voluntarily excluded from participation in this transaction, in addition to other remedies available to the Federal Government, the department or agency with which this transaction originated may pursue available remedies, including suspension and/or debarment. Certification Regarding Debarment, Suspension, Ineligibility an Voluntary Exclusion--Lower Tier Covered Transactions.

(1) The prospective lower tier participant certifies, by submission of this proposal, that neither it nor its principals is presently debarred, suspended, proposed for debarment, declared ineligible, or voluntarily excluded from participation in this transaction by any Federal department or agency.

(2) Where the prospective lower tier participant is unable to certify to any of the statements in this certification, such prospective participant shall attach an explanation to this proposal.

RECORD RETENTION**.** The Contractor is aware that it must retain all records pertinent to expenditure incurred under this Contract for a period of three (3) years after the termination of all activities funded under this Contract. Records for any displaced person must be kept three (3) years after he/she has received final payment.

Notwithstanding the above, if there are litigation, claims, audits, negotiations or other actions that involve any of the records cited and that have started before the expiration of the three-year period, then such records must be retained until completion of the actions and resolutions of all issues, or the expiration of the three-year period, plus the current year whichever occurs later. See Department of Public Examiners for its record retention policy.

AVAILABILITY OF FINANCIAL STATEMENTS. All records and financial statements, to include a copy of the independent audit report, shall be made available to authorized personnel from the State or Federal Program Office, the Examiners of Public Accounts or their representatives, for audit and inspection purposes.

HIPAA CLAUSE. This clause is necessitated by the application of the Health Insurance Portability and Accountability Act of 1996 ("HIPAA"), as amended by the American Recovery and Reinvestment Act of 2009 (Pub. L. No. 111-5) (the "HITECH Act"), any associated regulations and the federal regulations published at 45 CFR parts 160 and 164 (sometimes collectively referred to as "HIPAA"). References to this clause are to the Code of Federal Regulations, hereinafter “CFR.”

The parties agree to use and disclose Protected Health Information in compliance with the Standards for Privacy of Individually Identifiable Health Information (“Privacy Rule”). The definitions set forth in the Privacy Rule are incorporated by reference into this Contract (45 C.F.R. §§ 160.103 and 164.501). The Parties likewise agree to take all necessary precautions to protect the integrity of electronic protected health information (e-PHI) by complying with the HIPAA Security Rule.

INTERPRETATION CLAUSE. Where there is an apparent conflict among the Contract documents which cannot be resolved by interpretation, this document controls.

[REMAINDER OF PAGE INTENTIONALLY LEFT BLANK.]

Contractor:
(Contractor Name)

Signed: _____
(Owner or Authorized Representative)

Date: _____

Address:
(Company Address)
(Second Address Line)
(City, State, Zip)

Telephone: (Telephone Number)
Fax: (Fax Number)

Contractor please type or print your email address: (Email Address)

Social Security or FEIN:
(SS# or FEIN#)

Alabama Department of Public Health
This Contract has been reviewed as to content

Signed: _____
(Bureau Director/Area Admin)

Date: _____

APPROVED:
Alabama Department of Public Health

Signed: _____
Scott Harris, M.D.
Acting State Health Officer

Date: _____

APPROVED:
State of Alabama

Signed: _____
Kay Ivey, Governor

Date: _____

BUSINESS ASSOCIATE AGREEMENT

BETWEEN

THE ALABAMA DEPARTMENT OF PUBLIC HEALTH

AND

This Agreement is entered into by and between the **Alabama Department of Public Health,** (**"Covered Entity"**), an agency of the State of Alabama, and _____, (**"Business Associate"**) and is effective as of _____.

WHEREAS, Covered Entity and Business Associate have entered into a Contract ("Contract") in which Business Associate has agreed to provide certain services to Covered Entity. In connection with that Contract, Business Associate creates, receives, maintains or transmits Protected Health Information ("PHI") from, to, or on behalf of Covered Entity. This information is protected by the Health Insurance Portability and Accountability Act of 1996 ("HIPAA"), the Health Information Technology for Economic and Clinical Health Act, Title XIII of the American Recovery and Reinvestment Act of 2009, (the "HITECH Act"), and the associated regulations promulgated by the Secretary ("HIPAA Rules").

WHEREAS, it is desirable, in order to further the continued efficient operations of Covered Entity to disclose to Business Associate certain PHI, and Business Associate has certain responsibilities with respect to that PHI; and

WHEREAS, in light of the foregoing requirements of HIPAA, the HITECH Act, and the HIPAA Rules, Business Associate and Covered Entity agree to be bound by the terms and conditions of this Agreement.

NOW THEREFORE, in consideration of the mutual promises herein, the parties agree as follows:

1. **Definitions**.

a. Catch-all definition: The following terms used in this Agreement shall have the same meaning as those terms in the HIPAA Rules: Breach, Designated Record Set, Disclosure, Individual, Minimum Necessary, Notice of Privacy Practices, Protected Health Information, Required by Law, Secretary, Security Incident, Subcontractor, Unsecured Protected Health Information, and Use.

b. **Business Associate** shall have the meaning given to such term in 45 CFR § 160.103.

c. **Covered Entity** shall have the meaning given to such term in 45 CFR § 160.103

d. **HIPAA Rules** means the Privacy, Security, Breach Notification, and Enforcement Rules at 45 CFR Parts 160 and 164.

2. **Permitted Uses and Disclosures.**

a. **Purposes**. Except as otherwise limited in this Agreement, Business Associate may only use or disclose PHI to perform functions, activities or services for, or on behalf of, Covered Entity as specified in the Contract, provided that such use or disclosure would not violate HIPAA or applicable state law if done by Covered Entity, or the minimum necessary and related Privacy and Security policies and procedures of Covered Entity. All such uses and disclosures shall be consistent with the minimum necessary requirements of HIPAA. Business Associate is directly liable under HIPAA for the impermissible Use or Disclosure of PHI it handles on behalf of Covered Entity.

b. **De-Identified Data**. Business Associate is not authorized to de-identify PHI or to use or disclose any de-identified PHI of Covered entity except as otherwise provided in the Contract. If de-identification is specified in the Contract, Business Associate shall de-identify the information in accordance with 45 CFR 164.514(a) – (c).

c. **Use for Administration of Business Associate.** Except as otherwise limited in this Agreement, the Business Associate may use PHI for the proper management and administration of Business Associate, or to carry out the legal responsibilities of Business Associate.

d. **Disclosure for Administration of Business Associate.** Except as otherwise limited in this Agreement, Business Associate may disclose PHI for the proper management and administration of Business Associate, provided that (i) the disclosure is Required by Law; or (ii) the Business Associate obtains reasonable assurances from the person to whom the information is disclosed that the PHI will remain confidential and be used or further disclosed only as Required by Law or for the purpose for which it was disclosed to the person; and, (iii) the person agrees to notify the Business Associate and Covered Entity of any instances of which it is aware in which the confidentiality of the information has been breached.

3. **Covered Entity to Inform Business Associate of Privacy Practices and Restrictions.**

a. **Notice of Privacy Practices.** Covered Entity shall notify Business Associate of any limitation(s) in the Notice of Privacy Practices of Covered Entity under 45 CFR 164.520, to the extent that such limitation may affect Business Associate's use or disclosure of protected health information.

b. **Restriction on Use or Disclosure**. Covered Entity shall notify Business Associate of any restriction on the use or disclosure of PHI that covered entity has agreed to or is required to abide by under 45 CFR § 164.522, to the extent that such restriction may affect Business Associate's use or disclosure of PHI.

c. **Revocation of Permission to Use or Disclose.** Covered Entity shall notify Business Associate of any changes in, or revocation of, the permission by an individual to use or disclose his or her PHI, to the extent that such changes may affect Business Associate's use or disclosure of PHI.

4. **Permissible Requests by Covered Entity.** Except as set forth in Section 2 of this Agreement, Covered Entity shall not request Business Associate to use or disclose PHI in any manner that would not be permissible under Subpart E of 45 CFR Part 164 if done by Covered Entity.

5. **Obligations of Business Associate.**

a. **Use and Disclosure**. Business Associate agrees not to use or disclose PHI other than as permitted or required by the Contract or as Required by Law. Business Associate shall comply with the provisions of the Agreement relating to privacy and security of PHI and all present and future provisions of HIPAA that relate to the privacy and security of PHI that are applicable to Covered Entity and/or Business Associate.

b. **Appropriate Safeguards**. Business Associate will use appropriate safeguards as are necessary to prevent the use or disclosure of PHI, except as provided for in this Agreement, and comply with Subpart C of 45 CFR Part 164 with respect to Electronic Protected Health Information. Business Associate represents and warrants that Business Associate:

i. Has implemented and will continue to maintain administrative, physical, and technical safeguards that reasonably and appropriately protect the confidentiality, integrity, and availability of PHI as required by the Security Rule; and

ii. Will comply with 74 FR 19006 Guidance Specifying the Technologies and Methodologies That Render PHI Unusable, Unreadable, or Indecipherable to Unauthorized Individuals for Purposes of the Breach Notification Requirements under Section 13402 of Title XIII. With regard to electronic PHI not covered by the Guidance published at 74 FR 19006, Business Associate will protect electronic PHI at rest and in transit through encryption that complies with State of Alabama Information Technology Policy 683-00: Encryption.

iii. Shall ensure that any agent or subcontractor that creates, receives, maintains, or transmits PHI on behalf of the Business Associate agrees to the same restrictions, conditions, and requirements that apply to the

Business Associate with respect to such information.

c. **Breach Notification.** Business Associate shall promptly, and in any event within three (3) business days, report to Covered Entity any of the following:

i. Any use or disclosure of PHI not permitted by this Business Associate Agreement of which Business Associate becomes aware;

ii. Any Security Incident of which Business Associate becomes aware; and

iii. The discovery of a Breach of Unprotected Health Information.

A Breach is discovered as of the first day on which the Breach is known, or reasonably should have been known, to Business Associate or any employee, officer or agent of Business Associate. Any notice of a Security Incident or Breach of Unsecured Protected Health Information shall include (1) the date of discovery; (2) the data elements involved; (3) the identification of each Individual whose PHI has been, or is reasonably believed by Business Associate to have been, accessed, acquired or disclosed during such Security Incident or Breach; (4) where the PHI or confidential data is believed to have been improperly transmitted; (5) the probable cause(s) of the improper use or disclosure; (6) a description of the proposed plan for preventing similar future incidents; and (7) whether any federal or state laws requiring breach notification are triggered. Any such notice shall be directed to Covered Entity's Privacy Officer.

d. **Investigation.** Business Associate shall reasonably cooperate and coordinate with Covered Entity in the investigation of any violation of the requirements of this Business Associate Agreement and/or any Security Incident or Breach.

e. **Mitigation.** Business Associate agrees to mitigate, to the extent practical, any harmful effect that is known to Business Associate or its employees, officers, Subcontractors or agents of a use or disclosure of PHI by Business Associate in violation of this Agreement. Business Associate shall keep Covered Entity fully apprised of all mitigation efforts, and all associated costs shall be borne by the Business Associate. This includes, but is not limited to, costs associated with notifying affected individuals.

f. **Reports and Notices**. Business Associate shall reasonably cooperate and coordinate with Covered Entity in the preparation of any reports or notices to the Individual or other authorities required to be made under HIPAA, the HITECH Act, HIPAA Rules, or any other federal or state laws. Any such reports or notices shall be subject to the prior written approval of Covered Entity.

g. **Agents/Subcontractors**. Business Associate agrees to ensure that any agent and/or subcontractor that creates, receives, maintains or transmits PHI on behalf of Business Associate agrees in writing to restrictions and conditions at least as stringent as those that apply to Business Associate pursuant to this

Agreement with respect to such PHI. Failure to include such requirement in any subcontract or agreement may result in Covered Entity's termination of the Agreement. If Business Associate becomes aware of a pattern of activity or practice of an agent and/or subcontractor that constitutes a material breach or violation of any such restrictions or conditions, Business Associate shall take reasonable steps to cure the breach or end the violation, and if such steps are unsuccessful, to terminate the contract or arrangement with such agent and/or subcontractor.

h. **Access to Designated Record Sets.** To the extent that Business Associate possesses or maintains PHI in a Designated Record Set, Business Associate agrees to provide access, at the request of Covered Entity, in the time, format and manner reasonably requested by Covered Entity to PHI in a Designated Record Set to enable Covered Entity to fulfill its obligations under HIPAA. If an Individual makes a request directly to Business Associate, Business Associate shall notify Covered Entity of the request within three (3) business days of such request and will cooperate with Covered Entity and allow Covered Entity to send the response to the Individual.

i. **Amendment to Designated Record Sets.** To the extent that Business Associate possesses or maintains PHI in a Designated Record Set, Business Associate agrees to make any amendment(s) to PHI in a Designated Record Set that the Covered Entity directs or agrees to at the request of Covered Entity or an Individual, and in the time and manner reasonably requested by Covered Entity. If an Individual makes a request to amend PHI directly to Business Associate, Business Associate shall notify Covered Entity of the request within three (3) business days of such request and will cooperate with Covered Entity and allow Covered Entity to send the response to the Individual.

j. **Access to Books and Records.** Business Associate agrees to make its internal practices, books, and records, including policies and procedures relating to the use and disclosure of PHI, as well as the PHI, received from, or created or received by Business Associate on behalf of Covered Entity available to Covered Entity, or to the Secretary, for the purpose of the Secretary determining Covered Entity's or Business Associate's compliance with HIPAA. Business Associate also agrees to make these records available to Covered Entity, or Covered Entity's contractor, for periodic audit of Business Associate's compliance with the Privacy and Security Rules. Upon Covered Entity's request, the Business Associate shall provide proof of compliance with HIPAA and HITECH data privacy/protection guidelines, certification of a secure network and other assurance relative to compliance with the Privacy and Security Rules. This section shall also apply to Business Associate's subcontractors, if any.

k. **Accountings.** Business Associate agrees to document disclosures of PHI and information related to such disclosures that would be required for Covered Entity to respond to a request by an Individual for an accounting of disclosures of

PHI in accordance with HIPAA. This should include a process that allows for an accounting to be collected and maintained by Business Associate and its agents or subcontractors for at least six (6) years from the date of disclosure, or longer if required by state law. At a minimum, such documentation shall include:

i. the date of disclosure;

ii. the name of the entity or person who received the PHI, and if known, the address of the entity or person;

iii. a brief description of the PHI disclosed; and

iv. a brief statement of purposes of the disclosure that reasonably informs the individual of the basis for the disclosure, or a copy of the individual's authorization, or a copy of the written request for disclosure.

l. **Requests for Accountings.** Business Associate agrees to provide to Covered Entity or an Individual, in the time and manner reasonably requested by Covered Entity, information collected in accordance with Section 5.k. of this Agreement, to permit Covered Entity to respond to a request by an Individual for an accounting of disclosures of PHI in accordance with HIPAA. If an Individual makes a request for an accounting of disclosures of PHI directly to Business Associate, Business Associate shall notify Covered Entity of the request within three (3) business days of such request and will cooperate with Covered Entity and allow Covered Entity to send the response to the Individual. The duty of the Business Associate and its agents and subcontractors to assist Covered Entity with any HIPAA required accounting of disclosures survives the termination of the Contract.

m. **Privacy Requirements.** To the extent Business Associate is to carry out one or more of Covered Entity's obligation(s) under Subpart E of 45 CFR Part 164, Business Associate shall comply with the requirements of Subpart E that apply to the covered Entity in the performance of such obligation(s).

n. **Data Ownership.** The PHI, and any related information created or received from or on behalf of Covered Entity, is and shall remain the property of Covered Entity. Neither Business Associate nor its agents or subcontractors shall hold any data ownership rights with respect to the PHI.

o. **Assistance in Litigation or Administrative Proceedings.** Business Associate shall make itself and any subcontractors, workforce or agents assisting Business Associate in the performance of its obligations under this Agreement, available to Covered Entity at no cost to Covered Entity, to testify as witnesses, or otherwise, in the event of litigation or administrative proceedings being commenced against Covered Entity, its officers or employees based upon claimed violations of HIPAA, the HIPAA Regulations or other laws relating to security and privacy, which involves action or inaction by Business Associate, except where Business Associate or its subcontractor, workforce or agent is a

named as an adverse party.

p. **Remuneration for PHI**. Business Associate is prohibited from directly or indirectly receiving any remuneration in exchange for an individual's PHI without the written authorization of the individual. Business Associate will refrain from marketing activities that would violate HIPAA, including specifically Section 13406 of the HITECH Act.

6. Term and Termination.

a. **Term.** This Agreement shall be effective as of the date of the Contract and shall terminate upon termination of the Contract or on the date Covered Entity terminates for cause as authorized in paragraph (b) of this Section, whichever is sooner.

b. **Termination for Cause.** Business Associate authorizes termination of this Agreement by Covered Entity, if Covered Entity determines Business Associate has violated a material term of the Agreement. Covered Entity may, at its sole discretion, allow Business Associate a reasonable period of time to cure the material breach before termination.

c. **Duties at Termination.**

i. Upon termination of the Contract for any reason, Business Associate shall return or destroy, at Covered Entity's option, all PHI received from Covered Entity, or created, maintained, or received by Business Associate on behalf of Covered Entity, that the Business Associate still maintains in any form. Business Associate shall retain no copies of the PHI. This provision shall apply to PHI that is in the possession of subcontractors or agents of Business Associate.

ii. In the event that Business Associate determines that returning or destroying the PHI is not feasible, Business Associate shall provide to Covered Entity notification of the conditions that make return or destruction infeasible. Upon mutual agreement of the parties that return or destruction is infeasible, Business Associate shall extend the protections of this Agreement to such PHI and limit further uses and disclosures of such PHI to those purposes that make the return or destruction of the PHI infeasible, for so long as Business Associate maintains such PHI. This shall also apply to all agents and subcontractors of Business Associate.

d. **Judicial or Administrative Proceedings.** Covered Entity may terminate this Agreement, effective immediately, if (1) Business Associate is named as a defendant in a criminal proceeding for a violation of HIPAA, the HIPAA Regulations, or other security or privacy laws or (2) a finding or stipulation that Business Associate has violated any standard or requirement of HIPAA, the HIPAA Regulations, or other security or privacy laws is made in any

administrative or civil proceeding in which Business Associate is a party or has been joined. Business Associate shall be subject to prosecution by the Department of Justice for violations of HIPAA/HITECH and shall be responsible for any and all costs associated with prosecution.

e. **Notices.** Any notices required under this Agreement will be sent in writing via certified mail, return receipt requested and also via electronic mail.

For Business Associate:

_____

_____

_____

_____

_____

_____

_____

_____

For Covered Entity:

Karen Bishop
Interim Privacy Officer
Alabama Department of Public Health
201 Monroe Street
Montgomery, AL 36104
Phone: (334) 206-5209
Fax: (334) 206-5874
Karen.Bishop@adph.state.al.us

f. **Survival.** The obligations of Business Associate under this Section shall survive the termination of this Agreement.

7. Miscellaneous.

a. **No Third-Party Beneficiaries.** Nothing express or implied in this Agreement is intended to confer, nor shall anything herein confer, upon any person other than Covered Entity, Business Associate and their respective successors or assigns, any rights, remedies, obligations or liabilities whatsoever.

b. **Regulatory References.** A reference in this Agreement to a section in the HIPAA Rules means the section as in effect or as amended.

c. **Interpretation.** Any ambiguity in this Agreement shall be interpreted to permit compliance with the HIPAA Rules.

d. **Amendment.** The parties agree to take such action as is necessary to amend this Agreement from time to time as is necessary for compliance with the requirements of the HIPAA rules and any other applicable law.

IN WITNESS WHEREOF, the authorized representatives of the parties sign effective the date above.

BUSINESS ASSOCIATE	**COVERED ENTITY**
_____	Alabama Department of Public Health
By: _____	By: _____
Printed Name: _____	Printed Name: _____
Title: _____	Title: _____

State of Alabama_____)

County of _____)

CERTIFICATE OF COMPLIANCE WITH THE BEASON-HAMMON ALABAMA TAXPAYER AND CITIZEN PROTECTION ACT (ACT 2011-535, as amended by Act 2012-491)

DATE: _____

RE Contract/Grant/Incentive (*describe by number or subject):*

_____by and between
_____ (Contractor/Grantee) and
_____ (State Agency, Department or Public Entity)

The undersigned hereby certifies to the State of Alabama as follows:

1. The undersigned holds the position of _____with the Contractor/Grantee named above, and is authorized to provide representations set out in this Certificate as the official and binding act of that entity, and has knowledge of the provisions of THE BEASON-HAMMON ALABAMA TAXPAYER AND CITIZEN PROTECTION ACT (ACT 2011-535 of the Alabama Legislature, as amended by Act 2012-491) which is described herein as "the Act".
2. Using the following definitions from Section 3 of the Act, select and initial either (a) or (b), below, to describe the Contractor/Grantee's business structure.

   BUSINESS ENTITY. Any person or group of persons employing one or more persons performing or engaging in any activity, enterprise, profession, or occupation for gain, benefit, advantage, or livelihood, whether for profit or not for profit. "Business entity" shall include, but not be limited to the following:

   a. Self-employed individuals, business entities filing articles of incorporation, partnerships, limited partnerships, limited liability companies, foreign corporations, foreign limited partnerships, foreign limited liability companies authorized to transact business in this state, business trusts, and any business entity that registers with the Secretary of State.

   b. Any business entity that possesses a business license, permit, certificate, approval, registration, charter, or similar form of authorization issued by the state, any business entity that is exempt by law from obtaining such a business license and any business entity that is operating unlawfully without a business license.

   EMPLOYER. Any person, firm, corporation, partnership, joint stock association, agent, manager, representative, foreman, or other person having control or custody of any employment, place of employment, or of any employee, including any person or entity employing any person for hire within the State of Alabama, including a public employer. This term shall not include the occupant of a household contracting with another person to perform casual domestic labor within the household.

   ____ *(a)* The Contractor/Grantee is a business entity or employer as those terms are defined in Section 3 of the Act.

   ____ *(b)* The Contractor/Grantee is not a business entity or employer as those terms are defined in Section 3 of the Act.

3. As of the date of this Certificate, Contractor/Grantee does not knowingly employ an unauthorized alien within the State of Alabama and hereafter it will not knowingly employee, hire for employment, or continue to employ an unauthorized alien within the State of Alabama;
4. Contractor/Grantee is enrolled in E-Verify unless it is not eligible to enroll because of the rules of that program or other factors beyond its control.

Certified this _____ day of _____ 20____.

_____
Name of Contractor/Grantee/Recipient

By: _____

Its _____

The above Certification was signed in my presence by the person whose name appears above, on

This _____ day of _____ 20____.

WITNESS: _____

_____
Printed Name of Witness

2016 ADR Manual Addendum

Changes made to the ADR Manual
Version 2: November 3, 2016

Client Report:

9. Health Insurance. (See pages 20-21)

Guidance on reporting client health insurance when Ryan White funds are used to pay for premiums, copays, and/or deductibles has changed to include both response options, "private" AND "no insurance".

AIDS DRUG ASSISTANCE PROGRAM DATA REPORT (ADR)

INSTRUCTION MANUAL

2016

Release Date: September 26, 2016

Version 2: November 3, 2016

HIV/AIDS Bureau
Division of Policy and Data
Health Resources and Services Administration
U.S. Department of Health and Human Services 5600
Fishers Lane, Room 7C-07
Rockville, MD 20857

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Icons Used in this Document

In addition to the content updates, icons are also featured throughout the text to alert you to particularly important and/or useful information. You will find the following icons in this document:

The Note icon highlights information that you should know when completing your ADR.

The Tip icon points out recommendations and suggestions that may make completing the ADR easier.

The question mark icon points out common questions that we have received from ADAPs and may help you to complete the ADR.

Introduction

The Ryan White HIV/AIDS Treatment Extension Act of 2009 (Public Law 111-87, October 30, 2009) provides the Federal HIV/AIDS programs in the Public Health Service (PHS) Act under Title XXVI flexibility to respond effectively to the changing epidemic. Its emphasis is on providing life-saving and life-extending services for people living with HIV/AIDS across the country and on providing resources to targeted areas with the greatest need.

All Program Parts of the Ryan White HIV/AIDS Program (RWHAP) specify the Health Resources and Services Administration's (HRSA's) responsibilities in the allocation and administration of grant funds, as well as the evaluation of programs for the population served, and the improvement of the quality of care. Accurate records of the recipients of RWHAP funding, the services provided, and the clients served continue to be critical to the implementation of the legislation and thus are necessary for HRSA to fulfill its responsibilities.

The RWHAP legislation authorizes a portion of Part B funds to be designated for the AIDS Drug Assistance Program (ADAP), which primarily provides medications for the treatment of HIV disease. ADAP funds may also be used to provide access to medications through the purchase of health insurance for eligible clients and for services that enhance access, adherence, and monitoring of drug treatments. All 50 States and Territories and the District of Columbia receive ADAP grants.

The HIV/AIDS Bureau (HAB) requires all ADAPs report client-level data using the ADAP Data Report (ADR). The ADR was developed and implemented in 2013. The ADR enables HAB to evaluate the impact of the ADAP program on a national level and allows HAB to characterize the individuals using the program, describe the ADAP-funded services being used, and delineate the costs associated with these services. The ADAP client-level data submitted will be used to:

- monitor the clinical outcomes of clients receiving care and treatment through ADAP
- monitor the use of ADAP funds in addressing the HIV/AIDS epidemic in the United States
- monitor the support provided by ADAP to the most vulnerable communities, especially minorities
- address the data needs of Congress and the Department of Health and Human Services (HHS) concerning the HIV/AIDS epidemic and the RWHAP
- monitor progress towards the goals of the National HIV/AIDS Strategy

HAB uses an encrypted Unique Client Identifier (eUCI) to ensure client confidentiality and limits data collection to only that information reasonably necessary to accomplish the purpose of the ADR.

Technical support for the ADR is available to ADAPs through the HAB Web site at http://hab.hrsa.gov/manageyourgrant/index.html or the Target Center Web site at https://careacttarget.org/library/data-technical-assistance.

What's New

There have been no revisions to the reporting requirements for the 2016 ADR. Please review the manual for added clarification on existing requirements.

About the ADAP Report

The ADR includes two components: (1) the Grantee Report, and (2) the Client Report. All ADAPs are required to submit both reports.

The Grantee Report is a collection of basic information about recipient characteristics and policies.
The Client Report (or client-level data) is a collection of records (one record for each client enrolled in the ADAP) which includes the client's encrypted unique identifier, basic demographic data, and enrollment and certification information. A client's record may also include data about the ADAP-funded insurance and medication received, including the costs of these services, as well as HIV clinical information.

ADAPs are required to submit the ADR annually.

The 2016 ADR is due on **June 5, 2017.**

Who is an ADAP client?

An ADAP client is any individual who is certified as eligible to receive ADAP services, regardless of whether the individual used ADAP services during the reporting period.

During the reporting period, an ADAP client may have:

- received medications and/or insurance assistance
- been placed on a waiting list
- been disenrolled
- been eligible, but did not receive any services

What are ADAP services?

The ADAP is a state-administered program authorized under Part B of the RWHAP to provide FDA-approved medications to low-income clients with HIV disease who have no coverage or limited health care coverage. ADAPs may also use program funds to purchase health insurance for eligible clients and for services that enhance access to, adherence to, and monitoring of antiretroviral therapy.

Medication Assistance Services

Medication assistance services are the purchases of U.S. Food and Drug Administration (FDA) approved medications for the treatment of HIV disease and the prevention and treatment of opportunistic infections. These medications are purchased with ADAP funds on behalf of a client.

Health Insurance Assistance Services

Health insurance assistance services are the provisions of financial assistance for clients to maintain continuity of health insurance or to receive medical benefits under a health insurance program. This includes premium payments (partial or full), Medicare Part D co-insurance, deductibles, true out-of-pocket costs (TrOOP), and co-insurance under catastrophic coverage. Co-pays and deductibles for medications are also considered health insurance assistance services, not medication assistance services, and should be reported in this section, not in the Drug and Drug Expenditures section.

Services Provided under the ADAP Flexibility Policy

HAB Policy Notice 07-03 allows recipients greater flexibility in the use of ADAP funds and permits expenditures of ADAP funds for services that improve access to medications, increase adherence to medication regimens, and help clients monitor their progress in taking HIV-related medications. To use ADAP dollars for services under the ADAP Flexibility Policy, recipients ***must*** request approval annually in their grant application or through the prior approval process in the EHB. ADAP dollars used for services under the ADAP Flexibility Policy are not reported on the ADR.

How is the ADR submitted to HAB?

The ADR is submitted online using HAB's ADR Web Application. Recipients access the ADR Web Application via the HRSA Electronic Handbooks for Applicants/Recipients (EHBs), a Web-based grants administration system. The EHBs are located at https://grants.hrsa.gov/webexternal.

If you need help navigating the EHBs, contact the HRSA Contact Center at 1-877-464-4772.

The ADR Grantee Report is completed by filling out the online forms in the ADR Web Application. After completing the Grantee Report, recipients upload the Client Report as an XML (eXtensible Mark-up Language) file from within the Grantee Report. For additional information, see the *Submitting Client- Level Data to HAB* section on page 15 of this manual.

Who submits the ADR?

The submission of the ADR is a condition of the RWHAP Part B grant award. Each Part B recipient of record must complete both components of the ADR. The recipient of record (formerly referred to as the grantee of record) is the agency that receives ADAP funding directly from HRSA.

What are the reporting periods?

The Grantee Report and the Client Report have different reporting periods.

For the Grantee Report, ADAPs report data based on the grant year reporting period, April 1, 2016 to March 31, 2017.

For the Client Report, ADAPs report client-level data for clients enrolled during the calendar year reporting period, January 1, 2016 to December 31, 2016.

Important Dates to Note

Date	Client XML File	Grantee Report
Monday, February 6, 2017	2016 ADR Test Your XML and Data Quality Feature Opens	-----
Thursday, April 6, 2017	2016 ADR Web System opens for 2016 data collection	
Monday, April 24, 2017	Target upload date for all 2016 ADR client-level data files	-----
Monday, June 5, 2017	ADRs must in be "Submitted" status by 6:00 PM ET	

Please make sure to visit the HAB Web site: http://hab.hrsa.gov/manageyourgrant/adr.html at the beginning of the report submission period to obtain up-to-date information regarding the reporting deadlines.

The Grantee Report

For the Grantee Report, ADAPs will be reporting data based on the grant year reporting period, April 1, 2016 to March 31, 2017. Each ADAP completes the Grantee Report.

The first section of the Grantee Report is the Cover Page (see Figure 1) which contains basic recipient information. Recipients must update, enter, and/or verify the following recipient information.

Cover Page

1. Recipient name (display only): The recipient name must match the organization name on the Notice of Award (NoA). There should be no abbreviations or acronyms unless they are also used in the NoA.

2. Grant number (display only): This is the grant number displayed on your NoA.

Figure 1. ADR Grantee Report Online Form: Cover Page

3. DUNS number (display only): This number, assigned by Dun & Bradstreet, indicates the recipient's credit worthiness.

4. Recipient address (display only): This address should match the mailing address of the recipient of record. There should be no abbreviations or acronyms unless they are also used in the NoA.

5. Contact information of person completing the Grantee Report: Enter name, title, email, telephone number, and FAX number. *You must complete this required data.*

The Cover Page items displayed on your screen reflect the information on the recipient of record that is stored in the EHBs. If the information is not correct for items 1-4, please contact the HRSA Contact Center to make corrections. For item 5, you may edit the contact information directly on your screen.

Once you've updated, entered, and/or verified the data on the Recipient Contact Information page, **click Save** to save the data and to also be advanced to the next section, ***Programmatic Summary Submission*.**

Programmatic Summary Submission

The next section is the *Programmatic Summary Submission* consisting of sub sections A through E, numbers 1-7. It should be completed for the grant year reporting period, April 1, 2015 to March 31, 2016.

Note the Navigation menu on the left side of the ADR Web application in ***Figure 1***. Under **Data Entry**, you can navigate through the Grantee Report by clicking on the question number.

You will not be able to save a page with missing data (a blank entry). To avoid losing data, you may enter "0" (zero) as a placeholder for any unknown data and return at a later time to enter the known data.

A. Program Administration

1. **ADAP Limits:** Indicate whether your program has adopted any of the following limits in order to control costs. You may check more than one box if applicable (see Figure 2).

    a. *Waiting list*—A list of clients who have been certified as eligible and have been enrolled to receive ADAP services, but are not receiving ADAP services due to caps on service enrollment or other cost-containment strategies.

    b. *Enrollment cap*—A limit on the maximum number of people who can be enrolled in your program and receive services at any given time. If your ADAP has capped enrollment, enter the maximum number of enrollees.

    c. *Capped number of prescriptions per month*—A limit on the number of prescriptions allowed per month. If your ADAP has capped prescriptions per month, enter the number per month.

    d. *Capped expenditure*—A limit on the maximum amount of dollars that can be spent per client.

If your ADAP has capped expenditures, enter the monetary cap per client and whether the cap applies monthly or annually.

e. *Drug-specific enrollment caps for ARVs or Hepatitis B & C medications*—A limit on the maximum number of clients who can receive a specific medication at any given time.

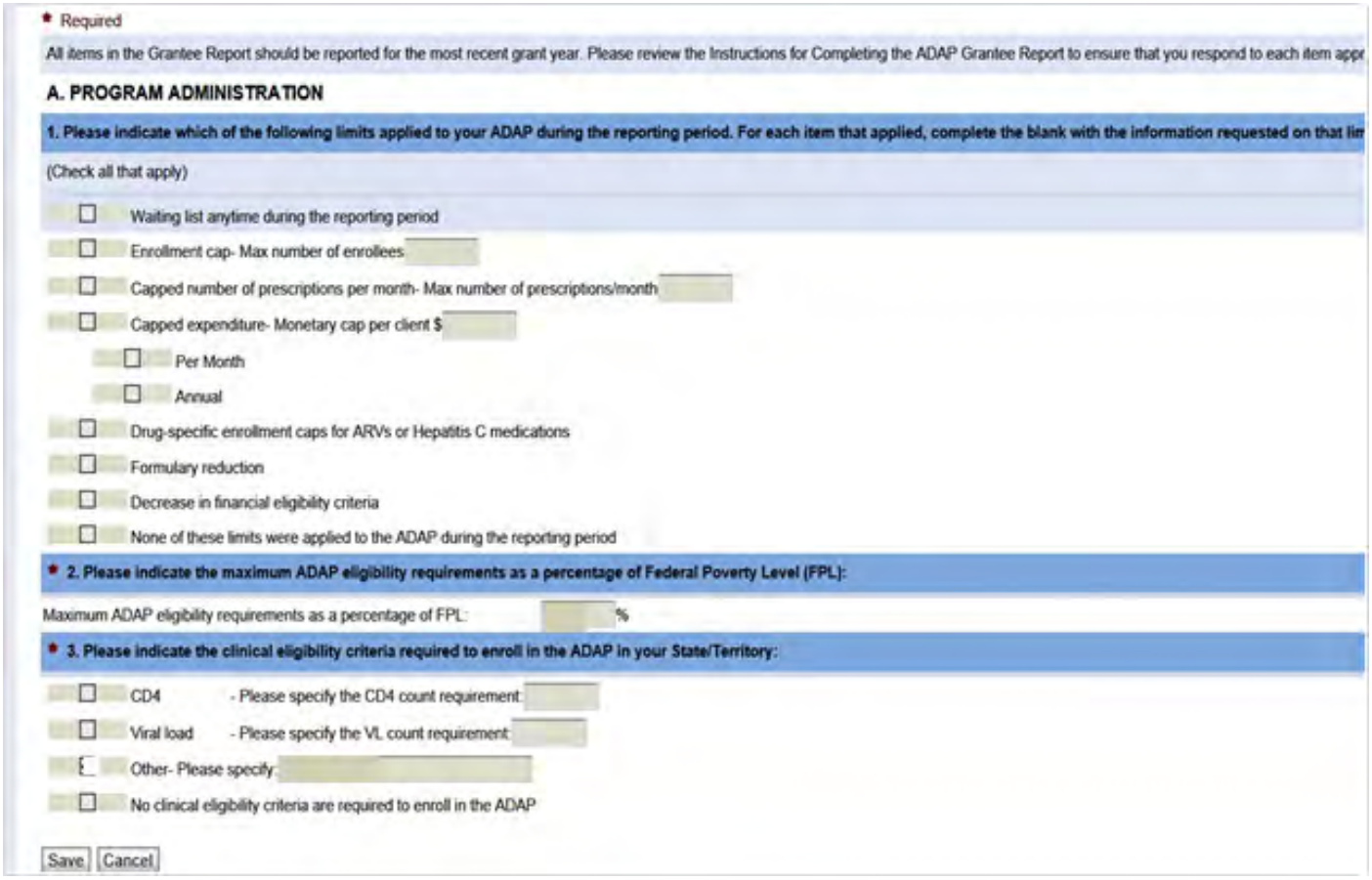
If your ADAP has adopted drug-specific enrollment caps, indicate the medications for which you have enrollment caps.

f. *Formulary reduction*—A change in your ADAP formulary that reduced the number of medications that are available to your clients.

g. *Decrease in financial eligibility criteria*— A change in your income eligibility requirement that decreased the Federal Poverty Level (FPL) criteria for participation in your ADAP.

h. *None of these limits were applied to the ADAP during the reporting period*—If your ADAP did not apply any limits, check this box as your only response to this question.

Figure 2. ADR Grantee Report Online Form: Screenshot of the Programmatic Summary Submission: Q #1-3



If you select **Enrollment Cap, Capped prescriptions or Capped expenditure**, you must enter the maximum limit for that option. For the **Drug-specific enrollment caps,** you must indicate the specific medication.

2. **ADAP income eligibility**: Enter the maximum income eligibility cap for participation in your State ADAP that was in place as of the end of the grant year. (see Figure 2). This should be expressed as a percentage of the FPL. For example, individuals living with HIV who have an income of 200 percent of the FPL or lower, may be eligible to participate. See Appendix C for additional information on how to calculate FPL.

Which FPL eligibility requirement should we report if we have different requirements for our medication and health insurance assistance services?

Answer: ADAPs should report their FPL requirement for medication services.

3. **Clinical criteria required to access ADAP:** Check all of the clinical eligibility criteria that are required (in addition to HIV positive status) for enrolling in the ADAP in your state or territory (see Figure 2).

    a. *CD4*— Indicate the threshold number in the space provided

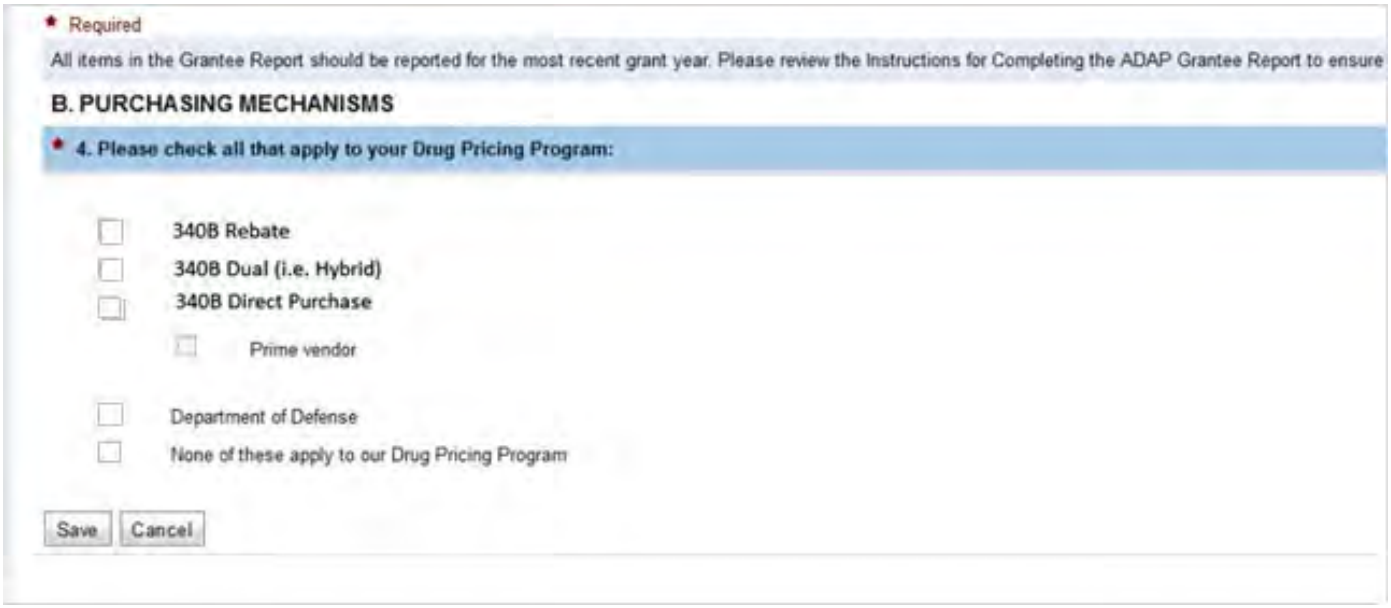
    b. *Viral load* — Indicate the threshold number in the space provided

    c. *Other* - Indicate each criterion used and any corresponding threshold number

    d. *No clinical eligibility is required to enroll in the ADAP*— only check if your ADAP does not require clinical eligibility criteria. Do not check any other options.

Click on the **Save button** before navigating to the next page or your data will be lost.

Figure 3. ADR Grantee Report Online Form:
Screenshot of the Programmatic Summary Submission: Q #4



Note: This screenshot will be revised for the 2016 ADR System. Response options, "340B Dual (i.e. Hybrid) and "None of these apply to our Drug Pricing Program" have been eliminated. See below, ***B. Purchasing Mechanisms,*** *for the updated 2016 response options.*

B. Purchasing Mechanisms

4. **Drug pricing cost-saving strategies:** Check all items that apply to your drug pricing program (see Figure 3). For complete definitions of the cost-saving strategies below, see Glossary.

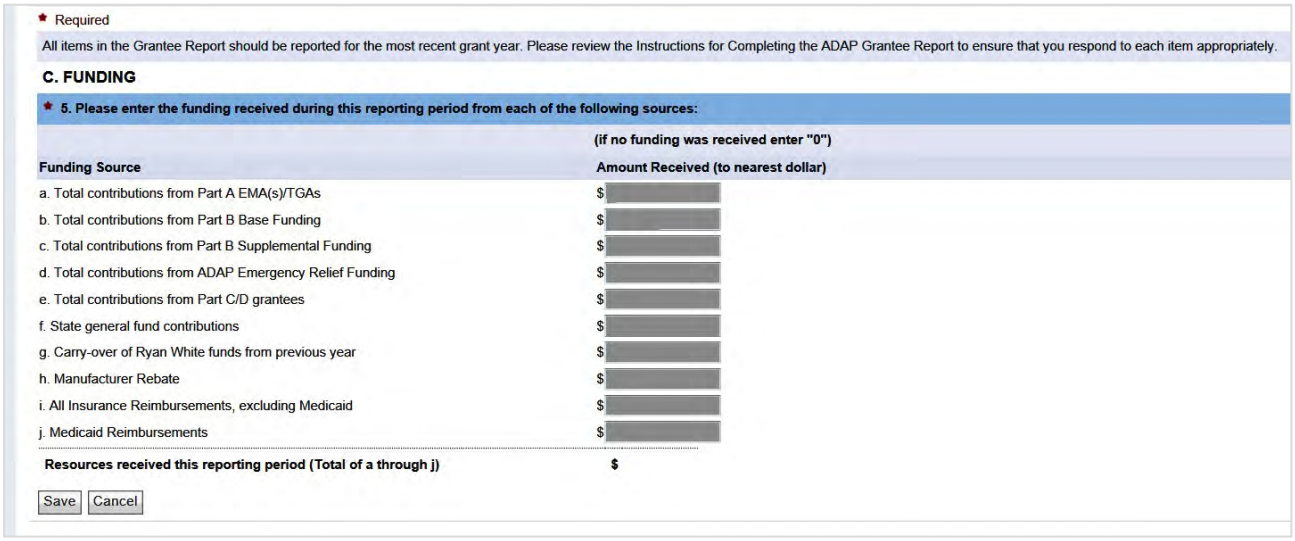
   If your ADAP participates in the 340B Drug Pricing Program that requires drug manufacturers to provide outpatient drugs to eligible health care organizations/covered entities at significantly reduced prices, please select the mechanism(s) through which your program has implemented the program:

   a. 340B Rebate - A prescription drug purchasing model in which ADAPs reimburse a network of retail pharmacies for costs associated with filling prescriptions for eligible clients. ADAPs submit 340B rebate claims to drug manufacturers.
   b. 340B Direct Purchase - A prescription drug purchasing model in which ADAPs purchase drugs directly from a manufacturer or wholesaler at the 340B pricing schedule.
      1. If your ADAP participates in the Prime Vendor Program that handles price negotiation and drug distribution responsibilities for members, please check, "Prime Vendor"

   If your ADAP participates in the following:

   c. Department of Defense: pharmaceutical cost-saving strategy administered by the Department of Defense.

Figure 4. ADR Grantee Report Online Form: Screenshot of the Programmatic Summary Submission: Q #5



* Required

All items in the Grantee Report should be reported for the most recent grant year. Please review the Instructions for Completing the ADAP Grantee Report to ensure that you respond to each item appropriately.

C. FUNDING

*** 5. Please enter the funding received during this reporting period from each of the following sources:**

Funding Source	(if no funding was received enter "0") Amount Received (to nearest dollar)
a. Total contributions from Part A EMA(s)/TGAs	$
b. Total contributions from Part B Base Funding	$
c. Total contributions from Part B Supplemental Funding	$
d. Total contributions from ADAP Emergency Relief Funding	$
e. Total contributions from Part C/D grantees	$
f. State general fund contributions	$
g. Carry-over of Ryan White funds from previous year	$
h. Manufacturer Rebate	$
i. All Insurance Reimbursements, excluding Medicaid	$
j. Medicaid Reimbursements	$
Resources received this reporting period (Total of a through j)	**$**

Save Cancel

C. Funding

5. **ADAP funding received during the reporting period**: Enter the amount of funding your program *received, not awarded*, from the sources listed during the reporting period (see Figure 4). Enter 0 if your ADAP did not receive funding from any given source during the period. Do not leave any boxes blank.

When you ask for Part B Base Funding, are you also asking us to include ADAP base funding in that total?

Answer: The term, Part B Base Funding, refers to any of your Ryan White Part B Base award that is used for ADAP services. Do not include your ADAP Base funding (formerly referred to as "earmark" funds) in this total.

We did not receive any new funding during the report period, am I permitted to enter zero in Item #5?

Answer: Report all funding received during the reporting period, not just new funding. You may enter "0" if you did not receive any funding from the list of sources.

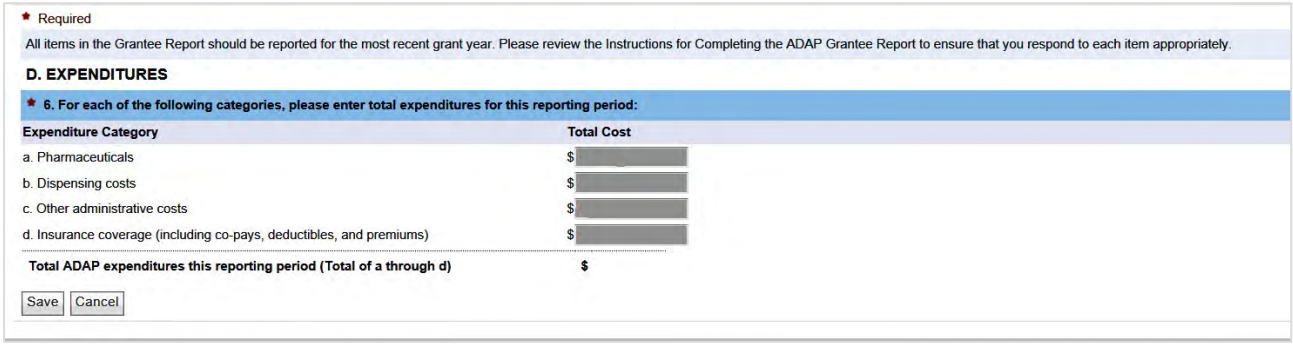
Do we include funding that we used for services under the ADAP Flexibility Policy, or just funding for medication and health insurance services?

Answer: Services funded through the ADAP Flexibility Policy are not reported on the ADR.

Where do we report State matches for ADAP?

Answer: State funds used in ADAP to meet the recipient's match requirement should be included in *f. State general fund contributions.*

Figure 5. ADR Grantee Report Online Form: Screenshot the Programmatic Summary Submission: #6



* Required

All items in the Grantee Report should be reported for the most recent grant year. Please review the Instructions for Completing the ADAP Grantee Report to ensure that you respond to each item appropriately.

D. EXPENDITURES

*** 6. For each of the following categories, please enter total expenditures for this reporting period:**

Expenditure Category	Total Cost
a. Pharmaceuticals	$
b. Dispensing costs	$
c. Other administrative costs	$
d. Insurance coverage (including co-pays, deductibles, and premiums)	$
Total ADAP expenditures this reporting period (Total of a through d)	**$**

Save Cancel

Note: This screenshot will be revised for the 2016 ADR System. Response options, "a. Pharmaceuticals" has been changed to "a. Full pay medication assistance" and "d. Insurance coverage" has been changed to "d. Health insurance assistance." See below, ***D. Expenditures*** *for the updated 2016 response options.*

D. Expenditures

6. **Expenditures:** Enter the total expenditures for pharmaceuticals, dispensing and other administrative costs, and health insurance coverage (including co-pays, deductibles and premiums) for the reporting period (see Figure 5). The total expenditures for the reporting period will be calculated automatically.

   a. Full pay medication assistance: Report ALL drugs fully-paid for by ADAP. If a drug is only partially paid for by ADAP, it must be reported as health insurance assistance and reported in *d. Health insurance coverage* below.
   b. Dispensing costs: fees paid by ADAP to distribute medications.
   c. Other administrative costs: all other fees excluding dispensing costs paid by ADAP that are related to purchasing and distributing medication such as shipping and handling and other bulk order fees. Do not include the general administrative costs of the ADAP (e.g. staffing costs) here.
   d. Health insurance assistance: any health insurance assistance, including co-pays, deductibles, and premiums, provided to ADAP clients paid by ADAP

E. ADAP Medication Formulary

7. **ADAP Medication Formulary**: A list of (a) ARVs, (b) A1-OI's, and (c) Hepatitis medications will be provided separately (see Figure 6 for ARVs as an example page). The medication's generic name appears first, followed by the brand name and then its D-code number.

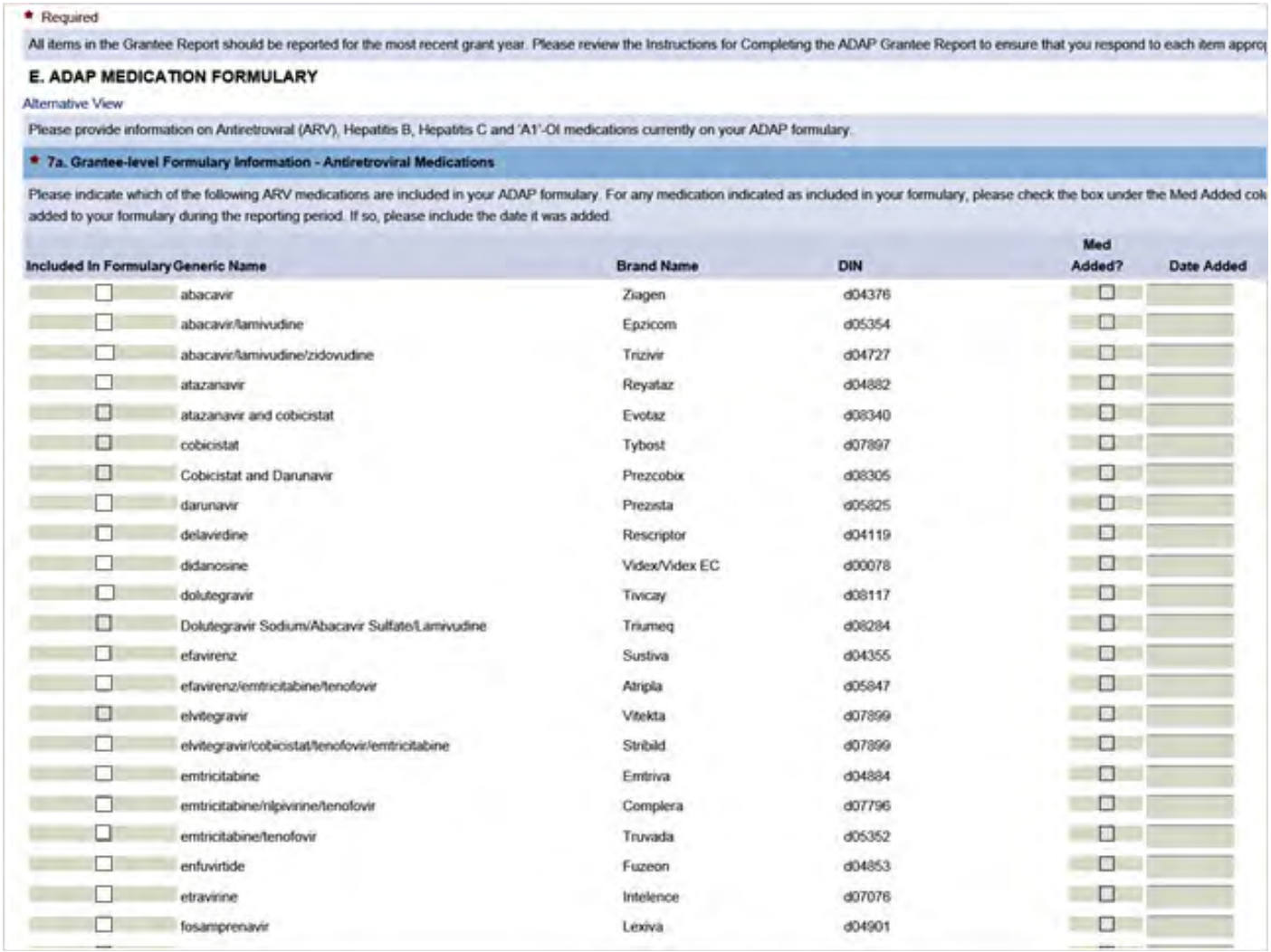
   For each list of medications, check the box on the left if your ADAP currently includes the medication in the formulary.

   If the medication was added to the formulary during the reporting period, check the box provided in the "Med Added" column and enter the date that the medication was added in the "Date Added" column.

The list of medications will automatically generate previous data (i.e. from your ADAP's last ADR submission). You will need to review the list again and enter any changes that were made during the current reporting period.

The columns can also be sorted to easily locate medications on your formulary.

Figure 6. ADR Grantee Report Online Form: Screenshot of the Programmatic Summary Submission: Example List of Medications



* Required

All items in the Grantee Report should be reported for the most recent grant year. Please review the Instructions for Completing the ADAP Grantee Report to ensure that you respond to each item appro

E. ADAP MEDICATION FORMULARY

Alternative View

Please provide information on Antiretroviral (ARV), Hepatitis B, Hepatitis C and 'A1'-OI medications currently on your ADAP formulary.

*** 7a. Grantee-level Formulary Information - Antiretroviral Medications**

Please indicate which of the following ARV medications are included in your ADAP formulary. For any medication indicated as included in your formulary, please check the box under the Med Added col added to your formulary during the reporting period. If so, please include the date it was added.

Included In Formulary	Generic Name	Brand Name	DIN	Med Added?	Date Added
☐	abacavir	Ziagen	d04376	☐	
☐	abacavir/lamivudine	Epzicom	d05354	☐	
☐	abacavir/lamivudine/zidovudine	Trizivir	d04727	☐	
☐	atazanavir	Reyataz	d04882	☐	
☐	atazanavir and cobicistat	Evotaz	d08340	☐	
☐	cobicistat	Tybost	d07897	☐	
☐	Cobicistat and Darunavir	Prezcobix	d08305	☐	
☐	darunavir	Prezista	d05825	☐	
☐	delaviridine	Rescriptor	d04119	☐	
☐	didanosine	Videx/Videx EC	d00078	☐	
☐	dolutegravir	Tivicay	d08117	☐	
☐	Dolutegravir Sodium/Abacavir Sulfate/Lamivudine	Triumeq	d08284	☐	
☐	efavirenz	Sustiva	d04355	☐	
☐	efavirenz/emtricitabine/tenofovir	Atripla	d05847	☐	
☐	elvitegravir	Vitekta	d07899	☐	
☐	elvitegravir/cobicistat/tenofovir/emtricitabine	Stribild	d07899	☐	
☐	emtricitabine	Emtriva	d04884	☐	
☐	emtricitabine/rilpivirine/tenofovir	Complera	d07796	☐	
☐	emtricitabine/tenofovir	Truvada	d05352	☐	
☐	enfuvirtide	Fuzeon	d04853	☐	
☐	etravirine	Intelence	d07076	☐	
☐	fosamprenavir	Lexiva	d04901	☐	

Do recipients have to report historical start dates in the formulary?

Answer: Recipients only need to include the "date added" for medications added to the formulary within the fiscal year reporting period. Recipients do not need to enter the "date added" if the medication was added prior to the fiscal year reporting period.

Next Step: Upload Your Client-Level Data

Once you are satisfied that your Grantee Reports is complete and correct, upload your client-level data. The Grantee Report cannot be submitted until the Client Report is uploaded into the ADR Web Application. The Client Report is a collection of ADAP client records that must be submitted in one or more properly formatted client-level data XML files. For more explanations on the client-level data elements, see the section, *The Client Report* on page 15. To learn how to upload the client-level data XML file, see the section *Importing the XML Client File* on page 29.

If you need help on completing the Grantee Report, contact Data Support at 1-888-640-9356 or e-mail RyanWhiteDataSupport@wrma.com.

The Client Report

For the Client Report, ADAPs should report client-level data for clients enrolled during the calendar year reporting period, January 1, 2016 to December 31, 2016.

Reporting Client-level Data

The Client Report should contain one record ("row" of data in a database) for each client enrolled in the ADAP during the reporting period. An enrolled client is an individual who is certified as eligible to receive services, whether or not the individual actually received ADAP services during the reporting period. For all enrolled clients, ADAPs must report client demographics and enrollment and certification data. For clients who received services, ADAPs must report whether they received health insurance services and/or medications services and their related data. Note that clinical data is only required for clients who received medication services. See appendix A: *Required Client-Level Data Elements* to determine the client-level data elements required to be reported for an enrolled client.

Submitting Client-level Data to HAB

The Client Report (i.e., client-level data set) must be uploaded in one or more properly formatted XML file(s). XML is a standard, simple, and widely adopted method of formatting text and data so that it can be exchanged across different computer platforms, languages, and applications. To learn how to upload the client-level data XML file, see the section *Importing the XML Client File* on page 29.

ADAPs need to extract the client-level data elements from their systems into the proper XML format before they can be uploaded to the HAB server. If your ADAP uses an ADR Ready System such as CAREWare, eCOMPAS or Provide Enterprise, no special action will be required to generate the XML file. These ADR Ready Systems are able to export the data in the required XML format.

Be sure you are using the latest version of your ADR Ready System.

If you do not use an ADR Ready System, you will need to use a program that extracts the data from your system and inserts it into an XML file that conforms to the rules of the ADR XML schema. The schema and related documents are available at https://careacttarget.org/library/adap-data-report-adr-download-package. HAB has also created the tool, TRAX to help ADAPs create their XML file. To download the application and manual, go to https://careacttarget.org/library/trax-adr.

If you need assistance in creating your XML file(s), contact DART at Data.TA@caiglobal.org.

Client-level Data Fields

The *Client-level Data Fields* section outlines the data fields required to be submitted in the client-level data XML file. Due to the new and deleted data elements implemented in the past years, the numbering is not sequential, but rather is consistent with the unique identifier (ID number) in the ADR XML Schema as referenced above. For common program questions from recipients, see appendix B: Frequently Asked Program Questions from the Field.

Encrypted Unique Client Identifier

The XML file will contain one system field: encrypted Unique Client Identifier (eUCI). To protect client information, an eUCI is used for reporting Ryan White client data.

A Unique Client Identifier (UCI) is a unique 11-character alphanumeric code that is the same for the client across all provider settings. The UCI is derived from the first and third characters of a client's first and last name, his or her date of birth (MM/DD/YY), and a code for gender (1=male, 2=female, 3=transgender, 9=unknown).

An eUCI is a 40-character alphanumeric code created when SHA-1, a one- way hashing algorithm that meets the highest privacy and security standards, encrypts the client's UCI. SHA-1 is a trap door algorithm, meaning that the original UCI is unrecoverable from the eUCI. The resulting alphanumeric code, the eUCI, is used to distinguish one Ryan White client from all others in a region.

It is possible that different clients have identical 40-digit eUCIs. Therefore, ADAPs must add a 41st character at the end of the eUCI to provide additional distinction. If only one client within the ADAP data system has a given UCI, the suffix should be **U** for unique. If more than one client has the same UCI, the final character of the first client's eUCI needs to be **A**, the final character of the next client's eUCI needs to be **B**, and so on. The suffix prevents multiple clients from having the same eUCI.

The UCI must be encrypted with SHA-1 at the provider site BEFORE the data are submitted to HAB.

To learn more about the eUCI, view the resources available on the TARGET Center Web site at https://careacttarget.org/library/euci-and-adr-0.

Guidelines for Collecting and Recording Client Names

Recipients should develop business rules/operating procedures outlining the method by which client names should be collected and recorded, for example:

- Enter the client's entire name as it normally appears on documentation such as a driver's license, birth certificate, passport, or social security card.
- Follow the naming patterns, practices, and customs of the local community or region (i.e., for Hispanic clients living in Puerto Rico, record both surnames in the appropriate order).
- Avoid the use of nicknames (i.e., do not use Becca if the client's full name is Rebecca).
- Avoid using initials.

Recipients should instruct their staff on the correct entry of client names. Client names must be entered in the same way every time in order to avoid false duplicates.

Client Demographics

The purpose of the Client Demographics section is to describe the socio-demographic characteristics of all clients **enrolled** in the ADAP, **regardless of whether they received services.**

Reporting Client Race and Ethnicity

The Office of Management and Budget (OMB) Revisions to the Standards for the Classification of Federal Data on Race and Ethnicity provides a minimum standard for maintaining, collecting, and presenting data on race and ethnicity for all federal reporting purposes. The standards were developed to provide a common language for uniformity and comparability in the collection and use of data on race and ethnicity by federal agencies.

The standards have five categories for data on race: American Indian or Alaska Native; Asian; Black or African American; Native Hawaiian or Other Pacific Islander; and White. There are two categories for data on ethnicity: Hispanic or Latino and Not Hispanic or Latino. Identification of ethnic and racial subgroups is required for the categories of Hispanic/Latino, Asian, and Native Hawaiian/Pacific Islander. The racial category descriptions defined in October 1997 are required for all federal reporting, as mandated by the OMB. For more information, go to: http://aspe.hhs.gov/datacncl/standards/aca/4302/index.pdf.

HAB is required to use the OMB reporting standard for race and ethnicity. However, ADAPs can choose to collect race and ethnicity data in greater detail. If the agency chooses to use a more detailed collection system, the data collected should be organized so that any new categories can be aggregated into the standard OMB breakdown.

Recipients are required to report race and ethnicity for each client based on each client's self-report. Self-identification is the preferred means of obtaining this information. Recipients should not establish criteria or qualifications to determine a particular individual's racial or ethnic classification, nor specify how someone should classify himself or herself.

4. Ethnicity

Indicate the client's ethnicity based on his or her self-report.

- *Hispanic/Latino(a)*—A person of Cuban, Mexican, Puerto Rican, South or Central American, or other Spanish culture or origin, regardless of race. The term "Spanish origin" can be synonymous with "Hispanic or Latino." If a client identifies as Hispanic/Latino, go to Item 68 below and choose all Hispanic subgroups that apply.
- *Non-Hispanic*—A person who does not identify his or her ethnicity as Hispanic or Latino.

68. Hispanic/Latino Subgroup

Indicate the client's Hispanic/Latino subgroup based on his or her self-report.

- *Mexican, Mexican American, Chicano/a*
- *Puerto Rican*
- *Cuban*
- *Another Hispanic, Latino/a or Spanish origin*

5. Race (Select one or more)

Indicate the client's race based on his or her self-report.

- *American Indian or Alaska Native*—A person having origins in any of the original peoples of North and South America (including Central America), and who maintains tribal affiliation or community attachment.
- *Asian*—A person having origins in any of the original peoples of the Far East, Southeast Asia, or the Indian subcontinent including, for example, Cambodia, China, India, Japan, Korea, Malaysia, Pakistan, the Philippine Islands, Thailand, and Vietnam. If a client identifies as Asian, go to Item 69 below and choose all Asian subgroups that apply.
- *Black or African American*—A person having origins in any of the black racial groups of Africa.
- *Native Hawaiian or Other Pacific Islander*—A person having origins in any of the original peoples of Hawaii, Guam, Samoa, or other Pacific Islands. If a client identifies as Native Hawaiian/Pacific Islander, go to Item 70 below and choose all Native Hawaiian/Pacific Islander subgroups that apply.
- *White*—A person having origins in any of the original peoples of Europe, the Middle East, or North Africa.

"Unknown" is not a response option for the race and ethnicity subgroups. If you do not have these data for a given client, leave blank and the data will be missing. For additional assistance on how to deal with "unknown" responses in your data, please contact DART.

69. Asian Subgroup (Select one or more)

Indicate the client's Asian subgroup based on his or her self-report.

- *Asian Indian*
- *Chinese*
- *Filipino*
- *Japanese*
- *Korean*
- *Vietnamese*
- *Other Asian*

70. Native Hawaiian/Pacific Islander Subgroup (Select one or more)

Indicate the client's Native Hawaiian/Pacific Islander subgroup based on his or her self-report.

- *Native Hawaiian*
- *Guamanian or Chamorro*
- *Samoan*
- *Other Pacific Islander*

6. Current Gender

Indicate the client's current gender (the socially and psychologically constructed, understood, and interpreted set of characteristics that describe the current sexual identity of an individual) based on his or her self-report. Gender cannot be missing; one of the options below must be reported for current gender.

- *Male*—An individual with strong and persistent identification with the male sex.
- *Female*—An individual with strong and persistent identification with the female sex.
- *Transgender*—An individual whose gender identity is not congruent with his or her biological gender, regardless of the status of surgical and hormonal gender reassignment processes. Sometimes the term is used as an umbrella term encompassing transsexuals, transvestites, cross-dressers, and others. The term transgender refers to a continuum of gender expressions, identities, and roles, which expand the current dominant cultural values of what it means to be male or female.

7. Transgender

If the client is reported as **Transgender** in Item 6, indicate the following:

- *Male-to–Female*
- *Female-to–Male*
- *Unknown*

71. Sex at Birth

Indicate the biological sex assigned to the client at birth.

- *Male*
- *Female*

Sex at Birth should be completed for all clients.

9. Year of Birth

Indicate the client's birth year in the form *YYYY*. This data element is required.

Even though only the year of birth will be reported to HAB, ADAPs should collect the client's full date of birth. The client's birth month, day, and year are used to generate the UCI.

10. HIV/AIDS Status

Indicate the HIV/AIDS status of the client at the end of the reporting period.

- *HIV-positive, not AIDS*—Client has been diagnosed with HIV but has not been diagnosed with AIDS.

- *HIV-positive, AIDS status unknown*—Client has been diagnosed with HIV. It is not known whether the client has been diagnosed with AIDS.
- *CDC-defined AIDS*—Client is an HIV-infected individual who meets the CDC AIDS case definition for an adult or child.

11. Poverty Level

Report the client's annual household income as a percent of the Federal poverty measure as of the end of the reporting period. See appendix D: *Calculating Client Income Percentage of the Federal Poverty Measure Using HHS Federal Poverty Guidelines*. Report information from the most recent certification/recertification for each client.

- *Below 100% of the Federal poverty level*
- *100 – 138% of the Federal poverty level*
- *139 – 200% of the Federal poverty level*
- *201 – 250% of the Federal poverty level*
- *251 – 400% of the Federal poverty level*
- *401 – 500% of the Federal poverty level*
- *More than 500% of the Federal poverty level*

There are two slightly different versions of the *Federal poverty measure*—the poverty thresholds (updated annually by the U.S. Bureau of the Census) and the poverty guidelines (updated annually by HHS.) If your agency already uses one of these measures, use that to report this data item. Otherwise, HAB recommends and prefers that your organization use the HHS poverty guidelines to collect and report it. For more information on poverty measures and to see the 2016 HHS Poverty Guidelines, go to https://aspe.hhs.gov/poverty-guidelines.

12. High Risk Insurance

Indicate whether the client was in a High Risk Insurance Pool at any time during the reporting period. A High Risk Insurance Pool is a state or federal health insurance program that provides coverage for individuals who are denied coverage due to a preexisting condition or who have health conditions that would normally prevent them from purchasing insurance coverage in the private market.

- *No*
- *Yes*
- *Unknown*

13. Health Insurance

Report all sources of health insurance the client had **for any part of the reporting period**, regardless of whether the ADAP paid for it. If the client did not have health insurance at some time during the reporting period, report No insurance as well. (**Select one or more**).

- *Private – Employer* is private health insurance such as BlueCross/BlueShield, Kaiser Permanente and Aetna and is paid by an employer.

- *Private – Individual* is private health insurance such as BlueCross/BlueShield, Kaiser Permanente and Aetna and is paid by the client and/or RWHAP funds.

- *Medicare Part A/B* is a public health insurance program for people 65 years of age and older, some disabled people under 65 years of age, and people with End-Stage Renal Disease (permanent kidney failure treated with dialysis or a transplant). Part A (hospital insurance) covers inpatient care in hospitals and hospice and home health care. Part B (medical insurance) covers medically necessary services and supplies provided by Medicare such as outpatient care, doctor's services, physical or occupational therapists, and additional home health care.

- *Medicare Part D* is a stand-alone prescription drug coverage insurance.

- *Medicaid, Children's Health Insurance Program (CHIP), or other public plan.* Medicaid is a jointly funded, federal-state health insurance program for people with limited income and resources. CHIP provides health coverage to children in families who do not qualify for Medicaid. Other public plan is any federal or state-funded health insurance plan.

- *VA, Tricare or other military health care.* VA is health coverage for eligible Veterans. Tricare and other military health care are health care programs for uniformed service members, retirees and their families.

- *Indian Health Services (IHS)* provides health services to American Indians and Alaska Natives.

- *Other plan* means the client has an insurance type other than those listed above.

- *No insurance/uninsured* means the client did not have health insurance at some time during the reporting period. HAB classifies clients who have no way to pay for medical expenses other than with RWHAP funds as uninsured.

In general, insurance should be reported based on ***who*** pays for the insurance premium. If a client or employer pays for the premium, select *private*. If Ryan White funds are used to pay for premiums, copays or deductibles, select both *private* AND *no insurance*. For state or federally funded health insurance, select *Medicaid, Children's Health Insurance Program (CHIP) or other public plan*".

How do I report Medicare Advantage as a type of insurance?

Answer: Medicare Advantage is an alternative to private health insurance for Medicare beneficiaries. Report Medicare Advantage under Medicare Part A/B.

Enrollment and Certification

The purpose of the Enrollment and Certification section is to describe client enrollment patterns and certification processes. Report the applicable data elements in this section for all clients who were enrolled in the ADAP during the reporting period, whether or not they received services.

14. Was the client a new or existing client?

Report whether the client was new during the reporting period, even if the client was disenrolled at the end of the period.

- *New client* refers to individuals who meet all of the following criteria:
  - applied to your state ADAP for the first time ever
  - met the financial and medical eligibility criteria of the ADAP during the period for which you are reporting data

  Examples of clients who should **NOT** be included as a *new* client are the following:
  - clients who have been recertified as eligible or clients who have been re-enrolled after a period of having been decertified/disenrolled
  - clients who have moved out of the state and then returned
  - clients who move on and off ADAP because of fluctuations in eligibility for a Medicaid/ Medically Needy program, based on whether they met spend-down requirements.

- *Existing client* refers to individuals who meet the following criteria:
  - enrolled in your ADAP in a previous reporting period
  - are enrolled in the current reporting period, regardless of whether they ever used ADAP services

An individual enrolled in ADAP (new or existing client) may or may not use services. Use of services is not required to be an enrolled client.

15. Date Completed Application Received (Complete if client is a new client.)

For all new clients, report the date that the completed application was received by the ADAP program. Each ADAP should have a policy of when an application is considered completed and approved and apply it consistently to all applicants. Indicate this date in the form *MM/DD/YYYY*.

16. Date Application Approved (Complete if client is a new client.)

For all new clients, report the date that the client was first approved to begin receiving ADAP services. For those ADAPs who may have two different application processes for medication or health insurance services or if a client applies to the program more than once within the reporting period, enter the first date a client is approved for any ADAP service. Indicate this date in the form *MM/DD/YYYY*. The date should be within the reporting period.

If a client is initially ineligible for ADAP and is declined and then 2 months later reapplies and is eligible, which date should be used for the completed application?

Answer: You should report the application date under which the client was approved.

If a new client application is approved in January but the application was received before (outside) the reporting period, what date should be reported for the application date?

Answer: You should report the actual date of the application received, even if outside the reporting period.

17. Date of Recertification (Complete if client has been enrolled for 6 or more months.)

All clients enrolled for more than 6 months or existing clients who were re-enrolled to receive services during the reporting period should have recertification dates. Report the date(s) the client was determined to be eligible to continue receiving ADAP services. Indicate date(s) in the form *MM/DD/YYYY*. Dates should be within the reporting period.

If a client fails to recertify one week after the 6-month anniversary of certification, is the client automatically disenrolled?

Answer: The recipient must ensure that eligibility is verified every 6 months, but are given flexibility as to whether they recertify all clients at the same time or have a rolling recertification based on some other factor (e.g. original enrollment date, birthdate, etc.). If a client does not recertify by the date specified by the recipient, the client is ineligible for the program as of that date; there is no grace period or cushion.

What should we report if we have more than 2 recertification dates?

Answer: HAB reviews these data to determine compliance with the policy of recertification of clients at least every 6 months. You should report the 2 dates that would meet this criteria."

All individuals enrolled in ADAP, regardless of whether or not they receive services, must be recertified every 6 months. This includes clients on a waiting list. Information on client eligibility determinations and recertification requirements can be found at http://hab.hrsa.gov/manageyourgrant/pinspals/pcn1302clienteligibility.pdf

18. Enrollment Status

Indicate the enrollment status of the client **at the end of the reporting period**.

- *The client is enrolled in ADAP but did not need/request any services*
- *The client is enrolled in ADAP but is on a waiting list*
- *The client is enrolled in ADAP and received ADAP-funded medications or health insurance services during the reporting period*
- *The client was disenrolled from ADAP*

If the client is currently enrolled, skip to Item 20.

19. Reason(s) for Disenrollment

Indicate ***all*** reasons for disenrollment/discharge. Choose the best reason(s) that apply to your ADAP's disenrollment policies. If the reason is unknown, please report under **Other/unknown**.

- *The client is ineligible due to change in ADAP eligibility criteria*
- *The client is ineligible for ADAP due to no longer meeting ADAP eligibility criteria*
- *The client did not recertify*
- *The client did not fill prescription as required by program*
- *The client is deceased*
- *Other*

If a new client application is approved but the first service is not received during the reporting year, what data should be reported for this client?

Answer: You should report Date Completed Application Received (Item #15) and Date Application Approved (Item #16) and for Item #18, report the option of "enrolled, but did not need/request any services."

ADAP Services

ADAP services are health insurance assistance and medication assistance services provided to enrolled clients in the ADAP program. ADAP funds, regardless of its source (state funds, Ryan White Part B ADAP, Ryan White Part B formula, Part B Supplemental Funding, ADAP Emergency Relief Fund, Part A contributions, 340B rebates, ADAP Crisis Task Force Rebates, etc.) were used to provide these services. All ADAP services that a client received during the reporting period should be reported in these sections. Additional definitions for ADAP services can be found in the "What are ADAP Services?" section on page 3 of this manual.

ADAP Health Insurance Services

The purpose of the ADAP Health Insurance Services section is to describe ADAP-funded health insurance assistance services and expenditures. ADAP-funded health insurance assistance includes premiums (partial or full), Medicare Part D co-insurance, deductibles, TrOOP, and co-insurance under catastrophic coverage. Co- pays and deductibles for medications are also considered health insurance assistance services, not medication services, and should be reported in this section, not in the *Drugs and Drug Expenditures* section. Lastly, report the ADAP-funded health insurance services your clients received during the reporting period based on when the premiums, deductibles, co-pays, etc. were paid, **not according to the coverage period**.

A *full premium payment* is 100% of the premium paid for by the ADAP. This is common when an ADAP is purchasing insurance on behalf of the client.
A *partial premium payment* is when a portion of the premium (i.e. less than 100%) is paid for by the ADAP. Examples include if the ADAP is paying the employee-share of a premium or the non-subsidy part of an insurance premium.

20. Receipt of Health Insurance Services

Indicate whether the client received ADAP-funded health insurance assistance during the reporting period including premiums (partial or full), Medicare Part D co-insurance, deductibles, TrOOP, and co- insurance under catastrophic coverage. Co-pays and deductibles for medications are also considered health insurance

assistance services and should be reported in this section, not in the Drugs and Drug Expenditures section.

- *Yes* (If the response is Yes, complete Items 67, 21, 22 and 23)
- *No* (If the response is No, skip to Item 25)

67. Type of Health Insurance Assistance Received

Indicate the types of health insurance service(s) that the client received during the reporting period. Choose all that apply.

- *Full premium payment* is 100% of the premium paid for by the ADAP.
- *Partial premium payment* is when a portion of the premium (i.e. less than 100%) is paid for by the ADAP.
- *Copay/deductible including Medicare Part D co-insurance, co-payment or donut hole coverage*

21. Amount Paid for Premiums

Indicate the total amount *($0 to $100,000)* of insurance premiums, ***including premiums paid for Medicare Part D***, paid on behalf of the client during the reporting period. This includes any premium paid (partial or full) during the reporting period, regardless of the time frame that the premium covers (i.e., if the time frame covered extends outside the reporting period).

If an amount was entered, complete Item 22.

22. Months Coverage of Premiums Paid

Indicate the total number of months *(0 to 12)* of coverage for which the insurance premium in Item 21 was paid. Include all months, even if they fall outside of the reporting period. If ADAP pays part of the premium, report the full coverage period of the policy. ADAPs do not need to prorate the months based on the portion of the premium paid.

23. Amount Paid for Co-pays and Deductible

Indicate the total amount *($0 to $100,000)* of medication deductibles and co-pays paid on behalf of the client ***including Medicare Part D deductibles and co-pays or donut hole coverage*** during the reporting period. This includes any medication deductibles and co-pays paid during the reporting period, regardless of when the services were delivered.

Drugs and Drug Expenditures

The purpose of the *Drugs and Drug Expenditures* section is to describe the ARVs, Hepatitis B, Hepatitis C and A1-OI medications paid for in full by ADAP and dispensed to clients during the reporting period. This section also describes the total expenditures for those medications. Please note that this section is only for clients who were dispensed medications that were paid for in full by ADAP.

ADAP payments for medication co-pays or deductibles are considered health insurance assistance services and should be reported in the *Health Insurance Services* section.

25. Receipt of Medication Services

Indicate whether ADAP-funded medications were dispensed to this client during this reporting period. Only report ARVs, Hepatitis B, Hepatitis C and A1-OI medications included in your ADAP formulary that were paid for in full with ADAP funds.

- *Yes* (If the response is Yes, complete Items 26, 27, 28 and 29)
- *No* (If No, this is the end of this client's record)

26. Medication(s) Dispensed

Report each ADAP-funded medication dispensed to the client during the reporting period. **Do not report medications other than ARVs, Hepatitis B and C and A1- OI medications.** Use the five-digit drug code *(d-xxxxx)* of the medication. Drug codes (d-codes) are unique 5-digit codes assigned by the Multum Drug Database.

You may be able to get d-codes from your pharmacy, PBM or other provider. If you use CAREWare, d-codes are already built into the system. You may also make a request to HAB to access the Multum Database via https://careacttarget.org/library/hab-grantee-request-form-multum-medication-information.

For more information on how to report medications using d-codes, go to *Tools for Reporting Client Medications* at https://careacttarget.org/library/adr-tools-reporting-client-medications.

27. Medication Dispensed Date

Report the date each ADAP-funded medication listed in Item 26 was dispensed. Indicate this date in the form *MM/DD/YYYY*.

28. Day(s) Supply of Medication

Indicate the number of days for which each medication listed in Item 26 was dispensed to the client during the reporting period. Report the number of days in 30-day increments (*1 through 30, 60, 90, ...360*) Anything less than 30 days should be reported as the actual number of days supplied (e. g. 14 days).

29. Amount Paid for Medication

Indicate the total cost of each ADAP-funded medication *($0 to $100,000)* listed in Item 26 that was dispensed to the client during the reporting period. Cost should be reported per medication dispensed. Include the total costs paid for each prescription that is dispensed, even if the medication prescription period extended beyond the reporting period. See example below.

Example of Medication Data

ClientId	MedicationId	MedicationStartDate	MedicationDays	MedicationCost
1	d05847	11/5/2016	7	$1,948

ClientId	MedicationId	MedicationStartDate	MedicationDays	MedicationCost
1	d05847	11/14/2016	90	$2,598
2	d03984	10/5/2016	180	$100
2	d04774	10/5/2016	180	$1,413

May recipients report medications for health insurance assistance clients?

Answer: No, medications not paid in full under ADAP should not be reported in the Drugs and Drug Expenditures section of the Client-level Report. Amounts paid for co-pays and deductibles for medications should be reported in the Health Insurance Service section under Amount Paid for Co-pays and Deductibles.

A client was enrolled in ADAP and then was eligible for Medicaid. Medicaid granted retroactive eligibility and ADAP was back billed for services paid by ADAP. How do we report this client?

Answer: Data for these clients should be reported in the Client Report. ADAP services that are retroactively paid for by Medicaid (i.e., back billing) should be reported. ADAPs are not required to go back into their data system and delete services for which they back billed Medicaid and received reimbursement.

Clinical Information

The purpose of the Clinical Information section is to describe the clinical characteristics of ADAP clients who received medications paid in full by ADAP (ARVs, Hepatitis B, Hepatitis C and A1-OI medications **only**). Clinical information is required to be reported for each client who was dispensed ADAP-funded medications (as reported in Item 25) during the reporting period.

Clinical information must come from labs, other clinical sources or from the State Surveillance Program, not from client self-report.

Some clients may switch from receiving ADAP-funded medications to receiving health insurance services within the same reporting period. Is there a minimum amount of time during which a client must receive ADAP-funded medications for the clinical data to be required?

Answer: Clinical data must be reported on all clients who received ADAP funded-medications at any time during the reporting period.

32. CD4 Count Date

Report the date of the most recent CD4 count test administered to the client during the data collection period. The date must be in the form *MM/DD/YYYY*. The CD4 cell count measures the number of T- helper lymphocytes per cubic millimeter of blood. It is a good predictor of immunity. As CD4 cell count declines, the risk of developing opportunistic infections increases. The test date is the date the client's blood sample is taken.

33. CD4 Count Value

Indicate the value *(0 and 100,000,000)* of the most recent CD4 count test for the client during this reporting period.

34. Viral Load Date

Report the date of the most recent viral load test administered to the client during the data collection period. The date must be in the form *MM/DD/YYYY*. Viral load is the quantity of HIV RNA in the blood and is a predictor of disease progression. Test results are expressed as the number of copies per milliliter of blood plasma. The test date is the date the client's blood sample is taken.

35. Viral Load Value

Indicate the value *(0 and 100,000, 000)* of the most recent viral load test for the client during this reporting period. If a test result is undetectable, report the lower test limit for the viral load value which should be available from a clinical data source. If the test limit is not available, report zero (0).

A client is disenrolled before receiving a Viral Load and/or CD4 test during the reporting period. What should I report?

Answer: There are times when you do not have these data for all clients. You may use the comment box that will appear after you've submitted your ADR to explain the missing data. You will also find these missing data reflected in your Confirmation Report.

This is the end of the Client Report.

Importing the XML Client File

To upload a client-level data XML file, open your ADR Grantee Report in the EHB. From within the ADR Grantee Report, click the **Client Upload** link in the ADR Navigation menu. This will open another window. You can continue to follow the on-screen instructions to upload your XML file.

Recipients may upload more than one client-level data file to "build" the Client Report. Before uploading multiple client-level data XML files, recipients should understand the ADR Web Application's data merge rules. To learn more about the ADR Web Application merge rules, see https://careacttarget.org/library/adr-merge-rules-30.

Reviewing your Client Report

ADAPs should generate and review a Client-level Data Upload Confirmation and Data Completeness Reports before they submit their ADR to ensure quality data. The Confirmation Report is an aggregate report that can be used to verify that the counts and totals reported in your Client Report match data stored in your source system(s) (i.e., the correct number of clients, services, medications, and expenditures are being reported). The Completeness Report provides details on the completeness of your client level data and show gaps where data is not reported. Both reports are available only after you have uploaded client-level data into the ADR Web application. To run these reports, select the respective links in the ADR Navigation menu on the left hand side of the ADR Web page.

Report XML

After completing the ADR Grantee Report and uploading the client-level data XML file, you must validate your report. To validate your report, click **Validate** in the ADR Navigation menu. The validation process checks to make sure that your data are complete and correct. If your report has some potential data issues, you will receive **errors**, **warnings or alerts.** To address these data issues, you must:

- Correct data that received errors.
- Correct data that received warnings or write a comment for each uncorrected warning in order to submit your report. To write a comment, click the "Add Comment" link next to the warning message.
- Review alerts and correct them, if applicable. However, you are not required to fix or comment on alerts to submit your report.

Before uploading a new or corrected client-level data file, you must clear all previous client records by clicking on the Clear Clients link on the Navigation Menu or selecting the "Clear Client Records" box in the file upload window.

After you have addressed these data issues, you can re-upload your client XML file by clicking on the **Client Upload** link.

Submitting Your Report

When your report is complete, submit the Grantee and Client Reports by clicking on **Submit** in the ADR Navigation menu and following the instructions on your screen.

If you need help on completing the ADR, contact Data Support at 1-888-640-9356 or e-mail RyanWhiteDataSupport@wrma.com

Appendix A: Required Client-level Data Elements

- Report this data element

Field #	Client-Level Data Elements	Type of Client, by Services Received		
		All Enrolled Clients	Health Insurance Services	Medication Services
System Variables				
2	Encrypted UCI	●		
Client Demographics				
4	Ethnicity	●		
68	Hispanic/Latino Subgroup	●		
5	Race	●		
69	Asian Subgroup	●		
70	Native American/Pacific Islander Subgroup	●		
6	Gender	●		
7	Transgender	●		
71	Sex at Birth	●		
9	Year of Birth	●		
10	HIV/AIDS Status	●		
11	Poverty Level	●		
12	High Risk Insurance	●		
13	Health Insurance	●		
Enrollment and Certification				
14	New or Existing Client	●		
15	Date Completed Application Received (new client only)	●		
16	Date Application Approved (new client only)	●		
17	Date of Recertification	●		
18	Enrollment Status	●		
19	Reason(s) for Disenrollment	●		
ADAP Health Insurance Services				
20	Receipt of Health Insurance Services	●		
67	ADAP-funded health insurance assistance		●	
21	Amount Paid for Premiums		●	
22	Months Coverage of Premiums Paid		●	
23	Amount Paid for Co-pays and Deductibles		●	
Drugs and Drug Expenditures				
25	Receipt of Medication Services	●		
26	Medications Dispensed			●
27	Dispense Date for Medication			●
28	Days Supply of Medication			●
29	Amount Paid for Medication			●
Clinical Information				
32	CD4 Count Date			●
33	CD4 Count Value			●
34	Viral Load Date			●
35	Viral Load Value			●

Appendix B: Frequently Asked Program Questions from the Field

1. **Does the certification and recertification process count as an ADAP service that should be reported?**

   Certification and recertification is not an ADAP medication or health insurance service, and therefore should not be reported in the ADR.

2. **Should ADAPs stop reporting after the donut hole (Medicare)?**

   After leaving the donut hole, a Medicare Part D beneficiary enters the Catastrophic Coverage period. If ADAP pays the client's copayments during Catastrophic Coverage period, it should continue to report amounts under Amount Paid for Co-pays and Deductibles.

3. **Where do I report copays for medical visits in the ADR?**

   ADAP funds cannot be used to pay for medical visit co-pays. You should only report co-pays for medication co-pays in Items 67 and 23.

4. **What does the eUCI generator do? Does it create the UCI and then encrypt it?**

   The eUCI generator can both create the UCI and then convert the 12 character UCI into a 40-character string using the SHA-1 hashing algorithm. The SHA-1 is a trap door algorithm, meaning that the original UCI is unrecoverable from the eUCI and therefore meets the highest privacy and security standards. When using an ADR-Ready System such as CAREWare and TRAX, the eUCI is generated directly from the raw data elements when the XML file is created. For more information, see "the Encrypted Unique Client Identifier (eUCI): Application and User Guide" at https://careacttarget.org/library/encrypted-unique-client-identifier-euci-application-and-user-guide

5. **May ADAPs provide services to a client before eligibility has been determined? What if it is an emergency?**

   It is not allowable for an ADAP to provide services before a client has been determined to meet that ADAP's eligibility criteria (i.e., presumptive eligibility). Expedited enrollment (i.e., emergency enrollment) is allowed if the process ensures that clients have been determined eligible prior to services being provided. Providing temporary assistance to ADAP-eligible clients while eligibility is determined for Medicaid or other insurance (i.e., provisional status) is allowed, with the clear understanding that Medicaid is back-billed if Medicaid is awarded retroactively. Data for these clients should be reported in the ADR Client report. ADAP services that are retroactively paid for by Medicaid (i.e. back billing) should be reported. ADAPs are not required to go back into their data system and delete services for which they back billed Medicaid and received reimbursement.

6. **Is it permissible for ADAPs to purchase medications through their 340B program and bill insurance for their insurance clients?**

   It is allowable for a recipient to use ADAP funds to purchase medications at 340B pricing and to then bill the medication to insurance for ADAP-eligible clients with insurance, so long as they: (1) do not pass on the 340B pricing to the insurance company, and (2) treat the difference between the 340B price and the insurance payment as program income. ADAPs that purchase medications through 340B and then bill insurance are considered to be providing a health insurance service to the client, not a medication service. A

health insurance service is paying for a co-pay, deductible, insurance premium or Medicare Part D service. If an ADAP is not paying for any of these health insurance services, the client is not considered an ADAP client.

7. **Our program uses federal as well as non-federal funding for our ADAP clients. For the clients served with non-federal funds (such as state), can we use a different set of certification or reporting rules?**

   All funds that go into the ADAP program are considered ADAP funds and therefore must align with the ADAP guidelines (i.e., 'same program/same rules'); and all data should therefore be reported in the ADR. If, however, a state chooses to establish a separate program funded by non-ADAP funds, the state could choose to have different rules for that program and data for that program would not be reported on the ADR. The state needs to be aware that 340B pricing would not be available to the separate, non-ADAP-funded program unless the state is a 340B covered entity outside of the ADAP.

8. **Are ADAPs allowed to dispense more than a 30-day supply of medication?**

   Each state has the authority to determine its own policy on the maximum day supply of medication for its ADAP clients.

9. **Is an ADAP permitted to pay health insurance premiums for in-patient care?**

   ADAPs are allowed to pay health insurance premiums for plans that cover inpatient care. However, Ryan White funds may not be used to pay co-pays or deductibles for inpatient care.

10. **For reporting the medication cost, are we permitted to approximate the cost of ADAP medications purchased in bulk? Are there other ways to calculate the cost purchased in bulk?**

    ADAPs should not approximate cost for the purchase of medications. Each purchase includes quantity and price that would allow the ADAP to provide a specific cost for the medication. If the ADAP carries stock from one reporting period to the next, the ADAP should prorate the cost for the period for which they are reporting. The amount of medication cost reported in Item #29 must be the actual price calculated from the quantity purchased and the total price.

11. **Is HAB considering an alternative method of completing the ADR Grantee Report other than filling in the online forms (i.e., an ADR Grantee Report XML upload)?**

    HAB is exploring this possibility.

Appendix C: Calculating Client Income as a Percent of the Federal Poverty Measure Using HHS Federal Poverty Guidelines

Calculation Steps

Here are five easy steps you can use to determine a client's income as a percent of the Federal poverty measure using the U.S. Department of Health and Human Services Federal poverty guidelines (FPG):

1. Count the client's family size.
2. Add up the family income.
3. Look up the FPG for the family size, year, and geographic location.
4. Calculate the family income as a percent of the family FPG:

   family income / guideline * 100 = % family FPG

5. Use the percent of the family FPG to report the client percent of the Federal poverty measure for Item 12 of your ADR Client Report.

Background, Definitions, and Notes

To find the **Poverty Guidelines** and more information on poverty measurement, go to the HHS Poverty Guidelines, Research, and Measurement Web page at http://aspe.hhs.gov/POVERTY/index.cfm

The Federal poverty guidelines are dollar amounts that vary according to family size and are used to determine poverty status. HHS issues them each year in the *Federal Register*.

There are separate guidelines for the contiguous 48 States, Alaska, and Hawaii.

For example, an ADAP can define family size is the number of family members who live together. An individual living alone (or with only non-relatives) counts as a family of one.

Family income is the sum of income of all family members who live together.

- It includes pre-tax money (or "cash") income (earnings; unemployment compensation; Social Security; public assistance; veterans' payments; survivor benefits; pension or retirement income; interest; dividends; rents; royalties; income from estates, trusts, educational assistance, alimony, child support, assistance from outside the household, and other miscellaneous sources)

- It excludes non-cash benefits (e.g., food stamps, housing subsidies) and capital gains (or losses)

All family members have the same poverty status; thus all family members have the same income as a percent of the Federal poverty measure.

Appendix D: Glossary

ADAP	*AIDS Drug Assistance Program*—A state-administered program authorized under Part B of the RWHAP to provide FDA-approved medications to low-income clients with HIV disease who have no coverage or limited health care coverage. ADAPs may also use program funds to purchase health insurance for eligible clients and for services that enhance access to, adherence to, and monitoring of antiretroviral therapy.
ADAP client	An ADAP client is any individual who is enrolled in the ADAP, (i.e., certified as eligible to receive ADAP services, regardless of whether the individual used ADAP services during the reporting period).
ADAP Base Funds	Federal funds specifically designated to be used for the State/Territory ADAP.
ADAP Flexibility Policy	HIV/AIDS Bureau's (HAB) Policy Notice 07-03 provides recipients greater flexibility in the use of ADAP funds and permits expenditures of ADAP funds for services that improve access to medications, increase adherence to medication regimens, and help clients monitor their progress in taking HIV-related medications. Please note that to use ADAP dollars for services under the ADAP flexibility policy, recipients **must** request approval annually, in their grant application or through the prior approvals process in EHB.
ADAP Supplemental Drug Treatment Grant Award	Federal funds awarded to an ADAP with demonstrated severe need based on established criteria, in addition to the ADAP Base funds.
ADR Web application	HAB's online ADR Web Application is where recipients submit their ADR. Grantees access the ADR Web Application via the HRSA Electronic Handbooks for Applicants/Grantees (EHBs), a Web-based grants administration system.
Administrative costs	Administrative costs for medication purchases include items such as shipping and handling, and other bulk order fees.
AIDS	*Acquired Immune Deficiency Syndrome*—A disease caused by the humanimmunodeficiency virus.
ARV	Antiretroviral. A drug that interferes with the ability of a retrovirus, such as HIV, to make more copies of itself.
Capped expenditure	A limit on the amount of money to be spent on one service or client per month or per year.
CAREWare	CAREWare is a free, scalable software used for managing and monitoring HIV clinical and supportive care and producing reports.
CDC	Centers for Disease Control and Prevention. The U.S. Department of Health and Human Services agency that administers HIV/AIDS prevention programs, including the HIV Prevention Community Planning process, among others. The CDC is responsible for monitoring and reporting infectious diseases, administers HIV surveillance grants, and publishes epidemiologic reports such as the HIV/AIDS Surveillance Report.

CD4 or CD4+ cells	Also known as helper T-cells, these cells are responsible for coordinating much of the immune response. HIV's preferred targets are cells that have a docking molecule called "cluster designation 4" (CD4) on their surfaces. Cells with this molecule are known as CD4-positive (CD4+) cells. Destruction of CD4+ lymphocytes is the major cause of the immunodeficiency observed in AIDS, and decreasing CD4 levels appear to be the best indicator for developing opportunistic infections.
CD4 cell count	The number of T-helper lymphocytes per cubic millimeter of blood. The CD4 count is a good predictor of immunity. As the CD4 cell count decreases, the risk of developing opportunistic infections increases. The normal range for CD4 cell counts is 500 to 1,500 per cubic millimeter of blood. CD4 counts should be rechecked at least every 6 to 12 months if CD4 counts are greater than 500/mm3. If the count is lower, testing every 3 months is advised. A CD4 count of 200 or less indicates AIDS.
Combination therapy	Two or more drugs or treatments used together to achieve optimum results against HIV infection and/or AIDS. For more information on treatment guidelines, visit http://www.aidsinfo.nih.gov/
Confidential information	Information that is collected on the client and whose unauthorized disclosure could cause the client unwelcome exposure, discrimination, and /or abuse.
Coordinated benefits	The provision of services in such a way that clients do not receive duplicated services from multiple providers or payers.
Co-insurance	A form of medical cost sharing in a health insurance plan that requires an insured person to pay a percentage of medical expenses received.
Co-payment	A fee charged to an individual per visit or per prescription.
Deductible	An annual fixed dollar amount that an insured person pays before the health insurance starts to reimburse or make payments for covered medical services.
Department of Defense Drug Pricing Program	Drug pricing cost-saving strategy administered by the Department of Defense
Dispensing fees	The cost to pharmacies to dispense drugs which is then transferred as a fee to the buyer.
Dispensing of pharmaceuticals	The provision of prescription drugs to prolong life or prevent the deterioration of health.
Direct Purchase	A prescription drug purchasing model in which State ADAPs purchase drugs directly from a manufacturer or wholesaler at the 340B pricing schedule. ADAPs then distribute the drugs using a centralized State system or through their own pharmacies.
Donut hole coverage	The coverage gap of the Medicare Part D plan where, after a certain point, the beneficiary is 100% responsible for the costs of the medication.
Drug formulary	A list of pharmaceuticals that can be or should be preferentially prescribed within a reimbursement (insurance) program.
Drug pricing cost strategies	See 340B, direct purchase, prime vendor and Alternative Method Demonstration Project.
Dual Application	One application form for assistance that is used by both the ADAP and Medicaid, such that clients only need apply once and may receive services from both ADAP and Medicaid.
D-Codes	A five-digit drug identification number developed by Multum Cerner® to identify groups of medications. D-codes have the format d#####, and may also be referred to as 'd-codes' or 'HRSA codes.'

Electronic Handbook (EHB)	The HRSA Electronic Handbooks for Applicants/Grantees (EHBs) is a Web-based grants administration system. The EHBs are located at https://grants.hrsa.gov/webexternal.
Eligibility criteria	The standards set by a State ADAP, usually through an advisory committee, to determine who receives access to ADAP services. Financial eligibility is usually determined as a percentage of the Federal Poverty Level (FPL), such as 400 percent FPL. Medical eligibility is most often a positive HIV diagnosis. Eligibility criteria vary among ADAPs.
Epidemic	A disease that occurs clearly in excess of normal expectation and spreads rapidly through a demographic segment of the human population. Epidemic diseases can be spread from person to person or from a contaminated source such as food or water.
Fee-for-service	The method of billing for health services whereby a physician or other health service provider charges the payer (whether it be the patient or his or her health Insurance plan) separately for each patient encounter or service rendered.
Fiscal Year	The Ryan White HIV/AIDS Program Part B grant year of April 1 – March 31.
Fixed co-payment	A set fee charged to all clients per prescription filled.
Recipient of record	The official Ryan White HIV/AIDS Program recipient that receives funding directly from the Federal government (HRSA).
HAART	*Highly active antiretroviral therapy*—An aggressive anti-HIV treatment including a combination of three or more drugs with activity against HIV whose purpose is to reduce viral load to undetectable levels. Currently, antiretroviral therapies include several classes of drugs.
HIP	Health Insurance Program. A program of financial assistance for eligible individuals living with HIV to enable them to maintain continuity of health insurance or to receive medical benefits under a health insurance program. This includes premium payments, risk pools, co-payments, and deductibles.
HRSA	*Health Resources and Services Administration*—The HHS agency that is responsible for directing national health programs that improve the Nation's health by ensuring equitable access to comprehensive, quality health care for all. HRSA works to improve and extend life for people living with HIV/AIDS, provide primary health care to medically underserved people, serve women and children through State programs, and train a health workforce that is both diverse and motivated to work in underserved communities. HRSA is also responsible for administering the Ryan White HIV/AIDS Program.
Hybrid/Dual	A prescription drug purchasing model in which State ADAPs utilize both Direct Purchase and Rebate Models in purchasing and distributing medications under the 340 pricing schedule.
Manufacturers' rebates	Dollars received from drug manufacturers, which represent a percentage of the cost of the drug.
Medicaid	A jointly funded, federal-state health insurance program for certain low-income and needy people.
Medicaid/Medically Needy Program	The option to have a medically needy program allows States to extend Medicaid eligibility to additional qualified persons who may have too much income to qualify under the mandatory or optional categorically needy groups. This option allows them to spend down to Medicaid eligibility by incurring medical and/or remedial care expenses to offset their excess income, thereby reducing it to a level below the maximum allowed by that State's Medicaid plan
Medication Protocol	A document developed to ensure that medications are prescribed appropriately.

Monetary cap	A limit on the amount of money to be spent on one service or client per month or per year.
NDC	*National Drug Code*—The identifying drug number maintained by the FDA. For purposes of the Section 340B Drug Discount Program, the NDC number is used, including labeler code (assigned by the FDA and identifies the establishment), product code (identifies the specified product or formulation), and package size code when reporting requested information.
OMB	*Office of Management and Budget*—The office within the executive branch of the Federal Government that prepares the President's annual budget, develops the Federal Government's fiscal program, oversees administration of the budget, and reviews Government regulations.
Online interface	A shared intranet or Web site between the State's ADAP and Medicaid program.
Other negotiated rebates	Discounts negotiated between ADAP officials and drug companies on the price of medications.
Part B	The Part of the Ryan White HIV/AIDS Program that authorizes the distribution of Federal funds to States and Territories to improve the quality, availability, and organization of health care and support services for individuals with HIV disease and their families. The Ryan White HIV/AIDS Program emphasizes that such care and support is part of a continuum of care in which all the needs of individuals with HIV disease and their families are coordinated. The funds are distributed among States and Territories based, in part, on the number of AIDS cases in each State or Territory as a proportion of the number of AIDS cases reported in the entire United States.
Premium	The amount paid for health insurance by an individual and/or plan sponsor such as an employer.
PHSA	*Public Health Service Act*
PLWH	*People living with HIV*
Prime Vendor	A voluntary program of 340B-covered entities in which the prime vendor handles price negotiation and drug distribution responsibilities for members. Since the prime vendor has the potential to control a large volume of pharmaceuticals, it can negotiate favorable prices and develop a national distribution system that would not be possible for covered entities to obtain individually.
Prophylaxis	Treatment to prevent the onset of a particular disease (primary prophylaxis) or recurrence of symptoms in an existing infection that has been brought under control (secondary prophylaxis).
Rebate	A prescription drug purchasing model in which State ADAPs reimburse a broad network of retail pharmacies for costs associated with filling prescriptions for eligible clients. ADAPs then submit rebate claims to the manufacturer at the 340B pricing schedule.
Retroactive billing	Billing for services previously rendered rather than at the time of delivery.
Retrovirus	A type of virus that, when not infecting a cell, stores its genetic information on a single-stranded RNA molecule instead of the more usual double-stranded DNA. HIV is an example of a retrovirus. After a retrovirus penetrates a cell, it constructs a DNA version of its genes using a special enzyme, reverse transcriptase. This DNA then becomes part of the cell's genetic material.
RWHAP-funded service	A service paid for with Ryan White HIV/AIDS Program funds.

Ryan White HIV/AIDS Program (RWHAP)	Ryan White HIV/AIDS Treatment Extension Act of 2009—The federal legislation created to address the health care and service needs of people living with HIV/AIDS (PLWHA) disease and their families in the United States and its Territories. The Ryan White HIV/AIDS Program was enacted in 1990 (Pub. L. 101—381), reauthorized in 1996 as the Ryan White CARE Act Amendments of 1996, in 2000 as the Ryan White CARE Act Amendments of 2000, and in 2006 as the Ryan White HIV/AIDS Treatment Modernization Act of 2006. The most recent reauthorization was in 2009 as the Ryan White HIV/AIDS Treatment Extension Act of 2009
Section 340B Drug Discount Program	Administered by the Office of Pharmacy Affairs, this provision indicates that as a condition for participation in Medicaid, drug manufacturers must sign a pharmaceutical pricing agreement with the Secretary of the Department of Health and Human Services. This agreement States that the price charged for covered outpatient drugs will not exceed the statutory ceiling price (the average manufacturers' price reduced by the Medicaid rebate percentage).
Sliding scale co-payment	A fee charged to clients for filled prescriptions that varies based on the income of the client.
State Match for Supplemental Drug Treatment Award	Funding and/or resources from the State budget that matches, in part or in whole, the ADAP Supplemental Drug Treatment Grant Award.
XML	eXtensible Markup Language. A standard, simple, and widely adopted method of formatting text and data so that it can be exchanged across all of the different computer platforms, languages, and applications

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Information Technology Support Services

Acquired Immune Deficiency Syndrome (AIDS) Drug Assistance Program (ADAP) Data Reports (ADR) Release 4.0 XML Schema Implementation Guide

Date Last Updated: March 10 2016

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Version	Date	Description
1.0	6/23/2014	ADR 3.0 Release
1.1	12/12/2014	Revised to indicate whether data elements are required, to match the XML schema, and to update fields, as necessary.
1.2	12/16/2014	Added the document version number.

2.0	2/23/2016	The following updates were addressed in this version:
		• Removed the following tables since these elements were removed during the ADR 3.0 release:
		  ○ ReportPeriodId
		  ○ ADAPNumber
		  ○ MedicationDispensingFeeFlag
		  ○ MedicationDispensingFeeAmount
		• Changed the maximum allowed value for Medication Cost (item 29) from 20,000 to 100,000.
		• Changed the document title to “ADR XML Schema Implementation Guide Release 4.0”.
		• Applied updates to the URLs in Appendix A – Resources.
		• Applied updates to meet HRSA guidelines for document to be 508-compliant.

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1 Introduction

Grantees must submit Acquired Immune Deficiency Syndrome (AIDS) Drug Assistance Program (ADAP) Data Reports (ADR) to the Health Resources Services Administration's (HRSA) Human Immunodeficiency Virus (HIV)/AIDS Bureau (HAB) annually. To submit the ADR successfully, each grantee must complete the online section of the grantee report and create and upload one or more Extensible Markup Language (XML) files containing client-level data. The structure, sequence, values, and format of the data elements must conform to the definitions specified in this document. The client-level data XML file must then be uploaded to the ADR web application, where it is validated for conformance to the data schema and business rules. For instructions on how to upload the ADR client-level data XML files to the ADR web application, please see the ADR Instruction Manual available on the TARGET website (ADR Instruction Manual).

1.1 Purpose

The purpose of this document is to provide reference information to grantees on the allowable structure, sequence, values, and format of the ADR client-level data XML files. Grantees may use this information to be better prepared when they create their own applications and/or processes to extract the appropriate data from their data sources and convert it to the required XML format. All ADR client-level data XML files must conform to the definitions in this document.

The goal of this document is to help grantees reduce and/or avoid errors that may result when they generate and submit client-level data XML files to the ADR web application. This document includes data definitions that describe the meaning of each element in the ADR client-level data XML files. In addition, this document describes the required format of the XML file, provides examples of XML files, and includes references to the XML schema definitions that are used to validate the XML file. For grantees that are using the same application for submitting their Ryan White Services Report, the coding for similar data element values (such as demographics) for the ADR are consistent.

1.2 Audience

This document is intended for ADAP technical and/or administrative staff that must collect and report ADR client-level data elements in an XML file format to HRSA's HAB. Staff may include developers, data quality specialists, ADAP Administrators, or other individuals who are responsible for generating and submitting the ADR.

1.3 Structure of This Document

This document contains the following sections:

- **Section 1: Introduction** describes the purpose of the XML Schema Implementation Guide.
- **Section 2: Overview of the ADR Client-Level Data XML File** describes the main components of the ADR client-level data XML file.

- **Section 3: ADR Client-Level Data Elements** defines the individual client-level data elements required in the XML file.
- **Section 4: ADR Client-Level Data XML File Format** provides the the validation checks that the XML file must pass before the file Is accepted by the ADR web application as well as sample XML files.
- **Appendix A: Resources** contains a list of available resources, including the ADR client-level data XML schema definitions, sample XML files, and an ADR client-level data XML generation tool.
- **Appendix B: Acronyms** contains a list of acronyms used in this document and their definitions.

2 Overview of the ADR Client-Level Data XML File

As mentioned in the introduction, grantees must submit ADR client-level data to the ADR web application on an annual basis. The required file format for submitting the ADR report is XML. XML is a structured document standard for defining a file format, as well as for specifying allowed data element values, data element sequence, and the number of occurrences for data elements. XML is a platform-independent language that simplifies the process of exchanging data in a standardized way over the Internet between different applications.

2.1 Main Components of the Client-Level Data XML File

The ADR client-level data XML file consists of three components:

1) File Header.

2) Root Element.

3) Body Elements.

Body elements consist of both complex and simple data elements.

2.1.1 File Header

The file header is simply the first line of text in the XML file. It is static text and does not change. This first line of text contains the XML declaration—that is, the version of XML is being used, as well as what encoding method is being used. The following is an example of a File Header:

```
<?xml version="1.0" encoding="UTF-8"?>
```

2.1.2 Root Element

The Root Element consists of static text and does not change. A Root Element is required for every XML file, and it serves as “the parent” of all the other elements. For the ADR client-level data XML file, the Root Element is <CLD:ROOT>, and it appears as follows:

```
<CLD:ROOT xsi:schemaLocation="urn:adrNamespace AdrClientSchema.xsd"
```

```
xmlns:xsi="http://www.w3.org/2001/XMLSchema-instance"
xmlns:CLD="urn:adrNamespace">
```

In this example, CLD stands for “Client-Level Data.” In addition, the <CLD:ROOT> element contains extra information—called “attributes”—about the file. Each of the attributes has a name and value. The definitions of each attribute is contained in Table 1.

Table 1 - XML Attribute Definitions

Attribute Name	Definition
xsi:schemaLocation	The location of the XML schema definition file used to validate the client-level data XML file.
xmlns:xsi	The location of the XML schema instance used to determine the base XML schema standards.
xmlns:CLD	The XML schema namespace used for custom definitions within the XML file.

2.1.3 Body Elements

The body of the ADR client-level data XML file contains all the elements under the Root Element. In the following sample, the top-level elements under the <CLD:ROOT> element have been collapsed (i.e., their child elements have been hidden) to keep the code sample short.

```
<?xml version="1.0" encoding="UTF-8"?>
<CLD:ROOT xsi:schemaLocation="urn:adrNamespace AdrClientSchema.xsd"
xmlns:xsi="http://www.w3.org/2001/XMLSchema-instance" xmlns:CLD="urn:adrNamespace">
   <AdrClientReportXmlVersion>
   <AdrClientReport>
   <AdrClientReportRace>
     </AdrClientReportRace>
     <AdrClientReportHispanicSubgroup>
     </AdrClientReportHispanicSubgroup>
   <AdrClientReportAsianSubgroup>
     </AdrClientReportAsianSubgroup>
     <AdrClientReportNhpiSubgroup>
     </AdrClientReportNhpiSubgroup>
   <AdrClientReportMedicalInsurance>
     </AdrClientReportMedicalInsurance>
   <AdrClientReportDisenrollmentReason>
     </AdrClientReportDisenrollmentReason>
   <AdrClientReportMedication>
   <Medication>
   </Medication>
     </AdrClientReportMedication>
   </AdrClientReport>
```

```
</CLD:ROOT>
```

The body contains “simple” and “complex” elements. In XML, "simple" elements do not contain any “child” elements while “complex” elements are elements that contain other “child” elements.

The example below shows the format for a complex element.

```
<ComplexElement>
      <SimpleElement1>A valid value</SimpleElement1>
      <SimpleElement2>Another valid value</SimpleElement2>
</ComplexElement>
```

The <ComplexElement> element is “complex” because it contains other elements, whereas the <SimpleElement1> and <SimpleElement2> elements are “simple" elements because they do not contain other elements.

In the ADR client-level data XML file, the complex data elements must appear in a specific order and contain simple data elements in order to pass the validation check.

Likewise, the simple data elements must appear in a specific order, and the data they contain must conform to the specific rules defined in this data dictionary document to pass the validation check.

For more information about the other validation checks that the file must pass, please see Section 4: ADR Client-Level Data XML File Format.

3 ADR Client-Level XML Data Elements

This section includes definitions for all the data elements (both complex and simple) in the body of the ADR client-level data XML file. The definitions are presented in tables, and each table includes one or more of the following metadata:

- **Id** – Indicates the data element’s unique identifier and is used consistently across all public ADR documents.
- **Variable Name** – Indicates the name of the complex element.
- **Element Name** – Indicates the name of the element in the XML file.
- **Parent Element** – Indicates the name of the parent element.
- **Definition** – Gives a description of what the element means and/or for what it is used.
- **Required** – Indicates whether or not a value must be provided for the element when submitting the ADR. Some elements are optional and do not need values.
- **Occurrence** – Indicates how many times the element can occur in the file.
- **Allowed Values –** Describes the values that can be used, cannot be used, or must be used for a given element.
- **Schema** – Depicts the XML format for the element.

Empty or “null” data element tags are not permitted in the XML file. For example, data elements of the form <tag></tag> or <tag /> are not allowed.

3.1 Complex Elements

The complex elements in the ADR client-level data XML file are listed and described in the following sub-sections. These elements are the containers for all the simple elements defined in Section 3.2: Simple Elements. Each complex element, except for AdrClientReportXmlVersion contains a required attribute, CLD_ID, that indicates the relationship between each complex element. For example, complex elements with a value of "1" for the CLD_ID indicate that this set of complex elements all belong to the same client.

3.1.1 AdrClientReportXmlVersion

Field	Description
Id	Not applicable
Variable Name	AdrClientReportXmlVersion
Definition	Complex data element containing information about which version of the ADR XML schema is being used and which version of the vendor's application is being used to generate the ADR XML file. It includes data such as the schema version, vendor name, vendor application version, vendor phone number, etc.
Required	Yes
Occurrence	1 per file
Allowed Values	Not applicable
Schema	<AdrClientReportXmlVersion>... </AdrClientReportXmlVersion>

3.1.2 AdrClientReport

Field	Description
Id	Not applicable
Variable Name	AdrClientReport
Definition	Complex data element containing non-repeating client information, such as the client's unique identifier, birth year, etc.
Required	Yes
Occurrence	1 per client
Allowed Values	Not applicable
Schema	<AdrClientReport >... </AdrClientReport>

3.1.3 AdrClientReportRace

Field	Description
Id	Not applicable
Variable Name	AdrClientReportRace
Definition	Complex data element containing race Ids. Allows multiple race Ids to be reported.
Required	Yes
Occurrence	1 per client

Field	Description
Allowed Values	Not applicable
Schema	<AdrClientReportRace>... </AdrClientReportRace>

3.1.4 AdrClientReportMedicalInsurance

Field	Description
Id	Not applicable
Variable Name	AdrClientReportMedicalInsurance
Definition	Complex data element containing medical insurance Ids. Allows multiple medical insurance Ids to be reported.
Required	Yes
Occurrence	1 per client
Allowed Values	Not applicable
Schema	<AdrClientReportMedicalInsurance >... </AdrClientReportMedicalInsurance>

3.1.5 AdrClientReportDisenrollmentReason

Field	Description
Id	Not applicable
Variable Name	AdrClientReportDisenrollmentReason
Definition	Complex data element containing reasons for why disenrollment is being reported.
Required	Yes, only if DisenrollmentReasonId is true
Occurrence	0 to 1 per client
Allowed Values	Not applicable
Schema	<AdrClientReportDisenrollmentReason >... </AdrClientReportDisenrollmentReason>

3.1.6 AdrClientReportMedication

Field	Description
Id	Not applicable
Variable Name	AdrClientReportMedication
Definition	Complex data element containing medication information, such as medication Id, start date, cost, etc.
Required	Yes, only if MedicationsDispensedFlag is true
Occurrence	0 to N per client
Allowed Values	Not applicable
Schema	<AdrClientReportMedication >... </AdrClientReportMedication>

3.2 Simple Elements

The simple data elements are categorized under the following seven logical "groupings" or sub-sections:

- XML Schema Version Elements
- System Variables Elements
- Demographic Elements
- Enrollment and Certification Elements
- Insurance Services Elements
- Drug and Drug Expenditure Elements
- Clinical Elements

The purpose of these sub-sections or groupings is to further organize the elements to make them easier to find in the dictionary as well as the XML file.

Important: *Some of the data elements are not required. If no data for a particular client is being provided for an element, then remove that element entirely from the client's record (i.e., remove the data element's start tag, end tag, and value.)*

3.2.1 XML Schema Version Elements

The following XML Schema Version elements are designed to capture data about which version of the ADR XML schema is being used.

3.2.1.1 AdrSchemaVersion

Field	Description
Id	XV1
Element Name	AdrSchemaVersion
Parent Element	AdrClientReportXmlVersion
Definition	The currently supported ADR XML schema version.
Allowed Values	2.0.0
Required	Yes
Occurrence	1 per file
Schema	`<AdrSchemaVersion>2.0.0</AdrSchemaVersion>`

3.2.1.2 Vendor

Field	Description
Id	XV2
Element Name	Vendor
Parent Element	AdrClientReportXmlVersion
Definition	The name of your application that is used to generate the ADR XML file.
Allowed Values	Text from 1 to 150 characters excluding special characters, such as < and >.
Required	Yes
Occurrence	1 per file

Field	Description
Schema	`<Vendor>Rx-REX</Vendor>`

3.2.1.3 VendorVersionNumber

Field	Description
Id	XV3
Element Name	VendorVersionNumber
Parent Element	AdrClientReportXmlVersion
Definition	The version of your application that is used to generate the ADR XML file.
Allowed Values	Text from 1 to 150 characters excluding special characters, such as < and >.
Required	Yes
Occurrence	1 per file
Schema	`<VendorVersionNumber>1.0.2.0</VendorVersionNumber>`

3.2.1.4 VendorTechnicalContactName

Field	Description
Id	XV4
Element Name	VendorTechnicalContactName
Parent Element	AdrClientReportXmlVersion
Definition	The name of the technical contact responsible for maintaining your application that is used to generate the ADR XML file.
Allowed Values	Text from 1 to 150 characters excluding special characters, such as, < and >.
Required	Yes
Occurrence	1 per file
Schema	`<VendorTechnicalContactName>John, Doe</VendorTechnicalContactName>`

3.2.1.5 VendorTechnicalContactEmail

Field	Description
Id	XV5
Element Name	VendorTechnicalContactEmail
Parent Element	AdrClientReportXmlVersion
Definition	The email address of the technical contact responsible for maintaining your application that is used to generate the ADR XML file.
Allowed Values	The technical contact email address must be a valid email address no greater than 150 characters in length.
Required	Yes
Occurrence	1 per file
Schema	`<VendorTechnicalContactEmail>JohnDoe@Somewhere.com</VendorTechnicalContactEmail>`

3.2.1.6 VendorTechnicalContactPhone

Field	Description
Id	XV6

Field	Description
Element Name	VendorTechnicalContactPhone
Parent Element	AdrClientReportXmlVersion
Definition	The telephone number of the technical contact responsible for maintaining your application that is used to generate the ADR XML file.
Allowed Values	Must be a valid telephone number in the format 999,999,9999 [x99999], where the extension is optional, but there must be a space before the "x".
Required	Yes
Occurrence	1 per file
Schema	`<VendorTechnicalContactPhone>123,456,789</VendorTechnicalContactPhone>`

3.2.2 System Variables Elements

The following System Variables XML elements are designed to capture unique identifying information for each client.

3.2.2.1 ClientUci

Field	Description
Id	2
Element Name	ClientUci
Parent Element	AdrClientReport
Definition	The encrypted, unique client identifier generated by the HAB UCI generation utilities.
Allowed Values	A 41-character upper-cased, hexadecimal string plus a single character in the range A-Z.
Required	Yes
Occurrence	1 per client
Schema	`<ClientUci>AEC5C1142DE217CD1FA5CBEDB99ED2E265E8E4F8U</ClientUci>`

3.2.3 Client Demographics Elements

The following Clinical Demographics XML elements are designed to capture data about the socio-demographic characteristics of all clients enrolled in the ADAP, whether or not they received services.

3.2.3.1 EthnicityId

Field	Description
Id	4
Element Name	EthnicityId
Parent Element	AdrClientReport
Definition	The client's ethnicity.
Allowed Values	A valid ethnicity identifier from the EthnicityLkup table: 1 = Hispanic 2 = Non-Hispanic
Required	No

Field	Description
Occurrence	1 per client
Schema	`<EthnicityId>2</EthnicityId>`

3.2.3.2 RaceId

Field	Description
Id	5
Element Name	RaceId
Parent Element	AdrClientReportRace
Definition	The client's race.
Allowed Values	A valid race identifier from the RaceLkup table: 1 = White 2 = Black or African American 3 = Asian 4 = Native Hawaiian/Pacific Islander 5 = American Indian or Alaskan Native
Required	Yes
Occurrence	1 to 5 per client
Schema	`<RaceId>1</RaceId>`

3.2.3.3 AdrClientReportHispanicSubgroup

Field	Description
Id	68
Element Name	AdrClientReportHispanicSubgroup
Parent Element	AdrClientReport
Definition	Value indicating the client's Hispanic/Latino breakdown.
Allowed Values	A valid Hispanic Subgroup identifier from the HispanicSubgroupLkup table: 1 = Mexican, Mexican American, or Chicano/a 2 = Puerto Rican 3 = Cuban 4 = Another Hispanic, Latino/a, or Spanish origin
Required	Yes, only if the client's Ethnicity Id is Hispanic
Occurrence	1 – 4 per client

Schema	`<AdrClientReportHispanicSubgroup>`
	`<SubgroupId>3</SubgroupId>`
	`<SubgroupId>1</SubgroupId>`
	`</AdrClientReportHispanicSubgroup>`

3.2.3.4 AdrClientReportAsianSubgroup

Field	Description
Id	69
Element Name	AdrClientReportAsianSubgroup
Parent Element	AdrClientReport
Definition	Value indicating the client's Asian breakdown.
Allowed Values	A valid Asian Subgroup identifier from the AsianSubgroupLkup table:

Field	Description
	1 = Asian Indian 2 = Chinese 3 = Filipino 4 = Japanese 5 = Korean 6 = Vietnamese 7 = Other Asian
Required	Yes, only if the client's RaceId is Asian
Occurrence	1 – 7 per client

Schema	`<AdrClientReportAsianSubgroup>`
	`  <SubgroupId>3</SubgroupId>`
	`  <SubgroupId>1</SubgroupId>`
	`</AdrClientReportAsianSubgroup>`

3.2.3.5 AdrClientReportNhpiSubgroup

Field	Description
Id	70
Element Name	AdrClientReportNhpiSubgroup
Parent Element	AdrClientReport
Definition	Value indicating the client's Native Hawaiian or Pacific Islander breakdown.
Allowed Values	A valid NHPI Subgroup identifier from the NhpiSubgroupLkup table: 1 = Native Hawaiian 2 = Guamanian or Chamorro 3 = Samoan 4 = Other Pacific Islander
Required	Yes, only if the client's RaceId is Native Hawaiian/Pacific Islander
Occurrence	1 – 4 per client

Schema	`<AdrClientReportNhpiSubgroup>`
	`  <SubgroupId>4</SubgroupId>`
	`  <SubgroupId>1</SubgroupId>`
	`</AdrClientReportNhpiSubgroup>`

3.2.3.6 GenderId

Field	Description
Id	6
Element Name	GenderId
Parent Element	AdrClientReport
Definition	The client's gender.
Allowed Values	A valid gender identifier from the GenderLkup table: 1 = Male 2 = Female 3 = Transgender 4 = Unknown ***Note:*** *Unknown is identified using 9 when generating the encrypted, unique client identifier (eUCI).*

Field	Description
Required	Yes
Occurrence	1 per client
Schema	`<GenderId>1</GenderId>`

3.2.3.7 TransgenderId

Field	Description
Id	7
Element Name	TransgenderId
Parent Element	AdrClientReport
Definition	The client's transgender status.
Allowed Values	A valid transgender identifier from the TransgenderLkup table: 1 = Male-to-Female 2 = Female-to-Male 3 = Unknown
Required	Yes, only if the client's gender Id is reported as transgender.
Occurrence	0 or 1 per client
Schema	`<TransgenderId>3</TransgenderId>`

3.2.3.8 SexAtBirthId

Field	Description
Id	71
Element Name	SexAtBirthId
Parent Element	AdrClientReport
Definition	The biological sex assigned to the client at birth.
Allowed Values	A valid sex at birth identifier from the SexAtBirthLkup table: 1 = Male 2 = Female
Required	No
Occurrence	1 per client
Schema	`<SexAtBirthId>1</SexAtBirthId>`

3.2.3.9 BirthYear

Field	Description
Id	9
Element Name	BirthYear
Parent Element	AdrClientReport
Definition	The year in which the client was born.
Allowed Values	Four digit years that cannot be greater than the reporting year.
Required	Yes
Occurrence	1 per client
Schema	`<BirthYear>1900</BirthYear>`

3.2.3.10 HivAidsStatusId

Field	Description
Id	10
Element Name	HivAidsStatusId
Parent Element	AdrClientReport
Definition	Client's HIV/AIDS status at the end of the reporting period.
Allowed Values	A valid HIV/AIDS status identifier from the HivAidsStatusLkup table: 2 = HIV-Positive, not AIDS 3 = HIV-Positive, AIDS status unknown 4 = CDC-defined AIDS
Required	No
Occurrence	1 per client
Schema	`<HivAidsStatusId>4</HivAidsStatusId>`

3.2.3.11 PovertyLevelId

Field	Description
Id	11
Element Name	PovertyLevelId
Parent Element	AdrClientReport
Definition	Client's annual household income as a percent of the Federal Poverty Level (FPL) at the end of the reporting period.
Allowed Values	A valid Federal poverty level identifier from the PovertyLevelLkup table: 13 = Below 100% of the FPL 9 = 100-138% of the FPL 10 = 139-200% of the FPL 11 = 201-250% of the FPL 12 = 251-400% of the FPL 7 = 401-500% of the FPL 8 = More than 500% of the FPL
Required	No
Occurrence	1 per client
Schema	`<PovertyLevelId>10</PovertyLevelId>`

3.2.3.12 HighRiskInsuranceId

Field	Description
Id	12
Element Name	HighRiskInsuranceId
Parent Element	AdrClientReport
Definition	Value indicating if the client was in a High Risk Insurance Pool at any time during the reporting period.
Allowed Values	A valid High Risk Insurance identifier from the HighRiskInsuranceLkup table: 1 = No 2 = Yes 3 = Unknown
Required	No

Field	Description
Occurrence	1 per client
Schema	`<HighRiskInsuranceId>1</HighRiskInsuranceId>`

3.2.3.13 MedicalInsuranceId

Field	Description
Id	13
Element Name	MedicalInsuranceId
Parent Element	AdrClientReportMedicalInsurance
Definition	Value indicating all sources of the client's health insurance during the reporting period.
Allowed Values	A valid medical insurance identifier from the MedicalInsuranceLkup table: 10 = Private – Employer 11 = Private – Individual 8 = Medicare Part A/B 9 = Medicare Part D 12 = Medicaid, CHIP, or other public plan 13 = VA, Tricare, or other military health care 14 = IHS 15 = Other Plan 16 = No Insurance/uninsured
Required	Yes
Occurrence	1 to 8 per client
Schema	`<MedicalInsuranceId>11</MedicalInsuranceId>`

3.2.4 Enrollment and Certification Elements

The following Enrollment and Certification elements capture client enrollment patterns and certification processes.

3.2.4.1 NewEnrollmentFlag

Field	Description
Id	14
Element Name	NewEnrollmentFlag
Parent Element	AdrClientReport
Definition	Value indicating if the client is newly enrolled. Newly enrolled clients in ADAP for this reporting period meet all the following criteria: applied to ADAP for the first time ever; and met the financial and medical eligibility criteria of the ADAP during the period for which you are reporting data. Examples of clients who should not be included in this number are the following: • Clients who have been recertified as eligible. • Clients who have been re-enrolled after a period of having been decertified/disenrolled. • Clients who have moved out of the state and then returned.

Field	Description
	• Clients who moved on and off ADAP because of fluctuations in eligibility for a Medicaid/Medically Needy program, based on whether they met spend-down requirements. An existing ADAP client is a client who met the following criteria: • Enrolled in ADAP in a previous reporting period. • Continues to be enrolled in the current reporting period, regardless of whether they used ADAP services in either reporting period. ***Note:*** *An individual enrolled in ADAP (new or existing client) may or may not use services. Use of services is not required to be an enrolled client.*
Allowed Values	0 for No or 1 for Yes
Required	No
Occurrence	1 per client
Schema	`<NewEnrollmentFlag>0</NewEnrollmentFlag>`

3.2.4.2 ApplicationReceivedDate

Field	Description
Id	15
Element Name	ApplicationReceivedDate
Parent Element	AdrClientReport
Definition	The date that the completed application was received by the ADAP.
Allowed Values	A valid date on or before the last date of the reporting period in the format mm,dd,yyyy.
Required	Yes, only if client is reported as newly enrolled
Occurrence	0 for existing clients and 1 for newly enrolled clients
Schema	`<ApplicationReceivedDate>10,29,2014</ApplicationReceivedDate>`

3.2.4.3 ApplicationApprovalDate

Field	Description
Id	16
Element Name	ApplicationApprovalDate
Parent Element	AdrClientReport
Definition	The date that the client was approved to begin to receive ADAP services. This is when the client was first enrolled in the ADAP.
Allowed Values	A valid date on or before the last date of the reporting period in the format mm,dd,yyyy.
Required	Yes, only if client is reported as newly enrolled
Occurrence	0 for existing clients and 1 for newly enrolled clients
Schema	`<ApplicationApprovalDate>03,27,2014</ApplicationApprovalDate>`

3.2.4.4 RecertificationDate

Field	Description
Id	17

Field	Description
Element Name	RecertificationDate
Parent Element	AdrClientReportRecertificationDate
Definition	The dates on which the client was determined to be eligible to continue to receive ADAP services. ***Note:*** *All individuals enrolled in ADAP, regardless of whether they received services, must be recertified every six months. This includes clients on a waiting list. The minimum activities for recertification include: financial eligibility determination; ensuring that ADAP is the Payer of Last Resort; and appropriate documentation (i.e.: financial/insurance – or lack thereof/denial of coverage).*
Allowed Values	Valid dates on or before the last date of the reporting period in the format mm,dd,yyyy.
Required	No
Occurrence	Up to 2 per client
Schema	`<RecertificationDate>10,29,2014</RecertificationDate>`

3.2.4.5 EnrollmentStatusId

Field	Description
Id	18
Element Name	EnrollmentStatusId
Parent Element	AdrClientReport
Definition	The status of the individual in the ADAP at the end of the reporting period.
Allowed Values	A valid enrollment status identifier from the EnrollmentStatusLkup table: 8 = Enrolled, receiving services 9 = Enrolled, on waiting list 10 = Enrolled services not requested 11 = Disenrolled
Required	No
Occurrence	1 per client
Schema	`<EnrollmentStatusId>11</EnrollmentStatusId>`

3.2.4.6 DisenrollmentReasonId

Field	Description
Id	19
Element Name	DisenrollmentReasonId
Parent Element	AdrClientReportDisenrollmentReason
Definition	The reasons the client was disenrolled or discharged during the reporting period.
Allowed Values	A valid disenrollment reason identifier from the DisenrollmentReasonLkup table: 9 = Ineligible due to change in ADAP eligibility 10 = Ineligible for ADAP, no longer meets ADAP eligibility 4 = Did not recertify 5 = Did not fill prescription, as required by program

Field	Description
	6 = Deceased 7 = Dropped out, no reason given 11 = Other/Unknown
Required	Yes, only if the client's enrollment status Id is reported as disenrolled
Occurrence	1 to 6 per client, where Other/Unknown is mutually exclusive
Schema	`<DisenrollmentReasonId>6</DisenrollmentReasonId>`

3.2.5 Insurance Services Elements

The following Insurance Services elements capture data about ADAP-funded insurance assistance services and expenditures. ADAP-funded insurance assistance includes premiums, co-payments (i.e., co-pays), and deductibles. Co-pays and deductibles for medications should be reported through these elements.

3.2.5.1 InsuranceAssistanceReceivedFlag

Field	Description
Id	20
Element Name	InsuranceAssistanceReceivedFlag
Parent Element	AdrClientReport
Definition	A value indicating if the client received ADAP-funded insurance assistance during the reporting period, including Medicare Part D. This includes premiums, deductibles, and co-payments for which ADAP funds were used.
Allowed Values	0 for No or 1 for Yes.
Required	No
Occurrence	1 per client
Schema	`<InsuranceAssistanceReceivedFlag>1</InsuranceAssistanceReceivedFlag>`

3.2.5.2 InsuranceAssistanceType

Field	Description
Id	67
Element Name	InsuranceAssistanceTypeId
Parent Element	AdrInsuranceAssistanceReceived
Definition	The type of insurance service(s) that the client received during the reporting period.
Allowed Values	A valid insurance assistance identifier from the InsuranceAssistanceTypeLkup table: 1 = Full Premium payment 2 = Partial Premium payment 3 = Co-pay/deductible including Medicare Part D co-Insurance, co-payment, or donut hole coverage.
Required	Yes, if client indicated that insurance assistance was received
Occurrence	1 to 3 per client
Schema	`<InsuranceAssistanceTypeId>1</InsuranceAssistanceTypeId>`

3.2.5.3 InsurancePremiumAmount

Field	Description
Id	21
Element Name	InsurancePremiumAmount
Parent Element	AdrClientReport
Definition	The total amount of insurance premium paid on behalf of the client. This pertains to any premium paid during the reporting period, including Medicare Part D, regardless of the time frame that it covers (i.e., if it extends outside the reporting period).
Allowed Values	An integer value between 0 and 100,000. Do not include dollar signs or commas.
Required	Yes, only if the client received insurance assistance during the reporting period.
Occurrence	1 if client received insurance assistance, otherwise 0
Schema	`<InsurancePremiumAmount>100</InsurancePremiumAmount>`

3.2.5.4 InsurancePremiumMonthCount

Field	Description
Id	22
Element Name	InsurancePremiumMonthCount
Parent Element	AdrClientReport
Definition	The total amount of months of coverage for which insurance premium was paid. Report all months even if they fall outside the reporting period.
Allowed Values	An integer value between 0 and 12.
Required	Yes, only if the client received insurance assistance during the reporting period.
Occurrence	1 if client received insurance assistance, otherwise 0
Schema	`<InsurancePremiumMonthCount>2</InsurancePremiumMonthCount>`

3.2.5.5 InsuranceDeductibleAndCopayAmount

Field	Description
Id	23
Element Name	InsuranceDeductibleAndCopayAmount
Parent Element	AdrClientReport
Definition	The total amount of insurance deductibles and co-pays paid on behalf of the client, including Medicare Part D. The amount reported should be based on the date that the deductible or co-pay was paid.
Allowed Values	An integer value between 0 and 100,000. Do not include dollar signs or commas.
Required	Yes, only if the client received insurance assistance during the reporting period
Occurrence	1 if client received insurance assistance, otherwise 0
Schema	`<InsuranceDeductibleAndCopayAmount>0</InsuranceDeductibleAndCopayAmount>`

3.2.6 Drug and Drug Expenditure Elements

The following Drug and Drug Expenditure XML elements are designed to capture data about ADAP-funded medications dispensed to clients and total expenditures for those services. These elements are only for clients who were dispensed ADAP-funded medications paid in full by ADAP (i.e., not clients for whom only the co-pay or deductible was paid). This includes Antiretroviral (ARV), Hepatitis B, Hepatitis C, and A1-O1 medications.

3.2.6.1 MedicationsDispensedFlag

Field	Description
Id	25
Element Name	MedicationsDispensedFlag
Parent Element	AdrClientReport
Definition	A value indicating if ADAP-funded medications were dispensed to the client during the reporting period. ADAP-funded medications include any ARV, Hepatitis B, Hepatitis C, or A1-OI medication on your ADAP-formulary that was paid for in full with ADAP funds.
Allowed Values	0 for No or 1 for Yes
Required	No
Occurrence	1 per client
Schema	`<MedicationsDispensedFlag>1</MedicationsDispensedFlag>`

3.2.6.2 MedicationId

Field	Description
Id	26
Element Name	MedicationId
Parent Element	AdrClientReportMedication Medication
Definition	The dispensed medication five-digit drug code dispensed to the client during the reporting period.
Allowed Values	A valid drug code from the MedicationLkup table in the format d#####.
Required	Yes
Occurrence	1 or more if medications were dispensed to this client during the reporting period, otherwise 0
Schema	`<MedicationId>d03984</MedicationId>`

3.2.6.3 MedicationStartDate

Field	Description
Id	27
Element Name	MedicationStartDate
Parent Element	AdrClientReportMedication Medication
Definition	The dispense date for the medication dispensed to the client during the reporting period.
Allowed Values	A valid dispense date during the reporting period for each instance the

Field	Description
	medication was given to the client in the format mm,dd,yyyy.
Required	Yes, if medications were dispensed to this client during the reporting period, otherwise No
Occurrence	1 or more if medications were dispensed to this client during the reporting period, otherwise 0
Schema	`<MedicationStartDate>10,15,2012</MedicationStartDate>`

3.2.6.4 MedicationDays

Field	Description
Id	28
Element Name	MedicationDays
Parent Element	AdrClientReportMedication Medication
Definition	The number of days for which the medication was dispensed.
Allowed Values	An integer value between 1 and 360. Values should be from 1 through 30, and then in increments of 30 (i.e., 1 through 30, 60, 90, …, 360). For any value less than 30, report the actual number of days, otherwise report the number of days in 30 day increments.
Required	Yes, if medications were dispensed to this client during the reporting period, otherwise No
Occurrence	1 or more if medications were dispensed to this client during the reporting period, otherwise 0
Schema	`<MedicationDays>30</MedicationDays>`

3.2.6.5 MedicationCost

Field	Description
Id	29
Element Name	MedicationCost
Parent Element	AdrClientReportMedication Medication
Definition	Indicate the cost of each ADAP-funded medication listed in Item 26 that was dispensed to the client during the reporting period. Cost should be reported per medication per date dispensed. Include the amount paid for each prescription that is dispensed, even if the medication prescription period extended beyond the reporting period.
Allowed Values	An integer amount, rounded to the nearest dollar, between 0 and 100,000. Do not include dollar signs, commas, or cents.
Required	Yes, if medications were dispensed to this client during the reporting period, otherwise No
Occurrence	1 or more if medications were dispensed to this client during the reporting period, otherwise 0
Schema	`<MedicationCost>221</MedicationCost>`

3.2.7 Clinical Elements

The following Clinical Elements describe the clinical characteristics of ADAP clients who received ADAP-funded medications. All clients receiving ADAP-funded medications should have at least one CD4 test result and one viral load reported during the 12 month reporting period.

3.2.7.1 LastCd4Date

Field	Description
Id	32
Element Name	LastCd4Date
Parent Element	AdrClientReport
Definition	Value indicating the client's most recent CD4 test date during the reporting period.
Allowed Values	A valid date during the reporting period in the format mm,dd,yyyy.
Required	Yes, if client prescribed medication during the reporting period
Occurrence	0 to 1 per client
Schema	`<LastCd4Date>10,25,2014</LastCd4Date>`

3.2.7.2 LastCd4Count

Field	Description
Id	33
Element Name	LastCd4Count
Parent Element	AdrClientReport
Definition	Value indicating the client's most recent CD4 test count during the reporting period.
Allowed Values	A valid integer value between 0 and 100,000,000 (cells/mm3). Do not include commas.
Required	Yes, if client prescribed medication
Occurrence	0 to 1 per client
Schema	`<LastCd4Count>332</LastCd4Count>`

3.2.7.3 LastViralLoadDate

Field	Description
Id	34
Element Name	LastViralLoadDate
Parent Element	AdrClientReport
Definition	Value indicating the client's most recent viral load test date during the reporting period.
Allowed Values	A valid date during the reporting period in the format mm,dd,yyyy.
Required	Yes, if client prescribed medication
Occurrence	0 to 1 per client
Schema	`<LastViralLoadDate>04,25,2014</LastViralLoadDate>`

3.2.7.4 LastViralLoadCount

Field	Description
Id	35
Element Name	LastViralLoadCount
Parent Element	AdrClientReport
Definition	Value indicating the client's most recent viral load during the reporting period.
Allowed Values	A valid integer value between 0 and 100,000,000 (copies/mL). Do not include commas. For clients who are undetectable, report the lower test limit for the viral load count, if available, otherwise report 0.
Required	Yes, if client prescribed medication during the reporting period
Occurrence	0 to 1 per client
Schema	`<LastViralLoadCount>47</LastViralLoadCount>`

4 ADR Client-Level Data XML File Format

The ADR client-level data XML file structure and content is defined through a set of XML Schema Definition (XSD) files. The XSD files are used to validate the ADR client-level data XML files before they can be loaded into the ADR web application. Once loaded, further checks are performed by the ADR web application.

4.1 Validation Checks to Pass before File Is Accepted by ADR Web Application

The following validation checks must be satisfied before an ADR client-level data XML file will be accepted by the ADR web application:

- The XML file must have the .xml extension.
- The XML file must conform to the XML Schema Definition files.
- One and only one set of records per client is allowed in a single XML file.
  - An encrypted unique client identifier (ClientUci) may not be repeated within the same XML file.
  - A client is uniquely identified by their encrypted, Unique Client Identifier (eUCI). This value is represented in the ADR client-level data XML file by the ClientUci data element within the AdrClientReport complex element. The ClientUci value is an upper-cased, 40 character, hexadecimal value (0-9, A-F) followed by a single suffix from A through Z, which is used to further identify clients that may share the same base, 40 character encrypted UCI. The CLD_ID XML attribute is used to link the parent client record with its child records. The CLD_ID can be any integer value from 1 through 100000, but must be the same value for a single client.
- The XML complex data elements must appear in the specified order within the file. See Section 4.2: Sample XML File Format – Collapsed for an example of the sequencing required.

- The XML simple data elements must appear in the specified order within each complex data element. See Section 4.3: Sample XML File Format - Expanded for an example of the sequencing required.
- The XML simple data elements must conform to the definitions appearing in this document. Required fields must be reported and values must be valid and match the documented format, if defined.
- Empty or "null" data element tags are not permitted in the XML file (i.e., Data elements of the form <tag></tag> or <tag /> are not allowed.)

Important: *Some of the data elements are not required. If no data for a particular client is being provided for an element, then remove that element entirely from the client's record (i.e., remove the data element's start tag, end tag, and value.)*

4.2 Sample XML File Format – Collapsed

The following sample XML displays the complex data elements collapsed to show the required sequence of the complex elements.

Note: *The **CLD_ID** attribute name below indicates a unique Id for each client report and associated data such as race and medical insurance.*

```
<?xml version="1.0" encoding="UTF-8"?>
<CLD:ROOT xmlns:CLD="urn:adrNamespace" xmlns:xsi="http://www.w3.org/2001/XMLSchema-instance">
    <AdrClientReportXmlVersion>…</AdrClientReportXmlVersion>

    <AdrClientReport>

        <LastViralLoadCount>…</LastViralLoadCount>

        <AdrClientReportRace>…</AdrClientReportRace>

        <AdrClientReportHispanicSubgroup>…</AdrClientReportHispanicSubgroup>

        <AdrClientReportAsianSubgroup>…</AdrClientReportAsianSubgroup>

        <AdrClientReportNhpiSubgroup>…</AdrClientReportNhpiSubgroup>

        <AdrClientReportMedicalInsurance>…</AdrClientReportMedicalInsurance>

        <AdrClientReportRecertificationDate>…</AdrClientReportRecertificationDate>

        <AdrClientReportDisenrollmentReason>…</AdrClientReportDisenrollmentReason>

        <AdrClientReportMedication>

            <Medication>…</Medication>

        </AdrClientReportMedication>

        <AdrInsuranceAssistanceReceived>…</AdrInsuranceAssistanceReceived>

    </AdrClientReport>
```

```
</CLD:ROOT>
```

4.3 Sample XML File Format – Expanded

The following example shows a sample XML file with the complex data elements expanded in order to show the required sequence of the simple elements that are organized within them. Please note that this data are solely used as an example and represent the structure, sequence, values, and format of the data elements.

```
<CLD:ROOT xmlns:CLD="urn:adrNamespace" xmlns:xsi="http://www.w3.org/2001/XMLSchema-instance">

    <AdrClientReportXmlVersion>
        <AdrSchemaVersion>2.0.0</AdrSchemaVersion>
        <Vendor>Rx-REX</Vendor>
        <VendorVersionNumber>1.0.2.0</VendorVersionNumber>
        <VendorTechnicalContactName>John, Doe</VendorTechnicalContactName>
        <VendorTechnicalContactEmail>JohnDoe@Somewhere.com</VendorTechnicalContactEmail>
        <VendorTechnicalContactPhone>123,456,7890</VendorTechnicalContactPhone>
    </AdrClientReportXmlVersion>
    <AdrClientReport>
        <ClientUci>AEC5C1142DE217CD1FA5CBEDB99ED2E265E8E4F8U</ClientUci>
        <EthnicityId>1</EthnicityId>
        <GenderId>1</GenderId>
        <TransgenderId>3</TransgenderId>
        <BirthYear>1900</BirthYear>
        <HivAidsStatusId>4</HivAidsStatusId>
        <PovertyLevelId>10</PovertyLevelId>
        <NewEnrollmentFlag>0</NewEnrollmentFlag>
        <ApplicationReceivedDate>03,29,2014</ApplicationReceivedDate>
        <ApplicationApprovalDate>04,27,2014</ApplicationApprovalDate>
        <EnrollmentStatusId>11</EnrollmentStatusId>
        <InsuranceAssistanceReceivedFlag>1</InsuranceAssistanceReceivedFlag>
        <InsurancePremiumAmount>0</InsurancePremiumAmount>
        <InsurancePremiumMonthCount>2</InsurancePremiumMonthCount>
        <InsuranceDeductibleAndCopayAmount>0</InsuranceDeductibleAndCopayAmount>
        <MedicationsDispensedFlag>1</MedicationsDispensedFlag>
        <LastCd4Date>10,25,2014</LastCd4Date>
        <LastCd4Count>332</LastCd4Count>
        <LastViralLoadDate>04,25,2014</LastViralLoadDate>
        <LastViralLoadCount>47</LastViralLoadCount>
        <SexAtBirthId>1</SexAtBirthId>
        <AdrClientReportRace>
            <RaceId>1</RaceId>
            <RaceId>3</RaceId>
        </AdrClientReportRace>
        <AdrClientReportHispanicSubgroup>
            <SubgroupId>3</SubgroupId>
            <SubgroupId>1</SubgroupId>
        </AdrClientReportHispanicSubgroup>
        <AdrClientReportAsianSubgroup>
            <SubgroupId>3</SubgroupId>
            <SubgroupId>1</SubgroupId>
        </AdrClientReportAsianSubgroup>
        <AdrClientReportNhpiSubgroup>
            <SubgroupId>4</SubgroupId>
            <SubgroupId>1</SubgroupId>
```

```
    </AdrClientReportNhpiSubgroup>
    <AdrClientReportMedicalInsurance>
        <MedicalInsuranceId>11</MedicalInsuranceId>
        <MedicalInsuranceId>13</MedicalInsuranceId>
    </AdrClientReportMedicalInsurance>
    <AdrClientReportRecertificationDate>
    <RecertificationDate>10,29,2014</RecertificationDate>
        <RecertificationDate>10,15,2014</RecertificationDate>
    </AdrClientReportRecertificationDate>
    <AdrClientReportDisenrollmentReason>
        <DisenrollmentReasonId>6</DisenrollmentReasonId>
        <DisenrollmentReasonId>4</DisenrollmentReasonId>
    </AdrClientReportDisenrollmentReason>
    <AdrClientReportMedication>
        <Medication>
            <MedicationId>d03984</MedicationId>
            <MedicationStartDate>10,15,2014</MedicationStartDate>
            <MedicationDays>30</MedicationDays>
            <MedicationCost>221</MedicationCost>
        </Medication>
        <Medication>
            <MedicationId>d05352</MedicationId>
            <MedicationStartDate>10,15,2014</MedicationStartDate>
            <MedicationDays>30</MedicationDays>
            <MedicationCost>994</MedicationCost>
        </Medication>
        <Medication>
            <MedicationId>d05353</MedicationId>
            <MedicationStartDate>10,15,2014</MedicationStartDate>
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Appendix A: Resources

A.1 ADR Client XML Schema Definition Files

The ADR XML schema definitions and sample XML files can be downloaded from ADR Download Package.

A.2 TRAX (XML Generator)

The Tool for RSR and ADR XML Generation (TRAX) is a HAB tool that can be used to generate the ADR client-level data XML files. This tool is available on the TARGET Center website.

A.3 TARGET Center Website

The TARGET Center website contains a vast array of technical assistance resources including the TRAX application, webcasts, training materials, and reference documents, such as the ADR Instruction Manual.

Appendix B: Acronyms

ADAP	AIDS Drug Assistance Program
ADR	ADAP Data Report
AIDS	Acquired ImmunoDeficiency Syndrome
eUCI	Encrypted Unique Client Identifier
HAB	HIV/AIDS Bureau
HIV	Human Immunodeficiency Virus
HRSA	Health Resources and Services Administration
UCI	Unique Client Identifier
XML	Extensible Markup Language
XMLNS	XML Namespace
XSD	XML Schema Definition
XSI	XML Schema Instance

ADR Crosswalk

March 2016

Purpose

This document can help you compare the data you currently collect in your data management system to the data required in the ADAP Data Report (ADR). The Crosswalk is a table in which you list the variables and values in your data management system that corresponds to ADR data elements. Using this Crosswalk will help you to:

- Find the data you need to report
- Understand what you need to do to transform the data you have into the data you need to report
- Identify any missing data that you'll need to start collecting

Audience

This Crosswalk is intended for ADAP staff who must report client-level data elements in XML file format to the Health Resources and Services Administration (HRSA) HIV/AIDS Bureau (HAB).

Definitions

Variable: Refers to the name of a set of data pertaining to the client. Variables are also referred to as data elements or items.

ID: Identifies the variable. Each variable has been assigned an ID for convenient referencing between this document and the ADR Data Dictionary.

Values: Refers to the allowed values or response options corresponding to each variable.

Notes: This column in the Crosswalk can help you keep a record of the data transformations that you have to perform to provide the required ADR client-level data elements and allowed values. See example:

	YOUR DATA		**ADR DATA**
Variable	**Client Race**		**Race ID**
Values	*White*	→	*1*
	Black or African American	→	*2*
	Asian	→	*3*
	Native Hawaiian / PI	→	*4*
	Native American (AK native)	→	*5*

Updates

This document will be revised as variables and values are updated or when other global changes are made. The most up-to-date version of this document will be made available at https://careacttarget.org/library/trax-adr.

ADAP Data Report (ADR) Crosswalk

ADR				Your System		
ID	**Variable**	**Definition**	**Value**	**Variable**	**Value**	**Notes**
Client Demographics Elements						
4	Ethnicity	Client's ethnicity.	1. Hispanic 2. Non-Hispanic			
5	Race	Client's race.	1. White 2. Black or African American 3. Asian 4. Native Hawaiian/Pacific Islander 5. American Indian or Alaska Native			
68	Hispanic Subgroup	If Ethnicity = Hispanic (If ID 4=1, then ID 68 required), Client's Hispanic Sub-group (choose all that apply)	1. Mexican, Mexican American, Chicano/a 2. Puerto Rican 3. Cuban 4. Another Hispanic, Latino/a or Spanish origin			
69	Asian Subgroup	If Race = Asian (If ID 5=3, then ID 69 required), Client's Asian subgroup. (choose all that apply)	1. Asian Indian 2. Chinese 3. Filipino 4. Japanese 5. Korean 6. Vietnamese 7. Other Asian			
70	NHPI Subgroup	If Race = Native Hawaiian/Pacific Islander (If ID 5=4, then ID 70 required), Client's Native Hawaiian/Pacific Islander subgroup.(choose all that apply)	1. Native Hawaiian 2. Guamanian or Chamorro 3. Samoan 4. Other Pacific Islander			

Attachment D3. ADR Crosswalk

ADR				Your System		
ID	**Variable**	**Definition**	**Value**	**Variable**	**Value**	**Notes**
6	Gender	Client's current gender identity. This is the variable that is used for the eUCI.	1. Male 2. Female 3. Transgender 4. Unknown			
7	Transgender	If Gender = Transgender (If ID 6=3, then ID 7 required). Client's current transgender status.	1. Male-to-Female 2. Female-to-Male 3. Unknown			
71	Sex at Birth	The biological sex assigned to the client at birth.	1. Male 2. Female			
9	Birth Year	The year the client was born.	yyyy Must be less than or equal to the reporting period year.			
10	HIV/AIDS Status	Client's HIV/AIDS status at the end of the reporting period.	2. HIV +, not AIDS 3. HIV-positive, AIDS status unknown 4. CDC-defined AIDS			
11	Poverty Level	Client's percent of the Federal poverty level at the end of the reporting period.	13. Below 100% of the Federal poverty level 9. 100 -138% of the Federal poverty level 10. 139 - 200% of the Federal poverty level 11. 201 – 250% of the Federal poverty level 12. 251 – 400% of the Federal poverty level 7. 401 – 500% of the Federal poverty level 8. More than 500% of the Federal poverty level			
12	High Risk Insurance	If client was in a High Risk Insurance Pool at any time during the reporting period.	1. No 2. Yes 3. Unknown			

Attachment D3. ADR Crosswalk

ADR				Your System		
ID	**Variable**	**Definition**	**Value**	**Variable**	**Value**	**Notes**
13	Medical Insurance	Client's medical insurance. *Report **all** that apply.*	10. Private – Employer 11. Private - Individual 8. Medicare Part A/B 9. Medicare Part D 12. Medicaid, CHIP or other public plan 13. VA, Tricare and other military health care 14. IHS 15. Other plan 16. No Insurance/ uninsured			
Enrollment and Certification Elements						
14	New Enrollment	Newly enrolled clients in ADAP for this reporting period only.	0. No 1. Yes			
15	Application Received Date	The date that the completed application was received by the ADAP.	mm,dd,yyyy Must be on or before the last date of the reporting period.			
16	Application Approval Date	The date that the client was approved to begin to receive ADAP services. This is when the client was first enrolled in the ADAP.	mm,dd,yyyy Must be on or before the last date of the reporting period.			
17	Recertification Date	The dates on which the client was determined to be eligible to continue to receive ADAP services.	mm,dd,yyyy Must be on or before the last date of the reporting period.			

Attachment D3. ADR Crosswalk

ADR				Your System		
ID	**Variable**	**Definition**	**Value**	**Variable**	**Value**	**Notes**
18	Enrollment Status	The status of the individual in the ADAP at the end of the reporting period.	8. Enrolled, receiving services 9. Enrolled, on waiting list 10. Enrolled services not requested 11. Disenrolled			
19	Disenrollment Reason	The reasons the client was disenrolled or discharged during the reporting period. If ID 18=11, then ID 19 required.	9. Ineligible due to change in ADAP eligibility 10. Ineligible for ADAP, no longer meets ADAP eligibility 4. Did not recertify 5. Did not fill prescription, as required by program 6. Deceased 7. Dropped out, no reason given 11. Other/Unknown			
Insurance Service Elements						
20	Insurance Assistance Received Flag	A value indicating if the client received ADAP-funded insurance assistance during the reporting period, including Medicare Part D. This includes premiums, deductibles, and co-payments for which ADAP funds were used.	0. No 1. Yes			

Attachment D3. ADR Crosswalk

ADR				Your System		
ID	Variable	Definition	Value	Variable	Value	Notes
67	Insurance Assistance Type	The type of insurance service(s) that the client received during the reporting period.	1. Full Premium payment 2. Partial Premium payment 3. Co-pay/deductible including Medicare Part D co-Insurance, co-payment, or donut hole coverage.			
21	Insurance Premium Amount	The total amount of insurance premium paid on behalf of the client. This pertains to any premium paid during the reporting period, including Medicare Part D, regardless of the time frame that it covers (i.e., if it extends outside the reporting period).	An integer value between 0 and 100000. Do not include dollar signs or commas.			
22	Insurance Premium Month Count	The total amount of months of coverage for which insurance premium was paid. Report all months even if they fall outside the reporting period.	An integer value between 0 and 12.			

Attachment D3. ADR Crosswalk

ADR				Your System		
ID	**Variable**	**Definition**	**Value**	**Variable**	**Value**	**Notes**
23	Insurance Deductible and Copay Amount	The total amount of insurance deductibles and co-pays paid on behalf of the client, including Medicare Part D. The amount reported should be based on the date that the deductible or co-pay was paid.	An integer value between 0 and 100000. Do not include dollar signs or commas.			
Drug and Drug Expenditure Elements						
25	Medications Dispensed Flag	A value indicating if ADAP-funded medications were dispensed to the client during the reporting period. ADAP-funded medications include any ARV, Hepatitis B, Hepatitis C, or A1-OI medication on your ADAP-formulary that was paid for in full with ADAP funds.	0. No 1. Yes			
26	Medication ID	The dispensed medication five-digit drug code dispensed to the client during the reporting period.	A valid drug code from the medication lookup table in the format d######.			
27	Medication Start Date	The **dispense** date for the medication dispensed to the client during the reporting period.	mm,dd,yyyy A valid dispense date during the reporting period for each instance the medication was given to the client.			

Attachment D3. ADR Crosswalk

ADR				Your System		
ID	**Variable**	**Definition**	**Value**	**Variable**	**Value**	**Notes**
28	Medication Days	The number of days for which the medication was dispensed.	An integer value between 1 and 360. Values should be from 1 through 30, and then in increments of 30 (i.e., 1 through 30, 60, 90, …, 360). For any value less than 30, report the actual number of days, otherwise report the number of days in 30 day increments.			
29	Medication Cost	Indicate the cost of each ADAP-funded medication listed in Item 26 that was dispensed to the client during the reporting period. Cost should be reported per medication per date dispensed. Include the amount paid for each prescription that is dispensed, even if the medication prescription period extended beyond the reporting period.	An integer amount, rounded to the nearest dollar, between 0 and 100000. Do not include dollar signs, commas, or cents.			
Clinical Elements						
32	Last CD4 Date	Value indicating the client's most recent CD4 test date during the reporting period.	mm,dd,yyyy Must be within the reporting period start and end dates.			

Attachment D3. ADR Crosswalk

ADR				Your System		
ID	**Variable**	**Definition**	**Value**	**Variable**	**Value**	**Notes**
33	Last CD4 Count	Value indicating the client's most recent CD4 test count during the reporting period.	Integer value between 0 and 100000000 (cells/mm3). Do not include commas.			
34	Last Viral Load Date	Value indicating the client's most recent viral load test date during the reporting period.	mm,dd,yyyy Must be within the reporting period start and end dates.			
35	Last Viral Load Count	Value indicating the client's most recent viral load during the reporting period.	A valid integer value between 0 and 100000000 (copies/mL). Do not include commas. Report undetectable values as the lower bound of the test limit. If the lower bound is not available, report 0.			

VENDOR DISCLOSURE STATEMENT INFORMATION AND INSTRUCTIONS

Section 41-16-82, *Code of Alabama* 1975 requires the disclosure statement to be completed and filed with all proposals, bids, contracts, or grant proposals to the State of Alabama in excess of $5,000. The disclosure statement is not required for contracts for gas, water, and electric services where no competition exists, or where rates are fixed by law or ordinance. In circumstances where a contract is awarded by competitive bid, the disclosure statement shall be required only from the person receiving the contract and shall be submitted within ten (10) days of the award.

A copy of the disclosure statement shall be filed with the awarding entity and the Department of Examiners of Public Accounts, and if it pertains to a state contract, a copy shall be submitted to the Contract Review Permanent Legislative Oversight Committee. The address for the Department of Examiners of Public Accounts is as follows: 50N. Ripley Street, Room 3201,Montgomery,Alabama36130-2101. If the disclosure statement is filed with a contract, the awarding entity should include a copy with the contract when it is presented to the Contract Review Permanent Legislative Oversight Committee.

Pursuant to Section 41-16-84 (b), *Code of Alabama* 1975 the State of Alabama shall not enter into any contract or appropriate any public funds with any person who refuses to provide information as required.

Pursuant to Section 41-16-86, *Code of Alabama* 1975, any person who knowingly provides misleading or incorrect information on the disclosure statement shall be subject to a civil penalty of ten percent (10%) of the amount of the transaction, not to exceed $10,000.00. Also, the contract or grant shall be voidable by the awarding entity.

Definitions as Provided in Section 41-16-81, *Code of Alabama* 1975

1. **Family Member of a Public Employee** – The spouse or a dependent of the public employee.

2. **Family Member of a Public Official** – The spouse, a dependent, an adult child and his or her spouse, a parent, a spouse's parents, or a sibling and his or her spouse, of the public official.

3. **Family Relationship** – A person has a family relationship with a public official or public employee if the person is a family member of the public official or public employee.

4. **Person** – An individual, firm, partnership, association, joint venture, cooperative, or corporation, or any other group or combination acting in concert.

5. **Public Official and Public Employee** - These terms shall have the same meanings ascribed to them in Sections 36-25-1(23) and 36-25-1(24), *Code of Alabama* 1975, (see below) except for the purposes of the disclosure requirements of this article, the terms shall only include persons in a position to influence the awarding of a grant or contract who are affiliated with the awarding entity. Notwithstanding the foregoing, these terms shall also include the Governor, Lieutenant Governor, members of the cabinet of the Governor, and members of the Legislature. (Note: The definitions for public official and public employee are now denoted as Sections 36-25-1 (25) and 36-25-1 (26), *Code of Alabama* 1975. However, Section 41-16-86 (5), *Code of Alabama* 1975 has not been codified to reflect such updates.)

Section 36-25-1(25), *Code of Alabama* 1975, defines a **public employee** as any person employed at the state, county or municipal level of government or their instrumentalities, including governmental corporations and authorities, but excluding employees of hospitals or other health care corporations including contract employees of those hospitals or other health care corporations, who is paid in whole or in part from state, county, or municipal funds. For purposes of this chapter, a public employee does not include a person employed on a part-time basis whose employment is limited to providing professional services other than lobbying, the compensation for which constitutes less than 50 percent of the part-time employee's income.

Section 36-25-1(26), *Code of Alabama* 1975, defines a **public official** as any person elected to public office, whether or not that person has taken office, by the vote of the people at state, county, or municipal level of government or their instrumentalities, including governmental corporations, and any person appointed to a position at the state, county, or municipal level of government or their instrumentalities, including governmental corporations. For purposes of this chapter, a public official includes the chairs and vice-chairs or the equivalent offices of each state political party as defined in Section 17-13-40, *Code of Alabama* 1975.

Instructions

Complete all lines as indicated. If an item does not apply, denote N/A (not applicable). If you cannot include required information in the space provided, attach additional sheets as necessary.

THE DISCLOSURE STATEMENT MUST BE SIGNED, DATED, AND NOTARIZED PRIOR TO SUBMISSION.

http://ago.alabama.gov/Page-Vendor-Disclosure-Statement-Information-and-Instructions

State of Alabama
Disclosure Statement

Required by Article 3B of Title 41, Code of Alabama 1975

ENTITY COMPLETING FORM

ADDRESS

CITY, STATE, ZIP TELEPHONE NUMBER

STATE AGENCY/DEPARTMENT THAT WILL RECEIVE GOODS, SERVICES, OR IS RESPONSIBLE FOR GRANT AWARD

ADDRESS

CITY, STATE, ZIP TELEPHONE NUMBER

This form is provided with:

☐ Contract ☐ Proposal ☐ Request for Proposal ☐ Invitation to Bid ☐ Grant Proposal

Have you or any of your partners, divisions, or any related business units previously performed work or provided goods to any State Agency/Department in the current or last fiscal year?

☐ Yes ☐ No

If yes, identify below the State Agency/Department that received the goods or services, the type(s) of goods or services previously provided, and the amount received for the provision of such goods or services.

STATE AGENCY/DEPARTMENT	TYPE OF GOODS/SERVICES	AMOUNT RECEIVED

Have you or any of your partners, divisions, or any related business units previously applied and received any grants from any State Agency/Department in the current or last fiscal year?

☐ Yes ☐ No

If yes, identify the State Agency/Department that awarded the grant, the date such grant was awarded, and the amount of the grant.

STATE AGENCY/DEPARTMENT	DATE GRANT AWARDED	AMOUNT OF GRANT

1. List below the name(s) and address(es) of all public officials/public employees with whom you, members of your immediate family, or any of your employees have a family relationship and who may directly personally benefit financially from the proposed transaction. Identify the State Department/Agency for which the public officials/public employees work. (Attach additional sheets if necessary.)

NAME OF PUBLIC OFFICIAL/EMPLOYEE	ADDRESS	STATE DEPARTMENT/AGENCY

2. List below the name(s) and address(es) of all family members of public officials/public employees with whom you, members of your immediate family, or any of your employees have a family relationship and who may directly personally benefit financially from the proposed transaction. Identify the public officials/public employees and State Department/Agency for which the public officials/public employees work. (Attach additional sheets if necessary.)

NAME OF FAMILY MEMBER	ADDRESS	NAME OF PUBLIC OFFICIAL/ PUBLIC EMPLOYEE	STATE DEPARTMENT/ AGENCY WHERE EMPLOYED

If you identified individuals in items one and/or two above, describe in detail below the direct financial benefit to be gained by the public officials, public employees, and/or their family members as the result of the contract, proposal, request for proposal, invitation to bid, or grant proposal. (Attach additional sheets if necessary.)

Describe in detail below any indirect financial benefits to be gained by any public official, public employee, and/or family members of the public official or public employee as the result of the contract, proposal, request for proposal, invitation to bid, or grant proposal. (Attach additional sheets if necessary.)

List below the name(s) and address(es) of all paid consultants and/or lobbyists utilized to obtain the contract, proposal, request for proposal, invitation to bid, or grant proposal:

NAME OF PAID CONSULTANT/LOBBYIST	ADDRESS

By signing below, I certify under oath and penalty of perjury that all statements on or attached to this form are true and correct to the best of my knowledge. I further understand that a civil penalty of ten percent (10%) of the amount of the transaction, not to exceed $10,000.00, is applied for knowingly providing incorrect or misleading information.

Signature Date

Notary's Signature Date Date Notary Expires

Article 3B of Title 41, Code of Alabama 1975 requires the disclosure statement to be completed and filed with all proposals, bids, contracts, or grant proposals to the State of Alabama in excess of $5,000.

Revised: 09/2013

Attachment G. Cost Template – Annual Fee Schedule

Proposers must complete a cost proposal in the following format to be considered for award. Failure to complete will result in the disqualification of the proposal.

Instructions:

Proposal shall include all anticipated costs of successful implementation of all deliverables outlined in the RFP. Fees proposed will not be negotiated based on volume.

Annual Fee Schedules			
Year One			
Services	**Price**	**Estimated Annual Transactions**	**Yearly Total**
1. **Implementation Fee** – Onetime costs associated with initial implementation of services.	$	1 **(first year only)**	$
2. **Monthly Administrative Fees*** – Costs associated with execution of services.	$	12	$
3. **Training Fees** – Costs associated with participating in and/or providing annual trainings.	$	5	$
4. **Reporting Fees** – Monthly cost associated with generating required reports.	$	12	$
5. **Recoupment Fee** - Monthly costs associated with claims recoupment.	$	12	$
6. **Third Party Match Fee** – Monthly costs associated with third party enrollment identification and reporting	$	12	$
7. **Other Fees (Please specify)**	$		$
		Estimated Year One Fee Total:	**$**
Year Two			
Services	**Price**	**Estimated Transactions per Year**	**Yearly Total**
1. **Monthly Administrative Fees***	$	12	$
2. **Training Fees**	$	5	$
3. **Reporting Fees**	$	12	$
4. **Recoupment Fee**	$	12	$
5. **Third Party Enrollment Match Fee**	$	12	$
6. **Other Fees (Please Specify)**	$		$
		Estimated Year Two Fee Total:	**$**
Year Three			
Services	**Price**	**Estimated Transactions per Year**	**Yearly Total**
1. **Monthly Administrative Fees***	$	12	$
2. **Training Fees**	$	5	$
3. **Reporting Fees**	$	12	$
4. **Recoupment Fee**	$	12	$
5. **Third Party Enrollment Match Fee**	$	12	$
6. **Other Fees (Please Specify)**	$		$
		Estimated Year Three Fee Total:	**$**

Estimated Total Three (3) Year Fee Total:	**$**

Administrative Fees* Breakdown

Proposers must complete this chart to show the breakdown of Year 1 Administrative Fees* proposed above to be considered for award. If it is not completed, the Proposer will be disqualified from consideration. Fees proposed will not be negotiated based on volume.

Year 1

Expenditure Categories	Hourly Rate(for staff)	Total cost
Administrative Staff (list by position)		
Direct Labor Staff (list by position)		
Contracted Staff (list by position)		
Benefits		
Travel		

Attachment G. Cost Template – Annual Fee Schedule

Operating Costs:		
Rent		
Utilities		
Telephone		
Insurance		
Other (List):		
Office Supplies (List)		
Professional Services (list)		
Other Direct Costs (list)		

Proposers are strongly encouraged to use the template provided.

***Administrative Costs may include:**

- Usual and recognized overhead activities, including rent, utilities, and facility costs.
- Costs of management oversight of specific programs funded under this title, including program coordination; clerical, financial, and management staff not directly related to patient care; program evaluation; liability insurance; audits; computer hardware/software not directly related to patient care.

However, in accordance with the legislative mandates of the Ryan White HIV/AIDS Treatment Extension Act of 2009, and the Monitoring Standards for Ryan White Part A and B Grantees, administrative costs must be documented and shall not exceed 10 percent of the total resources contracted for direct client services.

Attachment H. Cost Template – Claims Table

Fees proposed in this table will be valid for the first year of the contract with discounts in subsequent years as reflected in II. A. Drug Pricing. Proposers must use the template provided.

Services	Actual Cost	Multiplier	Weighted Cost (Actual Cost x Multiplier)
Third Party Claims			
Dispensing fee per claim	$	0.20	$
Transaction fee per claim	$	0.20	$
340B Claims			
Dispensing fee per claim	$	0.15	$
Transaction fee per claim	$	0.15	$
Mail Order Claims			
Shipping fee per claim	$	0.10	$
Transaction fee per claim	$	0.10	$
Manual / Direct Member Reimbursement Third Party Claims			
Transaction fee per claim	$	0.10	$
		Total Weighted Per Claim Cost:	**$**