# 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***



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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.

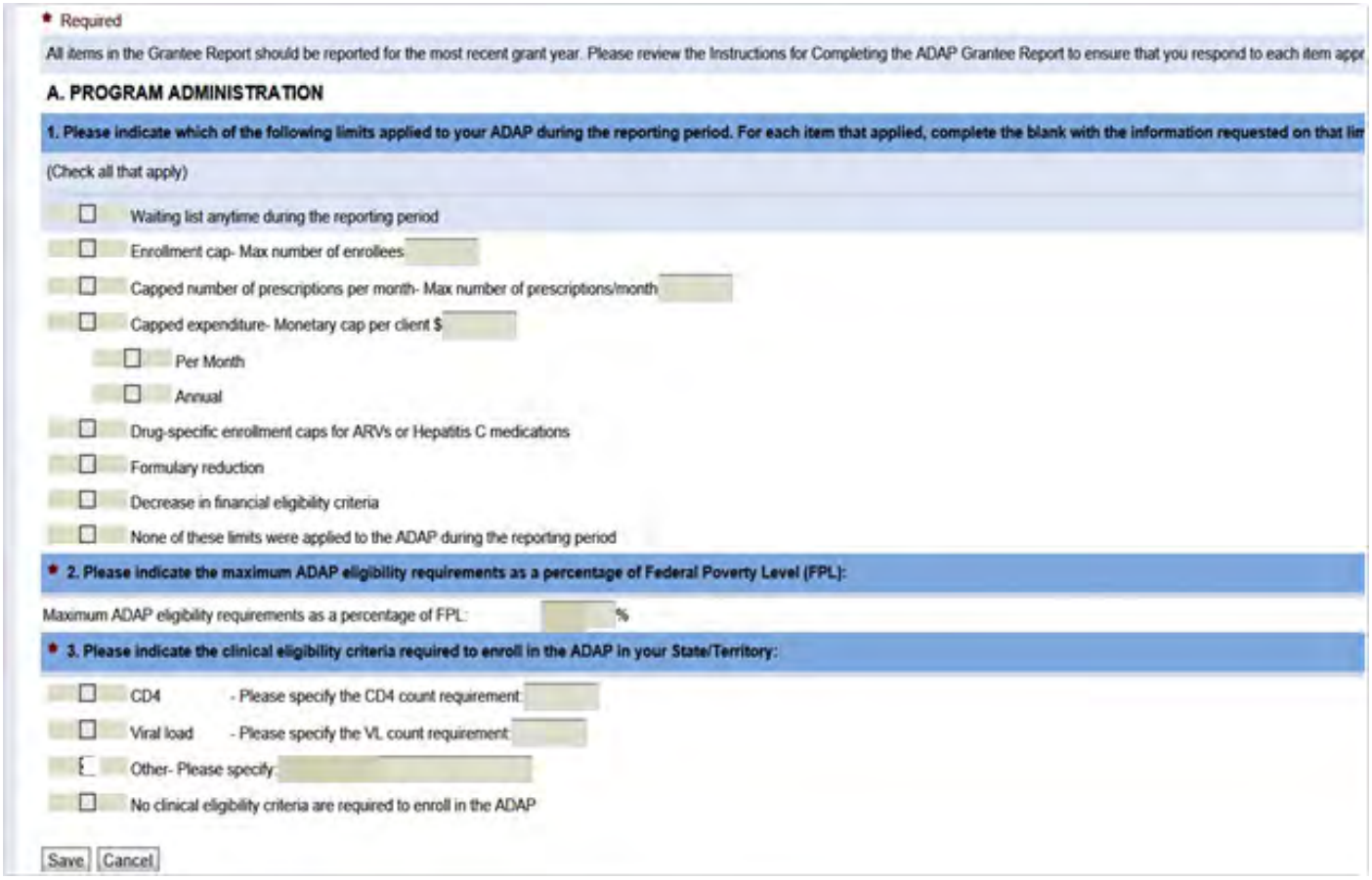
If your ADAP has adopted drug-specific enrollment caps, indicate the medications for which you have enrollment caps.

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

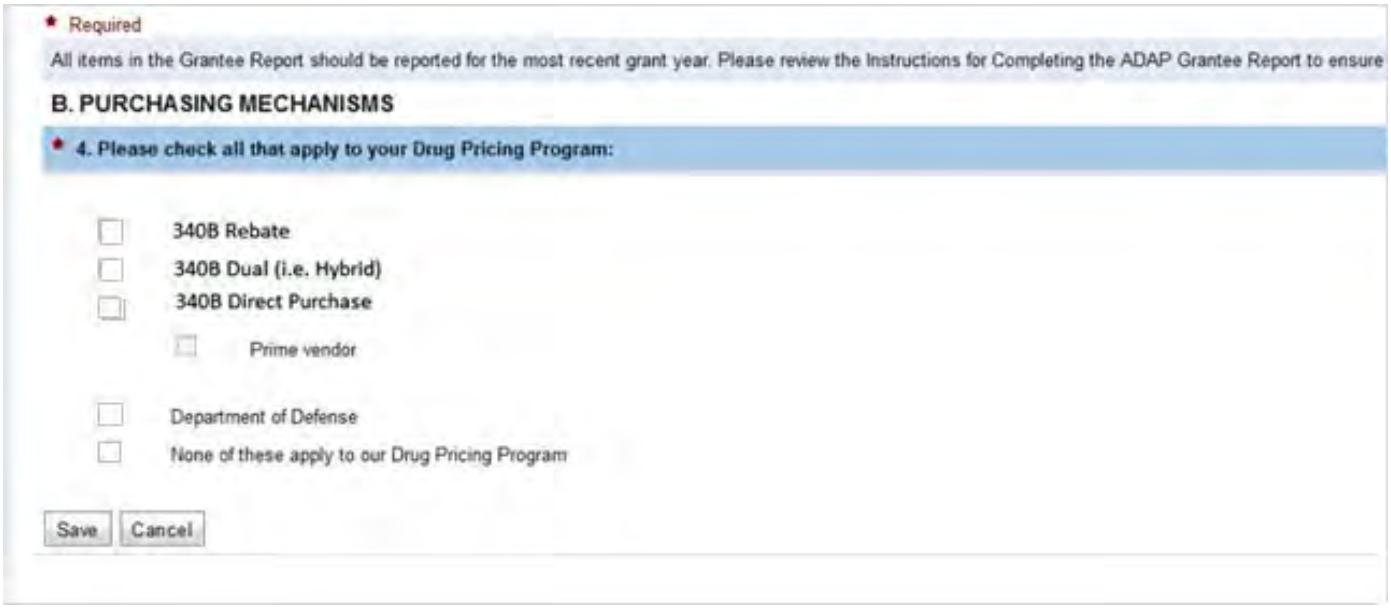
    c. *Other* - Indicate each criterion used and any corresponding threshold number

    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.

TIP

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.

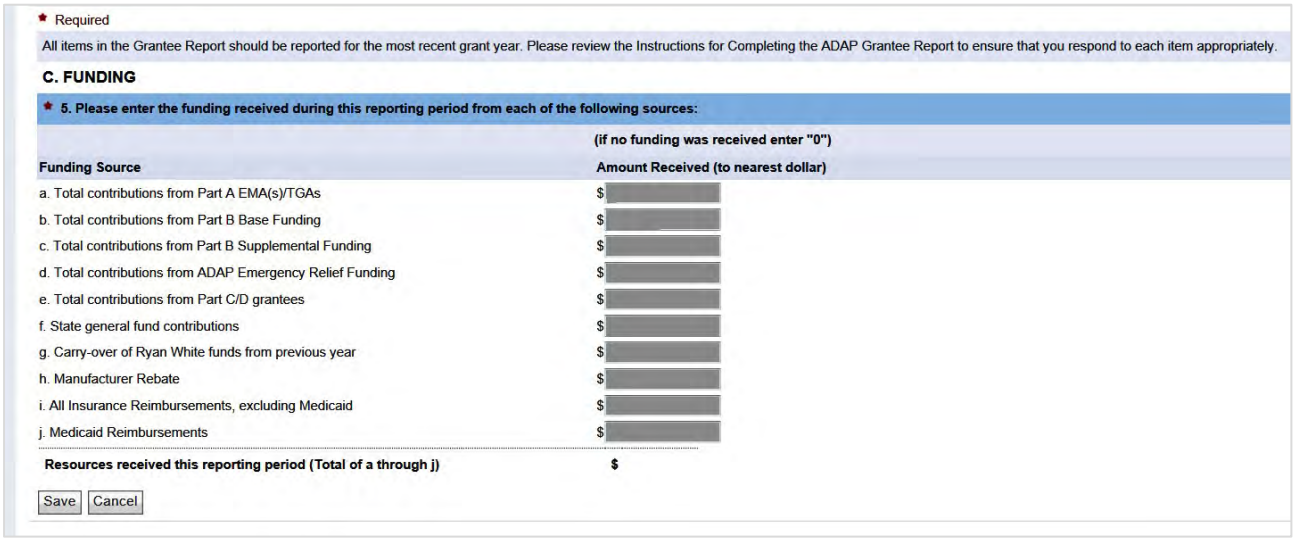
   If your ADAP participates in the 340B Drug Pricing Program that requires drug manufacturers to provide outpatient drugs to eligible health care organizations/covered entities at significantly reduced prices, please select the mechanism(s) through which your program has implemented the program:

   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")<br>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.

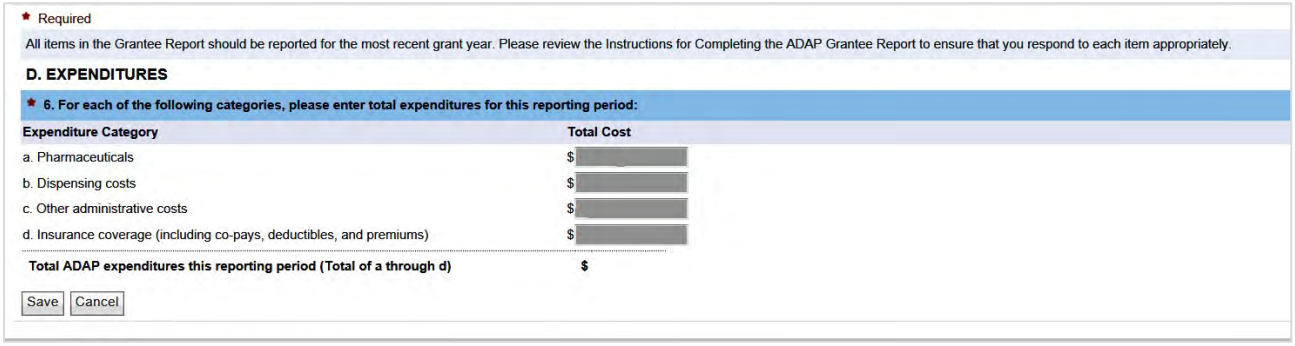
**Do we include funding that we used for services under the ADAP Flexibility Policy, or just funding for medication and health insurance services?**

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.

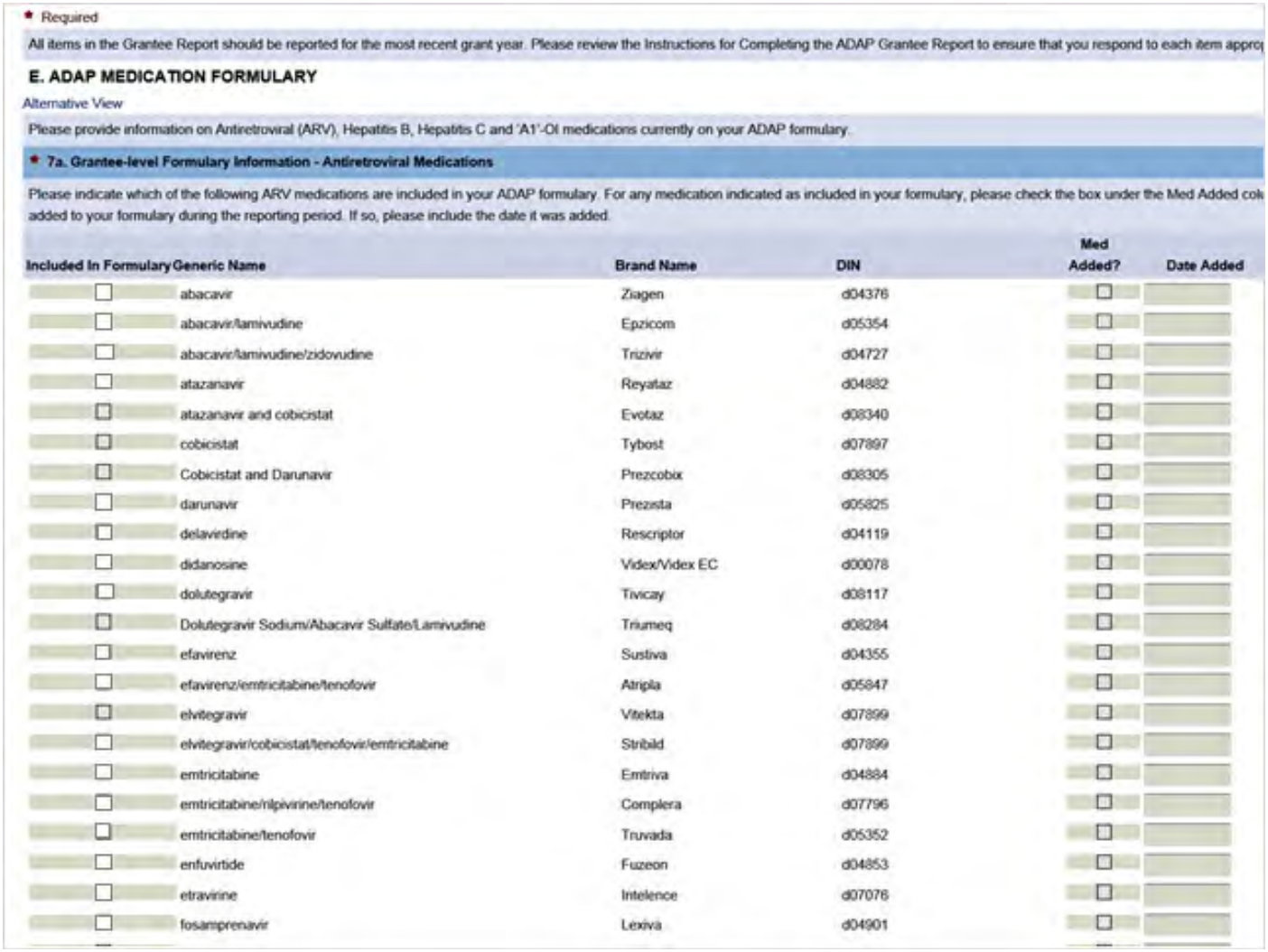
   For each list of medications, check the box on the left if your ADAP currently includes the medication in the formulary.

   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

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| **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. |

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| **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.' |

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| **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. |

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| **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. |

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| **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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