# AIDS DRUG ASSISTANCE PROGRAM DATA REPORT (ADR)

# INSTRUCTION MANUAL

# 2018

Release Date: January 15, 2019

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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 Manual

The following icons are used throughout this manual to alert you to important and/or useful information.



The note icon highlights information that you should know when completing this section.



The tip icon points out recommendations and suggestions that can make it easier to complete this section.



The question mark icon indicates common questions asked by ADAP recipients about this section with answers to the queries.

# Introduction

The Ryan White HIV/AIDS Program (RWHAP), first authorized by the U.S. Congress in 1990, is administered by the U.S. Department of Health and Human Services (HHS), Health Resources and Services Administration's (HRSA) HIV/AIDS Bureau (HAB).<sup>1</sup> HRSA's RWHAP uses dynamic data-driven and innovative approaches to provide a comprehensive system of care to achieve optimal health outcomes for people living with HIV (PLWH). Funds are provided to cities, states, and local community-based organizations that provide HIV medical care treatment, and essential support services to approximately half-a-million people in the United States living with diagnosed HIV infection. A smaller but equally critical portion is used to fund technical assistance, clinical training, and the development of innovative models of HIV care.

Of the nearly one million people living with diagnosed HIV in the United States, more than 50 percent receive high quality HIV medical care, treatment, and support services from the HRSA RWHAP each year. The HRSA RWHAP has developed a comprehensive system of care and treatment that provides the foundation for ending the HIV epidemic in the United States. The RWHAP is critical to ensuring that low-income uninsured or underserved PLWH are linked to medical care, retained in medical care, prescribed antiretroviral medications, and achieved viral suppression. HIV treatment is a recognized form of prevention. The HRSA RWHAP works toward four national HIV health outcome goals:

- 1. Reducing new infections;
- 2. Increasing access to care and improving health outcomes for people living with HIV;
- 3. Reducing HIV-related disparities and health inequities; and
- 4. Achieving a more coordinated national response to the HIV epidemic.

The HRSA RWHAP has been increasingly successful in achieving improved outcomes along the HIV care continuum.<sup>2</sup> 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. The following states, territories, and Pacific Island jurisdictions are eligible to apply for RWHAP ADAP funding: All 50 states, the District of Columbia, the Commonwealth of Puerto Rico, the U.S. Virgin Islands, Guam, American Samoa, the Commonwealth of the Northern Mariana Islands, the Republic of Palau, the Federated States of Micronesia, and the Republic of the Marshall Islands.

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 medication assistance 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; and
- monitor progress towards the national goals to end the HIV epidemic.

<sup>&</sup>lt;sup>1</sup> The Ryan White HIV/AIDS Treatment Extension Act of 2009–Title XXVI of the Public Health Service Act, as amended <u>https://hab.hrsa.gov/about-ryan-white-hivaids-program/ryan-white-hivaids-program-legislation</u>

<sup>&</sup>lt;sup>2</sup> HIV/AIDS Bureau HIV Performance Measures. <u>https://hab.hrsa.gov/clinical-quality-management/performance-measure-portfolio.</u>



HRSA 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 ADR's purposes.

ADR technical support is available to ADAPs through the HRSA HAB website at <u>https://hab.hrsa.gov/program-grants-management/ryan-white-hivaids-program-adap-data-report-adr</u> or the TargetHIV website at <u>https://targethiv.org/library/topics/adap-data-report-adr</u>.

## What's New

There are two changes to the reporting requirements for the 2018 ADR:

- In 2016, the ADR Instruction Manual began using the new term "recipient" to replace "grantee" to line up with Office of Management and Budget (OMB) vocabulary standards. To reflect this change, throughout the ADR manual and ADR web system, the first component of the ADR is now called the Recipient Report (formerly known as the Grantee Report).
- The ADR has made a change to the Client Report under the data element *HIV/AIDS Status* to include the response option *HIV-indeterminate (infants < 2 years only)*. See page 22 for more information.

There are no other revisions to the reporting requirements for the 2018 ADR. Please review the manual for added clarification on existing requirements.

# About the ADR

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

The Recipient 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 2018 ADR, consisting of the Recipient Report and Client Report, is due on June 3, 2019.

ADAPs are encouraged to upload their first Client Report by **April 22, 2019**, to address any technical and data quality issues in a timely manner.

# Who is an ADAP client?

An ADAP client is any person who is certified as eligible to receive ADAP services, regardless of whether the person 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, and/or
- been eligible but did not receive any services.

## What are ADAP services?

The ADAP is a state-administered program authorized under RWHAP Part B to provide U.S. Food and Drug Administration (FDA)-approved medications to low-income clients living with HIV who have limited or no 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 FDA-approved medications for the treatment of HIV 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 provision of financial assistance for clients to obtain and maintain continuity of health insurance. This includes premium payments (partial or full), Medicare Part D-related costs (coinsurance, deductibles, true out-of-pocket costs [TrOOP], and coinsurance under catastrophic coverage) and medication co-pays and deductibles.

## Services Provided under the ADAP Flexibility Policy

HRSA HAB Policy Notice 07-03 allows recipients greater flexibility in using ADAP base 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 base 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 base dollars used for services under the ADAP Flexibility Policy are not reported on the ADR.

# How is the ADR submitted to HRSA HAB?

The ADR is submitted online using HRSA 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 <u>https://grants.hrsa.gov/webexternal</u>.



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

### Who submits the ADR?

ADR submission 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 reporting period is the 12-month time period on which ADAPs base their ADR data. The Recipient Report and the Client Report have different reporting periods.

- **Recipient Report**: ADAPs report data based on the **grant year** reporting period, April 1, 2018, to March 31, 2019.
- **Client Report**: ADAPs report client-level data for clients enrolled during the **calendar year** reporting period, January 1, 2018, to December 31, 2018.

# **Important Dates**

Date	Client XML File	Recipient Report	
Monday, February 4, 2019	ADR Test Your XML and Data Quality Feature Opens		
Monday, April 1, 2019	ADR Web System opens for 2018 data collection		
Monday, April 22, 2019	Target upload date for all 2018 ADR client-level data files		
Monday, June 3, 2019	ADRs must in be "Submitted" status by 6:00 PM ET		



Be sure to visit the TargetHIV website: <u>https://www.targethiv.org/library/adr-submission-timeline</u> at the beginning of the report submission period to obtain up-to-date information regarding the reporting deadlines.

# **The Recipient Report**

For the Recipient Report, each ADAP will report data based on the grant year reporting period, April 1, 2018 to March 31, 2019.

The first section of the Recipient 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.

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Cover Page					
01-3	4. Recipient Address				
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- 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 Recipient Report: Enter name, title, email, telephone number, and FAX number. *You must complete this required data*.



The Cover Page items 1–4 reflect the information on the recipient of record stored in the EHBs. If the information is not correct for these items, contact the HRSA Contact Center (at 1-877-464-4772 or via online at <u>https://www.hrsa.gov/about/contact/ehbhelp.aspx</u>) 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 advance to the next section, Programmatic Summary Submission.

## Programmatic Summary Submission

The Programmatic Summary Submission section consists of subsections A through E, items 1–7. Complete it for the grant year reporting period April 1, 2018 to March 31, 2019.



Note the Navigation menu on the left side of the ADR web application in Figure 1. Under **Data Entry**, navigate through the Recipient 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,

enter 0 (zero) as a placeholder for any unknown data; once you have this data, you can return to this page to enter it.

#### A. Program Administration

- 1. **ADAP Limits.** Indicate whether your program has adopted any of the following limits to control costs. 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.
    - *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.
    - *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.
    - *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.
    - *Drug-specific enrollment caps for antiretrovirals (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.
    - *Formulary reduction*—A change in your ADAP formulary that reduced the number of medications that are available to your clients.
    - *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.
    - *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 Recipient Report Online Form: Screenshot of the Programmatic Summary Submission: Questions 1–3

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If you select *Enrollment Cap*, *Capped prescriptions or Capped expenditure*, enter the maximum limit for that option. For the *Drug-specific enrollment caps*, 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), 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. For additional information on how to calculate FPL, go to <u>https://aspe.hhs.gov/POVERTY/index.cfm.</u>



# 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 (<u>in</u> <u>addition to HIV positive status</u>) 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 **Save** before navigating to the next page or your data will be lost.

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

ADAP Data Report   EU   H	RSA EHBs - Google Chrome				- 0
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ata Entry •	B. PURCHASING MECHANISMS				
Cover Page	* 4. Please check all that apply to your Dr	ug Pricing Program			
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#### **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 the <u>Glossary</u>.

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, select the mechanism(s) through which your program has implemented the program:

- *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.
- *340B Direct Purchase*—A prescription drug purchasing model in which ADAPs purchase drugs directly from a manufacturer or wholesaler at the 340B pricing schedule.

If your ADAP participates in the Prime Vendor Program that handles price negotiation and drug distribution responsibilities for members, check *Prime Vendor*.

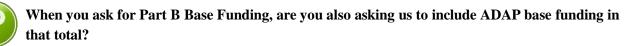
• *Department of Defense*—A pharmaceutical cost-saving strategy administered by the Department of Defense.

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

Welcome Recently	nizations Grants Free Clinics FOHC LALs Resources Accessed What's New Guide Me			Westwarter 218 General 2012 1010-41
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01-3	* 5. Please enter the funding received during this reporting period to	rom each of the following sources:		
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05	Funding Source	Amount Received (to nearest dollar)		
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06		S		
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06 07a 07b	c. Total contributions from Part B Supplemental Funding	s		
06 07a 07b 07c	c. Total contributions from Part B Supplemental Funding d. Total contributions from Part C/D recipients			
06 07a 07b 07c Client Upload	C. Total contributions item Part B Supplemental Funding     d. Total contributions from Part C/D recipients     e. State general fund contributions	4 4		
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#### 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.



**Answer**: The term "Part B Base Funding" refers to any of your RWHAP 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 0 in Question 5?

**Answer**: Report all funding received during the reporting period, not just new funding. Enter 0 for each funding source if you did not receive any funding from it.



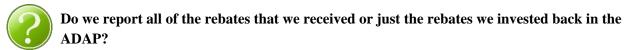
# Do we include funding that we used for services under the ADAP Flexibility Policy or just funding for medication and health insurance services?

Answer: Do not report services funded through the ADAP Flexibility Policy on the ADR.



#### Where do we report state matches for ADAP?

**Answer:** Include state funds used in ADAP to meet your match requirement in *e. State general fund contributions*.



Answer: Report only the rebates you invested back in the ADAP under "Funding Source."

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

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Cover Page	* 6. For each of the following categories, please ent	er total expenditures for this reporting period:			
04 05	Expenditure Category a. Full pay medication assistance b. Dispensing costs	Total Cost S			

#### D. Expenditures

- 6. **Expenditures.** Enter the total expenditures for pharmaceuticals, dispensing costs, 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.
  - e. *Full pay medication assistance*—Report ALL drugs fully paid for by ADAP. If ADAP only partially pays for a drug, reported it as health insurance assistance in *d. Health insurance assistance*.
  - f. *Dispensing costs*—Pharmacy expenses to distribute medications that are then transferred to the client and ADAP pays for.
  - g. *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 ADAP general administrative costs (e.g., staffing costs) here.
  - h. *Health insurance assistance*—Any health insurance assistance, including co-pays, deductibles, and premiums.

ADAP funds include all funding that is put into the program, regardless of source (e.g., state funds, Part A funds, rebates). Under *Expenditures*, report the total amount that was spent under each expenditure category, regardless of funding source.

#### E. ADAP Medication Formulary

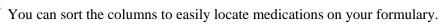
7. **ADAP Medication Formulary**. Lists of ARVs, A1-OIs, and Hepatitis B and C medications will be provided separately as items 7a, 7b, 7c, and 7d (see Figure 6, which shows Question 7a. ARV, as an example). The medication's generic name appears first, followed by the brand name and its D-code number.

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

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



The medications list will automatically generate previous data (i.e., from your ADAP's last ADR submission). Review the list again, and enter any changes made during the current reporting period.



#### Figure 6. ADR Recipient Report Online Form: Screenshot of the Programmatic Summary Submission: Question 7a

ts	All items in the Recipient Rep	ort should be reported for the most recent grant year. Please review the instruct	ions for Completing the ADAP Recipient Report	to ensure that you respond to each item appro-	priatety		
1	E. ADAP MEDICATION				5000030		
	Annutav Usu Annutav Usu Please provide information on Anterboviral (ARV), Hepatitis B, Hepatitis C and 'A1'-OI medications currently on your ADAP formulary.						
	* Ta. Reciptent-level Forms	ilary Information - Antiretroviral Medications					
	Please indicate which of the fo	plowing ARV medications are included in your ADAP formulary. If the medicatio	n was added to your formulary during the grant	year, check the box in the "Med Added" column	and enter the date that the medication was add	ed in the "Date Added" column.	
	Included In Formulary	Generic Name	Brand Name	DIN	Med Added?	Date Added	
	8	abacavir	Ziagen	d04376			
		abacavir/dolutegravir/famivudine	Triumeg	008294	0		
ad	8	abacavirfamivudine	Epzicom	d05354	0		
1	8	abacavir/famivudine/zidovudine	Trizivir	004727	8		
ents	8	afazanavir	Reyataz	004882	8		
nents	8	alazanavir and cobicistat	Evotaz	d08340			
10		biclegravir, emtricitabine, and tenofovir alafenamide	Biktarvy	d08736			
	8	cobicistat	Tybost	d07897			
1	8	cobicistat and darunavir	Prezcobix	d08305			
npleteness	8	darunavir	Prezista	005825	6		
	8	darunavir, cobicistat, emtricitabine, and tenofovir alafenamide	Symtuza	d08738	6		
Rules	8	delavirdine	Rescriptor	004119			
n	8	didanosine	Videx/Videx EC	000078	8		
	8	dolutegravir	Tivicay	008117	8		
	8	dolutegravin'itplvirine	Juluca	000580	6		
	2	dolutegravir sodium/abacavir suttate/lamivudine	Triumeg	d08284			
		doravirine	Pifeltro	d08872	0	2	
		doravirine, lamivudine, and tenofovir disoprovil fumarate	Delstrigo	d00876	0		
	8	efavirenz:	Sustiva	d04355	0		
		efavirenz/emtricitabine/lenofovir disoproxil	Atripia	005847	0		
	8	efavirenz, lamivudine, and tenofovir disoproxil fumarate	Symfi	d08743	0		
	8	efavirenz, lamivudine, and tenofovir disoproxil fumarate	Symfi Lo	d08743	8		
	8	elvitegravir/cobicistat/emtricitabine/tenofovir alafenamide	Genvoya	d07899			
	8	elvitegraviricobicistat/emtricitabine/tenofovir disoproxil	Stribild	d07899			
	2	emtricitabine	Emtriva	d04884			
	8	emtricitabine and tenofovir alafenamide	Descovy	d05352			
	8	emtricitabine/rilpivirine/tenofovir alafenamide	Odefsey	d07796			
	8	emtricitabine/rilpivirine/tenofovir disoprovil	Complera	d07796			
		emtricitabine/fenofovir disoproxil	Truvada	d05352	8		



TIP

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

**Answer:** Only include information for *Date added* for medications added to the formulary within the fiscal year reporting period. You do not need to enter information for *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 Recipient Report is complete and correct, your next step is to upload the Client Report, a collection of ADAP client records that you must submit in one or more properly formatted XML files. The Recipient Report cannot be submitted until the Client Report is uploaded into the ADR web application. See "The Client Report" (the following section) for more information. To learn how to upload the client-level data XML file, see "Importing the XML Client File" on page 28.

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

# **The Client Report**

ADAPs should report client-level data in the Client Report for clients enrolled during the calendar year reporting period January 1, 2018, to December 31, 2018.

# 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 a person who is certified as eligible to receive services, whether or not the person actually received ADAP services during the reporting period. For all enrolled clients, report client demographics and enrollment and certification data. For clients who received services, report whether they received health insurance services and/or medications services. (See Appendix A: Required Client-Level Data Elements to determine the client-level data elements required for an enrolled client.)

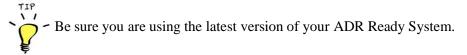
# Submitting Client-level Data to HRSA HAB

Upload the Client Report (i.e., client-level data set) 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 "Importing the XML Client File" on page 28.

Extract the client-level data elements from your system into the proper XML format before uploading the data to the HRSA HAB server.

### If you have an ADR-ready system

If your ADAP uses an ADR-ready system such as CAREWare, Provide Enterprise, or SCOUT, these systems will export the data into the required XML format. For more information on ADR-ready systems, go to <a href="https://targethiv.org/library/adr-ready-system-status">https://targethiv.org/library/adr-ready-system-status</a>.



### If you do not have an ADR-ready system

If you do not use an ADR-ready system, 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 <a href="https://targethiv.org/library/adap-data-report-adr-download-package">https://targethiv.org/library/adap-data-report-adr-download-package</a>. HRSA HAB has also created a tool, TRAX for the ADR, to help ADAPs create their XML file. To download the application and manual, go to <a href="https://targethiv.org/library/trax-adr">https://targethiv.org/library/adap-data-report-adr-download-package</a>.

 $\int_{Q}^{TP}$  - If you need assistance in creating your XML file(s), contact DART at <u>Data.TA@caiglobal.org.</u>

## **Client-level Data Fields**

This section outlines the required data fields in the client-level data XML file. Because data elements have been added and deleted over the past few years, the numbering is not sequential, but it is consistent with the unique identifier (ID number) in the ADR XML schema. (See <u>Appendix B: Frequently Asked Program Questions from the Field</u> for answers to questions about how to enter data.)

# 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 RWHAP 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 RWHAP client from all others in a region.

It is possible for different clients to have identical 40-digit eUCIs. Therefore, ADAPs must add a 41st character at the end of the eUCI to provide additional distinction and prevent multiple clients from having the same eUCI. 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 should be **A**, the final character of the next client's eUCI should be **B**, and so on.

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



- To learn more about the eUCI, view the resources on the TargetHIV website at

https://targethiv.org/library/encrypted-unique-client-identifier-euci-application-and-user-guide.

## **Guidelines for Collecting and Recording Client Names**

It's a good idea to 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 (e.g., for Hispanic clients living in Puerto Rico, record both surnames in the appropriate order).
- Avoid using nicknames (e.g., do not use Becca if the client's full name is Rebecca).
- Avoid using initials.

Instruct your staff on the correct entry of client names. Client names must be entered in the same way every time to avoid false duplicates.

## **Client Demographics**

The purpose of the Client Demographics section is to describe the sociodemographic 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: <u>https://aspe.hhs.gov/datacncl/standards/aca/4302/index.pdf</u>.

HRSA 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 your agency chooses to use a more detailed collection system, organize the data collected 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 that client's self-report. Do not establish criteria or qualifications to determine a particular person's racial or ethnic classification, and do not specify how a person should classify himself or herself.

#### 4. Ethnicity

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

• *Hispanic/Latino*—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, 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 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 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 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 a person's current sexual identity) based on his or her self-report. You cannot leave the Gender field blank; you must report one of the options below 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 Male to Female*—An individual whose sex assigned at birth was male but who identifies their gender as female, regardless of the status of social gender transition or surgical and hormonal sex reassignment processes.
- *Transgender Female to Male*—An individual whose sex assigned at birth was female but who identifies their gender as male, regardless of the status of social gender transition or surgical and hormonal sex reassignment processes.
- *Transgender Other*—An individual who identifies as transgender but does not identify with the other transgender options and/or does not identify with the binary positions of male/female. These individuals may or may not engage in social gender transition or surgical and hormonal sex reassignment processes (e.g., gender non-conforming, genderqueer, non-binary, gender fluid, bi-gender, etc.).
- *Unknown*—Indicates the client's gender category is unknown or was not reported or does not fit within one of the available options

#### 7.1 Sex at Birth

Indicate the biological sex assigned to the client at birth.

- Male
- Female



Complete Sex at Birth 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 HRSA 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 has HIV and meets the CDC AIDS case definition for an adult or child.
- *HIV-indeterminate* (infants < 2 years only)—A child under the age of 2 whose HIV status is not yet determined but was born to a woman living with HIV.

#### 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 percent of the Federal poverty level
- 100–138 percent of the Federal poverty level
- 139–200 percent of the Federal poverty level
- 201–250 percent of the Federal poverty level
- 251–400 percent of the Federal poverty level
- 401–500 percent of the Federal poverty level
- More than 500 percent 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, HRSA 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 2018 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 people 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/uninsured* 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 ages 65 and older, some disabled people under age 65, 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. HRSA HAB classifies clients who have no way to pay for medical expenses other than with RWHAP funds as uninsured.



# Do I report a client's source of health insurance differently when ADAP has paid for their premium, co-pays, and/or deductibles?

Answer: Report that the client is receiving private health insurance: *Private—Individual*.



#### 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*.



#### How do I report Medigap as a type of insurance?

**Answer:** Medigap is a Medicare Supplemental Insurance plan sold by private insurance companies designed to fill in the gaps left by original Medicare A & B. Report Medigap under *Private—Individual*.

# Enrollment and Certification

The purpose of the Enrollment and Certification section is to describe client enrollment patterns and certification processes during the reporting period. Report the applicable data elements 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 BOTH of the following criteria:
  - applied to your state ADAP for the first time ever, and
  - met the ADAP's financial and medical eligibility criteria 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; or
- 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 clients who meet the following criteria:
  - enrolled in your ADAP in a previous reporting period;
  - were previously enrolled, disenrolled, and now again enrolled after reapplying; or
  - are enrolled in the current reporting period, regardless of whether they ever used ADAP services.

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



All dates reported for application received, application approved, and recertification should fall within the reporting period.

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

For all new clients, report the date that the ADAP received the completed application. 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 ADAPs that 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 reapplies 2 months later and is eligible, which date should be used for the completed application?

Answer: Report the application date when 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:** Report the actual date the application was received, even if it was 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. See the table below for number of recertification requirements.

Type of Client	Number of Recertification Dates to Report
New client enrolled before July 1	1
New client enrolled after July 1	0
Existing client	2



# 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:** HRSA 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 criterion.



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 <a href="https://hab.hrsa.gov/sites/default/files/hab/Global/pcn1302clienteligibility.pdf">https://hab.hrsa.gov/sites/default/files/hab/Global/pcn1302clienteligibility.pdf</a>.

#### 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.



If a client's **only** ADAP service was for medication co-pay and/or deductible and was later reimbursed, report the client as *enrolled in ADAP but did not need/request any services*. Clients who did not receive services should NOT be reported as *enrolled in ADAP and received ADAP-funded medications or health insurance services*.

#### **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, report under *Other*.

- 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 client does not receive the first service during the reporting year, what data should be reported for this client?

**Answer:** Report *Date Completed Application Received* (Item 15) and *Date Application Approved* (Item 16). For Item 18, report *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. ADAP funds, regardless of their 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. Report all ADAP services that a client received during the reporting period in these sections. Additional definitions for ADAP services are in "What are ADAP Services?", page 5.

### ADAP Health Insurance Services

The purpose of the ADAP Health Insurance Services section is to describe ADAP-funded health insurance assistance services and expenditures. This includes premiums (partial or full), Medicare Part D-related costs (coinsurance, deductibles, TrOOP, and coinsurance under catastrophic coverage), and medication co-pays and deductibles. Medication co-pays, deductibles, and coinsurance are considered health insurance assistance services, not medication services, so report them in this section, not in "Drugs and Drug Expenditures." Report the ADAP-funded health insurance services your clients received during the reporting period based on when the premiums, deductibles, co-pays, and other fees were paid, **not according to the coverage period**.



A *full premium payment* is when the ADAP pays 100 percent of the premium. This is common when an ADAP is purchasing insurance on behalf of the client.

A *partial premium payment* is when the ADAP pays a portion of the premium (i.e., less than 100 percent). For example, this is the case if the ADAP is paying the employee share of a premium or the nonsubsidy 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 coinsurance, deductibles, TrOOP, and coinsurance under catastrophic coverage. Co-pays and deductibles for medications are also considered health insurance assistance services, so report them 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 when the ADAP pays 100 percent of the premium.
- Partial premium payment is when the ADAP pays a portion of the premium (i.e., less than 100 percent).
- Co-pay/deductible including Medicare Part D coinsurance, 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 by 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 you entered an amount, complete Item 22.

#### 22. Months Coverage of Premiums Paid

Indicate the total number of months (0 to 12) of coverage for which the ADAP paid the insurance premium in Item 21. Include all months, even if they fall outside 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 Medication 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.

# ?

#### How do you report the full coverage of a drug for insured clients?

**Answer:** If the drug is not covered by the insurance program, report it as medication assistance. If the drug is covered by the insurance program but the ADAP is paying the full amount of the drug because the client has not yet met their deductible, report it as a co-pay/deductible.

## 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 that your ADAP pays for in full and that are dispensed to clients during the reporting period. This section also describes the total expenditures for those medications.



ADAP payments for medication co-pays or deductibles are considered health insurance assistance services; report them in *Health Insurance Services*.

#### 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 your ADAP paid for in full.

- 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 medications, and A1- OI medications.** Use the medication's 5-digit drug code (*d*-*xxxxx*). 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. Make a request to access the Multum Database via <a href="https://targethiv.org/library/hab-grantee-request-form-multum-medication-information">https://targethiv.org/library/hab-grantee-request-form-multum-medication-information</a>.

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

#### 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 that 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*). Report anything less than 30 days 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. Report costs per medication dispensed. Include the total costs paid for each dispensed prescription, even if the medication prescription period extended beyond the reporting period. See the example below.

ClientId	MedicationId	MedicationStartDate	MedicationDays	MedicationCost
1	d05847	11/5/2016	7	\$1,948
1	d05847	11/14/2016	90	\$2,598
2	d03984	10/5/2016	180	\$100
2	d04774	10/5/2016	180	\$1,413

#### **Example of Medication Data**



#### May recipients report medications for health insurance assistance clients?

**Answer:** No, do not report medications not paid in full in the "Drugs and Drug Expenditures" section. Report amounts paid for by co-pays and deductibles for medications 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:** Report data for these clients 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 that ADAP paid for in full (ARVs, Hepatitis B, Hepatitis C, and A1-OI medications **only**). Report clinical information 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 reporting 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 (*between 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 (*between 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 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. Use the comment box that appears after you've submitted your ADR to explain the missing data. You will also find these missing data reflected in your Upload Completeness 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 Recipient Report in the EHB. From within the ADR Recipient Report, click the **Client Upload** link in the ADR Navigation menu. This will open another window. Continue to follow the on-screen instructions to upload your XML file.



You can upload more than one client-level data file to build the Client Report. Before uploading multiple client-level data XML files, you should understand the ADR web application's data merge rules. To learn more about these rules, see <u>https://targethiv.org/library/adr-merge-rules-60.</u>

## **Reviewing Your Client Report**

Generate and review a Client-Level Data Upload Completeness Report (UCR) before you submit your ADR to ensure quality data. The UCR will display your uploaded data by data element so you can review your data quality and identify both missing and incorrect data. This report is 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 side of the ADR web page. For instructions on how to use the UCR, go to https://targethiv.org/sites/default/files/file-upload/resources/RSR\_In\_Focus\_UCR\_Final%2002202018.pdf.

## **Report Validation**

After completing the ADR Recipient 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, do the following:

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

## Uploading a New or Corrected Client Report

Before uploading a new or corrected client-level data file, clear all previous client records by clicking 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, re-upload your client XML file by clicking the Client Upload link.

## Submitting Your Report

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

If you need help completing the ADR, call Data Support at 1-888-640-9356 or e-mail
 <u>RyanWhiteDataSupport@wrma.com</u>

# **Appendix A: Required Client-level Data Elements**

• Report this data element.

		Type of C	lient, by Services	Received
Field #	Client-Level Data Elements	All Enrolled Clients	Health Insurance Services	Medication Services
	System Variables			
2	Encrypted UCI	•		
	Client Demographics			
4	Ethnicity	٠		
68	Hispanic/Latino Subgroup	•		
5	Race	•		
69	Asian Subgroup	•		
70	Native American/Pacific Islander Subgroup	•		
6	Gender	•		
71	Sex at Birth	٠		
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	•		
. –	Date Completed Application Received (new			
15	client only)	•		
16	Date Application Approved (new client only)	•		
17	Date of Recertification	•		
18	Enrollment Status	•		
19	Reason(s) for Disenrollment	•		
20	ADAP Health Insurance Services	•		
20 67	Receipt of Health Insurance Services ADAP-funded Health Insurance Assistance	•		
07	service		•	
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, so it 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 co-payments during the Catastrophic Coverage period, it should continue to report amounts under *Amount Paid for Co-pays and Deductibles*.

#### 3. Where do I report co-pays for medical visits in the ADR?

ADAP funds cannot be used to pay for medical visit co-pays. Only report co-pays for medications 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 11-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 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 <a href="https://targethiv.org/library/encrypted-unique-client-identifier-euci-application-and-user-guide">https://targethiv.org/library/encrypted-unique-client-identifier-euci-application-and-user-guide</a>.

# 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 are considered ADAP funds and therefore must align with the ADAP guidelines (i.e., same program/same rules); and all data should 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 inpatient care?

ADAPs are allowed to pay health insurance premiums for plans that cover inpatient care. However, RWHAP 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 they are reporting on. 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 HRSA HAB considering an alternative method of completing the ADR Recipient Report other than filling in the online forms (i.e., an ADR Recipient Report XML upload)?

HRSA HAB is exploring this possibility.

# Appendix C: 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	Any individual who is enrolled in the ADAP (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	HRSA 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. To use ADAP dollars for services under the ADAP flexibility policy, recipients <b>must</b> 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	Where recipients submit their ADR; it is accessible via the HRSA Electronic Handbooks for Applicants/Recipients (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 human immunodeficiency 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	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 HHS agency that administers HIV/AIDS prevention programs, including the HIV Prevention Community Planning process. The CDC is responsible for monitoring and reporting infectious diseases, administering HIV surveillance grants, and publishing 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

Confidential information	Information collected on the client; unauthorized disclosure of this information could cause the client unwelcome exposure, discrimination,
Coinsurance	A form of medical cost sharing in a health insurance plan that requires an insured person to pay a percentage of medical expenses.
Co-payment	A fee charged to an individual 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 that is then transferred as a fee to the buyer.
Dispensing of pharmaceuticals	The provision of prescription drugs to prolong life or prevent health deterioration.
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 percent 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, and prime vendor
Dual application	One application form for assistance that is used by both the ADAP and Medicaid so that clients only need to apply once and may receive services from both ADAP and Medicaid.
D-codes	A 5-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/Recipients (EHBs). A web- based grants administration system. The EHBs are accessible at <u>https://grants.hrsa.gov/webexternal</u> .
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) (e.g., 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	
Fiscal year Fixed co-payment	rendered.

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.
HRSA	This includes premium payments, risk pools, co-payments, and deductibles.
HKSA	Health Resources and Services Administration—The HHS agency responsible for directing national health programs that improve the nation's
	health by ensuring equitable access to comprehensive and 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 RWHAP.
Manufacturers' rebates	Dollars received from drug manufacturers that represent a percentage of the
	cost of the drug.
Medicaid/medically needy	The option to have a medically needy program allows states to extend
program	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
Monetary cap	A limit on the amount of money to be spent on one service or client per
	month or per year.
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.
Other negotiated rebates	Discounts negotiated between ADAP officials and drug companies on the
	price of medications.
<b>RWHAP Part B</b>	The RWHAP Part 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 people living with HIV and their
	families. RWHAP emphasizes that such care and support are part of a
	continuum of care in which the needs of people living with HIV and their
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. As 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
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.
<b>Retroactive or back billing</b>	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 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.
<b>RWHAP-funded service</b>	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 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, reauthorized in 2000 as the Ryan White CARE Act Amendments of 2000, and reauthorized in 2006 as the Ryan White HIV/AIDS Treatment Modernization Act of 2006. The most recent
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 HHS Secretary. 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).
XML	eXtensible Markup Language. A standard, simple, and widely adopted method of formatting text and data so that it can be exchanged across all the different computer platforms, languages, and applications.

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