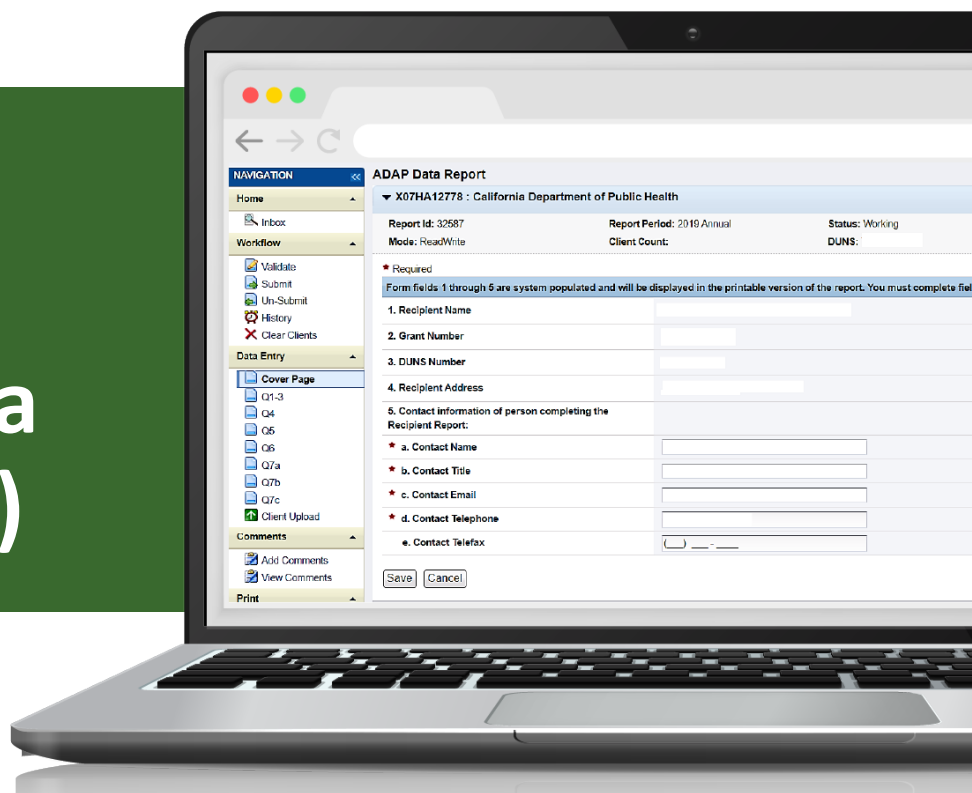


AIDS Drug Assistance Program Data Report (ADR)



Instruction Manual 2019

Release Date: December 17, 2019

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HIV/AIDS Bureau Division of Policy and Data
Health Resources and Services Administration
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HRSA
Health Resources & Services Administration

WRMA
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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 ADAPs with answers provided.



The star icon designates this guidance has been updated.

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).¹ HRSA's RWHAP uses dynamic data-driven and innovative approaches to provide a comprehensive system of care to achieve optimal health outcomes for people with HIV. 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 are used to fund technical assistance, clinical training, and the development of innovative models of HIV care.

Of the nearly one million people with 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 people with HIV are linked to medical care, retained in medical care, prescribed antiretroviral medications, and achieve viral suppression. HIV treatment is a recognized form of prevention. In line with the National HIV/AIDS Strategy 2020, 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.² The RWHAP legislation authorizes a portion of Part B funds to be designated for the AIDS Drug Assistance Program (ADAP), which provides medications for the treatment of HIV disease, 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

¹ The Ryan White HIV/AIDS Treatment Extension Act of 2009—Title XXVI of the Public Health Service Act, as amended <https://hab.hrsa.gov/about-ryan-white-hiv-aids-program/ryan-white-hiv-aids-program-legislation>

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

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 (with the exception of the 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) 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 is 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 toward the national goals to end the HIV epidemic.
- disseminate data on client sociodemographics and service utilization via the publicly available ADAP Report.



Note: 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.



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

What's New



There are no revisions to the reporting requirements for the 2019 ADR. Please review the manual for the star icon for updated 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 also includes data about any 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.



Note: The 2019 ADR, consisting of the Recipient Report and Client Report, is due on **June 1, 2020**.



Note: ADAPs are encouraged to upload their client-level data by **April 20, 2020**, to allow enough time to address any technical and data quality issues.

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 received 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?

As defined in HAB Policy Clarification Notice 16-02, 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 no coverage or limited health care coverage... ADAPs can provide access to medication by using program funds to purchase health care coverage and through medical cost sharing for eligible clients...ADAPs may use a limited amount of program funds for activities that enhance access to, adherence to, and monitoring of antiretroviral therapy with prior approval.”

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 and hepatitis. These medications are purchased with ADAP funds on behalf of a client.

Health Insurance Assistance Services

Health insurance assistance services support 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 HSRA Electronic Handbooks for Applicants/Recipients (EHBs). 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. ADAPs access the ADR Web Application via the EHBs, a web-based grants administration system. The EHBs are located at <https://grants.hrsa.gov/webexternal>.



Tip: If you need help navigating the EHBs, contact the HRSA Help Desk at 1-877- GO4-HRSA (1-877-464-4772) or via online at <https://www.hrsa.gov/about/contact/ehbhelp.aspx>.

The ADR Recipient Report is completed by filling out the online forms in the ADR Web Application. After completing the Recipient Report, ADAPs 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 19 of this manual.

Steps to Submitting Your ADR



Step 1.
Complete and submit your Recipient Report.



Step 2.
Create Client Report XML using ADR System or TRAX.



Step 3.
Ensure date quality using tools within the ADR.



Step 4.
Correct any errors and submit your Client Report.

Who submits the ADR?


ADR submission is a condition of the RWHAP Part B grant award. Each RWHAP Part B recipient of record must complete both components of the ADR. The recipient 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 RWHAP Part B **grant year** reporting period, April 1, 2019, to March 31, 2020.
- **Client Report:** ADAPs report client-level data for clients enrolled during the **calendar year** reporting period, January 1, 2019, to December 31, 2019.

Important Dates

	Date	Client Report (XML File)	Recipient Report
	Monday, February 3, 2020	ADR Test Your XML and Data Quality Feature Opens	— —
	Monday, April 6, 2020	ADR Web System opens for 2019 data collection	
	Monday, April 20, 2020	Target upload date for all 2019 ADR client-level data files	— —
	Monday, June 1, 2020	ADRs must in be “Submitted” status by 6:00 PM ET	



Tip: Be sure to visit the TargetHIV website <https://www.targethiv.org/searches/adr> at the beginning of the report submission period to obtain up-to-date information, materials, and webinar series schedule.

The Recipient Report

For the Recipient Report, each ADAP will report data based on the grant year reporting period, April 1, 2019 to March 31, 2020.

The first section of the Recipient Report is the Cover Page (see Figure 1) which contains basic recipient information. ADAPs 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 Recipient Report Online Form: Cover Page

The screenshot shows the 'ADAP Data Report' online form. The left sidebar contains navigation links: Home, Inbox, Workflow, Data Entry, Cover Page, Q1-3, Q4, Q5, Q6, Q7a, Q7b, Q7c, Client Upload, Comments, Add Comments, View Comments, and Print. The main content area displays the 'Cover Page' form. At the top, it shows the report ID (X07HA12778) and a session expiration timer (28:26). Below this, a summary bar provides key details: Report ID: 32587, Report Period: 2019 Annual, Status: Working, Due Date: 1/19/2020 9:59:39 AM (60 days left), Mode: ReadWrite, Client Count, DUNS, and Last Modified. The form fields are organized into a table-like structure with labels and input areas. A red asterisk indicates required fields. A note states: 'Form fields 1 through 5 are system populated and will be displayed in the printable version of the report. You must complete fields 5a through 5d. Field 5e is optional.' The fields are: 1. Recipient Name (California Department of Public Health), 2. Grant Number (X07HA12778), 3. DUNS Number (79-915-0615), 4. Recipient Address (Sacramento, CA 95899-7426), 5. Contact information of person completing the Recipient Report: a. Contact Name (Cindy Ly), b. Contact Title, c. Contact Email (retester1@hotmail.com), d. Contact Telephone ((916) 449-5981), e. Contact Telefax. At the bottom, there are 'Save' and 'Cancel' buttons.

Field	Value
1. Recipient Name	California Department of Public Health
2. Grant Number	X07HA12778
3. DUNS Number	79-915-0615
4. Recipient Address	, Sacramento, CA 95899-7426
5. Contact information of person completing the Recipient Report:	
a. Contact Name	Cindy Ly
b. Contact Title	
c. Contact Email	retester1@hotmail.com
d. Contact Telephone	(916) 449-5981
e. Contact Telefax	

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.*



Note: 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 Help Desk (at 1-877-464-4772 or via online at <https://www.hrsa.gov/about/contact/ehbhelp.aspx>) 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

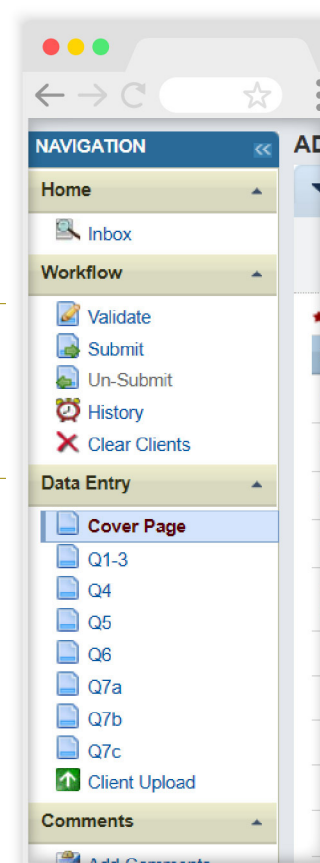
The Programmatic Summary Submission section consists of subsections A through E, items 1–7. Complete it for the grant year reporting period April 1, 2019 to March 31, 2020.



Tip: 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.



Tip: 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. You can also print out the Programmatic Summary Section to complete and then enter your data electronically at a later time.



A. Program Administration

1. **ADAP Limits.** Indicate whether your ADAP has adopted any of the following limits to control costs. Check more than one box if applicable (see Figure 2).

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

ADAP Data Report

Report ID: 32587 Report Period: 2019 Annual Status: Working Due Date: 1/18/2020 9:59:39 AM (60 days left)

Mode: ReadWrite Client Count: DUNS: Last Modified:

REMINDER:
The Recipient Report (Questions 1 – 7) should be reported for the grant year April 1, 2019 – March 31, 2020, whereas the uploaded client level data should be 2019 calendar year data.

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

A. PROGRAM ADMINISTRATION

1. Please indicate which of the following limits applied to your ADAP during the reporting period. For each item that applied, complete the blank with the information requested on that limit.
(Check all that apply)

- ☐ Waiting list anytime during the reporting period
- ☐ Enrollment cap- Max number of enrollees
- ☐ Capped number of prescriptions per month- Max number of prescriptions/month
- ☐ Capped expenditure- Monetary cap per client \$
 - ☐ Per Month
 - ☐ Annual
- ☐ Drug-specific enrollment caps for ARVs, Hepatitis B, or Hepatitis C medications
- ☐ Formulary reduction
- ☐ Decrease in financial eligibility criteria
- ☐ None of these limits were applied to the ADAP during the reporting period

2. Please indicate the maximum ADAP eligibility requirements as a percentage of Federal Poverty Level (FPL):
Maximum ADAP eligibility requirements as a percentage of FPL: %

3. Please indicate the clinical eligibility criteria required to enroll in the ADAP in your State/Territory:
(Check all that apply)

- ☐ CD4 - Please specify the CD4 count requirement:
- ☐ Viral load - Please specify the VL count requirement:
- ☐ Other- Please specify:
- ☐ No clinical eligibility criteria are required to enroll in the ADAP



Note: If you select *Enrollment Cap*, *Capped prescriptions* or *Capped expenditure*, enter the maximum limit for that option.

- ADAP income eligibility.** Enter the maximum income eligibility for participation in your 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, people with HIV who have an income of 400 percent of the FPL or lower may be eligible to participate. For additional information on how to calculate FPL, go to <https://aspe.hhs.gov/POVERTY/index.cfm>.



Question: 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:** Your ADAP may require clinical criteria for ADAP eligibility. 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).

- *CD4—Indicate the threshold number that your ADAP required in the space provided*
- *Viral load—Indicate the threshold number that your ADAP required in the space provided*
- *Other—Indicate each criterion used and any corresponding threshold number that your ADAP required*
- *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 **Save** before navigating to the next page or your data will be lost.

B. Purchasing Mechanisms

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

ADAP Data Report

Report Id: 32587 Report Period: 2019 Annual Status: Working Due Date: 1/18/2020 9:59:39 AM (60 days left)

Mode: Read/Write Client Count: DUNS: / Last Modified:

REMINDER:
The Recipient Report (Questions 1 – 7) should be reported for the grant year April 1, 2019 – March 31, 2020, whereas the uploaded client level data should be 2019 calendar year data.

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

B. PURCHASING MECHANISMS

4. Please check all that apply to your Drug Pricing Program:

☒ 340B Rebate

☐ 340B Direct Purchase

☐ Prime vendor

☐ Department of Defense

Save Cancel

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 [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, 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.

C. Funding

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

ADAP Data Report

Report Id: 32587 Report Period: 2019 Annual Status: Working Due Date: 1/18/2020 9:59:39 AM (60 days left)

Mode: ReadWrite Client Count: DUNS: Last Modified:

REMINDER:
The Recipient Report (Questions 1 – 7) should be reported for the grant year April 1, 2019 – March 31, 2020, whereas the uploaded client level data should be 2019 calendar year data.

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

C. FUNDING

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

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

Save Cancel

5. ADAP funding received during the reporting period. Enter the amount of funding your program received from the sources listed below 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.

- *Total contributions from Part A EMA(s)/TGAs*
- *Total contribution from Part B Base Funding*
- *Total Contributions from Part B Supplemental Funding*
- *Total contributions from Part C/D recipients*
- *State general funding contributions*
- *Carry-over of Ryan White funds from previous year*
- *Manufacturer Rebates Reinvested in the ADAP*
- *All Insurance Reimbursements, excluding Medicaid*
- *Medicaid Reimbursements*



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

Answer: No. The term “RWHAP 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.



Question: 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.



Question: 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 funding used through the ADAP Flexibility Policy on the ADR.



Question: 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.



Question: Do we report all of the rebates that we received or just the rebates we invested back in the ADAP?

Answer: Report only the rebates you invested back in the ADAP under “Manufacturer Rebates Reinvested in the ADAP.”

D. Expenditures

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

ADAP Data Report

Report Id: 32587 Report Period: 2019 Annual Status: Working Due Date: 1/18/2020 9:59:39 AM (60 days left)

Mode: ReadWrite Client Count: DUNS: Last Modified:

REMINDER:
The Recipient Report (Questions 1 – 7) should be reported for the grant year April 1, 2019 – March 31, 2020, whereas the uploaded client level data should be 2019 calendar year data.

D. EXPENDITURES

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

Expenditure Category	Total Cost
a. Full pay medication assistance	\$
b. Dispensing costs	\$
c. Other administrative costs	\$
d. Health insurance assistance (including co-pays, deductibles, and premiums)	\$
Total ADAP expenditures this reporting period (Total of a through d)	\$ 0

Save Cancel

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.

- *Full pay medication assistance—Report ALL drugs fully paid for by ADAP. If ADAP only partially pays for a drug, report it as health insurance assistance in d. Health insurance assistance.*
- *Dispensing costs—Pharmacy expenses to dispense and/or distribute medications to clients.*
- *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.*
- *Health insurance assistance—Any health insurance assistance, including premiums and medication co-pays and deductibles.*



Note: ADAP funds include all funding that is put into the program, regardless of source (e.g., state funds, RWHAP 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, Opportunistic Infection medications (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. See page 35 for more information on D-code numbers.

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.



Note: 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

ADAP Data Report

Report Id: 32587 | Report Period: 2019 Annual | Status: Working | Due Date: 1/18/2020 9:59:39 AM (60 days left)

Mode: ReadWrite | Client Count: | DUNS: | Last Modified: |

REMINDER:
The Recipient Report (Questions 1 – 7) should be reported for the grant year April 1, 2019 – March 31, 2020, whereas the uploaded client level data should be 2019 calendar year data.

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. Recipient-level Formulary Information - Antiretroviral Medications

Please indicate which of the following ARV medications are included in your ADAP formulary. If the medication 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 added in the "Date Added" column.

Included In Formulary	Generic Name	Brand Name	DIN	Med Added?	Date Added
<input checked="" type="checkbox"/>	abacavir	Ziagen	d04376	<input type="checkbox"/>	
<input checked="" type="checkbox"/>	abacavir/dolutegravir/lamivudine	Triumeq	d08284	<input type="checkbox"/>	
<input checked="" type="checkbox"/>	abacavir/lamivudine	Epzicom	d05354	<input type="checkbox"/>	
<input checked="" type="checkbox"/>	abacavir/lamivudine/zidovudine	Trizivir	d04727	<input type="checkbox"/>	
<input checked="" type="checkbox"/>	atazanavir	Reyataz	d04882	<input type="checkbox"/>	
<input checked="" type="checkbox"/>	atazanavir and cobicistat	Evotaz	d08340	<input type="checkbox"/>	
<input checked="" type="checkbox"/>	bictegravir, emtricitabine, and tenofovir alafenamide	Biktarvy	d08736	<input type="checkbox"/>	
<input checked="" type="checkbox"/>	cobicistat	Tybost	d07897	<input type="checkbox"/>	
<input checked="" type="checkbox"/>	cobicistat and darunavir	Prezcobix	d08305	<input type="checkbox"/>	
<input checked="" type="checkbox"/>	darunavir	Prezista	d05825	<input type="checkbox"/>	



Question: Do ADAPs 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 *Uploading the XML Client File* on page 39.



Tip: If you need help completing the Recipient Report, call Ryan White 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, 2019, to December 31, 2019. The Client Report should contain one record 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 and required 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 for an enrolled client.)

Submitting Client-level Data to HRSA HAB

ADAPs need to extract client-level data from their systems into the proper XML format before uploading the data to the HRSA EHB. 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 *Uploading the XML Client File* on page 39.

If you have an ADR-ready system

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



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

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 generates an XML file that conforms to the rules of the ADR XML schema. The schema and related documents are available at <https://targethiv.org/library/adap-data-report-adr-download-package>. 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 <https://targethiv.org/library/trax-adr>.



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

Client-level Data Elements

This section outlines the required data fields in the client-level data XML file. Each data field is referenced by the ID number (unique identifier) and variable or element name as referenced in the ADR Client XML schema.

System Variables

ID 2. Encrypted Unique Client Identifier

Element Name: ClientUci

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, 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 by the ADAP **BEFORE** the data are submitted to HRSA HAB.



Tip: 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>.



Tip: Guidelines for Collecting and Recording Client Names

ADAPs 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 (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: <https://aspe.hhs.gov/datacatalog/standards/aca/4302/index.pdf>.

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 ADAP chooses to use a more detailed collection system, organize the data collected so that any new categories can be mapped to the standard OMB breakdown.



Note: ADAPs 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 person's racial or ethnic classification, and do not specify how a person should classify their race.

ID 4. Ethnicity

Element Name: EthnicityID

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.

ID 68. Hispanic/Latino Subgroup

Element Name: AdrClientReportHispanicSubgroup

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*

ID 5. Race (Select one or more)

Element Name: RaceID

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.



Note: “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 at Data.TA@caiglobal.org.

ID 69. Asian Subgroup (Select one or more)

Element Name: AdrClientReportAsianSubgroup

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

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

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

Element Name: AdrClientReportNhpiSubGroup

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*

ID 6. Current Gender

Element Name: GenderId

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 client 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

ID 71. Sex at Birth

Element Name: SexAtBirthID

Indicate the biological sex assigned to the client at birth.

- *Male*
- *Female*



Note: Complete Sex at Birth for all clients.

ID 9. Year of Birth

Element Name: BirthYear

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



Note: 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.

ID 10. HIV/AIDS Status

Element Name: HivAidsStatusId

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.

ID 11. Poverty Level

Element Name: PovertyLevelId

Report the client's annual household income as a percent of the federal poverty measure as of the end of the reporting period. 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*



Note: 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 ADAP already uses one of these measures, use that to report this data item. Otherwise, HRSA HAB recommends and prefers that your ADAP use the HHS poverty guidelines to collect and report it. For more information on poverty measures and to see the 2019 HHS Poverty Guidelines, go to <https://aspe.hhs.gov/poverty-guidelines>.

ID 12. High-Risk Insurance

Element Name: HighRiskInsuranceId

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*

ID 13. Health Insurance**Element Name: HighRiskInsuranceId**

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, people under age 65 with certain disabilities, and people with end-stage renal disease (permanent kidney failure treated with dialysis or a transplant) or amyotrophic lateral sclerosis (also known as Lou Gehrig's disease). Medicare Part A (hospital insurance) covers inpatient care in hospitals, skilled nursing facility care, nursing home care, hospice care, and home health services. Medicare Part B (medical insurance) covers medically necessary services and supplies and preventive services.
- *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.
- *Veteran's Administration (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.



Question: Do I report a client's source of health insurance differently when ADAP has paid for their premium?

Answer: No, you do not report a client's source of health insurance differently when ADAP has paid for their premium. Report that the client is receiving private health insurance: *Private—Individual*.



Question: How do I report Medicare Advantage/ Medicare Part C as a type of insurance?

Answer: Medicare Advantage or Medicare Part C is an alternative to private health insurance for Medicare beneficiaries. Report Medicare Advantage under *Other*



Question: 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.

ID 14. Was the client a new or existing client?

Element Name: NewEnrollmentFlag

Report whether the client was new during the reporting period, regardless of the client's enrollment status 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 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.*



Note: 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.

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

Element Name: ApplicationReceivedDate

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 complete and approved and apply it consistently to all applicants. Indicate this date in the form *MM/DD/YYYY*.



Note: The date a new client's completed application was received can be a date prior the reporting period. For example, a new client application was received in December (prior to the reporting period) and was approved in January (within the reporting period).

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

Element Name: ApplicationApprovalDate

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.



Note: The date a new client's application was approved should be within the reporting period.



Question: 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.



Question: 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*.

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

Element Name: RecertificaionDate

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



Question: What should we report if we have more than two 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 only report the two dates that would meet this criterion.



New Note: If a client has an application approval date on or after July 1, 2019, do not report a recertification date since they have not met the requirement for recertification every 6 months.

ID 18. Enrollment Status

Element Name: EnrollmentStatusId

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 to receive services.*
- *The client is enrolled in ADAP and received ADAP-funded medications and/or health insurance services during the reporting period.*
- *The client was disenrolled from ADAP.*

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



Note: 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*.

ID 19. Reason(s) for Disenrollment

Element Name: DisenrollmentReasonId

Indicate ALL reasons for disenrollment/discharge. 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*

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, RWHAP Part B ADAP, RWHAP Part B, RWHAP Part B Supplemental, ADAP Emergency Relief, RWHAP 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?* on page 5.



Note: If a client did not receive any health insurance assistance or medication assistance services, report in Item 18. Enrollment Status, *“The client is enrolled but did not need/request any services.”*

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.**



Note: A *full premium payment* is when the ADAP pays 100 percent of the premium. This is common when an ADAP is purchasing health 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 a health insurance premium.



New Question: Are ACA insurance premiums paid by ADAP considered full or partial payments?

Answer: ACA insurance premiums paid by ADAP are considered partial payments due to the premium tax credit.

ID 20. Receipt of Health Insurance Services

Element Date: InsuranceAssistanceReceivedFlag

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.)

ID 67. Type of Health Insurance Assistance Received

Element Name: InsuranceAssistanceTypeID

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. These co-pay and deductible payments refer to ADAP paying for additional medication costs.*

ID 21. Amount Paid for Premiums

Element Name: InsurancePremiumAmount

Indicate the total amount (\$0 to \$100,000) of health 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).

ID 22. Months Coverage of Premiums Paid

Element Name: InsurancePremiumMonthCount

Indicate the total number of months (0 to 12) of coverage for which the ADAP paid the health 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.

ID 23. Amount Paid for Medication Co-pays and Deductible

Element Name: InsuranceDeductibleAndCopayAmount

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.



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

Answer: If the drug is not covered by the health insurance program, report it as medication assistance. If the drug is covered by the health 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.

Medication Assistance Services

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.



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

ID 25. Receipt of Medication Services

Element Name: MedicationsDispensedFlag

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.)

ID 26. Medication(s) Dispensed

Element Name: MedicationID

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.



Note: If you use CAREWare, d-codes are already built into the software. If you need d-code information for your ADRA, you can make a request to access the Multum Database via <https://targethiv.org/library/hab-grantee-request-form-multum-medication-information>.



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

ID 27. Medication Dispensed Date

Element Name: MedicationStartDate

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

ID 28. Day(s) Supply of Medication

Element Name: MedicationDays

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 (30, 60, 90, ... 360). Report anything less than 30 days as the actual number of days supplied (e.g., 14 days).

ID 29. Amount Paid for Medication

Element Name: MedicationCost

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.



Note: Do not include dispensing fees in amount paid for medication. Dispensing fees are reported in your Recipient Report.



Note: Report rebate prices in the amount paid for medication.

Example of Medication Data

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



Question: May ADAPs report medications for health insurance assistance clients?

Answer: Medications paid for in full should be reported 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*.



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

Answer: Report data for this client 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.



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



Question: 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.

ID 32. CD4 Count Date

Element Name: LastCd4Date

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.

ID 33. CD4 Count Value

Element Name: LastCD4Count

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

ID 34. Viral Load Date

Element Name: LastViralLoadDate

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.

ID 35. Viral Load Value

Element Name: LastViralLoadCount

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.



Question: 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. Add a validation comment to 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.



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

Uploading 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.

The screenshot shows the ADAP Data Report interface. On the left is a navigation menu with sections: Home, Inbox, Workflow (with links for Validate, Submit, Un-Submit, History, and Clear Clients), and Data Entry (with links for Cover Page, Q1-3, Q4, Q5, Q6, Q7a, Q7b, Q7c, and a highlighted Client Upload link). The main content area is titled 'ADAP Data Report' and shows details for report X07HA12778, including Report ID, Report Period (2019 Annual), Status (Working), Due Date (1/18/2020 9:59:30), Mode (ReadWrite), Client Count, DUNS, and Last Modified. Below this is a REMINDER section with a warning icon and text stating that the recipient report questions should be for the grant year April 1, 2019 – March 31, 2020, while client data should be for the 2019 calendar year. Another warning states that files larger than 29MB cannot be uploaded and must be zipped. The CLIENT UPLOAD section includes a blue instruction bar, a file selection area with a 'Choose File' button (showing 'No file chosen') and 'Upload File' and 'Cancel' buttons, and a note to validate the report before submission. At the bottom, it mentions that the feature only works with ADR Client XML files or compressed zip files conforming to the ADR Client-Level Data XML Schema Definition, with a link to the schema definitions.



Note: 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 <https://targethiv.org/library/adr-merge-rules-60>.

Ensuring Data Quality

After you have uploaded your client-level data, you are ready to check and make sure that your data is correct and complete. This section will describe the tools in the EHB that help you to ensure that you are submitting high quality data.

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.

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.



Tip: If you need help completing the ADR, call Ryan White 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		Type of Client, by Services Received		
	Client-Level Data Elements	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	●		
71	Sex at Birth	●		
9	Year of Birth	●		
10	HIV 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 service		●	

Field #	Client-Level Data Elements	Type of Client, by Services Received		
		All Enrolled Clients	Health Insurance Services	Medication Services
21	Amount Paid for Premiums		•	
22	Months Coverage of Premiums Paid		•	
23	Amount Paid for Co-pays and Deductibles		•	
Medication Assistance Services				
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

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

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

- 2. Should ADAPs stop reporting after the client leaves 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 <https://targethiv.org/library/encrypted-unique-client-identifier-euci-application-and-user-guide>.

- 5. 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.

- 6. 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.

Appendix C: Glossary

Term	Definition
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 living with HIV and meets the income and other eligibility criteria as established by the state ADAP.
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 must request approval annually in their grant application or through the prior approvals process in EHB.
ADAP Supplemental Grant Award	Additional federal funds awarded to a RWHAP Part B (as a component of the RWHAP Part B award) who demonstrate severe need in ADAP, based on established criteria and data provided in the ADR.
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.”

Term	Definition
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.
Confidential information	Information collected on the client; unauthorized disclosure of this information could cause the client unwelcome exposure, discrimination, and/or abuse.
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.

Term	Definition
Electronic Handbook (EHB)	The HRSA Electronic Handbooks for Applicants/Recipients (EHBs). A web- based grants administration system. The EHBs are accessible 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) (e.g., 400 percent FPL). Medical eligibility must include 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 RWHAP 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 RWHAP recipient that receives funding directly from the Federal government (HRSA).
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 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 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.
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.

Term	Definition
RWHAP Part 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 families are coordinated.
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 individually.
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 or back 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 double-stranded DNA. HIV is an example of a retrovirus. After a retrovirus penetrates a cell, it constructs a DNA version of its genes using a special enzyme, reverse transcriptase. This DNA then becomes part of the cell's genetic material.
RWHAP-funded service	A service paid for with Ryan White HIV/AIDS Program funds.
Ryan White HIV/AIDS Program (RWHAP)	Ryan White HIV/AIDS Treatment Extension Act of 2009—The Federal legislation created to address the health care and service needs of people living with HIV/AIDS 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 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 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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