

**INSTRUCTIONS FOR COMPLETING
THE AIDS DRUG ASSISTANCE PROGRAM
QUARTERLY REPORT**

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INSTRUCTIONS FOR COMPLETING THE ADAP QUARTERLY REPORT

Public reporting burden for this collection of information is estimated to average 7.5 hours per respondent year including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information.

An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. The OMB control number for this project is 0915-0294.

WHO COMPLETES THE ADAP QUARTERLY REPORT?

The ADAP Quarterly Report is a condition of the Part B grant award. Each grantee of record must complete the form. The grantee may designate one person to take responsibility for the completion of the form. However, the name and contact information of the ADAP Coordinator or Administrator must be entered in Item #6 on the Cover Page. HRSA does not require any other data submissions by ADAP grantees.

WHAT ARE THE DUE DATES?

The ADAP Quarterly Report is due on the last day of the month following the completion of the quarter. The table below provides the general schedule.

Quarter	Period	Report Due Date
1*	April 1–June 30	July 31
2	July 1–September 30	October 31
3	October 1–December 31	January 31
4	January 1–March 31	April 30

***Section 2 of the ADAP Quarterly Report (Annual Submission) is completed and submitted only once each year, with the first quarterly report of the ADAP fiscal year.**

In the event that one of these due dates falls on a Saturday, Sunday, or Federal holiday, the due date would be the next business day.

HOW DO GRANTEES SUBMIT REPORTS?

The ADAP Quarterly Report is a ‘Deliverable’ in the HRSA Electronic Handbooks (EHBs). This means that in order to complete and to submit the AQR, ADAP grantees must first be registered with the HRSA EHBs. For information on registering in the EHBs, follow the instructions on the HRSA EHBs home page - <https://grants.hrsa.gov/webexternal/>.

If additional assistance is required, grantees should contact the HRSA Call Center using the contact information shown below.

ADAP grantees must review their data carefully before submission. If you need to change already submitted data and the submission deadline has not passed, you may request to ‘Un-submit’ and correct the data. You may not request an ‘Un-submit’ after the submission deadline. HAB must approve an ‘Un-submit’ request before you can make any changes.

To submit data online, go to the EHBs home page - <https://grants.hrsa.gov/webexternal/>.

FOR FURTHER ASSISTANCE

For further assistance call the HRSA Call Center:

HRSA Call Center

Email:

Toll Free: **1-877-464-4772 or (877) Go4-HRSA**

Local DC
Metro Area: **(301) 998-7373**

Fax: **(301) 998-7377**

Hours: **Monday thru Friday 9:00am – 5:30pm ET**

HRSA Electronic Handbooks: <https://grants.hrsa.gov/webexternal/>

The HRSA Call Center is closed on government holidays.

SECTIONS OF THE REPORT

COVER PAGE

After you have successfully registered with the HRSA EHBs, much of the information in the Cover Page will be populated automatically. However, you can still edit the items in the Cover Page, including:

1. *Grantee Name*

The grantee name must match the organization name on the Notice of Grant Award. There should be no abbreviations or acronyms unless they are also used in the Notice of Grants Award (NOGA).

2. *Grant number*

This is the grant number displayed on your Notice of Grant Award.

3. *ADAP number*

This is a four-digit State ADAP number assigned by HAB, Division of Service Systems (DSS). If you do not know the ADAP number for your program, contact your HRSA Project Officer.

4. *D-U-N-S number*

This number, assigned by Dun & Bradstreet, indicates the grantee's credit worthiness. D-U-N-S numbers can be requested from <http://www.dnb.com/us/>

5. *Grantee address*

This address should match the mailing address of the grantee of record. There should be no abbreviations or acronyms unless they are also used in the NOGA.

6. *Contact information*

The name, title, telephone, and fax numbers, as well as e-mail address of the person who administers or coordinates the State or Territory ADAP should be provided.

7. *Report quarter*

The report quarter is the one for which you are submitting the report (i.e., the quarter that was just completed).

Verify that all information is correct, edit as needed, and then proceed to Section 1. If entering the ADAP four-digit number into the online system does not populate the fields, check your ADAP number again and retry. If it still does not work, you should contact your Project Officer at HRSA to verify the number or contact the technical assistance contractor cited on the Web page.

If you cannot submit your AQR online for any reason, you should contact the HRSA Call Center to indicate the problem and make alternative arrangements for your mandatory data submission.

SECTION 1: QUARTERLY SUBMISSION

This section must be completed *every quarter*. These questions include Client, Funding, and Expenditure information.

A. Client Utilization

1. Unduplicated client counts

a. Total number of unduplicated clients enrolled in ADAP at any time during the quarter
Unduplicated clients refers to the total number of individuals who are enrolled or certified as eligible to receive medications in your ADAP, regardless of whether they used ADAP services during the quarter for which you are reporting data. To obtain an unduplicated client count, an individual receiving multiple units of service must be counted only once. Anonymous clients should *not* be reflected in this total.

Note: ADAPs must provide actual counts of clients rather than estimates.

b. Total number of NEW clients enrolled in the ADAP

New clients enrolled in the ADAP this quarter refers to individuals who applied to ADAP for the first time ever and met the financial and medical eligibility criteria of the ADAP during the quarter for which you are reporting data, regardless of whether they used ADAP services. The number of new clients enrolled should be less than the number reported in Item 1a.

Note: Item 1b does not include individuals who have been recertified as eligible or individuals who have been reinstated as enrolled clients after a period of having been decertified. Examples of clients who should **NOT** be included in this number are the following:

- Clients who have moved out of the State and then returned, and
- 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.

c. Total number of unduplicated clients receiving at least one drug

This item refers to the total number of *unduplicated clients* who received *at least one* drug through the ADAP during the quarter for which you are reporting data. This should be an unduplicated number that counts each client only once, even if the client has had several prescriptions filled through the ADAP. This number should be less than or equal to Item 1a.

d. Total number of *NEW clients* receiving at least one drug

This item refers to the number of *new clients* this quarter who also received *at least one* drug during the quarter for which you are reporting data. This number should be less than or equal to Item 1b.

e. Clients who received any type of insurance service (premiums, co-pays, deductibles)

Indicate the total number of clients for whom ADAP funds were used to pay insurance premiums, co-payments, deductibles, or other health insurance services during the quarter for which you are reporting data. This number should be less than or equal to Item 1a.

f. *NEW clients* who received any type of insurance service (premiums, co-pays, deductibles)

Indicate the number of *new clients* for whom ADAP funds were used to pay insurance premiums, co-payments, deductibles, or other health insurance services during the reporting quarter. This number should be less than or equal to Item 1b.

2. Gender

The totals in columns a–f of the table in Item 2 must be the same as the numbers provided in the corresponding lines in Item 1. For this item, the clients should be asked to self-identify their gender. Clients who identify with more than one category (e.g., “male” and “transgender”) should be classified as “unknown/unreported.” The columns should provide the following information:

a. By total enrolled clients

Provide an unduplicated count of the total number of clients who are male, female, transgender, or unknown/unreported. The total for this column should equal Item 1a. The total of this column will be calculated automatically.

b. By newly enrolled clients

Provide an unduplicated count of the total number of newly enrolled clients (during the reporting period) who are male, female, transgender, or unknown/unreported. The total for this column should equal Item 1b. The total of this column will be calculated automatically.

c. By total clients served

Provide an unduplicated count of the total number of clients who received at least one medication during the reporting quarter and who are male, female, transgender, or unknown/unreported. The total for this column should equal Item 1c. The total of this column will be calculated automatically.

d. By new clients served

Provide an unduplicated count of the total number of newly enrolled clients who received at least one medication during the reporting quarter and who are male, female, transgender, or unknown/unreported. The total for this column should equal Item 1d. The total of this column will be calculated automatically.

e. By insurance clients

Provide an unduplicated count of the total number of clients for whom ADAP funds were used to pay for insurance (including premiums, co-pays, and deductibles) during the reporting quarter and who are male, female, transgender, or unknown/unreported. The total for this column should equal Item 1e. The total of this column will be calculated automatically.

f. By new insurance clients

Provide an unduplicated count of the total number of newly enrolled clients for whom ADAP funds were used to pay for insurance (including premiums, co-pays, and deductibles) during the reporting quarter and who are male, female, transgender, or unknown/unreported. The total for this column should equal Item 1f. The total of this column will be calculated automatically.

3. Age

The totals in columns a–f of the table in Item 3 must be the same as the numbers provided in the corresponding line in Item 1. For this item, provide the number of clients by their age categories. If there are clients who do not provide their age and the health care provider makes an educated estimate for the purposes of treatment, the estimate should be reported, and this should also be noted in the Comments or Clarifications section (Item 13). Report clients whose age cannot be determined as “unknown/unreported.” The columns should provide the following information:

a. By total enrolled clients

Provide an unduplicated count of the total number of clients who fit into each age category. The total for this column should equal Item 1a. The total of this column will be calculated automatically.

b. By newly enrolled clients

Provide an unduplicated count of the total number of newly enrolled clients (during the reporting period) who fit into each age category. The total for this column should equal Item 1b. The total of this column will be calculated automatically.

c. By total clients served

Provide an unduplicated count of the total number of clients who received at least one medication during the reporting quarter and who fit into each age category. The total for this column should equal Item 1c. The total of this column will be calculated automatically.

d. By new clients served

Provide an unduplicated count of the total number of newly enrolled clients who received at least one medication during the reporting quarter who fit into each age category. The total for this column should equal Item 1d. The total of this column will be calculated automatically.

e. By insurance clients

Provide an unduplicated count of the total number of clients for whom ADAP funds were used to pay for insurance (including premiums, co-pays, and deductibles) during the reporting quarter who fit into each age category. The total for this column should equal Item 1e. The total of this column will be calculated automatically.

f. By new insurance clients

Provide an unduplicated count of the total number of newly enrolled clients for whom ADAP funds were used to pay for insurance (including premiums, co-pays, and deductibles) during the reporting quarter who fit into each age category. The total for this column should equal Item 1f. The total of this column will be calculated automatically.

Please note the following for Items 4 and 5:

The total number of clients reported in each individual column a–f when summed across the Item 4 and Item 5 tables must equal the total number of clients reported in the corresponding line in Item 1. For example, the sum of the total number of enrolled clients reported in column a in Item 4 and the total number of enrolled clients reported in column a in Item 5 must equal the total number of enrolled clients reported in Item 1a. Client ethnicity and race must be self-reported – do not assume or guess.

4. Racial distribution for total unduplicated Hispanic/Latino(a) ADAP clients:

For this item, report Hispanic/Latino(a) clients according to their self-reported race. See the glossary for definitions of OMB-approved race and ethnicity categories. The columns should provide the following information:

a. By total enrolled clients

Provide an unduplicated count of the total number of Hispanic/Latino(a) clients who identified with each racial category. The total of this column will be calculated automatically. (The sum of Item 4a-Total and Item 5a-Total must equal Item 1a.)

b. By newly enrolled clients

Provide an unduplicated count of the total number of newly enrolled Hispanic/Latino(a) clients (during the reporting period) who identified with each racial category. The total of this column will be calculated automatically. (The sum of Item 4b-Total and Item 5b-Total must equal Item 1b.)

By total clients served

Provide an unduplicated count of the total number of Hispanic/Latino(a) clients who received at least one medication during the reporting quarter who identified with each racial category. The total of this column will be calculated automatically. (The sum of Item 4c-Total and Item 5c-Total must equal Item 1c.)

By new clients served

Provide an unduplicated count of the total number of newly enrolled Hispanic/Latino(a) clients who received at least one medication during the reporting quarter who identified with each racial category. The total of this column will be calculated automatically. (The sum of Item 4d-Total and Item 5d-Total must equal Item 1d.)

By insurance clients

Provide an unduplicated count of the total number of Hispanic/Latino(a) clients for whom ADAP funds were used to pay for insurance (including premiums, co-pays, and deductibles) during the reporting quarter who identified with each racial category. The total of this column will be calculated automatically. (The sum of Item 4e-Total and Item 5e-Total must equal Item 1e.)

By new insurance clients

Provide an unduplicated count of the total number of newly enrolled Hispanic/Latino(a) clients for whom ADAP funds were used to pay for insurance (including premiums, co-pays, and deductibles) during the reporting quarter who identified with each racial category. The total of this column will be calculated automatically. (The sum of Item 4f-Total and Item 5f-Total must equal Item 1f.)

5. Racial distribution for total unduplicated non-Hispanic/Latino(a) ADAP clients:

For this item, report non-Hispanic/Latino(a) clients according to their self-reported ethnicity and race. See the glossary for definitions of OMB-approved race and ethnicity categories. The columns should provide the following information:

a. By total enrolled clients

Provide an unduplicated count of the total number of non-Hispanic/Latino(a) clients who identified with each racial category. The total of this column will be calculated automatically. (The sum of Item 4a-Total and Item 5a-Total must equal Item 1a.)

b. By newly enrolled clients

Provide an unduplicated count of the total number of newly enrolled non-Hispanic/Latino(a) clients (during the reporting period) who identified with each racial category. The total of this column will be calculated automatically. (The sum of Item 4b-Total and Item 5b-Total must equal Item 1b.)

c. By total clients served

Provide an unduplicated count of the total number of non-Hispanic/Latino(a) clients who received at least one medication during the reporting quarter who identified with each racial category. The total of this column will be calculated automatically. (The sum of Item 4c-Total and Item 5c-Total must equal Item 1c.)

By new clients served

Provide an unduplicated count of the total number of newly enrolled non-Hispanic/Latino(a) clients who received at least one medication who identified with each racial category. The total of this column will be calculated automatically. (The sum of Item 4d-Total and Item 5d-Total must equal Item 1d.)

By insurance clients

Provide an unduplicated count of the total number of non-Hispanic/Latino(a) clients for whom ADAP funds were used to pay for insurance (including premiums, co-pays, and deductibles) during the reporting quarter who identified with each racial category. The total of this column will be calculated automatically. (The sum of Item 4e-Total and Item 5e-Total must equal Item 1e.)

d. By new insurance clients

Provide an unduplicated count of the total number of newly enrolled non-Hispanic/Latino(a) clients for whom ADAP funds were used to pay for insurance (including premiums, co-pays, and deductibles) during the reporting quarter who identified with each racial category. The total of

this column will be calculated automatically (The sum of Item 4f-Total and Item 5f-Total must equal Item 1f.)

6. **Total number of clients on HAART**

Provide the number of ADAP clients receiving *less than three* antiretroviral medications, *either three or four* antiretroviral medications, or *more than four* antiretroviral medications. The total number of clients reported in this item may not exceed the number reported in Item 1c. However, in the rare event that a client experiences a significant change in antiretroviral therapy during the quarter, the categories in Item 6 may not be mutually exclusive. For example, if a client goes from say, two to three antiretroviral therapies in the same quarter, the totals may exceed the number reported in Item 1c. In this case, provide an explanation in Item 13 (Comments and Clarifications). Combination drugs count as multiple medications (e.g., Combivir should be counted as two drugs).

Note: The categories in Item 6 are mutually exclusive in most cases; that is, clients generally should *not* be counted in more than one category.

7. **Clients served whose annual household incomes are less than 200 percent of the Federal Poverty Level (FPL)**

Provide the percentage of ADAP clients enrolled (*reported in Item 1a*) whose annual household income was less than 200 percent of the FPL at the end of the reporting period or based on the client's most recent recertification for eligibility. Information on the current poverty guidelines can be found at the following Web address: <http://aspe.hhs.gov/poverty/>.

8. **ADAP limits**

Indicate whether your program has any of the following limits on ADAP and provide the maximum limit for that option. You may check as many boxes as applicable:

- a. Enrollment cap—A limit on the maximum number of people who can be enrolled in your program at any given time.
- b. Waiting list—A list of people who are not receiving services but who will be served as openings become available. There may be several reasons why people are not receiving services, such as limited funding and the limit on the number of people already being served.
- c. Capped expenditures—The maximum amount of dollars that can be spent, usually per client.
- d. Drug-specific enrollment caps—A limit on the maximum number of people who can receive a specific medication at any given time. Indicate the ARV and Hepatitis C medications, if any, that have enrollment caps. For each medication indicated, provide the maximum number of enrollees in the space provided.

- **Note:** If any of the boxes are checked, you must fill in the maximum limit for that option.

9. **Changes in program**

Check all of the developments and changes to your program that occurred during the reporting quarter. If you have changed the income or medical eligibility criteria for enrollment in the ADAP, specify the new criteria. If there were no changes or developments in your ADAP during the reporting quarter check the last box, “No changes or developments.”

B. Funding

This item requests funding received during this quarter from sources other than Ryan White HIV/AIDS Program ADAP-earmarked funds. Funding reported here includes annual amounts received during the second, third, or fourth quarter from the State. For example, if your State funds typically are received in July, you would put the entire amount in the second quarterly report under Item 10c. Your response to Item 10c for quarters 1, 3, and 4 would then be “0.”

10. ADAP funding received during quarter

Report the amount of funding your program received from the sources listed during the reporting quarter. This item is requesting information on funding *received*, not awarded. Enter “0” if your ADAP did not receive funding from any given source during the quarter. Do not leave any boxes blank.

Note: This item is different from Item 14, which asks for funding received annually from sources that routinely award funds by the close of the first quarter of the fiscal year.

C. Expenditures

These items record expenditures during the reporting quarter.

11. Expenditures

Provide the total expenditures for pharmaceuticals, dispensing and other administrative costs, insurance coverage, and the flexibility policy (for adherence, access, and monitoring services) for the reporting quarter. Administrative costs include items such as shipping and handling, and other bulk order fees. The total expenditures for the quarter will be calculated automatically

Note: Insurance coverage includes co-payments, deductibles, and premiums for which ADAP funds were used.

Note: Approval from HAB’s Grants Management Office is required to have the flexibility to spend ADAP funds on services other than the provision of pharmaceuticals (HAB Policy Notice 07-07). Requests to fund additional services with ADAP funds must be submitted annually to HAB’s Grants Management Office.

Drug pricing

From the list of ARVs, Hepatitis B and Hepatitis C treatment medications provided, check the boxes corresponding to the medications you purchased and/or dispensed during the reporting quarter.

For each medication **purchased**, provide the total price you paid for the medication before rebates. Do not include Dispensing fees and other administrative costs here.

For each medication **dispensed** during the quarter, report the number of clients who received this medication at least once during the reporting quarter.

To complete Question #12:

- **Column 1** – Check the ARVs, Hepatitis B, and Hepatitis C treatment medications you purchased and/or dispensed.
- **Column 2** provides the generic names for ARVs, Hepatitis B, and Hepatitis C treatment medications. **Column 3** provides the brand names. When using the web-based reporting system, these columns can be used to sort the medication list to more easily locate medications that were purchased and/or dispensed.
- **Column 4** contains the drug code (d-code) for each ARV, Hepatitis B, and Hepatitis C treatment medication.
- For each ARV, Hepatitis B, and Hepatitis C treatment medication purchased during the reporting quarter, enter the total cost of the medication before rebates in **Column 5**.

Note: This is the price you paid to purchase the medication this quarter. The total cost entered here must not include Dispensing fees and other administrative costs. In the event of price changes during the quarter, use the last quoted price.

- **Column 6** - For each medication dispensed, enter the number of clients receiving that drug at least once during the quarter.

12. *Comments or clarifications*

This is an optional item to allow you to clarify or expand your answers to items in Section 1 of the report. For example, if you wish to explain significant changes in price for a drug from a prior quarter, please put that information here. If an answer to an item does not comply with the requested information (e.g., a provider guessed the age of clients), please explain in this space.

SECTION 2: ANNUAL SUBMISSION

This section is completed once each year and submitted with the first quarterly report of the fiscal year, which is due July 31.

A. Funding

13. *ADAP funding*

The funding your program received from the sources listed for the **current fiscal year** are pre-populated from the funding information maintained on each ADAP grantee. You do not need to change these pre-populated fields.

14. *ADAP formulary list*

Use the Microsoft Excel template available from <http://hab.hrsa.gov/tools.htm> to report all medications in your ADAP formulary.

15. Annual ADAP cost per client

For clients enrolled and receiving medications for a full 12-month period, provide an estimate of the annual ADAP cost per client during the previous grant year. Exclude clients who received medications for less than the 12-month period. If your program provides medications as well as insurance services to your clients, provide the annual ADAP cost per client only for the clients receiving medications.

- a. Rebate States: Report an estimate of the annual ADAP cost per client before and after rebates.
- b. Direct Purchase States: Report an estimate of the annual ADAP cost per client.
- c. Rebate and Direct Purchase Hybrids: Report an estimate of the annual ADAP cost per client before and after rebates.

B. Eligibility Requirements

Report the eligibility requirements to enroll in your ADAP.

16. ADAP financial eligibility

Enter the maximum income eligibility cap for participation in the ADAP. This should be expressed as a percentage of the Federal Poverty Level (FPL). For example, individuals living with HIV who have an income of 200 percent of the FPL or lower may be eligible to participate. Information on the current poverty guidelines can be found at the following Web address: <http://aspe.hhs.gov/poverty/>.

17. Frequency of client re-certification

Indicate whether your ADAP requires clients to be recertified as eligible to participate in ADAP on an Annual, Semiannual, or Other basis. If you select “Other,” indicate how often recertification is required.

18. Clinical criteria required to access ADAP

Check all of the clinical eligibility criteria for *enrolling* in the ADAP in your State/Territory. For CD4 count or viral load (VL) medical criteria, indicate the threshold number in the space provided. For “Other” medical criteria, indicate each criterion used and the corresponding threshold number.

C. Cost-Saving Strategies

Report efforts by your ADAP to use resources efficiently.

19. 340B Drug pricing program

Check all items that apply to your State’s 340B Drug Pricing Program. If the ADAP uses another cost-saving strategy, check “Other” and indicate in the space provided the method and the strategy. Definitions of cost-saving strategies can be found in the Glossary.

State ADAP coordination with Medicaid and State-only Pharmacy Assistance Programs

Indicate which methods your ADAP uses to coordinate with Medicaid. If you have no coordination with Medicaid or State-only Pharmacy Assistance, check the last box. See the Glossary for definitions of methods.

Comments or clarifications

This is an optional item to allow you to clarify or expand your answers to items in Section 2 of the report. For example, if you wish to explain your Drug Pricing Program in more depth, do so here. If an answer to an item does not comply with the requested information (e.g., you did not indicate clinical eligibility criteria), please explain in this space.

QUALITY ASSURANCE CHECKLIST

We highly recommend that you use the following checklist to ensure the quality and reliability of the data that you report in the ADAP Quarterly Report.

- The report includes information on all clients served and services delivered during the quarter for which you are reporting data.
- Section 1 is completed each quarter and there are no unanswered items.
- Section 2 is completed and submitted with the first quarterly report of the year and all items are completed.
- The full name of the grantee of record is identified on the cover page *and* matches the name on the Notice of Grant Award.
- A valid D-U-N-S number is provided.
- Item 1 provides an unduplicated count—not an estimate—of the number of clients served.
- The column totals for columns a–f in Items 2 and 3 are the same as the corresponding lines in Item 1.
- The column totals for columns a–f in Item 4 plus the corresponding column totals in Item 5 are the same as the corresponding lines in Item 1.

GLOSSARY OF ADAP QUARTERLY REPORT TERMS

ADAP	<i>AIDS Drug Assistance Program</i> —A State-administered program authorized under Part B of the Ryan White HIV/AIDS Treatment Extension Act of 2009 that provides FDA-approved medications to low-income individuals with HIV disease who have limited or no coverage from private insurance or Medicaid.
ADAP Earmark	Federal funds specifically designated to be used for the State/Territory ADAP.
ADAP Flexibility Policy	HIV/AIDS Bureau’s (HAB) Policy Notice 00-02 provides grantees greater flexibility in the use of ADAP funds and permits expenditures of ADAP funds for services that improve access to medications, increase adherence to medication regimens, and help clients monitor their progress in taking HIV-related medications. Please note that grantees <i>must</i> request approval annually, in writing, to use ADAP dollars for services other than medications.
ADAP Number	A four-digit number used to identify specific State/Territory ADAPs. This number is assigned by the HAB Division of Service Systems (DSS).
ADAP Supplemental Drug Treatment Grant Award	Federal funds awarded to an ADAP with demonstrated severe need based on established criteria, in addition to the earmark fund. Generally these awards require a separate application.
AIDS	<i>Acquired immune deficiency syndrome</i> —A disease caused by the human immunodeficiency virus.
Alternative Method Demonstration Project	A program of the Office of Pharmacy Affairs that allows for a formal process of testing alternative methods of participating in the 340B drug discount program. New methods of accessing discounted drugs in successful time-limited demonstrations are incorporated into the 340B program’s published guidelines.
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.
Antiretroviral	A substance that fights against a retrovirus, such as HIV. (See Retrovirus)
APA	<i>AIDS pharmaceutical assistance</i> —A local pharmacy assistance program implemented by a Part A EMA/TGA or Part B State program. The Part B Grantee, consortium or Part A Planning Council contracts with one or more organizations to provide medications to clients. These organizations may or may not provide other services (e.g., primary care, case management) to the patients or clients that they serve through a Ryan White (or other funding sources) contract with their grantee.
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.
Black or African American	A person having origins in any of the black racial groups of Africa.
Capped expenditure	A limit on the amount of money to be spent on one service or client per month or per year.

Case management services	A range of client-centered services that link clients with health care, psychosocial, and other services. Ensures timely and coordinated access to medically appropriate levels of health and support services and continuity of care, through ongoing assessment of the client's and other key family members' needs and personal support systems. Also includes inpatient case management services that prevent unnecessary hospitalization or that expedite discharge from inpatient facility. Key activities include: (1) initial assessment of service needs; (2) development of a comprehensive, individualized service plan; (3) coordination of services required to implement the plan; (4) client monitoring to assess the efficacy of the plan and (5) periodic re-evaluation and adaptation of the plan as necessary over the life of the client. May include client-specific advocacy and/or review of utilization of services.
CDC	<i>Centers for Disease Control and Prevention</i> —The DHHS agency that administers HIV/AIDS prevention programs, including the HIV Prevention Community Planning process, among other programs. The CDC monitors and reports infectious diseases, administers AIDS surveillance grants, and publishes epidemiologic reports such as the HIV/AIDS Surveillance Report.
CD4 or CD4+ cells	Also known as “helper” T-cells, these cells are responsible for coordinating much of the immune response. HIV's preferred targets are cells that have a docking molecule called “cluster designation 4” (CD4) on their surfaces. Cells with this molecule are known as CD4-positive (CD4+) cells. Destruction of CD4+ lymphocytes is the major cause of the immunodeficiency observed in AIDS, and decreasing CD4 levels appear to be the best indicator for developing opportunistic infections.
CD4 cell count	The number of T-helper lymphocytes per cubic millimeter of blood. The CD4 count is a good predictor of immunity. As the CD4 cell count decreases, the risk of developing opportunistic infections increases. The normal range for CD4 cell counts is 500 to 1,500 per cubic millimeter of blood. CD4 counts should be rechecked at least every 6 to 12 months if CD4 counts are greater than 500/mm ³ . If the count is lower, testing every 3 months is advised. A CD4 count of 200 or less indicates AIDS.
Combination therapy	Two or more drugs or treatments used together to achieve optimum results against HIV infection and/or AIDS. For more information on treatment guidelines, visit http://www.aidsinfo.nih.gov/ .
Coordinated benefits	The provision of services by either ADAP or Medicaid, but not both, so that clients do not receive duplicated services.
Co-payment	A fee charged to a client per visit or per prescription.
DCBP	Division of Community Based Programs— The division within HRSA's HIV/AIDS Bureau that is responsible for administering Part C, Part D, and the HIV/AIDS Dental Programs (the Dental Reimbursement Program [DRP] and the Community-Based Dental Partnership Program [CBDPP]).
Dispensing of pharmaceuticals	The provision of prescription drugs to prolong life or prevent the deterioration of health.

Direct Purchase	A prescription drug purchasing model in which State ADAPs purchase drugs directly from a manufacturer or wholesaler at the 340B pricing schedule. ADAPs then distribute the drugs using a centralized state system or through their own pharmacies.
Drug formulary	A list of pharmaceuticals that can be or should be preferentially prescribed within a reimbursement (insurance) program.
DSP	<i>Division of Science and Policy</i> —The office within HRSA’s HIV/AIDS Bureau that serves as HAB’s principal source of program data collection and evaluation, the development of innovative models of HIV care, and the focal point for coordination of program performance activities and development of policy guidance. DSP advises the Associate Administrator of HAB and plans for the development of both science and policy proposals to support the mission of HAB. It also coordinates and develops collaborative efforts with other HHS components and all HRSA bureaus, including the Office of Planning and Evaluation, in the preparation of HIV/AIDS-related program policies.
DSS	<i>Division of Service Systems</i> —The division within HRSA’s HIV/AIDS Bureau responsible for administering Parts A and B (including the AIDS Drug Assistance Program).
DTTA	<i>Division of Training and Technical Assistance</i> —The division within HRSA’s HIV/AIDS Bureau that is responsible for administering the AIDS Education and Training Centers (AETC) program and technical assistance and training activities of the HIV/AIDS Bureau.
Dual Application	One application form for assistance that is used by both the ADAP and Medicaid, such that clients only need apply once and may receive services from both ADAP and Medicaid.
D-U-N-S Number	A D-U-N-S® Number is a unique, nine-digit sequence recognized as the universal standard for identifying and keeping track of businesses worldwide. If your agency does not have a number, you can request one by going to http://www.dnb.com/us/ .
D-Codes	A five-digit drug identification number developed by Multum Cerner® to identify groups of medications. D-codes have the format d#####, and may also be referred to as ‘d-codes’ or ‘HRSA codes.’ For more information, go to: http://www.multum.com/slog/LexDownload.asp .
Eligibility criteria	The standards set by a State ADAP, usually through an advisory committee, to determine who receives access to ADAP services. Financial eligibility is usually determined as a percentage of the Federal Poverty Level (FPL), such as 200% FPL. Medical eligibility is most often a positive HIV diagnosis. Eligibility criteria vary among ADAPs.
EMA	<i>Eligible Metropolitan Area</i> —The geographic area eligible to receive Part A Ryan White HIV/AIDS Program funds. The Census Bureau defines the boundaries of the eligible metropolitan area. The number of AIDS cases reported to the Centers for Disease Control and Prevention (CDC) determines eligibility. Some EMAs include just one city, and others are composed of several cities and/or counties. Some EMAs extend over more than one State.

Enrollment cap	A limit on the number of people who can be served by the program or who may be provided with any medication at any one time.
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.
Federal Poverty Level	A measure of income that indicates eligibility for Federal grant programs. Information on the current poverty guidelines can be found at http://aspe.hhs.gov/poverty/ .
Fixed co-payment	A set fee charged to all clients per prescription filled.
Grantee of record	The official Ryan White HIV/AIDS Program grantee that receives Federal funding directly from the Federal government (HRSA). This agency may be the same as the provider agency, or it may be the agency through which the provider agency is subcontracted.
HAART	<i>Highly active antiretroviral therapy</i> —An aggressive anti-HIV treatment including a combination of three or more drugs with activity against HIV whose purpose is to reduce viral load to undetectable levels. Currently, antiretroviral therapies include protease inhibitors, non-nucleoside reverse transcriptase inhibitors, nucleoside/nucleotide analogues, and fusion inhibitors.
HAB	<i>HIV/AIDS Bureau</i> —The bureau within the Health Resources and Services Administration (HRSA) of HHS that is responsible for administering the Ryan White HIV/AIDS Program. Within HAB, the Division of Service Systems administers Part A and Part B, including the AIDS Drug Assistance Program (ADAP); the Division of Community-Based Programs administers Part C and Part D, and the HIV/AIDS Dental Programs (the Dental Reimbursement Program [DRP] and the Community-Based Dental Partnership Program [CBDPP]); and the Division of Training and Technical Assistance administers the AIDS Education and Training Centers (AETC) program. The Bureau’s Division of Science and Policy administers the Special Projects of National Significance (SPNS) program.
Hispanic or Latino/a	A person of Mexican, Puerto Rican, Cuban, Central or South American, or other Spanish culture or origin, regardless of race.
HIV/AIDS status	The outcome of the client’s HIV test result, which includes: (1) HIV-positive not AIDS—client tested positive for and has been diagnosed with HIV, but has not advanced to AIDS; (2) HIV-positive AIDS status unknown—client tested positive for and has been diagnosed with HIV, but it is unknown whether the client has advanced to AIDS; (3) CDC-defined AIDS—client has advanced to and been diagnosed with CDC-defined AIDS; (4) HIV-negative (affected)—client is HIV-negative and is an affected partner or family member of an individual who is HIV-positive; and (5) unknown—HIV/AIDS status of the client is unknown and not documented.
HIV disease	Any signs, symptoms, or other adverse health effects due to the human immunodeficiency virus.

HRSA	<i>Health Resources and Services Administration</i> —The HHS agency that is responsible for directing national health programs that improve the Nation’s health by ensuring equitable access to comprehensive, quality health care for all. HRSA works to improve and extend life for people living with HIV/AIDS, provide primary health care to medically underserved people, serve women and children through State programs, and train a health workforce that is both diverse and motivated to work in underserved communities. HRSA is also responsible for administering the Ryan White HIV/AIDS Program.
Hybrid	A prescription drug purchasing model in which State ADAPs contract with a 340B entity to purchase and distribute medications at the 340B pricing schedule.
IDU	<i>Injection drug user</i>
Lead agency	The agency responsible for contract administration; also called a fiscal agent. An incorporated consortium sometimes serves as the lead agency.
Local, county, or State health department	Publicly-funded health department administered by a local, county, or State government.
Manufacturers’ rebates	Dollars received from drug manufacturers, which represent a percentage of the cost of the drug.
Medicaid	A jointly funded, Federal-State health insurance program for certain low-income and needy people.
Medicare	A health insurance program for people 65 years of age and older, some disabled people under 65 years of age, and people with End-Stage Renal Disease (permanent kidney failure treated with dialysis or a transplant).
Medication Protocol	A document developed to ensure that medications are prescribed appropriately. This document describes specific medical criteria that must be met before clients can be prescribed a specific medication(s).
More than one race	A person who identifies with more than one racial category.
Multum Drug List	Database of drugs and drug product nomenclature compiled, maintained and updated by the Multum Information Services, Inc, Colorado Center Tower One 2000 South Colorado Boulevard, Suite 11000, Denver, Colorado 80222.The Multum Drug List contains all the pertinent information that uniquely map each drug according to its National Drug Code (NDC). Multum also maintains the drug identification codes (d-codes).
Native Hawaiian or Other Pacific Islander	A person having origins in any of the original peoples of Hawaii, Guam, Samoa, or other Pacific Islands.
NDC	<i>National Drug Code</i> —The identifying drug number maintained by the FDA. For purposes of the Section 340B Drug Discount Program, the NDC number is used, including labeler code (assigned by the FDA and identifies the establishment), product code (identifies the specified product or formation), and package size code when reporting requested information.
New clients	Persons who received services from a provider for the first time ever during this reporting period. Individuals who returned for care after an extended absence are not considered to be new unless past records of their care are not available.

OI	<i>Opportunistic infection</i> —An infection or cancer that occurs in persons with weak immune systems due to AIDS, cancer, or immunosuppressive drugs such as corticosteroids or chemotherapy. Kaposi’s Sarcoma (KS), pneumocystis pneumonia (PCP), toxoplasmosis, and cytomegalovirus are all examples of opportunistic infections.
OMB	<i>Office of Management and Budget</i> —The office within the executive branch of the Federal Government that prepares the President’s annual budget, develops the Federal Government’s fiscal program, oversees administration of the budget, and reviews Government regulations.
Online interface	A shared intranet or Web site between the State’s ADAP and Medicaid program.
PHSA	<i>Public Health Service Act</i>
PLWA	<i>People living with AIDS</i>
PLWH	<i>People living with HIV</i> who know they are positive but do not yet have AIDS.
Primary health care service	Any preventive, diagnostic, or therapeutic health service received on an outpatient basis by a client who is HIV positive. Examples include medical, subspecialty care, dental, nutrition, mental health or substance abuse treatment, and pharmacy services; radiology, laboratory, and other tests used for diagnosis and treatment planning; and counseling and testing.
Prime Vendor	A voluntary program of 340B-covered entities in which the prime vendor handles price negotiation and drug distribution responsibilities for members. Since the prime vendor has the potential to control a large volume of pharmaceuticals, it can negotiate favorable prices and develop a national distribution system that would not be possible for covered entities to obtain individually.
Prophylaxis	Treatment to prevent the onset of a particular disease (primary prophylaxis) or recurrence of symptoms in an existing infection that has been brought under control (secondary prophylaxis).
Publicly funded community health center	Includes community health centers, migrant health centers, rural health centers, and homeless health centers.
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.
Recertification	A process for confirming that a client receiving ADAP-funded services is still eligible to receive those services.
Reporting period	The quarter for which the ADAP Quarterly Report covers. Quarter 1 -- April 1 – June 30 Quarter 2 -- July 1 – September 30 Quarter 3 -- October 1 - December 31 Quarter 4 -- January 1 – March 31
Retroactive billing	Billing for services previously rendered rather than at the time of delivery.

Retrovirus	A type of virus that, when not infecting a cell, stores its genetic information on a single-stranded RNA molecule instead of the more usual double-stranded DNA. HIV is an example of a retrovirus. After a retrovirus penetrates a cell, it constructs a DNA version of its genes using a special enzyme, reverse transcriptase. This DNA then becomes part of the cell's genetic material.
Ryan White HIV/AIDS Program	Ryan White HIV/AIDS Treatment Extension Act of 2009—The Federal legislation created to address the health care and service needs of people living with HIV/AIDS (PLWHA) disease and their families in the United States and its Territories. The Ryan White HIV/AIDS Program was enacted in 1990 (Pub. L. 101-381), reauthorized in 1996 as the Ryan White CARE Act Amendments of 1996, in 2000 as the Ryan White CARE Act Amendments of 2000, and in 2006 as the Ryan White HIV/AIDS Treatment Modernization Act of 2006. The most recent reauthorization was in 2009 as the Ryan White HIV/AIDS Treatment Extension Act of 2009.
Section 330 of PHS A	Supports the development and operation of community health centers that provide preventive and primary health care services, supplemental health and support services, and environmental health services to medically underserved areas/populations.
Section 340B Drug Discount Program	Administered by the Office of Pharmacy Affairs, this provision indicates that as a condition for participation in Medicaid, drug manufacturers must sign a pharmaceutical pricing agreement with the Secretary of the Department of Health and Human Services. This agreement states that the price charged for covered outpatient drugs will not exceed the statutory ceiling price (the average manufacturers' price reduced by the Medicaid rebate percentage).
Sliding scale co-payment	A fee charged to clients for filled prescriptions that varies based on the income of the client.
SPNS	<i>Special Projects of National Significance</i> —a branch of the Division of Science and Policy which advances knowledge and skills in the delivery of health and support services to underserved populations diagnosed with HIV infection. SPNS grants fund innovative models of care and support the development of effective delivery systems for HIV care. The SPNS Program is considered the research and development arm of the Ryan White HIV/AIDS Treatment Modernization Act of 2006 and provides the mechanisms to Assess the effectiveness of particular models of care, Support innovative program design, and Promote replication of effective models.
State Match for Supplemental Drug Treatment Award	Funding from the State budget that matches, in part or in whole, the ADAP Supplemental Drug Treatment Grant Award.
TGAs	<i>Transitional Grant Areas</i> – TGAs are those metropolitan areas that include communities with a population of 50,000 or more that have reported to the CDC a total of at least 1,000, but fewer than 2,000, cases of AIDS during the most recent five calendar years for which data are available (see Section 2609 (b)(c) of the Public Health Service Act).

Part A	The part of the Ryan White HIV/AIDS Program that provides direct financial assistance to designated Eligible Metropolitan Area (EMAs) or Transitional Grant Areas (TGAs) that have been the most severely affected by the HIV epidemic. The purpose of these funds is to deliver or enhance HIV-related: (1) outpatient and ambulatory health and support services, including case management and comprehensive treatment services for individuals and families with HIV disease; and (2) inpatient case management services that prevent unnecessary hospitalization or that expedite discharge, when medically appropriate, from inpatient facilities.
Part B	The part of the Ryan White HIV/AIDS Program that authorizes the distribution of Federal funds to States and Territories to improve the quality, availability, and organization of health care and support services for individuals with HIV disease and their families. The Ryan White HIV/AIDS Program emphasizes that such care and support is part of a continuum of care in which all the needs of individuals with HIV disease and their families are coordinated. The funds are distributed among States and Territories based, in part, on the number of AIDS cases in each State or Territory as a proportion of the number of AIDS cases reported in the entire United States.
Part C	The part of the Ryan White HIV/AIDS Program that provides support for Early Intervention Services, including preventive, diagnostic, and therapeutic services for HIV/AIDS clients. This particularly includes a continuum of comprehensive primary health care, referrals for specialty care, counseling and testing, outreach, case management, and eligibility assistance.
Part D	The part of the Ryan White HIV/AIDS Program that supports coordinated services and access to research for children, youth, and women with HIV disease and their affected family members.
Treatment adherence services	Provision of counseling or special programs to ensure readiness for, and adherence to, complex HIV/AIDS treatments.
Unduplicated client count	An accounting of clients in which a single individual is counted only once. For providers with multiple sites, a client is counted only once, even if he or she receives services at more than one of the provider's sites.
Viral load (VL) test	A test that measures the quantity of HIV RNA in the blood. Results are expressed as the number of copies per milliliter of blood plasma. This test is employed as a predictor of disease progression.
Waiting list	A list of people not yet enrolled or not yet receiving services but who will be served in turn when space becomes available.
White	A person having origins in any of the original peoples of Europe, the Middle East, or North Africa.