

## **AIDS Drug Assistance Program Treatments<sup>i</sup>**

### **Description:**

The AIDS Drug Assistance Program (ADAP) is a state-administered program authorized under Part B of the Ryan White HIV/AIDS Program (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. RWHAP ADAP recipients must assess and compare the aggregate cost of paying for the health insurance option versus paying for the full cost for medications and other appropriate HIV outpatient/ambulatory health services to ensure that purchasing health insurance is cost effective in the aggregate.

Eligible ADAP clients must be living with HIV and meet income and other eligibility criteria as established by the state.

### **Program Guidance:**

Each state funded for ADAP Treatments is responsible for:

- Establishing ADAP eligibility within the legislative guidelines of the Ryan White CARE Act and Health resources and Service Administration (HRSA/HAB) policies and guidelines<sup>ii</sup>.
- Determining the type, amount, duration and scope of ADAP services.
- Developing a list of covered drugs on its ADAP medication formulary.
- Ensuring that each class of antiretroviral medication is on its ADAP medication formulary.
- Providing outreach to individuals with HIV/AIDS, and as appropriate to the families of such individuals.
- Facilitating access to treatments.
- Encouraging, supporting and enhancing adherence to and compliance with antiretroviral treatment regimens, including related medical monitoring.

All service provision will comply with the Department of Health and Human Services (HHS) Guidelines and the Commonwealth of Virginia Department of Health (VDH) Service Standards for people living with HIV, including the following:

#### **1.0 Intake and Eligibility**

***National Monitoring Standards: Eligibility determination process requiring documentation in patient records of low-income status and eligibility based on a specified percent of the FPL and proof of an individual's HIV-positive status, and residency. Determination and documentation of patient eligibility every six months<sup>iii</sup>.***

#### **AIDS Drug Assistance Program Services**

VDH Service Standards (Revised: June 2017 and January 2019)

***HRSA, the funder for Ryan White HIV Services, prohibits continued HIV services, including medications to clients who are not recertified for eligibility of services by their specified date; therefore, if a client has not completed their annual certification or recertification at six months they may not be eligible for Ryan White services<sup>iv</sup>.***

Standard	Measure
<b>Eligibility</b>	
1.1) The client’s eligibility for Ryan White Part B services is determined.	1.1) Documentation of the client’s eligibility is present in the client’s record.
1.2) To be eligible for this service applicants must: <ul style="list-style-type: none"> <li>a) Be diagnosed with HIV</li> <li>b) Live in Virginia</li> <li>c) Have an individual or family income at or below 500% of the Federal Poverty Level (FPL)</li> <li>d) Ryan White Part B is the payer of last resort and other funding sources must be vigorously pursued. Providers are responsible to ensure that clients are screened and deemed ineligible for other payer sources covered by Federal or State programs such as Medicare, Medicaid, all other forms of insurance or third party payers such as private and commercial insurance plans, and other payers.</li> <li>e) Provide recertification every six months with proof of income, changes in insurance coverage, or any changes in residency</li> <li>f) <b>Client eligibility ensures Part B services are used as the payer of last resort.</b> Client must agree to participate in the insurance option client is eligible and that best meets the client’s medical needs regardless of preference.</li> </ul>	1.2) Documentation is present in files that verifies: <ul style="list-style-type: none"> <li>a) Client is diagnosed with HIV</li> <li>b) Client lives in Virginia</li> <li>c) Client meets income guidelines</li> <li>d) Client Medicaid status (gap of services)</li> <li>e) Recertification for continued eligibility for Part B services every six months</li> </ul> Client agrees to participate in insurance option that best meets their medical needs and for which the client is eligible.
<p><i>Note:</i> The Part B Program is the payer of last resort. This is interpreted as "funds received...will not be utilized to make payments for any item or service to the extent that payment has been made, or can reasonably be expected to be made..." by another payment source.<sup>v</sup></p>	

**AIDS Drug Assistance Program Services**

Intake	
<p>1.3) A completed ADAP application is submitted prior to initiation of services. An application is considered complete <u>only</u> when:</p> <ul style="list-style-type: none"> <li>a) All questions on the form are answered</li> <li>b) Form is signed and dated by client</li> <li>c) All supporting documents have been received by VDH.</li> </ul> <p><i>Note:</i> It is the responsibility of the referring agency to confirm all materials have been received by VDH. Once received, determination of the ADAP application will be made within 72 hours.</p>	<p>1.3) Documentation of the completed ADAP application is present in the client’s record, signed and dated.</p>
Recertification	
<p>1.4) Client must be recertified every six months to continue to receive Ryan White services. There is no grace period.</p>	<p>1.4) Documentation of recertification of the client’s eligibility every six months is present in the client’s record.</p>
<p><b><u>2.0 Key Services Components and Activities</u></b>  <i>Documentation that ADAP funds are used only to support eligible activities, including: a) provision of FDA approved medications, b) purchase of health insurance, c) assistance with medication co-pays, co-insurance and deductibles, and d) therapeutic services that enhance access to, adherence to, and monitoring of antiretroviral therapy.<sup>vi</sup></i></p>	
Standard	Measure
<p>2.1) Provision of ADAP services is documented by:</p> <ul style="list-style-type: none"> <li>a) Client eligibility</li> <li>b) Number of individuals served</li> <li>c) Medications provided.</li> </ul>	<p>2.1) Documentation of ADAP services provided.</p>
Provision of Services	
<p>2.2) Provide a formulary of medications to people living with HIV for the treatment of HIV disease and the prevention of opportunistic infections<sup>vii</sup>. The formulary must include pharmaceutical agents:</p> <ul style="list-style-type: none"> <li>a) From all the approved classes of antiretroviral medications in the PHS Clinical Practice Guidelines for use of Antiretroviral Agents in HIV-1 infected Adults and Adolescents</li> <li>b) Be FDA approved.</li> </ul> <p><i>Note:</i> A process must be used to secure the best price available for all products on the formulary including 340B pricing or better.</p>	<p>2.2) Documentation of medication formulary.</p>

<p>2.3) Provide outreach (awareness) to individuals with HIV/AIDS, and as appropriate the families of such individuals regarding ADAP and its programs to facilitate access to treatments for such individuals and to document progress in making therapeutics available.<sup>viii</sup></p>	<p>2.3) Documentation of state’s efforts and methods used to raise awareness.</p>
<p>2.4) Encourage, support, and enhance adherence to and compliance with treatment regimens including medical monitoring.<sup>ix</sup> Activities include:</p> <ul style="list-style-type: none"> <li>• Enabling individuals to gain access to drugs</li> <li>• Supporting adherence to the individual’s prescribed drug regimen in order to receive the full health benefits afforded by the medications.</li> <li>• Providing services to monitor the client’s progress in taking HIV-related medications.</li> </ul>	<p>2.4) Documentation of activities undertaken to improve access to medications and increase and support adherence to medication regimens.</p>
<p>2.5) Data sharing agreement in place with the Centers for Medicare and Medicaid (CMS) for the purpose of tracking True Out of Pocket Costs (TrOOP) for ADAP clients with Medicare Part D for whom ADAP is paying Medicare Part D Premiums, co-pays and deductibles.<sup>x</sup></p> <p><i>Note:</i> A data system necessary to track and account for ADAP payments for TrOOP costs must be established. These systems may be located at the ADAP’s PBM.</p>	<p>2.5) Documentation of amount of ADAP funds used to pay TrOOP for clients with Medicare Part D and a signed data sharing agreement between ADAP and CMS.</p>
<p>2.6) Facilitate client access to ADAP medication programs via:</p> <ul style="list-style-type: none"> <li>• Direct purchase medication program for clients not eligible for other programs or awaiting open enrollment</li> <li>• Insurance program</li> <li>• Medication co-pay, co-insurance and deductible assistance</li> <li>• Insurance continuation assistance.</li> </ul>	<p>2.6) Documentation of:</p> <ul style="list-style-type: none"> <li>• Medication distribution system for directly dispensing physician prescribed medications to eligible clients</li> <li>• Insurance purchasing program for eligible clients <ul style="list-style-type: none"> <li>▪ Health Insurance Marketplace Program (HIMAP)</li> </ul> </li> <li>• Medication co-pays, co-insurance and deductible assistance for eligible clients</li> </ul>

	<ul style="list-style-type: none"> <li>▪ Insurance Continuation Assistance Program (ICAP)</li> <li>▪ Medicare Part D Assistance Program (MPAP)</li> </ul>
<b>Transition and Discharge</b>	
<p>2.7) Client discharged when ADAP services are no longer needed, goals have been met, upon death or due to safety issues. (<i>see 2.8</i>)</p> <p><u>Prior to discharge:</u> Reasons for discharge and options for other service provision should be discussed with client. Whenever possible, discussion should occur face-to-face. If not possible, provider should attempt to talk with client via phone. If verbal contact is not possible, a certified letter must be sent to client's last known address. If client is not present to sign for the letter, it must be returned to the provider.</p> <p><u>Documentation:</u> Client's record must include:</p> <ol style="list-style-type: none"> <li>a) Date services start</li> <li>b) Special client needs</li> <li>c) Services needed/actions taken, if applicable</li> <li>d) Date of discharge</li> <li>e) Reason(s) for discharge</li> <li>f) Referrals made at time of discharge, if applicable.</li> </ol> <p><u>Transfer:</u> If client transfers to another location (state), agency or service provider, transferring agency will provide discharge summary and other requested records within 5 business days of request. If client moves to another area, transferring agency will make referral for needed services in the new location.</p> <p><u>Unable to Locate:</u> If client cannot be located, agency will make and document a minimum of three follow-up attempts on three separate dates (by phone or in person) over a three-month period after first attempt. A certified letter must be mailed to the client's last known mailing address within five business days after the last attempt to notify the client. The letter will state that the case will be closed within 30</p>	<p>2.7) Documentation of discharge plan and summary in client's record with clear rationale for discharge within 30 days of discharge, including certified letter, if applicable.</p>

days from the date on the letter if an appointment with the provider is not made.

Withdrawal from Service: If client reports that services are no longer needed or decides to no longer participate in the Service Plan, client may withdraw from services. Because clients may withdraw for a variety of reasons it may be helpful to conduct an exit interview to ensure reasons for withdrawal are understood, or identify factors interfering with the client's ability to fully participate if services are still needed. If other issues are identified that cannot be managed by the agency clients should be referred to appropriate agencies.

Administrative Discharge: Clients who engage in behavior that abuses the safety or violates the confidentiality of others may be discharged. Prior to discharging a client for this reason, the case must be reviewed by leadership according to that agency's policies. Clients who are discharged for administrative reasons must be provided written notification of and reason for the discharge, and must be notified of possible alternative resources. A certified letter that notes the reason for discharge and includes alternative resources must be mailed to the client's last known mailing address within five business days after the date of discharge, and a copy must be filed in the client's chart.

Case Closure	
<p>2.8) Case will be closed if client:</p> <ul style="list-style-type: none"> <li>• Obtains other resources for medication treatment;</li> <li>• No longer meets eligibility criteria;</li> <li>• Decides to transfer to another agency;</li> <li>• Needs are more appropriately addressed in other programs;</li> <li>• Moves out of state;</li> <li>• Fails to provide updated documentation of eligibility status thus, no longer eligible for services;</li> <li>• Fails to maintain contact with the ADAP staff for a period of three months despite three (3) documented attempts to contact client;</li> <li>• Can no longer be located;</li> <li>• Withdraws from or refuses funded services, reports that services are no longer needed, or no longer participates in the individual service plan;</li> <li>• Exhibits pattern of abuse as defined by agency’s policy.</li> <li>• Becomes housed in an “institutional” program anticipated to last for a minimum of 30 days, such as a nursing home, prison or inpatient program; or</li> <li>• Is deceased.</li> </ul>	<p>2.8) Documentation of case closure in patient’s record with clear rationale for closure.</p>
<p><b>3.0 Client Rights and Responsibilities</b>  <i>National Monitoring Standards: Provision of Part B funded HIV primary medical care and support services, to the maximum extent, without regard to either: the ability of the individual to pay for such services, or the current or past health conditions of the individuals served.<sup>xi</sup></i></p>	
Standard	Measure
<p>3.1) Services are available and accessible to any individual who meets program eligibility requirements.</p> <p>All providers shall be in compliance with all applicable federal, state, and local anti-discrimination laws and regulations, including but not limited to the American’s with</p>	<p>3.1) Written eligibility requirements and non-discrimination policy on file.</p>

<p>Disabilities Act. All providers shall adopt a non-discrimination policy prohibiting the refusal of rendering any service on the basis of fact or perception of race, color, creed, religion, national origin, ancestry, age, sex, sexual orientation, gender identity, domestic partner status, marital status, height, weight, disability, or HIV/AIDS diagnosis.</p> <p>Each provider shall make available to clients a process for requesting interpretation services, including American Sign Language.</p>	
<p>3.2) Client's Rights and Responsibilities policy exists which requires each client to sign &amp; date a form indicating they has been offered: a) explanation of the policy, and b) copy of <i>Client's Rights and Responsibilities</i> and to communicate client's understanding of the policy.</p>	<p>3.2) Written policy on file.</p>
<p>3.3) Explanation of <i>Client's Rights and Responsibilities</i> is provided to each client.</p> <p>Client rights include:</p> <ul style="list-style-type: none"> <li>○ Be treated with respect, dignity, consideration, and compassion;</li> <li>○ Receive services free of discrimination;</li> <li>○ Be informed about services and options available.</li> <li>○ Participate in creating a plan of services;</li> <li>○ Reach an agreement about the frequency of contact the client will have either in person or over the phone.</li> <li>○ File a grievance about services received or denied;</li> <li>○ Not be subjected to physical, sexual, verbal and/or emotional abuse or threats;</li> <li>○ Voluntary withdraw from the program;</li> <li>○ Have all records be treated confidentially;</li> </ul> <p>Have information released only when:</p> <ul style="list-style-type: none"> <li>○ A written release of information is signed;</li> <li>○ A medical emergency exists;</li> </ul>	<p>3.3) Current <i>Client's Rights and Responsibilities</i> form signed and dated by client and located in client's record.</p>



<ul style="list-style-type: none"> <li>○ There is an immediate danger to the client or others;</li> <li>○ There is possible child or elder abuse; or</li> <li>○ Ordered by a court of law.</li> </ul> <p>Client responsibilities include:</p> <ul style="list-style-type: none"> <li>○ Treat other clients and staff with respect and courtesy;</li> <li>○ Protect the confidentiality of other clients;</li> <li>○ Participate in creating a plan of service;</li> <li>○ Let the agency know any concerns or changes in needs;</li> <li>○ Make and keep appointments, or when possible, phone to cancel or change an appointment time;</li> <li>○ Stay in contact with the agency by informing the agency of change in address and phone number; respond to phone calls and mail and</li> <li>○ Avoid subjecting the agency’s staff to physical, sexual, verbal and/or emotional abuse or threats.</li> </ul>	
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**4.0 Grievance Process**

<b>Standard</b>	<b>Measure</b>
<p>4.1) Grievance policy exists which requires each client to sign &amp; date indicating they has been offered: a) explanation of the policy, b) copy of <i>Grievance Procedure</i> and c) communication of client’s understanding of the policy.</p> <p>Policy shall describe the process for resolving client grievances, including identification of whom to contact and applicable timelines.</p> <p>Policy shall be available in languages and formats (e.g. for persons with disabilities) appropriate to populations served.</p>	<p>4.1) Written grievance procedure on file, available in languages and formats appropriate to populations served.</p>
<p>4.2) Explanation of <i>Grievance Procedure</i> is provided to each client. Clients may file a grievance if their request for services is denied</p>	<p>4.2) Current <i>Grievance Procedure</i> form signed and dated by client and located in client’s record.</p>

or if they have any complaint or concern about the services received.	
4.3) Grievance process shall be fair and expeditious for resolution of client grievances.	4.3) Documentation of client grievances, status and resolution.
4.4) Review of grievance policy yearly with client signature.	4.4) Current <i>Client's Rights and Responsibilities</i> form signed and dated by client and located in client's record.
<b>5.0 Personnel Qualifications (including licensure)</b>	
<b>Standard</b>	<b>Measure</b>
5.1) All ADAP personnel will have experience and education commensurate with their duties and tasks.	5.1) Copy of qualifications in employee personnel file.
5.2) Newly employed ADAP personnel, must complete orientation within 2 weeks of hire and the following training within 180 days of hire: <ul style="list-style-type: none"> <li>• HIV 101</li> <li>• HIV Care Continuum</li> <li>• Affordable Care Act/Insurance Marketplace</li> <li>• Medicare Part D</li> <li>• Cultural competency</li> <li>• Legal ramifications, including confidentiality</li> <li>• HIV Prevention</li> </ul>	5.2) Documentation of training completed in personnel file.
<b>6.0 Cultural and Linguistic Competency</b>	
<b>Standard</b>	<b>Measure</b>
6.1) ADAP services are culturally and linguistically competent, client-guided and community based. At a minimum, documentation should include: <ul style="list-style-type: none"> <li>• Experience with providing services to the diverse ethnic, linguistic, sexual or cultural populations targeted;</li> <li>• Capacity of staff, including volunteers and Board, to design, provide and evaluate culturally and linguistically appropriate services;</li> <li>• List of cultural competency trainings completed by staff</li> </ul>	6.1) Documentation of cultural and linguistic competence as reported in annual Cultural and Linguistic Competency Report.
6.2) Easy-to-understand print and multimedia materials and signage in the languages commonly used by the populations in the service area shall be available. <sup>xiii</sup>	6.2) Culturally and linguistically appropriate materials and signage accessible.

**7.0 Privacy and Confidentiality (including securing records)**

Standard	Measure
7.1) Client confidentiality policy exists which include: 1) Release of information requirements, and b) Health Insurance Portability and Accountability Act.	7.1) Written client confidentiality policy on file at provider agency.
7.2) Client’s consent for release of information is determined.	7.2) Current <i>Release of Information Form</i> signed and dated by client and provider representative and located in client’s record. Each release form indicates who may receive the client’s information and has an expiration of not more than 12 months from date of signature.
7.3) Each client file is stored in a secure location. Electronic patient records are protected from unauthorized use.	7.3) Files stored in locked file or cabinet with access limited to appropriate personnel. Electronic files are secure with password protection and access is limited to appropriate personnel.
7.4) Annual submission of <i>Verification of Receipt of Assurance of Key Requirements</i> document by all staff that handle client identifying information.	7.4) Documentation of signed <i>Verification of Receipt of Assurance of Key Requirement</i> forms.

**8.0 Quality Management**

*National Monitoring Standards: Implement a Clinical Quality Management Program (CQM) to include: a) written QM plan; b) quality expectations for providers and services; c) method to report and track expected outcomes; d) monitoring of provider compliance with HHS treatment guidelines and Part B Program’s approved Standards of Care.<sup>xiii</sup>*

Standard	Measure
8.1) Measure and report client health outcomes using ADAP measures approved by VDH.	<p>8.1) Performance measurement data on the following indicators:</p> <ul style="list-style-type: none"> <li>• ADAP clients receiving medications or medication co-payments and/or deductibles, regardless of age, will have an HIV viral load less than 200 copies/mL at last HIV viral load test during the measurement year.</li> <li>• Percentage of ADAP applications that were approved or denied for new ADAP enrollment within two weeks of ADAP receiving a complete application during the measurement period.</li> <li>• Percentage of people enrolled in RW Part B-funded Program living with</li> </ul>

	<p>HIV and receiving ADAP services, regardless of age, who will have an HIV viral load less than 200 copies/mL at last HIV viral load test during the measurement.</p>
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<sup>i</sup> HRSA/HAB Ryan White HIV/AIDS Program Services: Clarifications on Ryan White Program Services: Clarifications on Eligible Individuals & Allowable Uses of Funds, Policy Clarification Notice #16-02, (10/22/18 revision).

<sup>ii</sup> HRSA/HAB Ryan White Part B ADAP Manual (2016), pp. 29-51.

<sup>iii</sup> HRSA/HAB Division of State HIV/AIDS Programs National Monitoring Standards for Part A and B Grantees: Universal (April, 2013), p. 4.

<sup>iv</sup> HRSA/HAB Ryan White HIV/AIDS Program Services: Clarifications on Ryan White Program Eligibility Determinations and Recertification Requirements, Policy Clarification Notice #13-02

<sup>v</sup> Public Health Service Act; Sections 2605(a)(6), 2617 (b) (7) (F), 2664 (f) (1), and 2671 (i).

<sup>vi</sup> HRSA/HAB Division of State HIV/AIDS Programs National Monitoring Standards—Program Part B (April, 2013), pp. 85-89.

<sup>vii</sup> HRSA/HAB Division of State HIV/AIDS Programs National Monitoring Standards—Program Part B (April, 2013), p. 5.

<sup>viii</sup> HRSA/HAB Division of State HIV/AIDS Programs National Monitoring Standards—Program Part B (April, 2013), p. 85.

<sup>ix</sup> HRSA/HAB Division of State HIV/AIDS Programs National Monitoring Standards—Program Part B (April, 2013), pp.86-87.

<sup>x</sup> HRSA/HAB Division of State HIV/AIDS Programs National Monitoring Standards—Program Part B (April, 2013), pp. 88-89.

<sup>xi</sup> HRSA/HAB Division of State HIV/AIDS Programs National Monitoring Standards—Program Part B (April, 2013), pp. 61-62.

<sup>xii</sup> National Standards for Culturally and Linguistically Appropriate Services (CLAS) in Health and Health Care. Available at:

<https://www.thinkculturalhealth.hhs.gov/assets/pdfs/EnhancedNationalCLASStandards.pdf>

<sup>xiii</sup> HRSA/HAB Division of State HIV/AIDS Programs National Monitoring Standards—Program Part B (April, 2013), p. 71.