Ryan White Part B
Aids Drug Assistance Program (ADAP)
Service Standard

Important: Prior to reading service-specific standards, please read the HRSA/HAB National Monitoring Standards—Universal, HRSA/HAB National Monitoring Standards—Part B, and the Universal Standards outlined in this document.

Service Category Definition

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 limited or no health care coverage. ADAPs may also use program funds to purchase health insurance for eligible clients and pay for services that enhance access to, adherence to, and monitoring of antiretroviral therapy. 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. ADAP clients must meet all eligibility criteria as established by the state (See eligibility section on page 3).

Purposes

- Provide FDA-approved medications to low-income clients with HIV disease who have no coverage or limited health care coverage
- Raise awareness of its programs to individuals with HIV and their families to facilitate access to treatment
- Share required data to track True Out-of-Pocket (TrOOP)

Components

- Assistance by paying for medication
- Paying for health insurance*
- Cost-Sharing Assistance*

*Health insurance premium and cost-sharing assistance are provisions of financial assistance for eligible individuals living with HIV to maintain a continuity of health insurance or to receive medical benefits under a health insurance program. This includes premium payments, co-insurance, co-payments, and deductible amounts.

Examples of allowable services billed to Health Insurance Premium and Cost-Sharing Assistance include co-payments for medications not covered by the ADAP formulary, office visit co-payments, etc. A “service unit” of Health Insurance Premium and Cost-Sharing Assistance is documented per service provided (i.e., one payment equals one service unit) as “Health

Insurance Premium and Cost-Sharing Assistance" in CAREWare, with a corresponding dollar amount.

Program Guidance

Each state funded for AIDS Drug Assistance Program Treatments is responsible for:

- Establishing ADAP eligibility within the legislative guidelines of the Ryan White CARE Act and HRSA/HAB policies and guidelines.
- 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 represented 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

Key Components

- ADAP funds are used only to support eligible activities
  - provision of FDA-approved medications
  - purchase of health insurance
- Assistance with medication co-pays, co-insurance and deductibles
- Therapeutic services that enhance access to, adherence to and monitoring of antiretroviral therapy

Key Activities

- Provision of Services
- Eligibility determination
- Ensuring payer of last resort
- Expenditure monitoring
- Records management

1.0 Provision of Services

(HIV/AIDS Programs National Monitoring Standards – Program Part B, Section L, 2013)

Standard	Measure	Documentation
1.1 Provide a formulary of medications to HIV- infected persons for the treatment of HIV disease and the prevention of opportunistic infections. https://dphhs.mt.gov/publichealth/hivstd/treatment	1.1.a A medication formulary that includes pharmaceutical agents from all the approved classes of antiretrovirals in the PHS Clinical	1.1.a. Notes in client file, verifying the client received the medication formulary

	Practice Guidelines for use of Antiretroviral Agents in HIV-infected Adults and Adolescents 1.1.b. Medications on the formulary are FDA approved. 1.1.c. Participation in National Association of State and Territorial AIDS Directors (NASTAD) ADAP Crisis Task Force Drug Discount Program	 1.1.b. Medications on the formulary are listed in the FDA directory of approved drugs. https://www.fda.gov/drugs/drug-approvals-and-databases/national-drug-code-directory 1.1.c. 340B Certification from HRSA/Office of Pharmacy Affairs (OPA) on file
1.2.a. State to provide outreach (awareness) to individuals with HIV/AIDS, and as appropriate, the families of such individuals regarding ADAP and its programs 1.2.b. State facilitates access to treatments for such individuals and to make therapeutics available	1.2.a. State's efforts and methods used to raise awareness of the ADAP and its programs to individuals with HIV/AIDS and their families. 1.2.b. Progress made in making therapeutics available to populations in needs of assistance.	1.2.a. and b. Notes on file regarding new ADAP enrollment of individuals with HIV/AIDS from populations or locations identified as hard to reach
1.3 ADAP to encourage, support, and enhance adherence to and compliance with treatment regimens including medical monitoring. Activities include : • Enabling individuals to gain access to drugs • Supporting adherence to the individual's prescribed drug regimen to receive the full	1.3. Five percent of ADAP's budget is being used for services that improve access to medications, increase and support adherence to medication regimens, and monitor client progress in taking HIV related medications.	1.3.a. Expenditures demonstrate that up to five percent of the ADAP budget is used for activities undertaken to improve access to medications, increase and support adherence to medication regimens, and help clients monitor their progress in taking HIV-related medications.

health benefits afforded by the medications. • Providing services to monitor the client's progress in taking HIV-related medications.		1.3.b. If applicable, documented explanations regarding extraordinary factors justifying the need to expend greater than 5% of the ADAP budget on adherence tools and techniques. Note: Currently there is a cap of 5% of ADAP funds for these activities. A waiver of ADAP funds up to 10% is possible if extraordinary circumstances can be documented.
1.4.a. Track 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. 1.4.b. Data systems necessary to track and account for ADAP payments for TrOOP costs.	1.4.a. Data sharing agreement in place with the Centers for Medicare and Medicaid (CMS) 1.4.b. Reports to ADAP that illustrate Part D payments and client advancement through the three tiers of Medicare Part D	1.4.a. Signed data sharing agreement between ADAP and CMS and expenditures of ADAP funds used to pay TrOOP for clients with Medicare Part D 1.4.b. The PBM submits detailed reports to ADAP that illustrate Part D payments and client advancement through the three tiers of Medicare Part D and their varied payment structures as the result of TrOOP being tracked
1.5.a. Facilitate client access to ADAP medication programs 1.5.b. Medication co-pay, co-insurance and deductible assistance	1.5.a. Direct purchase medication program for clients not eligible for other programs or awaiting open enrollment Insurance program 1.5.b. Insurance purchasing program for eligible clients	1.5.a. Medication distribution system for directly dispensing physician prescribed medications to eligible clients 1.5.b. Health Insurance Marketplace Program

1.5.c. Insurance continuation assistance	1.5.c. Referral to State Health Insurance Program (SHIP) counselors.	(HIMAP); Medication co-pays, co-insurance and deductible assistance for eligible clients 1.5.c. Procedures and policies in place for referring and ensuring eligible individuals continue to receive insurance assistance.

2.0 Eligibility and Intake

(HRSA/HAB DMHAP and DSHAP National Monitoring Standards-Universal-Part A & B, 2013 Section B, April 2013.)

- Eligibility determination process requiring documentation in patients' records of low-income status based on a specified percent of the FPL, proof of an individual's HIV-positive status, and Montana residency.
- Determination and documentation of patient eligibility every six months

Eligibility

2.1.a. The client's eligibility for Ryan White Part B services is determined.	2.1.a. Applicants must: Be diagnosed with HIV; Live in Montana; Apply through the MT DPHHS or one of the seven contracted agency's Ryan White Medical Case Management services; Have an individual or family income at or below 500% of the Federal Poverty Level (FPL); Provide proof of income, changes in insurance coverage, or any changes in residency every six months for recertification. Additionally, clients that file taxes must submit their most current 1040 tax return forms as proof of income or one of the other acceptable	2.1.a. Documentation of all eligibility items are in client's file.

2.1.b. Client agrees to participate in the insurance option that best meets the client's medical needs and for which the client is eligible.	forms of income as defined by the MT ADAP. 2.1.b. Agreement with client to participate in the most appropriate insurance option	2.1.b. Signed agreement in client file.
2.2. Ryan White Part B funds are used as the payer of last resort.	2.2. Ryan White Part B funds 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.	2.2 Denial of Medicaid and/or other programs' coverage of RW medications and/or services.

Intake

2.2) Eligibility for ADAP services is determined after receiving a completed application	2.2. Eligibility is determined within 14 days of completed application	2.2) Signed and dated eligibility determination (by ADAP provider) in client's record.

Referral

Standard	Measure	Documentation
2.3 A referral by a provider or a client self-referral is made for the initiation of services.	2.3 . A referral for ADAP is made on the intake/eligibility forms	2.3. Signed and dated referral (provider or client) in client file.

Recertification

Standard	Measure	Documentation
2.4 Client must be certified every six months to receive Ryan White Services. There is no grace period.	2.4.a. HIV diagnosis 2.4.b. income less than 500% FPL 2.4.c. MT residency	2.4.a. Signed and dated medical diagnosis in client file 2.4.b. Statement(s) of income in client file. 2.4.c. Power bill, or other documentation demonstrating MT residency in client file.

3.0 Expenditure Monitoring

(HRSA/HAB Division of State HIV/AIDS Programs National Monitoring Standards – Program Part B, 2013)

Standard	Measure	Documentation
3.1 Part B providers will effectively utilize and allocate expenditures	3.1.a. The Part B provider has a procedure to monitor/manage expenditures of Health Insurance Premium and Cost-Sharing that ensures funding will be available throughout the program year. 3.1.b. The Part B provider will track utilization of assistance. 3.1.c. The Part B provider must track use of funds to ensure the total combined amount per client must not exceed the determined award amount per contract year.	3.1.a. Procedure(s) for managing expenditures on file 3.1.b. Evidence of tracking system 3.1.c. Contract amounts are entered into the payment system not to exceed the determined award amount per contract year.
3.2 No payment may be made directly to clients, family, or household members.	3.2. Provide mechanism through which payment can be made on behalf of the client.	3.2. Part B and C providers will produce and maintain records demonstrating payments were made to appropriate members.

4.0 Records Management

(HRSA/HAB Division of State HIV/AIDS Programs National Monitoring Standards – Program Part B, Section A)

Standard	Measure	Documentation
4.1 Records will reflect compliance with the Health Insurance Premium and Cost-Sharing Assistance standards outlined above.	4.1 and 4.2. Part B providers of Health Insurance Premium and Cost-Sharing Assistance will maintain records for each client served.	4.1 and 4.2. Health Insurance Premium and Cost-Sharing records include: • Date client received assistance

4.2 Records should be complete, accurate, confidential and secure.		• Documentation that the client meets eligibility criteria • Copy of check of voucher • Amount

5.0 Transition and Discharge

Purpose

- A client is considered active within the agency when he or she actively seeks and receives services and has been seen or contacted within the time frame required by the Acuity Scale. The client's case may be closed for a variety of reasons, including:
- Client has satisfactorily met goals.
- The client moves out of state.
- The client decides to transfer to another agency.
- The client withdraws from or refuses Case Management services, reports that services are no longer needed, or no longer participates in the Case Management plan.
- The client can no longer be located.
- The client becomes housed in an "institutional" program anticipated to last for a minimum of 30 days, such as a nursing home, prison or inpatient program.
- The client's needs are more appropriately addressed in other programs.
- The client exhibits a pattern of abuse as defined by agency's policy.
- The client is deceased.

Standard	Measure	Documentation
5.1 Client discharged when ADAP services are no longer needed, goals have been met, upon death or due to safety issues. (see 5.2)	5.1 Services are no longer needed, special client needs have been addressed and/or need referrals, goals are met, provider establishes rationale for discharge.	5.1 Dated notes in client file that include the following: • Date services began • Special client needs • Services needed/actions taken, if applicable • Date of discharge • Reason(s) for discharge • Referrals made at time of discharge, if applicable
5.2 Reasons for discharge and options for other service provision(s) should be discussed with client. Whenever possible, discussion should occur face-	5.2. Record of discharge plan that includes clear rationale for discharge within 30 days of discharge, including certified letter, if applicable.	5.2 Record of discharge plan and summary of reasons for discharge, including certified letter, if applicable, is in client file.

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.		
5.3.a. If client transfers to another location (state), agency or service provider, transferring agency will provide discharge summary and other requested records. 5.3.b. If client moves to another area, transferring agency will make referral for needed services in the new location.	5.3.a. Provider will provide discharge summary and other requested records within five business days of request. 5.3.b. Transferring agency will make referral(s)	5.3.a. Dated discharge summary and any other requested records in client's file. 5.3.b. Dated referrals in client's file.

Unable to Locate

If a client cannot be located, the case management 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 Management case will be closed within thirty (30) days from the date on the letter if the client does not make an appointment with the Case Manager.

Withdrawal from Care

If a client reports that services are no longer needed or decides to no longer participate in the Care Plan, then the client may withdraw from services. Clients may decide to withdraw for a variety of reasons. It may be helpful to conduct an exit interview to ensure reasons for withdrawal are understood, or to better identify factors that are 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 case management agency, Case Managers are encouraged to refer these clients to agencies which are skilled in providing the needed services.

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 the Case Manager's supervisor 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.

Standard	Measure	Documentation
5.4 A discharge summary is written for every client.	5.4 Discharge summary must be written within 30 days of discharge.	5.4 Dated discharge summary in client file.
5.5 If applicable, a certified letter is sent to the client, informing him or her about the discharge.	5.5 The certified letter, if applicable, must be mailed to the client within two weeks of discharge.	5.5 A copy of the certified letter, if applicable, is placed in client's file.
5.6 Progress notes are included that lead up to the determination of discharge.	5.6 Progress notes are dated.	5.6 Dated progress notes are in each client's file.

6.0 Personnel Qualifications

(HRSA/HAB Division of State HIV/AIDS Programs National Monitoring Standards – Program Part B, Section C)

Standard	Measure	Documentation
6.1 Medical Case Managers (MCMs) must have a minimum of a B.A. in Social Work (BSW), M.A. in Social Work (MSW)—licensure preferred, or other related health or human service degree from an accredited college or university; or current MT-licensed Registered Nurse (RN) and an Association of Nurses in AIDS Care (ANAC) Certification (preferred); or related experience for a period of two years, regardless of academic preparation.	6.1.a. If licensed, a copy of the most current Montana license must be kept in the Medical Case Manager's personnel file. 6.1.b. Copies of degrees and/or certifications, demonstrating appropriate education and training.	6. 1. a. and b. Copies of degrees, certifications and/or licenses (as applicable) in personnel file.
6.2 All Medical Case Managers must complete a minimum training regimen within one year of their hire date that includes: (a) HIV Case Management Standards, (b) Counseling, Treatment	6.2 Copies demonstrating completion of required trainings Note: If newly hired Medical Case Managers have previously obtained all the required	6.2 Dated documentation of required/additional training should be kept in the Medical Case Manager's personnel file.

and Referral Services (CTRS) training to include HIV disease processes, treatment, testing, legal ramifications to include confidentiality, counseling/referral and prevention, (c) cultural competency and (d) AIDS Drug Assistance Program (ADAP)/Insurance training.	training, they do not need to repeat it.	
6.3 All Medical Case Managers, except Montana Licensed Clinical Social Workers (LCSW), Licensed Clinical Professional Counselors (LCPC) or nationally Certified Case Managers (CCM) must complete an MT DPHHS-approved basic case management training program within one year of their hire date [e.g. Mountain West AIDS Training Center (MWAETC) offers a variety of trainings and consultation services.	6.3.a.and b. and 6.4 Documents that demonstration completion of training(s)	6.3. and 6.4 Dated documentation of completion applicable training(s) in the Medical Case Manager's personnel file.
6.4 All Medical Case Managers are recommended to complete 12 hours of continuing education in HIV/AIDS each year. Appropriate continuing education opportunities will be identified by Case Managers .		

7.0 Grievance Policy

Purpose

To ensure that consumers may voice a complaint or grievance.

Procedures

All Ryan White providers must have a grievance policy that is posted in the facility. Additionally, all clients will receive a copy of the grievance procedure. The first step in filing a grievance is with the *agency providing the service*. Consumers may voice a complaint or grievance to their Case Manager. Clients are expected to attempt resolution at the local level. If, however, clients are unable to resolve the issue, they may pursue a second step—filing a grievance with the State Health Department. Within 30 days of the local determination, consumers may file the complaint or grievance in writing (See Appendix A for sample form) to:

Montana DPHHS
HIV/STD Program, Ryan White Part B
Attn: HIV Treatment Coordinator
1400 E. Broadway
Room C-211
Helena MT 59601

An applicant may submit a complaint on the following grounds:

- The client believes the sub-recipient is not treating them fairly.
- The client believes the sub-recipient is not providing quality services.
- The client was denied services.

The applicant (client) must state all the facts and arguments for the appeal in the form provided (Appendix A), to include detailed descriptions of the action the client is appealing and the relief or correction the applicant is requesting. The form *must* be signed by the client.

The Ryan White Part B Program Manager will respond in writing within 14 days of receipt of the grievance or complaint informing the client of the time and place of a meeting with the Ryan White Part B Program Manager and other appointed HIV/STD state staff.

Standard	Measure	Documentation
7.1.a. The Grievance Policy has been explained to each client. Clients may file a grievance if their request for services is denied or if they have any complaint or concern about the services received. 7.1.b. Policy shall describe the process for resolving client grievances, including identification of whom to contact and applicable timelines. 7.2 Policy shall be available in languages and formats (e.g. for persons with disabilities) appropriate to populations served.	7.1.a. and b. Each client is given a copy of the Grievance Policy to sign, indicating understanding of the reasons for filing a grievance, as well as the process for doing so.	7.1.a Signed and dated Grievance Policy in client file. 7.1.b. Written Grievance Policy on file. 7.2. Policy is available in languages and formats appropriate to populations served.

8.0 Linguistic Competency

Standard	Measure	Documentation
8.1.Health services are culturally and linguistically competent, client-guided and community based.	8.1.a. Experience with providing services to the diverse ethnic, linguistic, sexual or cultural populations targeted; 8.1.b.Capacity of staff, including volunteers and Board, to design, provide and evaluate culturally and linguistically appropriate services; 8.1.c. List of cultural competency trainings completed by staff	8.1 a and b: Documentation of cultural and linguistic experience/competence 8.1.c. Completed trainings documented in personnel files.
8.2 Each provider shall make available to clients the process for requesting interpretation services, including American Sign Language	8.2. Interpreter(s) is/are available.	8.2. A list of interpreters and contact information in program file.

9.0 Client Rights and Responsibilities

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.

Standard	Measure	Documentation
9.1 Services are available and accessible to any individual who meets program eligibility requirements.	9.1.a. Written eligibility requirements, following federal standards 9.1.b. Non-discrimination policy	9.1.a Proof of client's eligibility documented in client file 9.1.b. Non-discrimination policy on file.
9.2.a. All providers shall comply with all applicable federal, state, and local anti- discrimination laws and	9.2 Written policies, including the federal	9.2.a. Policies are on file.

regulations, including but not limited to the American's with Disabilities Act. 9.2.b. All providers shall adopt a non-discrimination policy prohibiting based on the 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 AIDS/HIV. 9.2.c. Each provider shall make available to clients the process for requesting interpretation services, including American Sign Language.	ADA policy and specific MT laws	9.2.b and c. Policies are posted for clients to view.
9.3.a. Clients understand their rights, which include: •Be treated with respect, dignity, consideration, and compassion; •Receive services free of discrimination; •Be informed about services and options available. •Participate in creating a plan of services; •Reach an agreement about the frequency of contact the client will have either in person or over the phone. •File a grievance about services received or denied; •Not be subjected to physical, sexual, verbal and/or emotional abuse or threats;	9.3.a. Client's Rights and Responsibilities policy on file 9.3.b. Policy has been explained to client.	9.3.a and 9.3.b Current Client's Rights and Responsibilities form signed and dated by client and located in client's record.

•Voluntary withdraw from the program; •Have all records be treated confidentially; •Have information released only when: •A written release of information is signed; •A medical emergency exists; •There is an immediate danger to the client or others; There is possible child or elder abuse; or b) Ordered by a court of law. Clients understand their responsibilities, which include: • Treat other clients and staff with respect and courtesy; • Protect the confidentiality of other clients; • Participate in creating in a plan of service; • Let the agency know any concerns or changes in needs; • Make and keep appointments, or when possible to phone to cancel or change an appointment time; • Stay in contact with the agency by informing the agency of change in address and phone number, as well as responding to phone calls and mail and • Not subject the agency's staff to physical, sexual,		

verbal and/or emotional abuse or threats. 9.3.b. Explanation of Client's Rights and Responsibilities is provided to each client.		

10. Secure Client Records, Privacy, and Confidentiality

Standard	Measure	Documentation
10.1. Client confidentiality is ensured	10.1.a. Client confidentiality policy that includes a Release of Information (ROI) 10.1.b. Health Insurance Portability and Accountability Act (HIPPA) compliance	10.1.a. Written client confidentiality policy on file at provider agency 10.1.b.HIPPA documentation is on file and posted where clients can view it.
10.2) Client's consent for release of information is determined.	10.2 Current Release of Information Form signed and dated by client and provider representative	10.2 Signed and dated ROI located in client file. Each release form indicates who may receive the client's information and has an expiration of not more than 12 months.
10.3) Electronic patient records are protected from unauthorized use.	10.3 Each client file is stored in a secure location.	10.3.a. Files stored in locked file or cabinet with access limited to appropriate personnel. 10.3.b. Electronic files are password protected with access limited to appropriate personnel.
10.4 Annual submission of Verification of Receipt of Assurance of Key Requirements	10.4. All staff that handle client-identifying information document	10.4 Signed Verification of Receipt of Assurance of Key Requirement forms on file

11.0 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. Care

11.1) Measure and report client health outcomes using ADAP measures approved by MT DPHHS.	11.1 Performance measurement data on the following indicators: a) 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. b) 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. c) Percentage of people enrolled in RW Part B-funded Program living with 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.