AIDS Drug Assistance Program Report

Prepared by

The Virginia State Health Commissioner for
The Chairmen of the House Appropriations and
Senate Finance Committees

October 1, 2016

The following report was developed in response to the directive under the VIRGINIA ACTS OF ASSEMBLY – CHAPTER 780, Item 292:

F. The State Health Commissioner shall monitor patients who have been removed or diverted from the Virginia AIDS Drug Assistance Program due to budget considerations. At a minimum, the Commissioner shall monitor patients to determine if they have been successfully enrolled in a private Pharmacy Assistance Program or other program to receive appropriate anti-retroviral medications. The Commissioner shall also monitor the program to assess whether a waiting list has developed for services provided through the ADAP program. The Commissioner shall report findings to the Chairmen of the House Appropriations and Senate Finance Committees annually on October 1.

EXECUTIVE SUMMARY

The Virginia Department of Health (VDH) eliminated the Virginia (VA) Acquired Immuno-deficiency Syndrome (AIDS) Drug Assistance Program (ADAP) waiting list in August 2012. As of March 31, 2016, 6,039 clients were enrolled in VA ADAP with approximately 78% receiving medications through insurance support and 22% directly receiving medications through local health departments (LHDs) or other distribution sites. Providing medication access through purchasing insurance plays a key role in ADAP sustainability.

Background

VA ADAP provides access to life-saving medications for the treatment of Human Immunodeficiency Virus (HIV) and related illnesses for low-income clients through the provision of medications or through assistance with insurance costs. The program is primarily supported with federal Ryan White (RW) Treatment Extension Act Part B grant funding, which is distributed using a formula based on living HIV and AIDS cases to all states and territories in the United States. ADAP also receives support from state general funds. Other funding sources include Medicaid reimbursements for clients who receive retroactive eligibility and rebates from pharmaceutical manufacturers.

Accomplishments

3,610 VA ADAP clients enrolled in qualified health plans available under the Patient Protection and Affordable Care Act (ACA) in 2016, an increase of 338 clients over 2015 ACA enrollment.

- The continuing collaboration between VDH and statewide ADAP stakeholders contributed to enrollment success. VDH provided regular updates on enrollment progress through multiple communication strategies and worked proactively with partners to identify and solve challenges to maximize insurance enrollment.
- VDH is collaborating with state-supported HIV/AIDS Resource and Consultation Centers and federally-supported AIDS Education and Training Centers to provide insurance education programs to community partners.

Challenges

- Client enrollment continues to increase disproportionately to funding, and the program is increasingly reliant upon several one-time sources of funding.
- Several variables will affect future program need, including ACA carrier availability, ACA plan premium costs and formulary composition, geographic coverage of plans, availability of rebates from the pharmaceutical industry, and whether VA will expand Medicaid to provide coverage for all persons with incomes at or below 138% of the federal poverty level (FPL).

Recommendations

- Expanding Medicaid could result in coverage for 68% of current VA ADAP clients with substantial cost savings to VA ADAP.
- Current projections indicate a range of additional funding needs from $8.7 million to a worst-case scenario of $36 million for April 2017 to March 2018. Careful monitoring of all variables and immediate reassessment will be necessary to determine if resources are adequate to serve all eligible clients in the next grant year (GY).

List of Acronyms

AAC	ADAP Advisory Committee
ACA	Affordable Care Act
ADAP	AIDS Drug Assistance Program
AIDS	Acquired Immunodeficiency Syndrome
CAC	Certified Application Counselor
CDC	Centers for Disease Control and Prevention
CD4	Cluster of Differentiation 4
DMAS	Department of Medical Assistance Services
ERF	Emergency Relief Funding
FPL	Federal Poverty Level
GY	Grant Year
HCV	Hepatitis C Virus
HIV	Human Immunodeficiency Virus
HPV	Human Papillomavirus
HRSA	Health Resources and Services Administration
ICAP	Insurance Continuation Assistance Program
LHD	Local Health Department
MOOP	Maximum Out-of-Pocket
MPAP	Medicare Part D Assistance Program
NASTAD	National Alliance of State and Territorial AIDS Directors
OIs	Opportunistic Infections
PLWH	Persons Living with HIV
PrEP	Pre-Exposure Prophylaxis
RW	Ryan White
SPAP	State Pharmaceutical Assistance Program
VA	Virginia
VDH	Virginia Department of Health

Background

VA ADAP provides access to life-saving medications for the treatment of HIV and related illnesses for low-income clients through the provision of medications or through assistance with insurance premiums and medication co-payments. During RW GY 2010[1], VA ADAP experienced historically high pharmaceutical expenditures and unprecedented program utilization compared to the previous two years due to rising unemployment rates and corresponding loss of insurance, expanded HIV testing efforts, and new HIV treatment guidelines recommending initiation of HIV treatment as early as possible. Subsequently, in November 2010, aggressive cost containment measures were instituted. These included the implementation of a waiting list for ADAP services, the transition of some clinically stable patients to other sources of medication access, a reduction to the ADAP formulary, and enrollment restrictions. Figure 1 below shows VA ADAP clients served and enrolled from April 2009 to March 2016, with an overlay of the waiting list period. VA ADAP defines a client as enrolled if their application for ADAP has been approved and they have not been disenrolled from the program. A client is considered served if they have received direct medications, a premium payment, or a medication cost share payment in a specific time period.

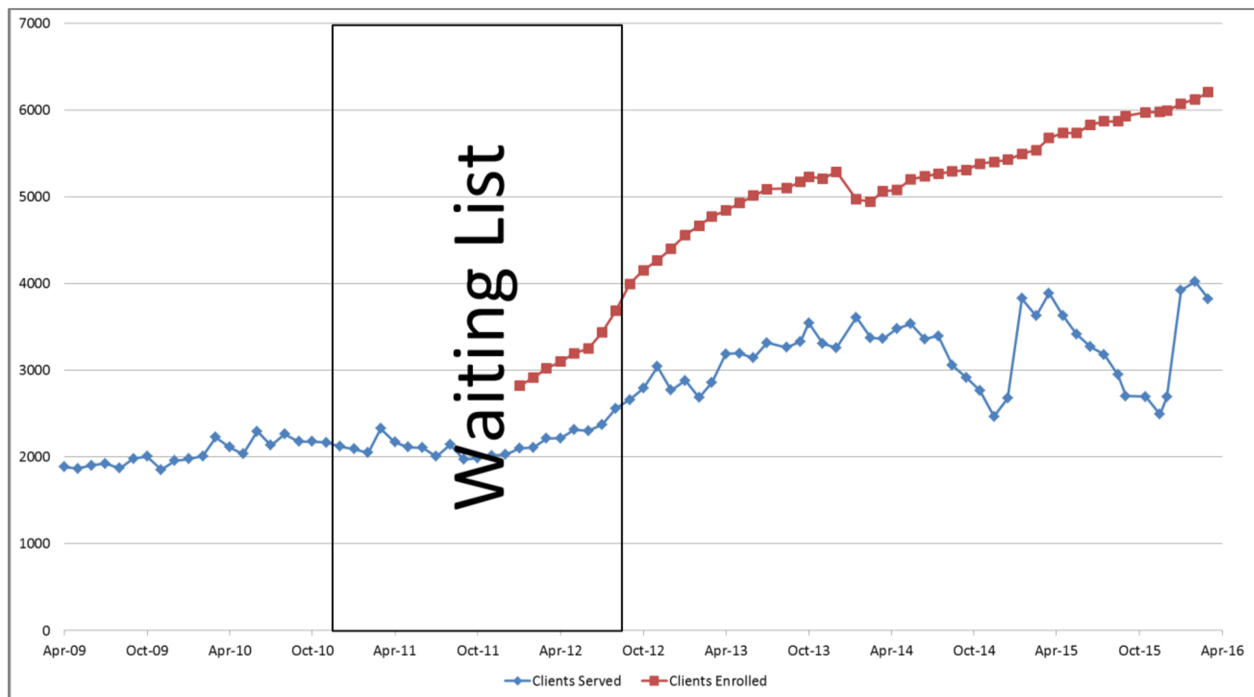

Figure 1. ADAP Clients Enrolled and Served: 2009 to 2016

VDH began enrolling new and wait-listed clients back onto ADAP who met certain clinical criteria in November 2011 due to increased program and pharmaceutical efficiencies and the availability of additional federal and state ADAP funds. VA ADAP began the final steps toward elimination of the waiting list in July 2012 based on the effectiveness of using a medical triaging process and supported by weekly monitoring of ADAP service utilization and expenditures. The ADAP waiting list was entirely eliminated by August 30, 2012.

[1] RW Part B GYs run from April 1 to March 31 and are named for the year in which they begin.

ADAP client enrollment continues to increase steadily with a net enrollment growth of 44 clients per month between April 2015 and March 2016, which accounts for clients disenrolling due to inactivity, death, moving out of state, or becoming ineligible for other reasons. As of March 31, 2016, 6,039 clients were enrolled in VA ADAP, with 78% receiving medications through insurance support and 22% directly receiving medications through LHDs or other distribution sites. Directly purchased medications and insurance cost support are provided in the following ways:

- ACA and Other Insurance: The ACA provides unprecedented access to health insurance for eligible residents of the United States. VA ADAP pays premiums and medication cost shares (co-payments, coinsurance, and deductibles) for plans that meet federal and state ADAP criteria. Payments for medication cost shares count toward an individual's annual total maximum-out-of-pocket (MOOP) expenditures and are capped annually at $6,850 (or less depending on income). Additionally, ADAP supports medication cost shares for eligible clients who have other forms of private insurance meeting federal and state ADAP criteria under the Insurance Continuation Assistance Program (ICAP). VA ADAP can support more than two clients annually through insurance for the cost of directly purchasing medications for one client.
- Medicare Part D Assistance Program (MPAP): The MPAP pays premiums and medication cost shares for ADAP-eligible clients enrolled in Medicare Part D. VA ADAP began paying these costs in 2007 supported by state-appropriated State Pharmaceutical Assistance Program (SPAP) funds. As client needs for this program increased, SPAP and ADAP funding were utilized. VA ADAP can support almost three clients annually on MPAP for the cost of directly purchasing medications for one client.
- Direct Purchase ADAP: Medications on the ADAP formulary are purchased at discounted rates by the Central Pharmacy and are sent to LHDs and other sites for client distribution. Clients who are not eligible for or unable to enroll in other insurance or Medicare Part D may receive medications through Direct Purchase ADAP.

The ADAP medication formulary includes antiretroviral medications indicated for the treatment of HIV, selected vaccines, antilipidemics, antiglycemics, mental health treatment medications, medications to treat hepatitis C virus (HCV) infection, medications to treat or prevent opportunistic infections (OIs), and smoking cessation medications and products. ADAP covers all cost shares for medications on selected insurance plans' formularies. Eligible clients must have family incomes at or below 400% FPL. The majority of enrolled clients (90%), however, have incomes below 250% FPL; and 57% of the VA ADAP population lives at or below 100% FPL. Eligibility is assessed every six months to ensure ADAP serves only those who meet program criteria.

Historically, Direct Purchase ADAP served the majority of clients. The majority (78%) of ADAP clients, however, now receive ACA, MPAP, or ICAP support. The cost savings and program revenue realized by serving clients through insurance has enabled the program to serve all eligible clients and add two single-tablet regimens to treat HIV, an additional HCV medication, and the human papillomavirus (HPV) vaccine to the formulary. Cost savings from insurance enrollment also allowed funding for oral health and medical case management, including treatment adherence and co-payments for laboratory services for RW Part B clients.

ACA Enrollment and Implementation

VDH facilitated the enrollment of 3,610 VA ADAP clients in ACA Marketplace plans during the 2016 enrollment period, an increase of 338 clients from the previous year. In response to a request from an insurance carrier, VA ADAP supported plans in all metal levels in 2016, including Gold and Platinum. Gold and Platinum plans have higher monthly premiums but lower deductible and out-of-pocket costs and were cost neutral to the program for clients who do not qualify for any ACA Marketplace plan credits or subsidies. Clients electing to have ADAP support the premium and medication cost share expenses could select between approved eligible plans available in their jurisdiction of residence. Clients at certain income and subsidy levels were instructed to enroll in a Silver level plan in order to maximize cost effectiveness. No single plan covered the entire state, and plan benefits and costs varied considerably.

Implementation Strategy

VA ADAP prioritized client groups for enrollment. Eligible clients that had not yet enrolled in an ACA plan were prioritized based on income and subsidy levels to ensure access to insurance. Clients with incomes of 101-250% FPL are most cost effective to insure, due to tax credits and subsidies, resulting in reduced premium and medication cost share amounts. Clients with incomes of 251-400% FPL were prioritized next, as they receive tax credits that lower their monthly premiums. Clients with incomes at or below 100% FPL were contacted next for enrollment. Although clients with incomes less than 100% of FPL receive no tax credit or subsidization for ACA plans, purchasing insurance remains more cost effective than directly purchasing medications for this group. Finally, clients eligible for insurance plan re-enrollment were contacted to obtain updated 2016 information.

In 2016, VA ADAP continued client engagement efforts utilized during the 2015 open enrollment period. Strategies included direct mailings to ADAP clients and were customized for those re-enrolling and those newly enrolling to ACA plans. The mailings provided information about VA ADAP-supported plans, directions for re-enrollment, and a referral list of selected Certified Application Counselor (CAC) enrollment sites. Letters were included with monthly medication refills provided through Direct Purchase ADAP to prepare clients for the transition to insurance. ADAP-supported plans and criteria for obtaining ADAP assistance with plan costs were posted to the ADAP website at www.vdh.virginia.gov/ADAP and were communicated widely to clients and other stakeholders.

VA ADAP recruited RW service contractors throughout the state to implement innovative strategies to help enroll clients into ACA plans. Contractors utilized CACs and enlisted the help of social workers and medical case managers. Staff were hired by contractors to travel to clients' homes, medical provider sites, and LHDs to assist with enrollment. Contractors referred eligible clients to community sites and developed an enrollment tracking system to coordinate efforts with VA ADAP. VA ADAP encouraged enrollment assistors to assess a client's potential need for services outside of medications when choosing an insurance plan.

VA ADAP continued communication with stakeholders by distributing a weekly email to RW providers, LHDs, clients, insurance assistors, and community advocates to keep them aware of changes, challenges, enrollment numbers, policy additions, and frequently asked questions. All communications were posted to the VA ADAP website. To streamline and track enrollment

efforts, VA ADAP held weekly statewide calls for CACs to provide updates on progress toward enrollment goals, information about ADAP-approved insurance plans and premium payment requirements, and an opportunity to address any concerns or problems. At the conclusion of open enrollment, VDH held debriefings with ADAP staff and leadership, CACs, and RW contractors to assess the overall ACA open enrollment process and to strategize how to improve the process for the next open enrollment period. An online survey was created and distributed to stakeholders, including medical providers, case managers, and clients, to obtain feedback and identify future needs. Survey responses indicated that the communication from VDH was helpful and that the Marketplace enrollment process as a whole was easier to navigate. Respondents identified concerns about the impact of clients' health literacy on their understanding of how to re-enroll and use health insurance effectively. Respondents indicated they would like to receive VDH's information earlier on which plans VA ADAP can cover. Unfortunately, delays in release of covered plans resulted from factors outside VDH's control, including the very short time frame between when plan information becomes available and the beginning of open enrollment, the complexity of the assessment required to determine which plans meet ADAP clients' needs, and the late request from a carrier to allow clients to enroll in Gold plans.

Challenges and Resolutions

VDH collaborated with the VA Bureau of Insurance to review insurance plan details before the third open enrollment period began. This allowed ADAP to prepare educational materials and instructions regarding ADAP insurance cost support as early as possible.

Navigating the re-enrollment process again presented challenges in 2016. All enrollees were required to contact the Marketplace to confirm income and any other changes that may have occurred prior to open enrollment, as changes to family size, marital status, income, or residence can impact tax credit eligibility. Some clients required repeated prompting to ensure this action occurred. VDH continued paying premiums based on prior rates for clients automatically re-enrolled to prevent gaps in coverage during the re-enrollment process. ADAP staff reconciled new premium amounts through time-intensive follow up with clients and insurance company representatives.

Incomplete medication formularies offered by insurers continued to be challenging. While no insurers eliminated HIV medications from their formularies, they also did not add medications. Despite this, widespread access problems did not occur. Providers continue to voice complaints regarding the amount of time required to complete the prior authorization and medication exception process through insurers. VA ADAP continually referred providers to the guidance created for each insurance company's unique medication exception and prior authorization procedures. This guidance is available on the VA ADAP website.

The Health Resources and Services Administration (HRSA) mandates that all RW-funded agencies vigorously pursue clients' enrollment into insurance. VDH requires RW Part B contractors to report their efforts to help clients enroll in and utilize insurance on a monthly basis to assure compliance with this rule. Clients are regularly screened for health coverage eligibility and educated about ACA-mandated consequences for not applying for health coverage, including financial penalties implemented by the federal government.

Current Utilization

ADAP utilization has continued to increase since the waiting list was eliminated in August 2012, as illustrated in Figure 2 below. Utilization reflects the calendar year structure of ACA and Medicare Part D plans. ADAP pays insurance-related medication cost shares and captures that data early in the year. As the year progresses, deductible and co-payment MOOP limits are met. Clients continue to access medications, but ADAP is not fully able to track that utilization since the program is not paying for those medications. VA ADAP has initiated an incentive payment to its pharmacy benefits manager to improve data capture with mixed results. Enrollment in VA ADAP was 6,039 as of March 31, 2016 with a net average of 44 new clients per month between April 2015 and March 2016.

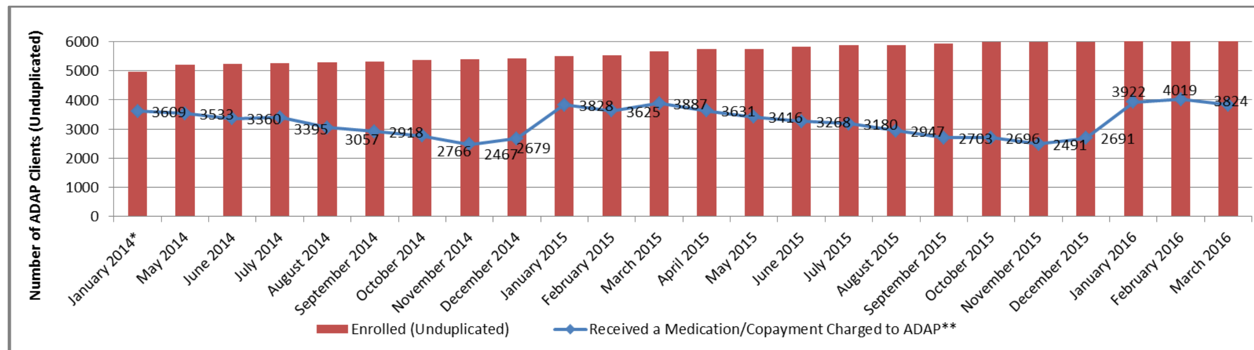

Figure 2. ADAP Clients Enrolled and Receiving Medications: Unduplicated 2014 to 2016

Figure 3 below illustrates monthly enrollment by program from January 2014 through March 2016. Enrollment has shifted from primarily Direct Purchase ADAP in early 2014 to the majority of clients enrolled in ACA in 2016. Eligible Direct Purchase ADAP clients will receive assistance enrolling in ACA plans during the next open enrollment period occurring November 1, 2016-January 31, 2017.

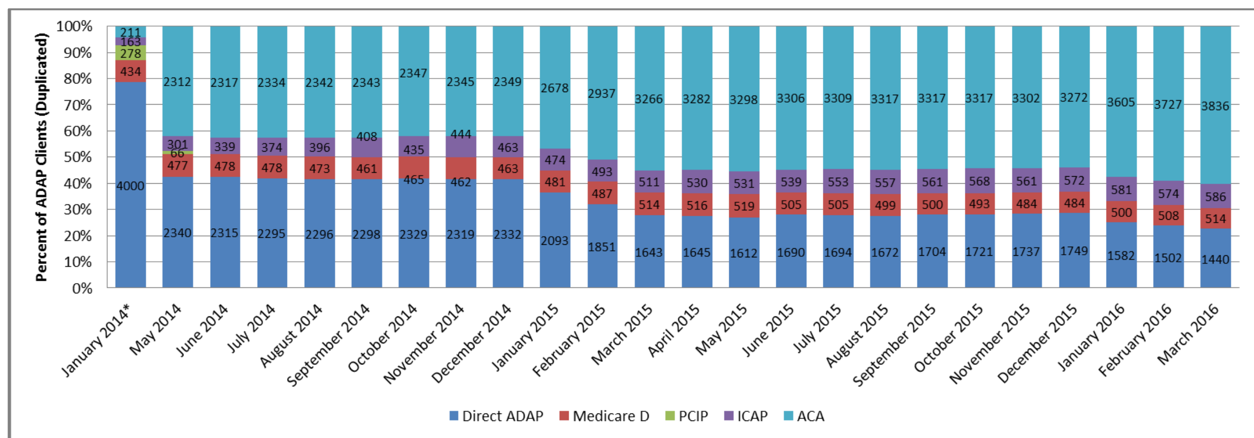

Figure 3. ADAP Enrolled by Program: 2014 to 2016

Note: Pre-Existing Condition Insurance Plans (PCIP) were a temporary feature of ACA used as a stop-gap method of coverage until the first open enrollment period with the asterisk (*) indicating the start of full ACA plan coverage.

Monitoring ADAP enrollment and utilization is critical to ensuring that resources can meet growing program need. Currently, the ADAP Leadership Team (a multidisciplinary group consisting of program, fiscal, pharmacy, and administrative staff) reviews program enrollment and utilization numbers by program component on a weekly basis.

Demand for ADAP services continues to grow and is driven by several key factors, including covering medication co-payments for those with private insurance, heightened national efforts expanding HIV testing, improved outreach efforts linking clients into care, and Department of Health and Human Services HIV treatment guidelines that support initiating treatment with medications early in the course of disease. The goal of early treatment initiation is to suppress HIV—lowering the amount of virus in the body. Viral suppression improves health outcomes for persons living with HIV (PLWH) and reduces transmission to uninfected individuals. Increasing medication access to more PLWH is key to effectively controlling the epidemic.

Figure 4 below illustrates viral loads for ADAP clients enrolled for at least 12 months as of March 2016 (n=4,929) have significantly improved from 46% with an undetectable viral load upon their intake into ADAP up to 70% with a current viral load that is undetectable (less than 200 copies/ml). Viral load is an important measure for individual, as well as community health, as undetectable viral loads decrease transmissibility of HIV.

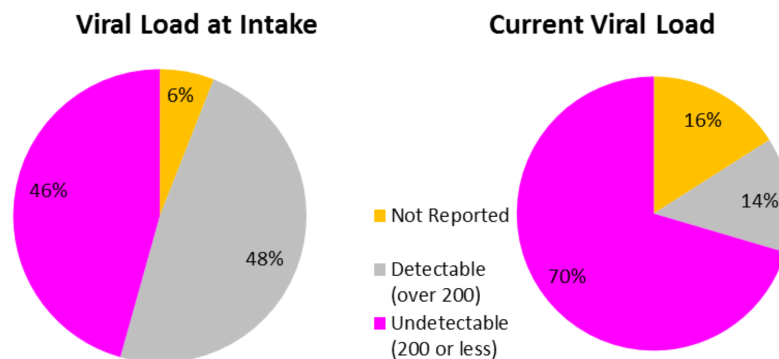

Figure 4. Clinical Outcomes: Viral Loads for ADAP Clients: March 2016

ADAP continually ensures services are provided only to those persons eligible and with medication need. Between April 2015 and March 2016, 1,178 persons were disenrolled from ADAP or denied upon initial application. Primary reasons for disenrollment included not picking up medications within the last six months (46.5%), having another payer source for medications, including Medicaid (30.9%), and moving out of state (10%).

Fiscal Status

Based on projections, anticipated ADAP costs for the current RW Part B GY, April 1, 2016, to March 31, 2017, (GY 2016) will be approximately $51 million before rebate revenue and $34.4 million after rebates. Federal funds, including RW Part B formula-based funding and $10.2 million in one-time ADAP Emergency Relief Funding (ERF), make up 67% of the current budget to meet that need. State funds make up 7%, including $2.6 million allocated to ADAP

and the $200,000 annual SPAP appropriation. Anticipated program revenue generated from pharmaceutical rebates and Medicaid retroactive billing comprise the remaining 26%. As discussed in the "Projections" section of this report, several unknown variables, such as 2017 insurance plans' premium costs and formulary composition, as well as an uncertain future for pharmaceutical manufacturers rebates to ADAP for medication co-payments, have a significant impact on ADAP sustainability. Current resources are adequate to cover projected premium increases up to 15%. If current insurance medication access (formularies, exception processes, and preauthorization requirements) or rebate structures change, an immediate reassessment will be necessary to determine whether available resources are adequate to serve all eligible ADAP clients.

Federal RW Part B funds awarded through HRSA are VA ADAP's largest funding source. The annual formula-based award amounts fluctuate due to changes in Congressional appropriations and the number and distribution of living HIV cases nationally. VA receives federal funding under RW Part B to provide services to those living with HIV who cannot otherwise afford medications or care. VA allocates approximately 72% of the federal award, including the ADAP ERF, to medication access (ADAP insurance support and direct medication purchase) with 17% supporting other health-related direct services and 11% supporting agency administration and program infrastructure.

As illustrated in the Figures 5 and 6 below, 55% of ADAP medication expenditures and 71% of insurance expenditures in GY 2015 were supported by federal funds. Federal funding included $10.2 million in ADAP ERF and a portion of the total award of $1.8 million in RW Part B Supplemental.[2] The amounts of both the ADAP ERF and RW Part B Supplemental are unpredictable. The ADAP ERF is competitively awarded, and previous awards have ranged from $3 million to $11 million. During GY 2015, ADAP ERF was used to directly purchase medications and insurance for ADAP-eligible clients. Of note, ADAP ERF has been awarded on varying time cycles by HRSA, and amounts in this report are being reported to synchronize with the RW GY 2015 (April 1, 2015 – March 31, 2016). The RW Part B Supplemental award is also competitive, and the GY (September 30, 2014 – September 29, 2015) differs from the RW GY. RW Part B Supplemental amounts represented in Figures 5 and 6 were for RW Part B Supplemental GY 2014 but expended during the portion of the GY that overlapped with RW GY 2015. Recent previous awards have ranged from $384 thousand in 2012 to $1.8 million in 2014.

[2] The purpose of RW Part B Supplemental is to complement the HIV care and treatment services provided by the states/territories through RW Part B and ADAP funds and is not restricted to medication access. The amount of funding is determined by the applicant's ability to demonstrate the need in the state/territory based on an objective and quantified basis.

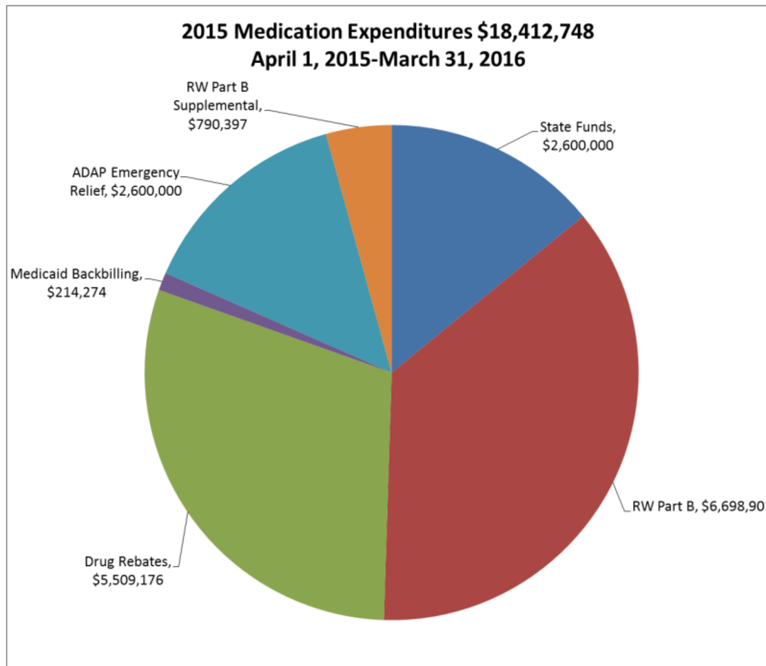

Figure 5. RW GY 2015 VA ADAP Medication Expenditures by Funding Source

Finally, state funds represented in Figures 5 and 6 reflect appropriations made in state fiscal year 2015 that were expended during the RW GY 2015. During GY 2015, state contributions to VA ADAP were $2.8 million (including the $200,000 SPAP appropriation). These funds were used to purchase medications and insurance.

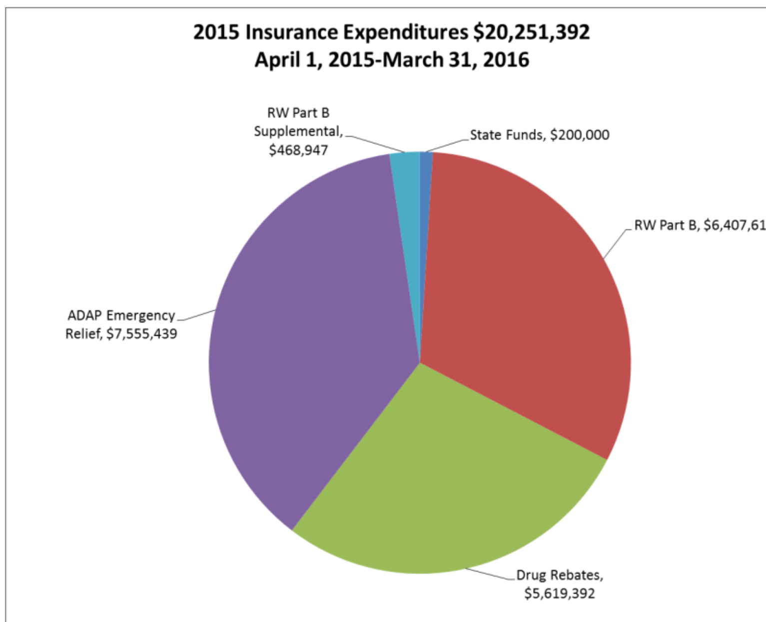

Figure 6. RW GY 2015 VA ADAP Insurance Expenditures by Funding Source

Procedures to Monitor Medication Inventory and Real-Time Utilization Data
VDH Central Pharmacy maintains a log of all ADAP medication purchases, including the balance of available funds for medication purchase, a process that was implemented in 2010. This information is helpful in calculating the daily direct purchase medication cost of operating ADAP. This enhanced monitoring of daily medication expenditures provides real-time information on medication costs used to support the ADAP.

Projections of Program Utilization and Costs

Forecasting for VA ADAP is done on a regular basis, as data on utilization for each program component (ACA, ICAP, MPAP, and directly purchased medications) is tracked monthly. The number of served clients (those actively receiving ADAP medications, a premium payment, or a medication cost share payment through insurance support) is the best predictor for ADAP costs. For GY 2015, 6,132 unduplicated clients received ADAP services with 2,024 receiving only direct medication services, 3,246 receiving only insurance services, and 862 receiving both direct medication and insurance services (some clients access medications to avoid treatment disruption until insurance support is established). For GY 2016 and GY 2017, 6,591 clients and 7,235 clients, respectively, are projected to receive services. The annual number of clients served is estimated using a formula based on a regression analysis of 15 years of historical data and utilizing monthly rather than annual averages. This methodology is necessary to account for monthly variances due to disenrollment, death, or ineligibility for ADAP for other reasons. Projections that do not account for monthly variations would result in under projection of program costs and over projection of clients served.

Projections for Medicare Part D and ACA insurance support account for the calendar year cost structure of the insurance plans (ADAP pays higher costs at the beginning of the calendar year and reduced or no costs as the year progresses once deductibles, coinsurance, and MOOP expenditures are satisfied.); client eligibility occurring throughout the year as a result of age or disability; and variations in MOOP expenditures based on client income and tax credit eligibility. For example, Medicare Part D has larger client cost outlays in the early part of the calendar year (paid by VA ADAP). When clients reach $4,850 in costs during the year, the cost outlay reduces to 5% of the medication costs. Most ADAP clients, whose HIV medications are costly, reach this limit by March, and then Medicare pays 95% of costs for the remainder of the year resulting in reduced costs to ADAP.

ACA costs for calendar year 2016 were released in late 2015, and the MOOP expenditures (paid by VA ADAP) for those not receiving any tax subsidies were no higher than $6,850 per person annually. Projections were completed for GY 2016 and GY 2017 using the data available for the ACA plans from 2016, as 2017 and 2018 cost structures are not yet available. For those receiving subsidy tax credits whose incomes are between 101% and 250% of the FPL, this MOOP expenditure is reduced to a percentage of the client's income and can be as low as $750 annually. Those with incomes between 101% and 400% FPL are also eligible for premium subsidies. Those with incomes below 100% FPL are not eligible for any subsidies, and ADAP pays full premiums and MOOP expenditures for those clients. Coverage through insurance is still more cost effective than purchasing medications due to capped costs and the ability to generate rebates from pharmaceutical companies on medication copayments.

Projections for client cost and utilization in 2016 through 2018 have been developed utilizing the current FPL distribution of the ADAP population and current enrollment numbers for ACA in 2016. The FPL distribution by program for clients enrolled in ADAP in March 2016 is illustrated in Figure 7 below. The majority of clients for both Direct Purchase ADAP (68.5%) and ACA (60.6%) are at or below 100% FPL. For ACA, this portion of the ADAP population is the most expensive to insure but is still more cost-effective than direct medication purchase. For the overall ADAP population, 66.2% are below 138% FPL and would be eligible for Medicaid expansion (last bar on right).

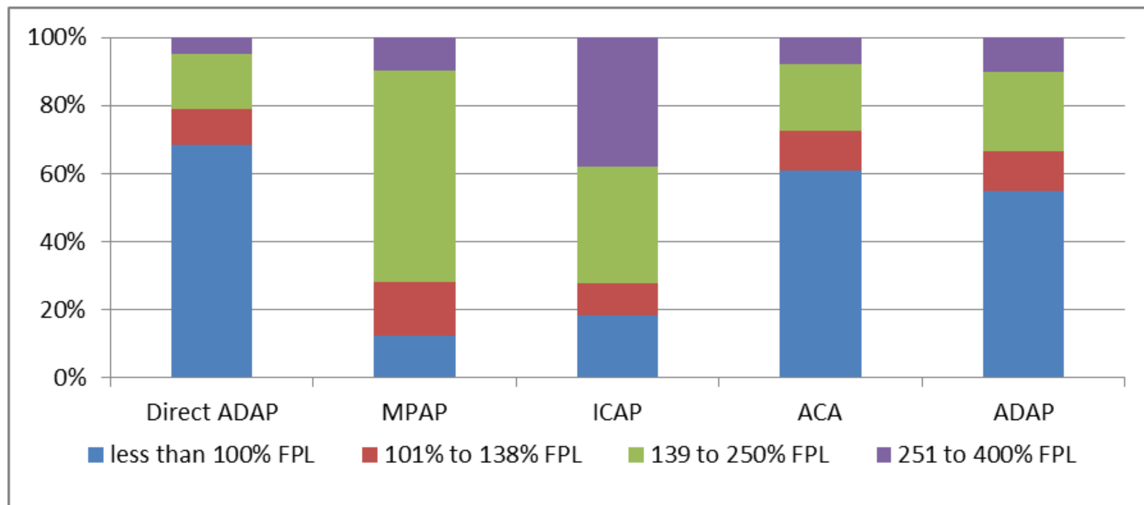

Figure 7. FPL Distribution by Program for Clients Enrolled in ADAP in March 2016

Using the average 2016 ACA costs from the plans supported by VA ADAP, average annual costs for the population at or below 100% FPL would be $11,050 per client per year ($6,850 out of pocket, $4,200 premiums). This annual cost is reduced by pharmaceutical rebates received on cost shares paid for medications. Rebates cannot be counted as funding for the same period in which the costs that generate them are incurred because rebates are typically received several months later as a result of pharmaceutical companies' payment practices.

Rebates

Rebates are paid by the pharmaceutical companies to state ADAPs through voluntary agreements where full rebates are received on partial payments for medications purchased through insurance cost shares with ADAP funding. Rebate terms are negotiated between the ADAP Crisis Taskforce, a representative group of state ADAPs led by the National Alliance of State and Territorial AIDS Directors (NASTAD). Rebates make up 45% of national ADAP funding and constituted 29% of the GY 2015 VA ADAP expenditures. Rebates can be strategically used to either purchase medications or offset other HIV program costs so that federal dollars can be maximized for medication purchase.

Calculating revenue projections from the rebates is challenging. The amount of rebate received varies over time. Medication prices, upon which rebates are based, are proprietary information that is not released by the pharmaceutical companies. There is also a significant lag time in receiving rebates after the initial cost outlay by ADAP. The rebate can be received from the

pharmaceutical company anywhere from 3 to 12 months after the initial copayment. These factors make it difficult to project rebate revenue and to ensure that the revenue will be available within a specific grant or fiscal year.

Cost Projections
Figure 8 below illustrates ADAP projections for the remaining and next RW GYs (which run April 1 through March 31) for three different scenarios. Costs associated with ACA plans for the next two calendar years are still unknown and will impact projections and subsequent budget needs. Premium cost changes will particularly influence projections, as those payments are made monthly for the entire year. Highest costs due to medication costs prior to meeting out-of-pocket limits generally are seen in the first quarter of the calendar year, which is the final quarter of the currently budgeted GY 2016. Substantial increases in premium costs during that time, therefore, could impact GY 2016 final quarter resource needs.

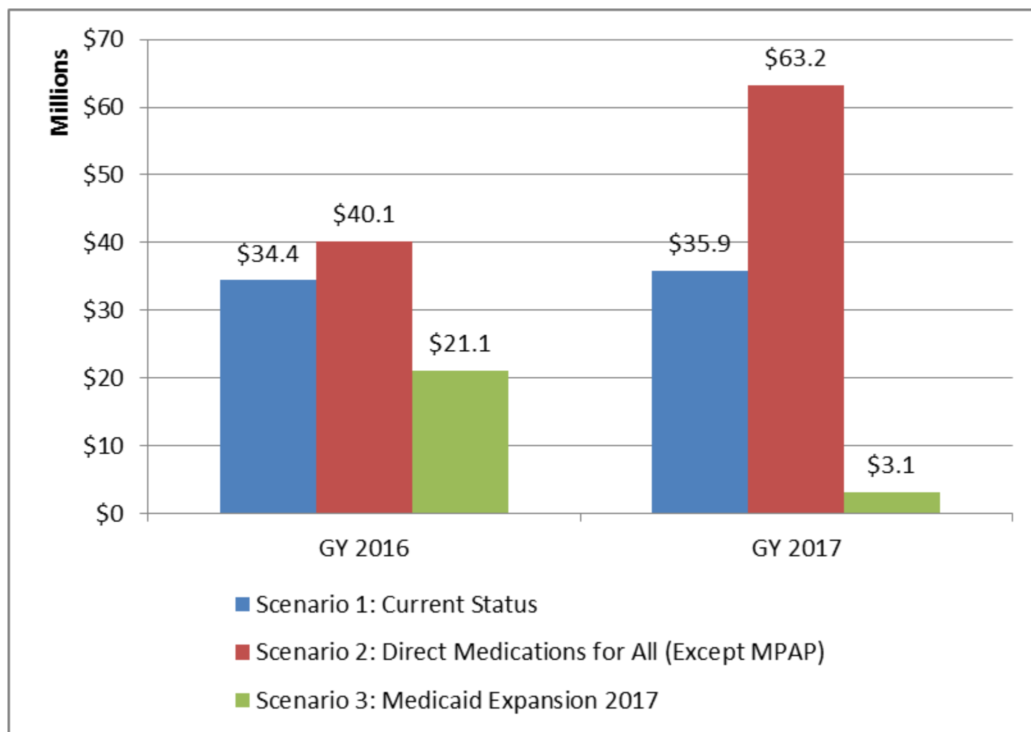

Figure 8. VA ADAP Projected Costs (Post Rebate): GY 2016 and GY 2017

The three scenarios in Figure 8 show the impact of different potential payer sources for ADAP clients. These scenarios include: 1) current continuation of ACA with 15% premium increases in 2017 and 2018; 2) the discontinuation of ACA and other insurance, except for Medicare Part D in 2017, with the majority of ADAP clients on direct purchase medications; and 3) Medicaid expansion in January 2017, which would reduce the number of persons on ADAP. Scenario 1 includes the following assumptions: 4,000 ADAP clients will be enrolled into ACA in calendar year 2017, and 4,300 will be enrolled in calendar year 2018. Scenarios 1 and 3 include the assumption that ACA premiums will increase by 15% in 2017 and 15% in 2018.

All scenarios also assume there is a 12-month time difference from when ADAP pays the copayment for the medication and when the rebate on that copayment is received. In Scenario 3, this leads to some cost savings at the beginning of GY 2017 due to a large amount of rebate revenue from the previous year combined with decreased enrollment in ADAP because of Medicaid expansion.

Scenario 1, which is the continuation of current ADAP practices and enrollment, shows that post-rebate costs for GY 2016 and GY 2017 range from $34M to $36M. Scenario 2, where ACA and other private insurance plans are not available for ADAP clients, increases costs in GY 2017 by $28.3M to $63.2M, as very little rebate revenue would be generated. In contrast, Scenario 3, Medicaid expansion in 2017, which would reduce the ADAP population by 66%, reduces costs in GY 2017 to $3.1M, as rebate revenue from GY 2016 still would be received.

Sustainment

As described in this report, a number of factors will impact the ability to continue to meet the growing demand for VA ADAP services. ADAP infrastructure and policy strive to support a program that is cost effective, carefully monitored, and beneficial to public health. Key drivers in determining how resources will meet the growing need include future costs related to insurance plans offered under the ACA (particularly premium costs and inclusion of all necessary HIV medications on insurance plan formularies), as well as the status of Medicaid expansion in VA.

Eligibility and Utilization Monitoring

VA ADAP will continue to monitor client eligibility and medication utilization to ensure the provision of cost-effective and clinically beneficial services. Criteria for enrollment into ADAP requires the applicant be a resident of the Commonwealth; have no other sources or personal ability to pay for medications or insurance coverage; receive income of 400% or less of the FPL; and have a documented diagnosis of HIV infection from a medical provider. Each ADAP enrollee is recertified for eligibility every six months. The recertification process ensures that enrollees continue to qualify financially for ADAP. It also allows VDH to quickly know if a current ADAP enrollee has been approved for Medicaid, Medicare, or private insurance coverage for medications so that the client can be served by the most cost-effective component of ADAP or disenrolled if they are no longer eligible. In addition, clients must consistently pick up their medications to remain eligible for VA ADAP. Inconsistent use of medications can result in viral resistance, making these costly medications ineffective. The client and medical provider are notified of ADAP disenrollment if the client does not access medications in a six-month period. ADAP services will continue if a mitigating factor, such as a medically indicated treatment break, is identified. Clients may reapply to ADAP as needed, if circumstances change. VA ADAP is assessing the provision of additional adherence-related services to support clients with achieving maximum health outcomes and further reducing transmission risks due to unsuppressed viral load.

Implementing Provisions of the ACA

Insurance purchase and support through the ACA is currently the most cost-effective mechanism for providing medications to VA ADAP clients. VA ADAP will continue to support efforts to ensure all eligible clients are enrolled into ACA plans during the next open enrollment period.

Currently, 22% of the VA ADAP population is not insured. VDH continues to focus on creating strategies that support insurance enrollment for eligible clients. Providers, LHDs, and other medication access sites have received lists of uninsured clients to determine if they are eligible for Marketplace enrollment, still reside in the Commonwealth, or if they qualify for Medicare or Medicaid. Additionally, VA ADAP is assessing the cost effectiveness and feasibility of enrolling clients into off-Marketplace plans. These plans, like those found through the Marketplace, would not have pre-existing condition clauses, would provide essential health benefits, and would expand access to medical care. It is important to note, however, that off-Marketplace plans would not have the benefit of ACA tax credits.

Prior to the beginning of open enrollment, VA ADAP will continue to work with the VDH Office of Licensure and Certification and the VA Bureau of Insurance to review plan details. Earlier assessment allows for the timely identification of plans that can be supported with ADAP funds so that clients and other stakeholders have this information at the beginning of the open enrollment period. The ability to determine supported plans early not only facilitates educational efforts to providers and clients but also identifies potential coverage issues.

VA ADAP will continue to engage and educate policy makers and other stakeholders about the necessity of ensuring access to all HIV antiretroviral medications either through improvements in insurance plans' formularies or a timely preauthorization/medication exception processes. VA ADAP also will continue efforts to educate partners and community groups about the needs of low-income PLWH, including the need for affordable insurance coverage and medication formulary adequacy. The state-supported HIV/AIDS Resource and Consultation Centers continue to develop statewide training for CAC sites, case managers, patient navigators, and service providers on how to enroll in and effectively use health insurance under ADAP.

Formulary Completeness

The completeness of ACA plan formularies varies by insurance carrier. Many carriers cover single-tablet HIV regimens and HCV medications through an administratively burdensome medication exception or prior authorization process completed by medical providers. If the insurance carrier approves an exception or prior authorization request, provision of that medication continues into the next year as long as the client stays on the same insurance plan. If insurers deny exception or prior authorization requests, VA ADAP works with medical providers to supply the needed medications. Insurance carriers also routinely request additional labs and invasive procedures, such as liver biopsies, to be conducted prior to authorizing HCV medications. These requirements act as barriers to timely medication access. VDH continues to participate in national discussions about the need to include all medications for communicable conditions of public health importance, including HIV and HCV medications, in Marketplace plans.

Maintaining Strong Community Partnerships

Collaboration and communication between VDH and statewide stakeholders have proven effective during previous enrollment periods. VA ADAP provides regular clear communication and enrollment resources prior to and during open enrollment to ADAP clients, medical providers, case managers, and other interested parties. As noted previously in this report, VDH

conducts internal and external debriefing activities on the successes and challenges of the open enrollment period and utilizes findings to inform future enrollment efforts.

ADAP Data System Improvements
In the past year, VA ADAP has made a number of improvements to its data systems and tracking to account for the changing nature of the program, including collecting information to track tax credits and other insurance credits that may result from clients changing their plans. Payments are reconciled with data received from the premium payment contractor and pharmacy benefit manager. Payment dates are tracked to ensure no disruption in coverage through missed payments. Notes are captured on an individual client basis to ensure any special circumstances for premium payments are recorded and are reviewed before monthly payment files are processed. The ADAP database continues to track all application and recertification data for clients. Reports on eligibility, enrollment, recertification, and service utilization are available for staff to run in real time. LHDs receive weekly data updates that include eligibility and enrollment status and date of the last prescription filled.

VDH has improved data sharing and quality. Data from HIV surveillance and RW services have been utilized to supplement missing laboratory data in ADAP, including Cluster of Differentiation 4 (CD4) counts and viral loads. Claims data from the Department of Medical Assistance Services (DMAS), which oversees Medicaid, is now obtained on a quarterly basis; and a match is run with ADAP data. Eligibility data from DMAS is obtained every two weeks and is matched with ADAP data to determine which clients may no longer be eligible for ADAP and which also may be eligible for Medicaid retroactive billing, thereby recouping ADAP expenditures if clients become retroactively eligible for Medicaid.

VDH received a Special Projects of National Significance Health Information Technology grant, which provided funding to improve reporting systems for ADAP, RW services, and HIV prevention in the state. The new system, e2Virginia, was launched in February 2016 and includes information on eligibility for ADAP and RW services, as well as medical data, such as viral loads, CD4 counts, and antiretroviral medication prescribing information.

VDH continues to utilize the in-house developed Care Markers Database, which houses data from a number of systems related to HIV diagnosis and care, including ADAP, HIV surveillance, and RW care data. The Care Markers Database allows VDH to more effectively monitor and improve client health outcomes (including ADAP clients) along the HIV care continuum. Out-of-care lists have been sent to community providers and medical staff to identify clients who may need re-engagement services. Coordinated efforts among medical sites, patient navigation programs, and other VDH programs will result in reaching clients and assisting them in engaging and remaining in care. Linking increased numbers of clients to care likely will increase the amount of resources needed to provide medications and purchase insurance for clients accessing care. At the same time, sustained retention of clients in care can result in more cost-efficient care; healthier clients with fewer serious acute illness episodes requiring hospitalizations or emergency room visits; and fewer new cases due to decreased transmission as a result of sustained viral suppression.

ADAP Advisory Committee

The ADAP Advisory Committee (AAC) was created in 1996, and is comprised of HIV/AIDS medical providers, a pharmacist, an ADAP client, and LHD representation. The Committee has traditionally advised VDH on programmatic, clinical, and educational issues, as well as formulary changes. Most recently, the AAC advised the inclusion of the HPV vaccine, as well as new medications for HIV and HCV to the ADAP formulary. HPV-related cancer occurs at increased rates in the HIV-infected population. Patients with HIV infection have twice the risk as HIV-uninfected patients for some of these cancers.[3] The AAC will continue to evaluate the impact of changes to statewide HIV services on medication access under the ACA and will assist VDH in program assessment and development.

Pre-exposure Prophylaxis

Pre-exposure Prophylaxis (PrEP) is a preventive biomedical intervention recommended by the Centers for Disease Control and Prevention (CDC) for people at substantial risk of acquiring HIV.[4] Gilead's Truvada (emtricitabine+tenofovir disoproxil fumarate), commonly used for the treatment of HIV infection, is the only medication currently approved by the Food and Drug Administration for use as PrEP. A once-daily oral dose of this medication has been shown to safely and effectively reduce the risk of HIV acquisition in adults. Several clinical trials have demonstrated substantial reductions (44-92%) in the rate of HIV acquisition, with higher levels of adherence and combination therapy (compared to tenofovir disoproxil fumarate alone) contributing to improved outcomes.[5,6,7,8] The United States Public Health Service has established clear national guidelines for safe, effective use of PrEP, and robust support for clinicians is available. Unfortunately, federal HIV prevention funds (administered by CDC) and RW funds (administered by HRSA) may not be used to purchase Truvada for PrEP or pay a significant portion of medical monitoring costs. As a result, additional work is needed to ensure reliable access. HRSA does encourage RW grantees to participate with the implementation of PrEP by leveraging their existing expertise and administrative and clinical infrastructures to set up PrEP programs. VDH is supporting PrEP access through collaboration with LHDs and several large clinics across the Commonwealth, medication distribution methods that were developed under ADAP, and federal grant funding for capacity building and infrastructure development in the VA Beach–Norfolk–Newport News Metropolitan Statistical Area. VDH is also collaborating with the District of Columbia Department of Health, the recipient of the same capacity building grant that includes areas in Northern VA, Maryland, and West VA. PrEP is a powerful HIV prevention tool and can be combined with other prevention methods to provide even greater protection than when used alone. The success of PrEP in combination with other

---

[3] Silverberg M, Xu L, Chao C, et al. Immunodeficiency, HIV RNA levels, and risk of non-AIDS-defining cancer. In: Program and abstracts of the 17th Conference on Retroviruses and Opportunistic Infections; February 16-19; 2010; San Francisco. Abstract 28.

[4] Centers for Disease Control. (2016). Pre-Exposure Prophylaxis. http: //www.cdc.gov/ hiv/risk/prep/index.html.

[5] Grant RM, Lama JR, Anderson PL, et al; iPrEx Study Team. Pre-exposure chemoprophylaxis for HIV prevention in men who have sex with men External Web Site Icon. N Engl J Med 2010;363(27):2587-99.

[6] Thigpen MC, Kebaabetswe PM, Paxton LA, et al; TDF2 Study Group. Antiretroviral pre-exposure prophylaxis for heterosexual HIV transmission in Botswana. N Engl J Med 2012;367(5):423-34.

[7] Baeten JM, Donnell D, Ndase P, et al; Partners PrEP Study Team. Antiretroviral prophylaxis for HIV prevention in heterosexual men and women. N Engl J Med 2012;367(5):399-410.

[8] Choopanya K, Martin M, Suntharasamai P, et al; Bangkok Tenofovir Study Group. Antiretroviral prophylaxis for HIV infection in injecting drug users in Bangkok, Thailand (the Bangkok Tenofovir Study): a randomised, double-blind, placebo-controlled phase 3 trial. Lancet 2013;381(9883):2083-90.

HIV prevention methods is of interest to ADAP because recent research indicates there are substantial lifetime medical cost savings from preventing HIV infection.[9]

Integrated Planning Between HIV Prevention and Care
HIV prevention and care are funded by separate government agencies (CDC and HRSA respectively) and have operated traditionally under different planning cycles with unique reporting requirements. The context of HIV prevention and care, however, has changed in the United States with the implementation of the ACA, updates to the National HIV/AIDS Strategy, and the White House HIV/AIDS Care Continuum Initiative, as well as advances in biomedical, behavioral, and structural strategies to prevent and control HIV. The CDC and HRSA are supporting the development of an Integrated HIV Prevention and Care Plan, which will serve as a roadmap to reduce new HIV infections, increase access to care, improve health outcomes for PLWH, reduce HIV-related health disparities and health inequities, and achieve a more coordinated response to the HIV epidemic. VA ADAP staff are part of a cross-unit team in the VDH Division of Disease Prevention that are developing the integrated plan for VA ensuring that ADAP-related goals and objectives are part of the overall sustainability of all HIV services across the Commonwealth.

Future Budget Needs
Several factors to be determined in the next few months will influence budgetary needs in upcoming years. These include insurance premium increases, insurance coverage of all necessary HIV medications, continuation of pharmaceutical industry rebates to ADAP, the availability of future ADAP ERF, and whether Medicaid expands in VA. VA ADAP has identified $27.2 million in reliably anticipated annual federal and state funding for GY 2017.

The additional funding sources of ADAP ERF and pharmaceutical company rebates that have supported ADAP services in prior years are not predictable and may vary substantially in availability or amount in future years. ADAP ERF has varied significantly over a six-year period. Funds are competitively awarded and are not guaranteed year to year. Funds awarded April 1, 2016, totaled $10.9 million and varied in overall relation to prior years (Year 1: $3 million; Year 2: $3.5 million; Year 3: $4.9 million; Year 4: $11 million; Year 5: $10.2 million). As discussed below under "Challenges," the future of pharmaceutical industry rebates is unknown until upcoming completion of national negotiations and the final release of new federal requirements.

If a worst case scenario of unavailable ADAP ERF and elimination of rebates occurs, then ADAP would face an unmet need of $36 million for a program that would cost $63.2 million (based on the second scenario illustrated in Figure 8). Other factors that could influence budgetary requests include but are not limited to: 1) Medicaid expansion, 2) changes in rebate revenue terms, 3) insurance formulary restrictions requiring purchase of uncovered drugs through Direct Purchase ADAP, 4) insurance coverage options for Marketplace ineligible clients, 5) increased number of clients due to testing and efforts to retain them in care, and 6) addition of medications to the VA ADAP formulary.

---

[9] Schackman, B. R., Fleishman, J. A., Su, A. E., Berkowitz, B. K., Moore, R. D., Walensky, R. P., … Losina, E. (2015). The Lifetime Medical Cost Savings from Preventing HIV in the United States. Medical Care, 53(4), 293–301. http://doi.org/10.1097/MLR.0000000000000308

Challenges

Instability in the Health Insurance Market

National experts on the ACA question whether current health insurance Marketplace premium rates for individuals are adequate for some insurers, especially if enrollees are, on average, less healthy than insurers anticipated. VDH is concerned with this because VA ADAP clients face significant health challenges and frequently utilize costly medications. While not all insurers have reported a difference between projected and actual costs, insurers that have could increase health insurance premiums or make other changes to decrease costs, such as reduce plan formularies, limit the provider network, or change geographic coverage areas.[10] Premium tax credits could offset premium increases for enrollees who have incomes between 100%-400% FPL; however, the majority of VA ADAP clients (57%) are below 100% FPL and are not eligible for credits. Additionally, insurers receive final approval for rates and plan details approximately four weeks before the start of open enrollment. VA ADAP has access to this information but significant changes in plan rates, formulary completeness, provider network, or insurer participation in the market discovered within four weeks of plan offerings could significantly challenge the ability of VA ADAP to maintain coverage for clients and may modify program need.

Rebates Received from Pharmaceutical Companies

While rebates have become an important revenue source supporting ADAP sustainability, their future remains uncertain. Revised federal 340B requirements that will address the future of rebates are expected to be released in late 2016. NASTAD anticipates changes that will require ADAPs pay both the premium and medication cost share in order to qualify for a rebate. The key change is the inclusion of the premium payment to the rebate criteria. VA ADAP pays for premiums for the majority of ACA clients, but most privately insured clients and some Medicare Part D clients continue to pay their own premiums or obtain support from other resources. Payments for medication costs where ADAP was not also paying associated premiums would make those medication payments ineligible for rebates. Currently, full rebates are received on partial payments (co-payments) for medications purchased through insurance with ADAP funding. Some discussions have included changes to the methodology under which rebates are paid for partial payments. A change in rebate terms could substantially reduce rebate revenue and change the ability to meet ongoing VA ADAP need. As the insurance assistance component of ADAP continues to grow, the rebate revenue is expected to become an even more vital piece of ADAP sustainability over time.

Treating ADAP Clients Co-infected with Hepatitis C

Approximately 25% of the HIV infected population in the United States is co-infected with HCV, which places them at increased risk for serious, life-threatening complications.[11] New drugs are available to cure HCV in more patients with fewer side effects. These newer medications are costly, with some pharmaceutical companies declining to negotiate lower costs with ADAP. Clients receiving medications through Direct Purchase ADAP can access these treatments through the ADAP formulary. Clients with health insurance, however, may have

[10] Claxton, G. and Levitt, L. What to Look for in 2017 ACA Marketplace Premium Changes. Retrieved from: http://kff.org/private-insurance/perspective/what-to-look-for-in-2017-aca-marketplace-premium-changes/

[11] Centers for Disease Control. (2014). HIV and Viral Hepatitis. http://www.cdc.gov/hepatitis/Populations/PDFs/HIVandHep-FactSheet.pdf

difficulty accessing these medications if their insurance plan does not include them on its formulary, if the plan requires onerous preauthorization processes, or if the medication exception or preauthorization requests are denied. VDH implemented a pilot treatment assistance program in April 2015 for VA ADAP clients co-infected with HIV and HCV. The program was advertised through social media, a letter to providers, medication bag inserts for Direct Purchase ADAP clients, discussions at quarterly contractors meetings for HIV Prevention and RW Part B service contractors, and targeted calls with the AAC and other ADAP stakeholders. Uptake to the treatment assistance program was slower than anticipated. The AAC and other providers supplied feedback regarding barriers they were experiencing to clients utilizing the program and VA ADAP revised eligibility criteria and processes in response. People infected with HCV face many of the same barriers to accessing treatment as many PLWH including comorbid conditions, a lack of awareness regarding infection, stigma, instability in their personal or work life, and difficulty navigating health or insurance systems.[12,13,14] Providers have important characteristics to consider regarding treatment and philosophy about how patients are determined to be ready for treatment.[15] The National Academies of Science, Engineering, and Medicine cited additional barriers to treatment, including that many insurers have restricted access to HCV treatment.[16] The VA ADAP HCV Treatment Assistance Program specifically addresses this barrier by providing immediate access to HCV medications when clinically indicated, even if an insurer denies.

Conclusion

VA ADAP has successfully managed medication access programs serving over 6,000 low-income PLWH in the Commonwealth. The program continues to support optimum health for those infected and protect the safety of residents of the Commonwealth through the reduction of HIV transmission resulting from effective medication therapy that reduces viral replication, resistance, and disease transmission. An ADAP medication waiting list was instituted in November 2010 and eliminated by August 2012 resulting from program changes, efficiencies, and additional resources, including the availability of insurance through the ACA. VDH anticipates continued growth of the program with 6,591 clients projected to be served during GY 2016. The sustainability of ADAP services will be determined by the availability of resources; enrollment growth, as well as Medicaid expansion; ACA insurance premium costs; medication formulary completeness; and the geographic availability of insurance plans.

[12] Evon, D. M., Simpson, K. M., Esserman, D., Verma, A., Smith, S., & Fried, M. W. (2010). Barriers to accessing care in patients with chronic hepatitis C: the impact of depression. Alimentary Pharmacology & Therapeutics, 32(9), 1163–1173. http://doi.org/10.1111/j.1365-2036.2010.04460.x

[13] McGowan, C. E. and Fried, M. W. (2012), Barriers to hepatitis C treatment. Liver International, 32: 151–156. doi: 10.1111/j.1478-3231.2011.02706.x

[14] Oramasionwu, C. U., Moore, H. N., & Toliver, J. C. (2014). Barriers to Hepatitis C Antiviral Therapy in HIV/HCV Co-Infected Patients in the United States: A Review. AIDS Patient Care and STDs, 28(5), 228–239. http://doi.org/10.1089/apc.2014.0033

[15] Osilla, K. C., Wagner, G., Garnett, J., Ghosh-Dastidar, B., Witt, M., Bhatti, L., & Goetz, M. B. (2011). Patient and Provider Characteristics Associated with the Decision of HIV Co-infected Patients to Start Hepatitis C Treatment. AIDS Patient Care and STDs, 25(9), 533–538. http://doi.org/10.1089/apc.2011.0048

[16] National Academies of Sciences, Engineering, and Medicine. 2016. Eliminating the public health problem of hepatitis B and C in the United States: Phase one report. Washington, DC: The National Academies Press.55555