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, 2015

The following report was developed in response to the directive under the VIRGINIA ACTS OF ASSEMBLY – CHAPTER 665, Item 287:

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 Immunodeficiency Syndrome (AIDS) Drug Assistance Program (ADAP) waiting list in August 2012. As of March 31, 2015, 5,634 clients were enrolled in VA ADAP, with approximately 75% receiving medications through insurance support and 25% 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 by 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

3,272 VA ADAP clients enrolled in qualified health plans available under the Patient Protection and Affordable Care Act (ACA), an increase of 962 clients over 2014 ACA enrollment. Based on National Alliance of State & Territorial AIDS Directors (NASTAD) data, 27% of all ADAP clients are enrolled in ACA plans nationally, compared to 57% of VA ADAP clients.

- A high degree of collaboration among statewide ADAP stakeholders contributed to enrollment success. Regular meetings and multiple communication strategies allowed VDH to provide updates on enrollment progress, identify challenges and work collaboratively 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 and consumers.

Challenges

- Client enrollment continues to increase, but funding has not proportionately risen, with the program increasingly reliant upon several one-time sources of funding.
- Several variables will affect future program need, including 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 under 138% of the federal poverty level (FPL).

Conclusions

- Expanding Medicaid would result in coverage for 70.4% of current VA ADAP clients and substantial cost savings to VA ADAP.
- Current projections indicate a range of additional funding needs from $2 million to a worst case scenario of $23 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

ACA	Affordable Care Act
ADAP	AIDS Drug Assistance Program
AIDS	Acquired Immunodeficiency Syndrome
CAC	Certified Application Counselor
CD4	Cluster of Differentiation 4
ERF	Emergency Relief Funding
FPL	Federal Poverty Level
GY	Grant Year
HCV	Hepatitis C Virus
HIV	Human Immunodeficiency Virus
HRSA	Health Resources and Services Administration
LHD	Local Health Department
MOOP	Maximum Out-of-Pocket
MPAP	Medicare Part D Assistance Program
NASTAD	National Alliance of State & Territorial AIDS Directors
PBM	Pharmacy Benefits Manager
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 copayments. As illustrated in Figure 1 below, VDH eliminated the VA ADAP waiting list in August 2012.

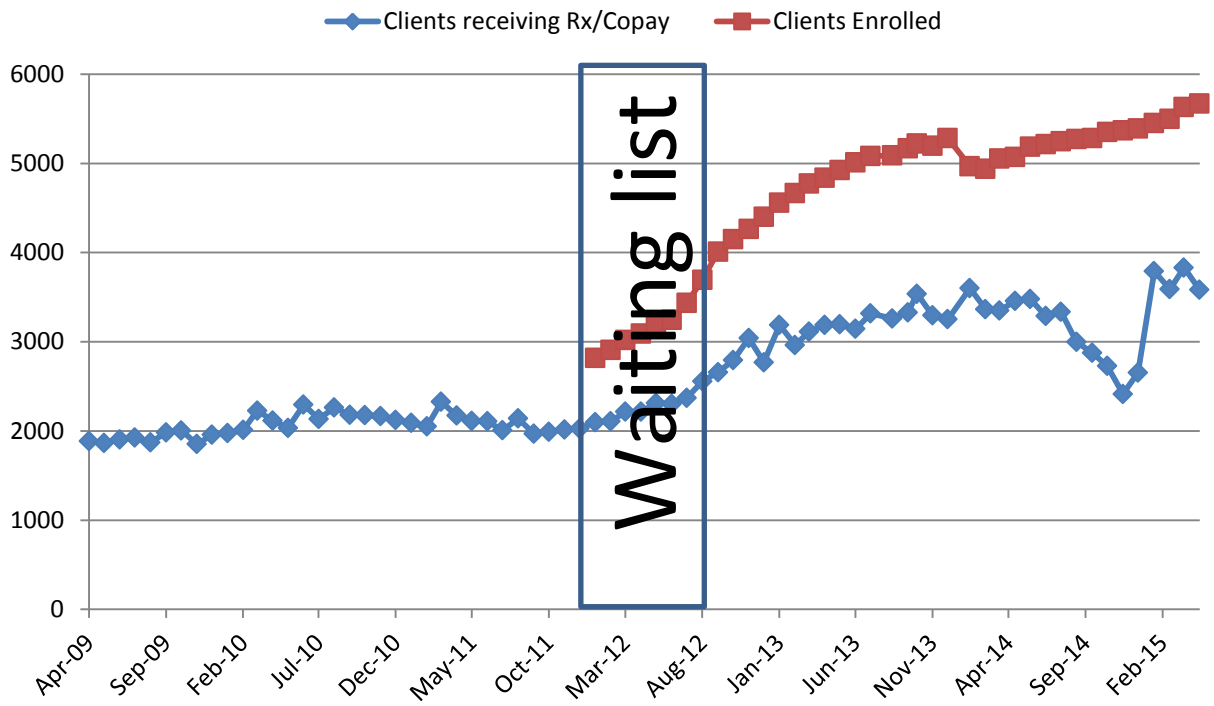

Figure 1. ADAP Wait List

The net growth in monthly ADAP client enrollment between April 2014 and March 2015 (accounting for clients disenrolling due to inactivity, death, moving out state or becoming ineligible for other reasons) has averaged 25 clients per month. As of March 31, 2015, 5,634 clients were enrolled in VA ADAP, with 75% receiving medications through insurance support and 25% directly receiving medications through LHDs or other distribution sites. VA ADAP provides insurance cost support or directly purchased medications in the following ways:

- ACA and Other Insurance: The ACA provides unprecedented access to health insurance for eligible United States residents. VA ADAP pays premiums and medication cost shares (copayments, coinsurance, and deductibles) for plans that meet federal and state ADAP criteria. Payments for medication cost shares count toward an individual annual total maximum out-of-pocket (MOOP) expenditures capped at $6,600 (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. 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 need for this program increased, both SPAP and ADAP funding support this service. VA ADAP can support two 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 distributed to LHDs and other distribution sites to provide to clients. 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; however, the majority of enrolled clients (93%) have incomes below 250% FPL, and 63% of the ADAP population lives at or below 100% FPL. Eligibility is assessed every six months to ensure ADAP only serves those who meet program criteria.

Historically, Direct Purchase ADAP served the majority of clients; and close to 75% of ADAP clients now receive ACA, MPAP, or other insurance support. The cost savings and program income realized by serving clients through insurance has enabled the program to serve all eligible clients and increase the ADAP formulary with the addition of smoking cessation and HCV medications. Cost savings from insurance enrollment also allowed funding for the reinstatement of services (e.g. dental care, treatment adherence counseling) for persons living with HIV that were curtailed or limited during the wait list period.

ACA Enrollment and Implementation

The 2014 Annual ADAP Report outlined the successes and challenges of the initial ACA open enrollment period. Lessons learned contributed to the successful enrollment of 3,272 VA ADAP clients into insurance during the second ACA open enrollment period, an increase of 962 clients over 2014 ACA enrollment. The success of the 2014/2015 effort is illustrated in Figure 2 below, as are challenges encountered.

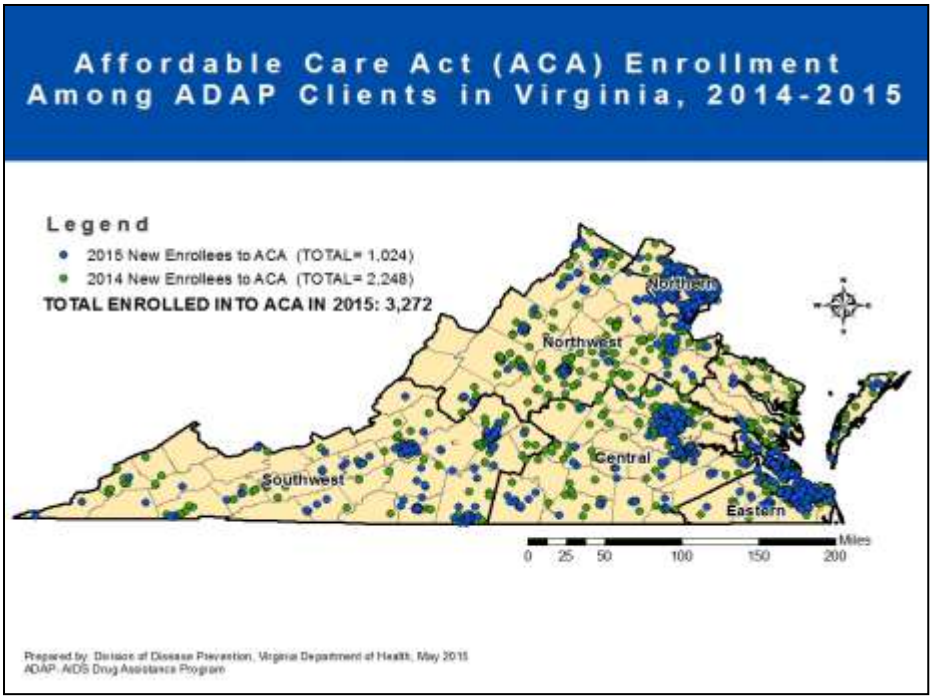

Figure 2. ACA ADAP Enrollment in VA, 2014-15

Previously, the Health Resources and Services Administration (HRSA) Policy 13-05 restricted use of ADAP funds for insurance purchase to plans with formularies comparable to antiretroviral coverage on the current state ADAP formulary. This policy prohibited ADAPs from purchasing plans with formularies that did not include certain medications, most notably single tablet antiretroviral regimens. Because effective treatment of HIV requires an unusually high degree of adherence to antiretrovirals, single tablet regimens (which include multiple antiretroviral medications in one pill) play an important role in decreasing the number of pills a person must ingest, thereby improving tolerability, adherence and treatment effectiveness. In 2015, a change in HRSA federal policy allowed ADAP funds to be used to purchase insurance that did not have complete antiretroviral coverage, as long as one medication per class was on the insurance plan formulary. While this provided greater flexibility in plan selection, some plans lacked adequate coverage for all antiretroviral medications needed for effective HIV treatment.

Due to this federal policy change, VA ADAP expanded its support to additional insurance plans, including all Silver and Bronze plans that were not "deductible only" for each insurance carrier. 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. Based on income and resulting subsidy levels in Silver plans, clients were instructed to enroll in either a Bronze or Silver level plan, in order to maximize cost effectiveness. Not one plan covered the entire state, and plan benefits and costs varied considerably.

Implementation Strategy

VA ADAP prioritized client groups for enrollment. Clients who were eligible for ACA plan re-enrollment were given the highest priority to ensure there was no lapse in coverage.

Enrollment of remaining clients was then prioritized based on income and subsidy levels. 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. Finally, all remaining eligible ADAP clients were contacted 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.

In 2015, VA ADAP expanded client engagement efforts in order to build on the 2014 enrollment success. Strategies included direct mailings to ADAP clients; customized for those re-enrolling and those newly enrolling to ACA plans. The mailings provided information about the VA ADAP-supported plans, directions for re-enrollment and a referral list of selected Certified Application Counselor (CAC) enrollment sites. VA ADAP created fliers in English and Spanish for distribution at medical case management and medication access sites to inform clients how to enroll in an ACA plan and provided tips to the newly insured on using insurance. Fliers and 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 consumers and other stakeholders.

VA ADAP enlisted the help of RW service contractors throughout the state, who implemented innovative strategies to help enroll clients into ACA plans. Contractors utilized CACs and enlisted the help of social workers and medical case managers. Contractors hired staff 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 continued communication with stakeholders by distributing a weekly email to RW providers, LHDs, consumers, insurance assistors and community advocates to keep them aware of changes, challenges, enrollment numbers, policy additions and frequently asked questions. The weekly communication also included instructions regarding medication exceptions and prior authorizations, in order to ensure timely access to antiretrovirals and other medications not on insurance plans' formularies. 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. In addition, calls helped to facilitate enrollment tracking.

VDH participated in statewide ADAP stakeholder roundtables organized by Virginia Organizations Responding to AIDS and pharmaceutical industry representatives. These roundtables were well attended by providers, consumers, health system administrators, insurance industry representatives, and trade associations. Participants shared challenges and successes related to client enrollment, and were updated by VDH on enrollment progress and ADAP operations. As in the prior open enrollment period, these meetings were valuable in providing a forum for all stakeholders to discuss strategies to support successful enrollment and to identify areas for improvement.

At the conclusion of open enrollment, VDH held debriefings with ADAP staff and leadership, CACs, participants at public hearings, and at statewide contractor meetings to assess the overall ACA open enrollment process and to collaborate with stakeholders on how to improve the process for the next open enrollment period. Surveys were created and distributed to stakeholders, medical providers, case managers and clients to gauge other challenges and future needs.

Challenges and Resolutions

Many of the challenges experienced in the inaugural open enrollment period were resolved prior to the second open enrollment period. Previous technical errors on the federal Health Insurance Marketplace's (Marketplace) website, Healthcare.gov, were corrected, and wait times for Marketplace telephone enrollments decreased substantially. As previously mentioned, VDH collaborated with the VA Bureau of Insurance to review insurance plan details before the second open enrollment period began. This allowed ADAP to prepare educational materials and instructions regarding ADAP insurance cost support before plan details were released publicly.

Currently, the Marketplace continues to offer plans based on a client's residential address, creating barriers for clients who wish to access medical care in other areas of the state. For example, if a client lives in a rural southern area of the state but attempts to access HIV care in an urban central area of the state, the medical provider in the central area may not be considered "in-network" under the client's insurance plan. In some instances, clients have been forced to change medical providers to access in-network coverage.

Navigating the re-enrollment process for the first time presented new challenges in 2015. All enrollees were required to contact the Marketplace to confirm income and any other changes that may have occurred prior to open enrollment, as major life changes such as marriage, divorce, having or adopting children, and income or residence can impact tax credit eligibility. Some clients required repeated prompting to ensure this action occurred. In some cases, insurance providers were delayed in sending updated premium information to clients, thereby delaying ADAP's ability to pay the new premium amounts. To prevent gaps in coverage during the re-enrollment process, VDH continued paying premiums based on prior rates for clients automatically re-enrolled. ADAP staff spent additional time and resources reconciling new premium amounts through aggressive follow-up with clients and insurance company representatives.

Incomplete medication formularies presented a challenge this year. Some companies reduced their formularies, removing two highly utilized single tablet antiretroviral regimens. No company increased their formulary to include additional HIV medications, although some companies retained complete formularies. Despite these changes, widespread access problems did not occur. Clients who re-enrolled into one company's plans (which serve a large number of ADAP clients) were able to remain on the removed medications without prior authorization or medication exceptions. New clients to these plans were provided access to the medications when prior authorization or medication exceptions were submitted by the medical provider. Providers voiced complaints regarding the amount of time taken to complete the prior authorization and medication exception process. This prompted VA ADAP to provide guidance for each insurance company's medication exception and prior authorization procedures on the VA ADAP website,

and provide education about the process to RW case managers, medical providers, LHD staff, consumers and stakeholders.

Some clients continue to experience challenges related to insurance plan restricting pharmacy options Some clients are required to use mail order pharmacies that would not participate with VA ADAP's pharmacy benefits manager (PBM). VA ADAP, along with national partners like NASTAD, continues to work with a specific large mail order pharmacy directly to resolve medication access barriers as the company will not coordinate benefits with ADAPs' PBMs. Clients are able to access medications at a retail pharmacy or through a specialty pharmacy only after steps are taken to opt out of the mail order requirement.

To assure compliance with the HRSA mandate that all funded agencies vigorously pursue clients' enrollment into insurance, RW Part B contractors are now required to report their efforts to help clients enroll in and utilize insurance on a monthly basis. Clients are regularly screened for health coverage eligibility and educated about ACA required consequences for not applying for health coverage.

Current Utilization

Since eliminating the VA ADAP waiting list in August 2012, utilization has continued to increase as illustrated in Figure 3 below. Between April 2014 and March 2015, VA ADAP enrolled a net average of 25 new clients per month. As of March 31, 2015, 5,634 clients were enrolled in VA ADAP.

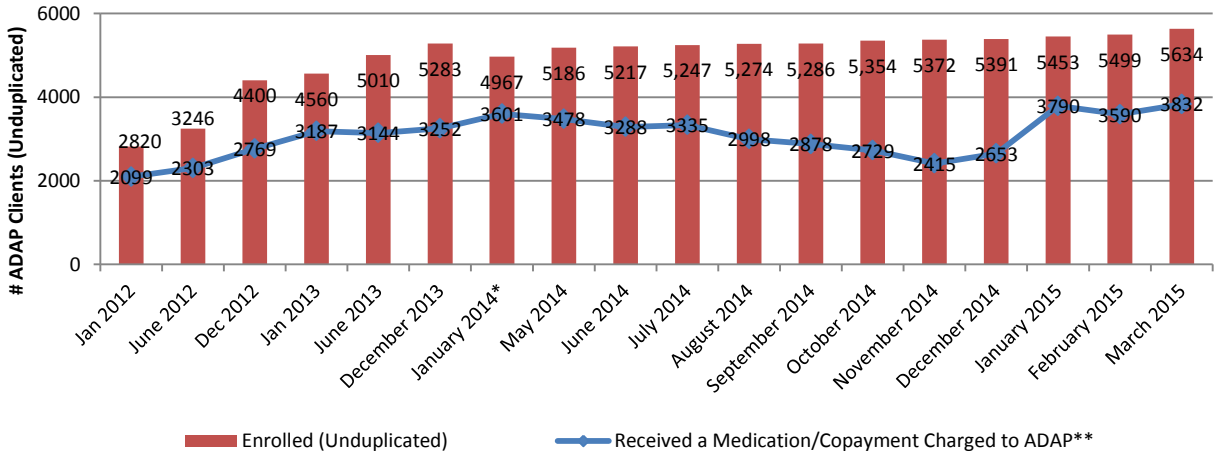

Figure 3. ADAP Clients Enrolled and Receiving Medications: Unduplicated 2012 to 2015

Figure 4 below illustrates enrollment by program. Seventy-five percent of clients were enrolled in insurance plans with 3,272 in ACA, 508 in Medicare Part D and 489 in other plans. The remaining 25% of clients (1,436) receive medications through Direct Purchase ADAP. Eligible Direct Purchase ADAP clients will receive assistance with enrolling into ACA plans during the next open enrollment period occurring November 1, 2015 – January 31, 2016.

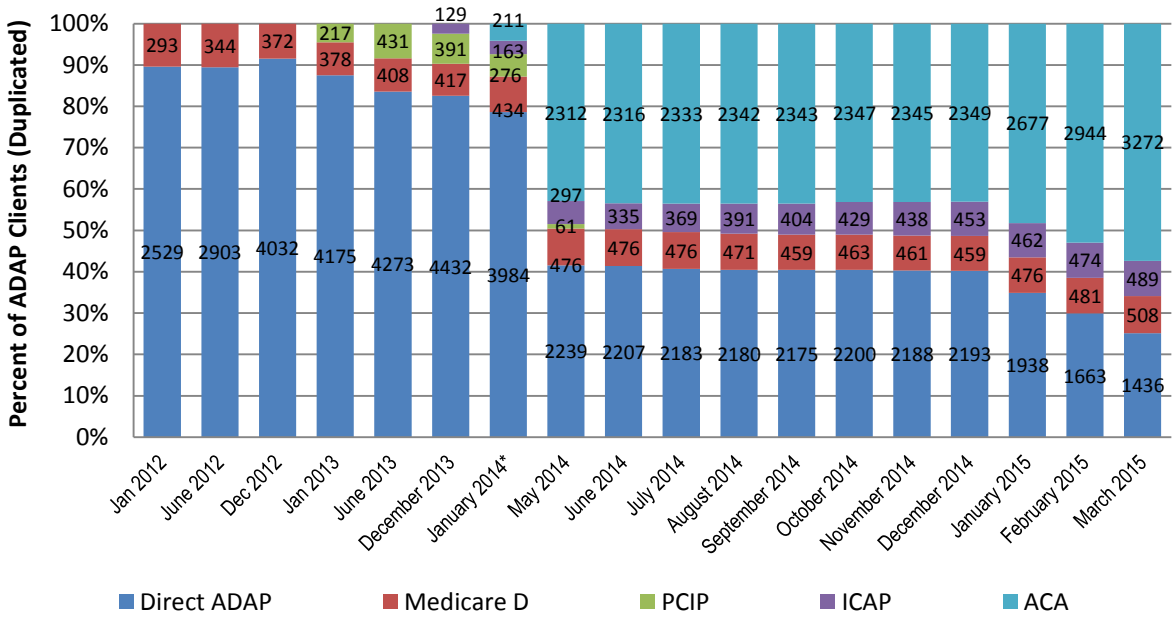

Figure 4. ADAP Enrolled by Program: 2012 to 2015

Note: Pre-Existing Condition Insurance Plans 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 enrollment and utilization is critically important to ensure resources can meet the growing 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 biweekly basis and sends monthly summaries to the Chief Deputy Commissioner of Public Health and Preparedness.

Between April 2014 and March 2015, 1,202 persons were disenrolled from ADAP or denied upon initial application. Primary reasons for disenrollment included not picking up medications within the last six months (54.5%), having another payer source for medications (26.1%), and moving out of state (6.2%).

Demand for ADAP services continues to grow, driven by several key factors. Department of Health and Human Services HIV treatment guidelines support initiating treatment with medications early in the course of disease to suppress HIV, lowering the amount of virus in the body (measured by a viral load laboratory test). Viral suppression, along with maintaining higher Cluster of Differentiation 4 (CD4) counts (a measure of immune system function), improves health outcomes for infected clients and reduces transmission to uninfected individuals. Increasing medication access to more people living with HIV is key to effectively controlling the the epidemic. The left graph in Figure 5A below illustrates that only one-third of new ADAP clients have a CD4 count over 500, and are initiating treatment early to maintain optimal health. The right graph shows improvement in CD4 counts while enrolled in ADAP.

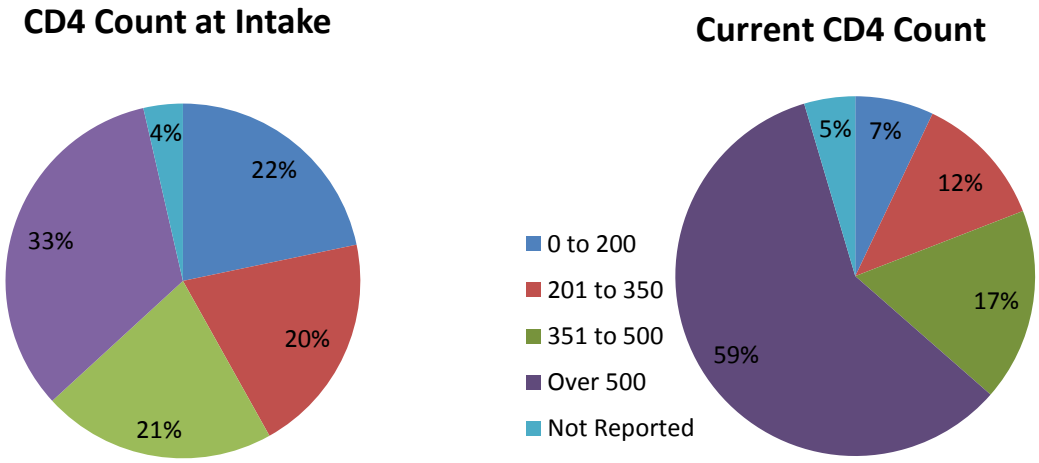

Figure 5A. CD4 Counts for ADAP Clients: March 2015

Figure 5B below illustrates viral loads for ADAP clients enrolled for at least 12 months as of March 2014 (n=4,193) have significantly improved from 46% with an undetectable viral load upon their intake into ADAP up to 72% 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.

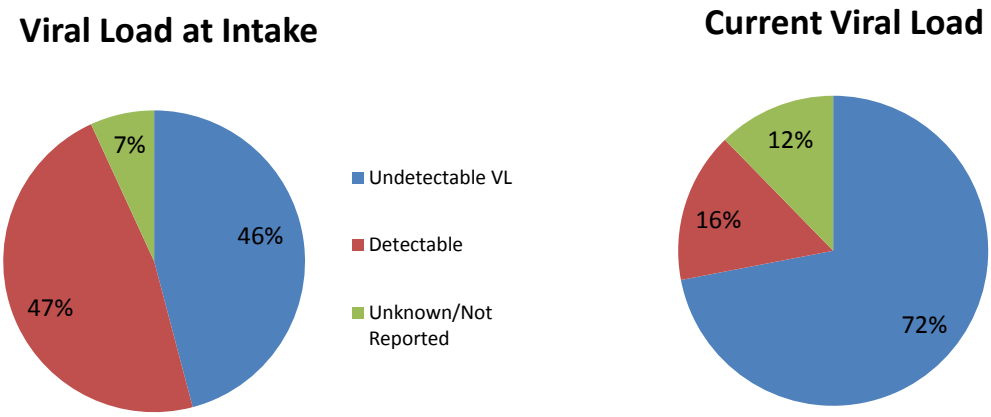

Figure 5B. Viral Loads for ADAP Clients: March 2015

Fiscal Status

Based on projections, anticipated ADAP costs for the current RW Part B GY, April 1, 2015 to March 31, 2016, (GY 2015) will be approximately $42 million. Unlike most budget cycles, HRSA labels the RW budget period by the year it begins. Federal funds, including RW Part B formula-based funding and $10.1 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. The remaining 26% is comprised of anticipated program revenue generated from pharmaceutical rebates and Medicaid retroactive billing. As discussed in the "Projections" section of this report, several unknown variables such as 2016 insurance plans' premium costs and formulary composition, as well as an uncertain future for pharmaceutical manufacturers rebates to ADAP for medication copayments have a significant impact on ADAP sustainability. Current resources are adequate to cover projected premium increases up to 15%. If current medication access (formularies, exception processes and preauthorization requirements) or rebate structure changes, 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 70% of the federal award to medication access (ADAP insurance support and direct medication purchase), with 18% supporting other health related direct services and 12% supporting agency administration and program infrastructure.

As illustrated in the Figures 6 and 7 below, 75% of ADAP medication expenditures and 83% of insurance expenditures in GY 2014 were supported by federal funds. Federal funding included $11 million in ADAP ERF. The amount of the ADAP ERF is unpredictable. It is competitively funded; previous awards have ranged from $3 million to $11 million. During GY 2014, ADAP ERF was used to directly purchase medications and insurance for eligible ADAP 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 2014 (April 1, 2014 – March 31, 2015).

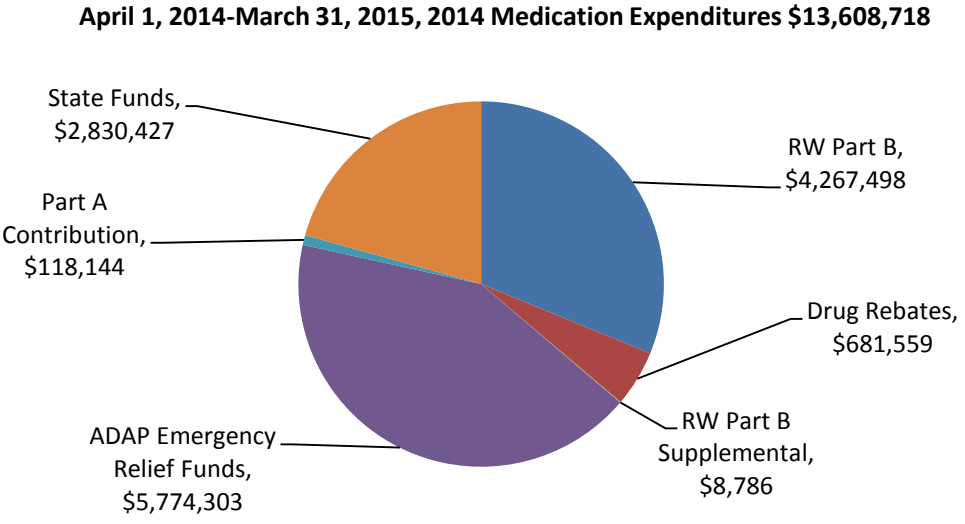

Figure 6. RW GY 2014 VA ADAP Medication Expenditures by Funding Source

Finally, state funds represented in Figures 6 and 7 reflect appropriations made in State Fiscal Year 2014 that were expended during the RW GY 2014. During GY 2014, state contributions to VA ADAP totaled slightly over $5.5 million. These funds were used to purchase medications and insurance. With average monthly client costs for providing direct purchase medications at $868 per person ($10,416 annually), these state funds sustained an estimated 759 clients on direct purchase medications. A smaller portion of the state funds, under $200,000, supplemented funding needs for insurance support, serving 26 clients. Average monthly costs per client for insurance for GY 2014 were $746 before rebates, but were reduced to $645 per month per client ($7,740 annually) after accounting for the rebate revenue received during GY 2014 on medication copayments.

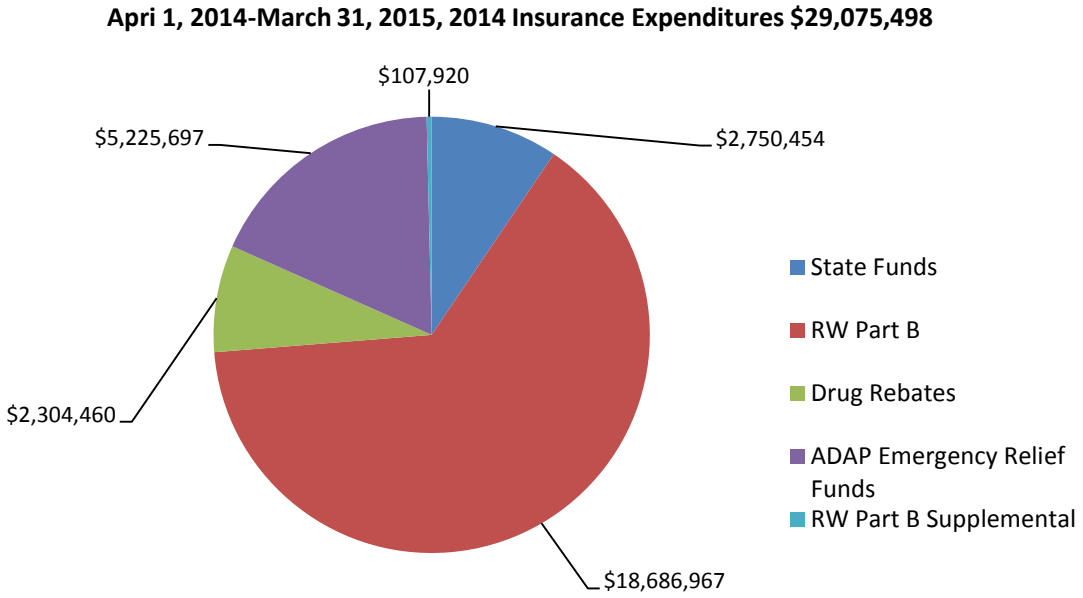

Figure 7. RW2014 VA ADAP Insurance Expenditures by Funding Source

During GY 2014, both RW Part A grantees that serve urban jurisdictions in VA (i.e., the City of Norfolk and the Northern VA portion of the Washington, D.C. eligible metropolitan area) made combined contributions to VA ADAP of $118,144. Part A grantees continue to be valuable partners in supporting full access to ADAP services for all clients. VA ADAP staff have maintained communication with Part A grantees and Planning Councils to support including ADAP in the annual Priority Setting and Resource Allocation process, and to encourage contributions throughout the year instead of a large contribution at the end of the year. This approach will assist with supporting insurance costs, which are maintained throughout the year as opposed to the prior practice of making large medication purchases at a point in time. Part A grantees have continued to experience cost savings as a result of the increasing proportion of insured clients through ADAP, and those cost savings can result in redirecting dollars to ADAP for insurance purchase as well as increased provision of HIV related services.

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 used to calculate 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/insurance, Medicare Part D, and Direct Purchase 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 2014, 5,815 unduplicated clients received ADAP services with 2,323 receiving only direct medication services, 1,764 receiving only insurance services and 1,728 receiving both direct medication and insurance services (some clients access medications to avoid treatment disruption until insurance support is established). For GY 2015, 6,277 clients are projected to receive services and 6,664 in GY 2016. The annual number of clients served is estimated through a formula, based on a regression analysis of 15 years of historical data, utilizing monthly rather than annual averages. This methodology of averaging by month is necessary to account for monthly variances due to disenrollment, death, or becoming ineligible 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, as well as 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 $4,070 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 2015 were released in late 2014 and the MOOP expenditures (paid by VA ADAP) for those not receiving any tax subsidies was no higher than $6,600 per person annually. Projections were completed for GY 2015, GY 2016 and GY 2017 using the data available for the ACA plans from 2015, as 2016 and 2017 cost structures are not yet available. For those receiving subsidy tax credits whose incomes are between 101% and 250% of the FPL, this MOOP expenditures 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 2015 have been developed utilizing the current FPL distribution of the ADAP population and current enrollment numbers for ACA in 2015. The FPL distribution by program for clients enrolled in ADAP in March 2015 is illustrated in Figure 8 below. The majority of clients for both Direct Purchase ADAP (70.1%) and ACA (63.1%) 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, 70.4% are below 138% FPL and would be eligible for Medicaid expansion (last bar on right).

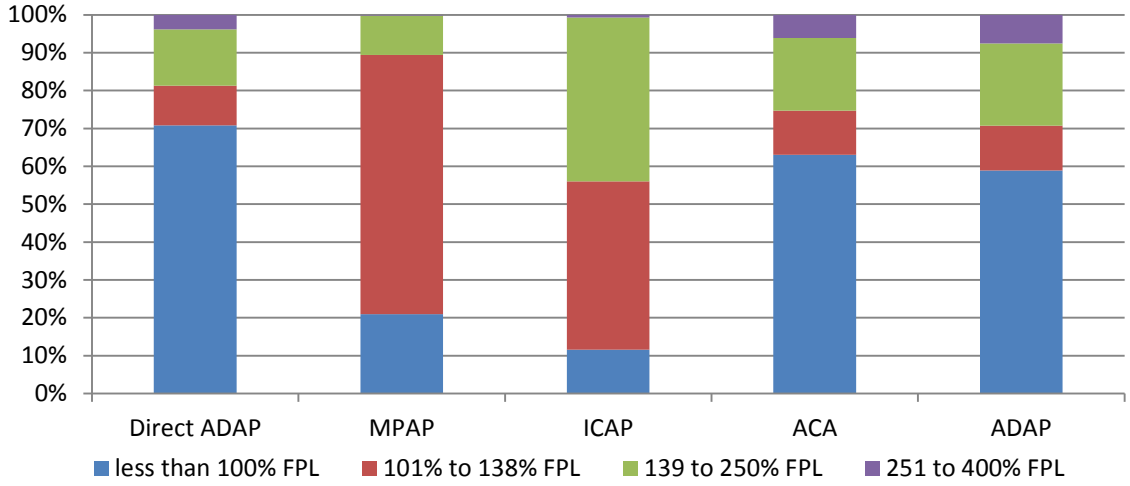

Figure 8. FPL Distribution by Program for Clients Enrolled in ADAP in March 2015

Using the average 2015 ACA costs from the plans supported by VA ADAP, average annual costs for the population at or below 100% FPL would be $10,056 per client per year ($6,600 out of pocket, $3,456 premiums).

This annual cost is lower than the average annual cost for a Direct Purchase ADAP client ($10,416), and the ACA cost may be further reduced by pharmaceutical rebates received on cost shares paid for antiretroviral medications. Rebates are not able to 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, based on 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. Rebates make up 40% of national ADAP funding[1] and constituted 15% of the GY 2014 VA ADAP expenditures. While rebates have become an important revenue source supporting ADAP sustainability, their future remains uncertain.

[1] National ADAP Monitoring Project Annual Report, NASTAD, February 2014, http://www.nastad.org/docs/NASTAD%20National%20ADAP%20Monitoring%20Project%20Annual%20Report%20-%20February%202014.pdf, p. 9.

Rebate terms are negotiated between the ADAP Crisis Taskforce (a representative group of state ADAPs led by NASTAD) and are paid by pharmaceutical companies nationally to state ADAPs through voluntary agreements. Currently, full rebates are received on partial payments for medications purchased through insurance cost shares with ADAP funding. Revised federal 340B requirements that will address the future of rebates are expected in the coming months. Final rules will be released after a 90 day comment period, and changes are anticipated to be implemented in January or February, 2016. Possibilities include four scenarios: no change with continuation of full rebates, although this scenario seems unlikely; a reduction of rebate amounts; cost neutral rebates where the program receives only what was paid toward client medication cost shares; or elimination of rebates altogether. A change in rebate terms could substantially 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. 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 projection from the rebates is challenging. The amount of rebate received varies over time. No formula is available that relates the rebates to the original cost outlay. 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 9 below illustrates ADAP projections for the next two RW GYs for four different scenarios. All 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 are generally seen in the first quarter of the calendar year, which is the final quarter of the currently budgeted GY 2015. Therefore, substantial increases in costs could impact GY 2015 final quarter resource needs.

The four scenarios in Figure 9 are related to the potential changes in rebates that are expected to occur in early 2016 and illustrate a low to high range of projected program cost. These scenarios include: Scenario 1) no changes to rebates, Scenario 2) rebates end as of February 2016, and Scenarios 3) and 4) a reduction in rebates as of February 2016 illustrated as a high and low range possibility as exact reductions are not known at this time. All scenarios include the following assumptions: that 4,000 ADAP clients will be enrolled into ACA in calendar year 2016, 4,500 in calendar year 2017 and 4,650 in 2018; that ACA premiums will increase by 10% in 2016 and 5% in 2017 and no increase in 2018. For Scenarios 2, 3, and 4 where there is a change in how rebates are structured, it is assumed that VDH will be able to bill under the current rebate structure for all drug copayments through January 2016. There is a twelve-month time difference from when ADAP pays the copayment for the medication and the rebate on that co-pay is received, there would be a large receipt of rebate revenue in April 2016 under Scenarios 2, 3, and 4 as the program billed for a year's worth of rebates under the old structure. This leads to some cost savings at the

beginning of GY 2016 due to a large one-time receipt of rebates under current agreements, but increased costs in GY 2017 due to decreased or absent rebates, compared to Scenario 1.

Without rebates, Scenario 2 shows that ADAP costs would increase in GY 2016 by $7.2 million and by $23 million in GY 2017. The more likely scenario is some reduction in rebates which is shown in Scenarios 3 and 4, which have a range of costs for GY 2016 and GY 2017. In these scenarios, either costs would decrease or increase in GY 2016 because of the increased rebate revenue in April 2016, but costs would increase in GY 2017.

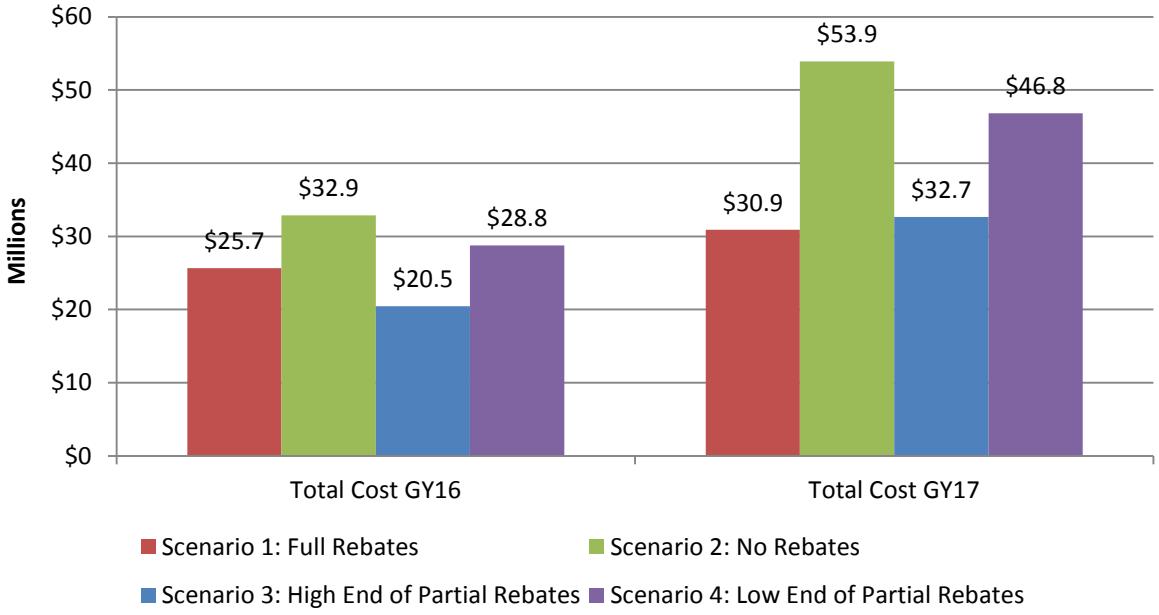

Figure 9. VA ADAP Projected Costs (Post Rebate): GY 2016 and GY 2017

Sustainment

As described in this report, a number of factors will impact the ability to continue meeting 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 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 to reside in the Commonwealth, have no other sources or personal ability to pay for medications or insurance coverage, 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. This 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 a 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.

If clients do not access medications within six months, they and their medical provider are notified of ADAP disenrollment. If a mitigating factor is identified (such as a medically indicated treatment break) client ADAP services will continue. Clients may reapply to ADAP as needed, if circumstances change.

Implementing Provisions of the ACA

VA ADAP will support efforts to ensure all eligible clients are enrolled into ACA plans during the next open enrollment period. Currently, 25% of the VA ADAP population is not insured. Efforts are currently focused on determining what proportion of the uninsured ADAP population is eligible for Marketplace plan enrollment and creating strategies on how to support enrollment for those who are eligible. Providers, LHDs and other medication access sites have received lists of uninsured clients to determine if they are eligible for Marketplace enrollment, to see if they still reside in the state or if they qualify for Medicare or Medicaid. If VA expanded Medicaid, 70.4% of the projected total ADAP population would be eligible as they fall below 138% of the FPL. For those that are not eligible for Marketplace enrollment, Medicaid or Medicare, VA ADAP is evaluating whether purchasing qualified health plans off the Marketplace is a financially viable option.

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 timely identification of which plans may be supported with ADAP funds so that consumers and stakeholders have this information at the beginning of the open enrollment period. The ability to determine supported plans early facilitates educational efforts to providers and clients, and identifies possible coverage issues.

VA ADAP will continue engaging with the community and educating 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 or medication exception process. VA ADAP will continue efforts to educate partners and community action groups about the needs of low-income persons living with HIV/AIDS, including the need for affordable insurance coverage and medication formulary adequacy. The state-supported HIV/AIDS Resource and Consultation Centers are developing statewide training for CAC sites, case managers, and patient navigators, service providers and people living with HIV/AIDS on how to enroll in and effectively use health insurance and service options under ADAP.

Formulary Completeness

As discussed in the report, many insurance carriers participating in the Marketplace are not covering single tablet HIV regimens on their published formularies. Most have provided those medications as a result of providers completing preauthorization or medication exception requests. VDH acknowledges and supports this response by insurance carriers, agreeing that it is a responsible public health approach for supporting the health of subscribers and lowering HIV transmission to others. VDH will continue to facilitate discussions between prescribers and insurance carriers to work toward increased time-efficient and streamlined processes, and will

continue to participate in national discussions about the need to include all medications for communicable conditions of public health importance (including HIV medications) in Marketplace plans. If access to single tablet regimens decreases, then budgetary needs to support ongoing medication access for clients will need to be reassessed.

Maintaining Strong Community Partnerships

Collaboration and communication that proved effective during the first open enrollment was replicated during the 2015 open enrollment period. VDH anticipates that Virginia Organizations Responding to AIDS and pharmaceutical industry partners will reconvene statewide stakeholders meetings in preparation for the next open enrollment period. These meetings have had increasingly diverse participation including insurance carriers, health care associations, VDH staff, ADAP clients, and a broad range of service providers. These meetings continue to provide a valuable forum for the exchange of information necessary to improve access to medication for people living with HIV/AIDS.

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 facilitate insurance enrollment and tracking utilization of ACA and private insurance assistance. These changes have included tracking client enrollment progress and collecting insurance premiums and medication cost share data needed to ensure timely payment by VA ADAP. Payments are reconciled with data received from the premium payment contractor and PBM. 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 CD4 counts and viral loads. Claims data from the Department of Medical Assistance Services , which oversees Medicaid, is now obtained on a quarterly basis, and a match is run with ADAP data. Eligibility data from the Department of Medical Assistance Services is obtained every two weeks and is matched with ADAP to determine which clients may no longer be eligible for ADAP and may also be eligible for Medicaid retroactive billing, recouping ADAP expenditures if clients become retroactively eligible for Medicaid.

VDH has received a Special Projects of National Significance Health Information Technology grant, which provides funding to improve reporting systems for ADAP, RW services, and HIV prevention in the state. The new system, e2Virginia, will integrate data reporting for HIV service delivery and give providers a more flexible and responsive system with reports that can be customized at the contractor level. The system is currently under development and a stakeholder meeting was held in July 2015, with an expected launch date of January 2016.

VDH has developed the 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 between 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 will likely 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, consumers, and LHD representation. As the structure of ADAP has changed significantly over the past year, with the majority of clients accessing medications through insurance support, the role of the AAC will evolve as well. The Committee has traditionally advised VDH on programmatic, clinical, educational issues and formulary changes. Most recently the committee advised inclusion of smoking cessation and HCV drugs to the ADAP formulary. Smoking prevalence is estimated to be at least two times higher among adults living with HIV than in the general population.[2] In the ACA Marketplace, smokers may pay up to 50% more than non-smokers for the same health plans. Giving patients the tools to quit smoking may impact program costs overall. The AAC's continuing role in evaluating the impact of changes to statewide HIV services on medication access under the ACA will assist VDH in program assessment and development.

HCV Medication Additions to Formulary

Approximately 25% of the HIV infected population is co-infected with HCV.[3] 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. Most insurance plans are including at least one newer medication on their medication formularies, but are often restricting access to people with very advanced disease or requiring nonclinical criteria, such as stable housing or documented ongoing abstinence from all illicit substances, to be met first. VA ADAP pays client copayment for these medications for eligible clients, and now provides the medications to clients who are not insured, or whose insurance plan denies treatment. As previously discussed, program resources may decline in the future with expected changes in rebate revenue and uncertain continuing federal supplemental funding. ADAP is pursuing aggressive marketing of the availability of these medications to providers and consumers in an effort to treat the majority of clients while resources are available. Theoretically, costs to support HCV treatment should decline over time as clients are cured, but provision of these medications will be reassessed if resources decrease.

[2] U.S. Department of Health and Human Services. AIDS.gov: HIV and Smoking [last updated 2014 Aug 12; accessed 2015 Mar 26].
[3] http://www.cdc.gov/hiv/pdf/library_factsheets_HIV_and_viral_Hepatitis.pdf.

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. VA ADAP has identified $27.9 million in reliably anticipated annual federal and state funding for GY 2016.

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 five-year period. Funds are competitively awarded and are not guaranteed year to year. Funds awarded April 1, 2015 totaled $10.1 million and varied in relation to prior years (Year 1: $3 million; Year2: $3.5 million; Year 3: $4.9 million, Year 4: $11 million). As reviewed earlier and illustrated in Figure 9, the future of pharmaceutical industry rebates is unknown until upcoming completion of national negotiations and the 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 $5 million for a program that would cost $32.9 million (based on the second scenario illustrated in Figure 9). 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.

Conclusion

VA ADAP has successfully managed medication access programs serving over 5,000 low-income persons living with HIV disease in the Commonwealth. The program continues to support optimum health for those infected, and to protect the safety of residents of the Commonwealth through reduction of HIV transmission resulting from effective medication therapy that reduces viral replication, resistance and transmission. An ADAP medication waiting list was instituted in November 2010, and eliminated by August 2012 resulting from program changes and the ability to benefit from additional resources, including the availability of insurance through the ACA. Continued growth of the program is anticipated, and it is projected that 6,277 clients will be serviced during GY 2015. Information about ACA insurance premium costs, medication formulary completeness, and Medicaid expansion will determine the next steps for continued sustainability of ADAP services.