# 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, 2014**

The following report was developed in response to the directive under the VIRGINIA ACTS OF ASSEMBLY – CHAPTER 2, 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) AIDS Drug Assistance Program (ADAP) waiting list in August 2012. As of June 30, 2014, 5,173 clients were enrolled in VA ADAP, with 60% receiving medications through insurance support and 40% 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.

## Accomplishments

- 2,310 VA ADAP clients enrolled in qualified health plans available under the Patient Protection and Affordable Care Act (ACA). VA ADAP clients account for about 2% of all clients receiving ADAP services but represent over 17% of ADAP clients enrolled to ACA insurance plans nationwide and 58% of ADAP clients enrolled to ACA plans in southern states.

- A high degree of collaboration among statewide ADAP stakeholders contributed to enrollment success. Regular meetings and multiple communication strategies allowed the 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 to provide insurance education programs to community partners and consumers.

## Challenges

- Client enrollment continues to increase, but federal and state funding has not proportionately risen, with the program 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).

- VDH reduced funds to HIV service contractors by more than 54% and allocated those funds to ADAP services to ensure an ADAP waiting list would not be implemented this year.

## Recommendations

- Expanding Medicaid would result in coverage for 72% of current VA ADAP clients and substantial cost savings to VA ADAP.

- A Medicaid demonstration project waiver (1115 Waiver) could serve HIV-positive persons who would otherwise be Medicaid eligible (if expanded Medicaid does not occur). VDH would be able to collaborate with the Department of Medical Assistance Services (DMAS) to apply for an HIV-specific 1115 Waiver.

- Current projections indicate a range of additional funding needs from $5M to a worst case scenario of $18M (assuming no Medicaid expansion and absence of future one-time funding sources) for the next grant year.

## 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. 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.

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 expenditure (MOOP) capped at $6,350 (or less depending on income). VA ADAP began paying for ACA plans during the inaugural open enrollment period beginning October 2013 for plans effective in calendar year 2014. VA ADAP also purchased Pre-Existing Condition Insurance Program (PCIP) plans in early 2013 for some clients before that federal program ceased enrollment. PCIP ended in April 2014 with impacted clients transitioned to other insurance or directly provided medications through ADAP. 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 need for this program has increased, both SPAP and ADAP funding support this service. SPAP funds continue to support premium payments for those clients at or below 300% FPL, while ADAP funds support medication cost shares and premiums for the few clients with incomes between 301 and 400% FPL. VA ADAP can support three to four 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, and medications to treat or prevent opportunistic infections (OIs). ADAP covers all cost shares for medications on selected plans' formularies. Eligible clients must have family incomes at or below 400% FPL; however, the majority of enrolled clients (85%) have incomes below 250%

FPL, and 63% of the ADAP population lives at or below 100% FPL. Eligibility is assessed every 6 months to ensure ADAP only serves those who meet program criteria.

Historically, Direct Purchase ADAP served the majority of clients. However, almost 60% of ADAP clients are now served under ACA, MPAP or other insurance support. By the end of State Fiscal Year (SFY) 2015, projections indicate over 89% of ADAP clients will be served under insurance program components. Cost savings realized by serving clients through these mechanisms have enabled the program to serve all eligible clients, averting an ADAP waiting list at the present time.

During the RW Part B Grant Year (GY) 2010 (April 2010-March 2011)[1], VA ADAP experienced steep increases in program utilization compared to the prior two years, and pharmaceutical expenditures reached a historic high. Additionally, rising unemployment rates and corresponding loss of insurance, expanded HIV testing efforts, new HIV treatment guidelines recommending initiation of HIV treatment as early as possible, and new medication regimens all contributed to the steep growth in ADAP utilization and expenditures during this period. Data analysis from 2007 to 2009 indicated that client enrollment and monthly medication costs steadily increased by 21% and 15% respectively.

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. At that time, ADAP enrollment criteria were limited to pregnant women, individuals 18 years old or younger, and people who were currently receiving treatment for an active OI.

In November 2011, due to increased program and pharmaceutical efficiencies and the availability of additional federal and state ADAP funds, VDH began enrolling new and wait-listed clients who met certain clinical criteria back onto ADAP. As funds were identified to sustain clients on ADAP over time (throughout GYs 2011 and 2012), a medical triaging process using client CD4 count (a marker of immunity, with lower CD4 counts indicating increased risk for illness) was used to identify clients for transition back to ADAP. In July 2012, based on the effectiveness of this approach and supported by weekly monitoring of ADAP service utilization and expenditures, VA ADAP began the final steps toward elimination of the waiting list.

By August 30, 2012, the ADAP waiting list had been eliminated. As a result, over 1,200 new clients were enrolled into the program and became eligible for receiving access to medications, as illustrated in Figure 1. One hundred new clients per month enrolled in the program exceeding pre-waiting list levels. The net growth in monthly ADAP client enrollment between July 2013 and June 2014 (accounting for clients disenrolling due to inactivity, death, moving out state or becoming ineligible for other reasons) has averaged 45 clients per month[2]. VA ADAP utilization is tracked by monitoring both the number of clients enrolled (those with completed eligibility determinations) and served (those receiving a prescription through insurance or Direct Purchase

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

[2] The average of 45 clients per month does not include January 2014 when a quality assurance review resulted in the disenrollment of 462 clients inactive for at least 6 months. Eligibility recertification practices were implemented to prevent additional backlogs of inactive clients. Ongoing monthly disenrollments for inactivity average approximately 60 clients a month.

ADAP). Reliable enrollment data was not available prior to January 2012, at which time VDH centralized eligibility determinations.

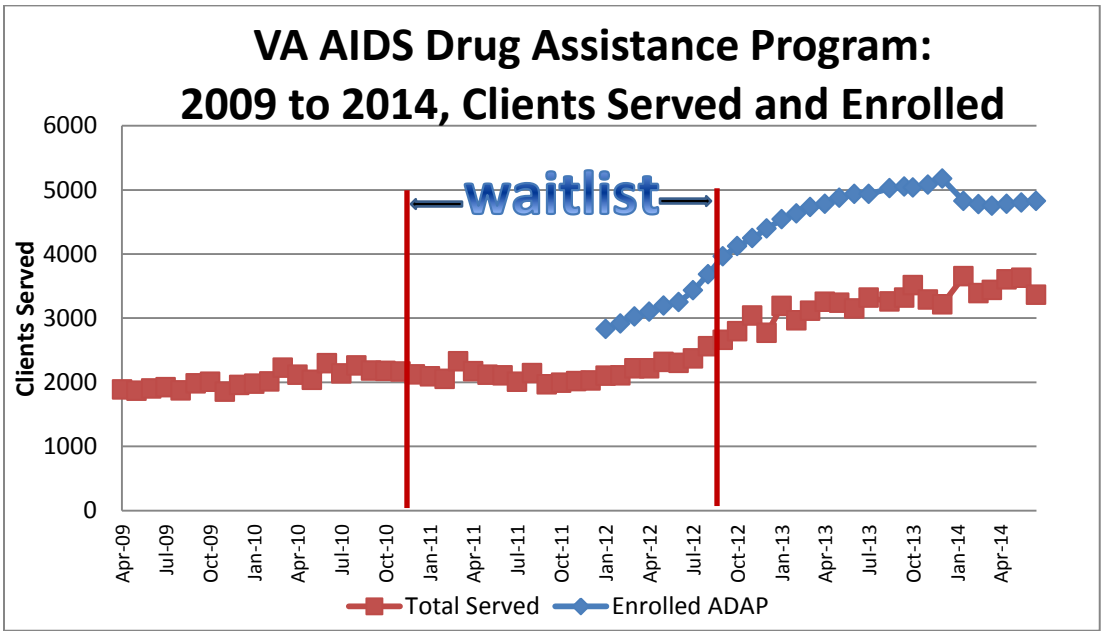



**Figure 1**

## ACA Enrollment and Implementation

The October 2013 Annual ADAP Report outlined the key role ACA insurance enrollment would play in continuing to meet clients' medication needs in a cost-effective manner. The success of this effort is outlined below, as are challenges encountered.

### *Preparation*

VA ADAP conducted a thorough review of the insurance plans offered through the ACA. At the time of the first open enrollment period, 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 and aggregate insurance costs less than paying for the full cost of directly purchasing medications. VA ADAP conducted an additional review to assess geographic coverage of plans, in an effort to provide insurance access to all VA ADAP clients, regardless of where they lived; that networks included current RW-funded medical providers, allowing clients to maintain long-term treatment relationships; and to identify pharmacy providers able to participate with both the insurance plan and VA ADAP's pharmaceutical benefits manager (PBM). The PBM pays medication cost shares and tracks progress toward satisfying deductibles, coinsurance, and MOOP.

VA ADAP identified one to two plans from each of six insurance carriers that met these minimal criteria. No one plan covered the entire state, and plan benefits and costs varied considerably. Clients electing to have ADAP support the premium and medication cost share expenses could select between eligible plans, if more than one option was available in their jurisdiction of residence. Based on income and resulting subsidy levels, clients were instructed to enroll in Bronze or Silver metal level plans, in order to maximize cost effectiveness. 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.

### *Implementation Strategy*

VA ADAP prioritized client groups for enrollment. Clients covered under PCIP were targeted first, as coverage was originally scheduled to end December 31, 2013. VA ADAP staff made initial contact with all PCIP clients by phone to facilitate enrollment and refer clients in need of in-person assistance to Certified Application Counselor (CAC) enrollment sites. VA ADAP provided CAC sites education about supported plans and tracked enrollment progress and successes. These efforts resulted in enrollment of 295 PCIP clients to ACA plans.

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. As of June 30, 2014, 2,310 VA ADAP clients were enrolled in ACA plans.

Extensive client engagement efforts contributed to enrollment success. Strategies included direct mailings to ADAP clients that provided information about the VA ADAP-supported plans and a referral list of selected 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 cards. Fliers and letters were included with monthly medication refills provided through Direct Purchase ADAP to prepare clients for the transition to insurance.

VA ADAP enlisted the help of RW service contractors throughout the state, who implemented innovative strategies to help enroll clients into ACA plans. Northwest region 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. A large RW contractor in the Northern region hired and trained four ACA enrollment assistors, and by April 2014 had reached 86% of their enrollment goal. A RW medical site, also in the Northern region, provided ADAP clients with on-site enrollment through their case managers and eligibility staff. The largest RW medical site in the Central region referred eligible clients to community sites and developed an enrollment tracking system to coordinate efforts with VA ADAP. VA ADAP staff supported the enrollment of the majority of Eastern region clients through telephone-based education and the facilitation of contact with Healthcare.gov, the federal enrollment system. LHD staff in the Southwest region assisted with enrollment efforts.

Beginning in September 2013, VA ADAP enhanced communication with stakeholders by distributing a weekly email to RW providers, LHDs, consumers, insurance assistors and community advocates. Topics included the cost-effectiveness of providing medication access by purchasing insurance, funding updates, information on how to apply for insurance, frequently

asked questions and answers, instructions for special enrollment periods, enrollment effort updates, statistics, and information about the debriefings. 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 enrollment goals and information about ADAP-approved insurance plans, to facilitate the tracking of enrollment, premium payment requirements, and to address any concerns or problems. At the conclusion of open enrollment, VDH held three debriefings with VDH staff and leadership, enrollment sites, CACs, case managers and various RW contractors to understand and assess the overall ACA open enrollment process, and to collaborate with stakeholders on how to improve the process for the next open enrollment period.

## *Challenges*

Healthcare.gov's release of critical ACA plan information (such as formularies, provider networks, and costs) was delayed several weeks. The federal government shutdown during that same timeframe hindered their communication about the enrollment process. The Healthcare.gov website suffered from multiple, well-publicized problems for the first 3 months of the enrollment period. These circumstances hampered VA ADAP's ability to fully analyze insurance plans. Labor intensive efforts, such as contacting each insurance carrier separately and developing alternative ways to access information, were required. Plans selected for ADAP support were finalized on December 3, 2013, and efforts to educate stakeholders about the plans were initiated at that time.

Unfortunately, several plans did not meet well-established standards of care for HIV infection, and therefore were not viable options for ADAP support. Plans offered by an insurance carrier with the broadest statewide coverage and the largest network of RW providers excluded two highly utilized antiretroviral combination medications from their formulary. Combination medications are standard of care due to the improved levels of adherence resulting from a single pill taken once a day. Effective treatment of HIV requires an unusually high level of adherence to suppress the virus, thereby reducing transmission and resistance. Since this was the only carrier in some areas of the state, no insurance plan option that met VA ADAP criteria was available for some clients. In addition, one insurance plan with better HIV medication coverage received disproportionately high ADAP enrollment, especially in areas where it was the only plan that met the criteria.

An additional challenge occurred when Healthcare.gov and its associated call center indicated all applicants with incomes below 138% of FPL needed to submit a Medicaid denial, regardless of Medicaid expansion status in their state of residence. Since Medicaid enrollment was not an option in states like Virginia that had not expanded their programs, VA ADAP contacted the National Alliance of State and Territorial AIDS Directors (NASTAD), who advocated with the Centers for Medicaid and Medicare Services (CMS), Consumer Information and Insurance Oversight branch. This resulted in a change in the enrollment process allowing clients in non-Medicaid expansion states to bypass this requirement. VA ADAP tested Healthcare.gov's website correction and confirmed that successful insurance enrollment occurred once this requirement to apply for a Medicaid denial was waived.

Because of these challenges, supporting client enrollment into ACA plans was time and labor intensive for both VA ADAP and the multiple stakeholders involved with the process.

VA ADAP staff spent from 4 to 6 hours per client during this process, extending work hours into the evening and up to seven days per week at times. The process for facilitating 2015 reenrollment of currently insured clients has not yet been released by the federal government. Unless there is an option to automatically reenroll clients desiring to stay on the same plan over into the next year, additional staff resources will be necessary to support this effort.

Clients have experienced challenges accessing medications through some insurance plans. Some clients were required to use mail order pharmacies that would not participate with VA ADAP's PBM. VA ADAP continues to work with insurance carriers to identify alternative solutions to medication access in these circumstances. Premium payment methods varied across carriers, preventing some enrollments. Some premiums paid by ADAP were not posted to clients' accounts for several days, resulting in incorrect disenrollments. Carriers refunded some premium payments to the client instead of the payer (VA ADAP), resulting in the need for additional staff efforts to recoup premium payments. VDH is working with the carrier insuring the largest number of VA ADAP clients to ensure any payment refunds are directed to VA ADAP when VA ADAP served as the payer. One carrier only allowed VDH to pay for one client premium per credit card, creating an unnecessary administrative barrier. VA ADAP continues to work with its contracted premium payment service to accommodate expedited check payments when needed, and to trouble-shoot problems encountered with premium payments.

Increased insurance enrollment has required some changes at agencies providing medical care to ADAP clients. First, these agencies needed to ensure their systems could accommodate an increase in insurance billing and claims processing. Second, to avoid duplicate payments and comply with federal RW payer of last resort requirements, VDH is transitioning how services reimbursable through insurance will be supported. Previously, the majority of medical costs were covered via salary support for health care staff. However, because most agencies will see a significant increase in insured clients and resulting reimbursement from insurance carriers, salary support is being phased out. Instead, VDH has established a fee-for-service arrangement for uninsured clients. This will prevent overlap of salary support and insurance reimbursement while continuing to fund care for uninsured individuals. In addition, VDH collaborated with NASTAD and the HIV Medicine Association to facilitate a meeting between all RW grantees to develop collaborative strategies to address these system changes. VDH also recruited participants for and contributed to a statewide training for RW service providers addressing how to track program income (revenue generated from insurance payments) in compliance with federal grant requirements.

### *Successes*

Based on NASTAD data, Virginia ADAP clients account for about 2% of all clients receiving ADAP services but represent over 17% of ADAP clients enrolled to ACA insurance plans nationwide and 58% of ADAP clients enrolled to ACA plans in southern states. Due to this success, VA ADAP was recognized by NASTAD at a national meeting and has been called on to participate in national discussions with federal government agencies associated with the ACA. Discussions addressed issues of national and state significance including the need to improve coordination of all RW funding to share the burden of health care costs, address challenges faced when insurance plan medication formularies lack critical antiretroviral medications, identify inadequate geographic coverage of ACA insurance plans that meet ADAP criteria and strengthen coordination of pharmacy benefits. ACA plan enrollment progress is depicted in Figure 2.

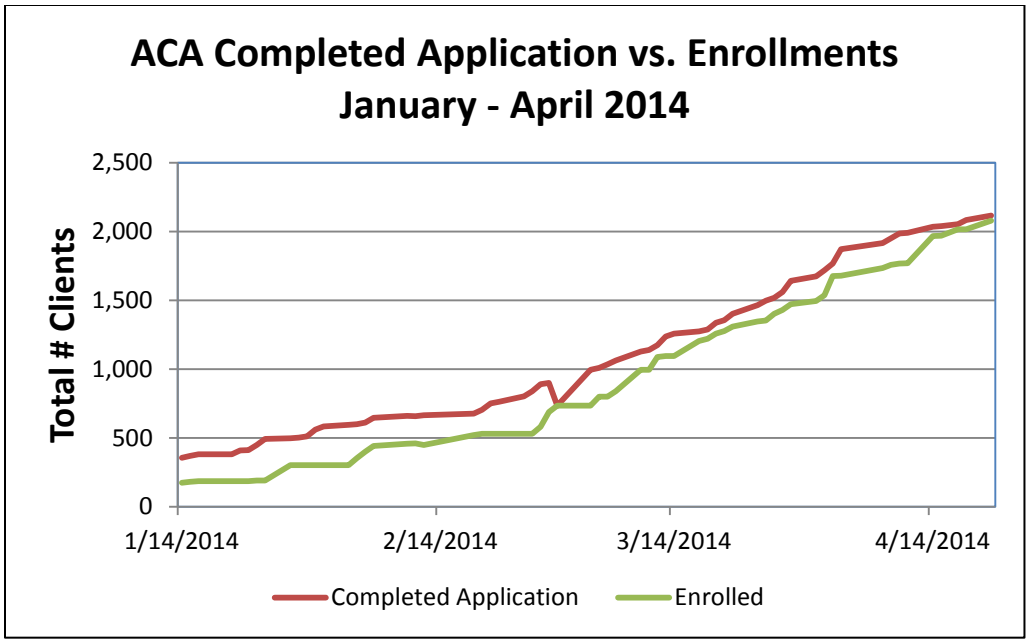



**Figure 2**

## Current Utilization

Since eliminating the VA ADAP waiting list in August 2012, utilization has continued to increase. As illustrated in Figure 3, between July 2013 and June 2014, VA ADAP enrolled an average of 45 net new clients per month. However, net program cost has not increased at a proportional rate due to the cost-effective use of insurance for the majority of VA ADAP clients, as well as continued national negotiations with pharmaceutical companies resulting in lower cost for directly purchased medications.

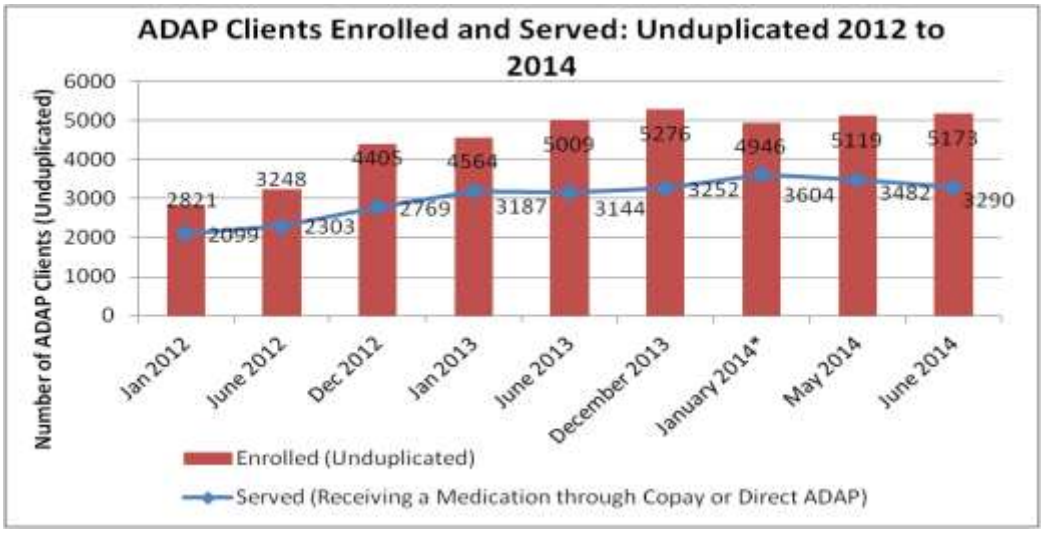



**Figure 3**

*Note: January 2014, disenrollment from Direct Purchase ADAP began for those not filling prescriptions within 6 months. 462 persons were disenrolled for this reason in January 2014.

As of June 30, 2014, 5,173 clients were enrolled in VA ADAP. Sixty percent receive services through ACA, MPAP or other insurance support, with 2,310 of those clients specifically enrolled in ACA plans. The remaining 40% of clients (2,060) receive medications through Direct Purchase ADAP. Figure 4 illustrates enrollment by program. Eligible Direct Purchase ADAP clients will be assisted with enrolling into ACA plans during the next open enrollment period occurring November 15, 2014 – February 15, 2015.

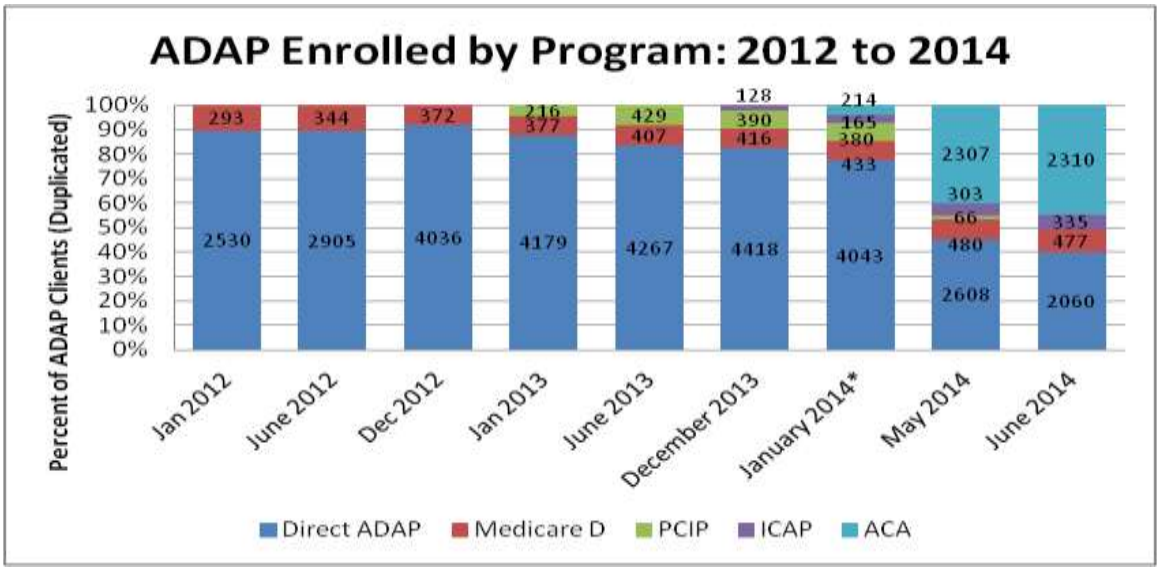



**Figure 4**

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 weekly basis and sends monthly summaries to the Chief Deputy Commissioner of Public Health and Preparedness.

Between July 2013 and June 2014, ADAP eligibility staff processed 1,616 new applications and 1,164 re-certifications. During this period, 1,727 persons were disenrolled from ADAP or denied upon initial application. Primary reasons included not picking up medications within the last 6 months (54%), having another payer source for medications (27%), and moving out of state (6.5%). Demand for ADAP services continues to grow, driven by several key factors. Department of Health and Human Services (DHHS) 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 CD4 counts, improves health outcomes for infected clients and reduces transmission to uninfected individuals. Increasing medication access to more persons with HIV will ultimately reduce the epidemic. The graph in Figure 5 illustrates that about one-third of new ADAP clients have a CD4 count over 500, and are initiating treatment early to maintain optimal health. When followed over time, the proportion of ADAP clients with higher CD4 counts increased to 56%, indicating increased health benefits supported by ADAP.

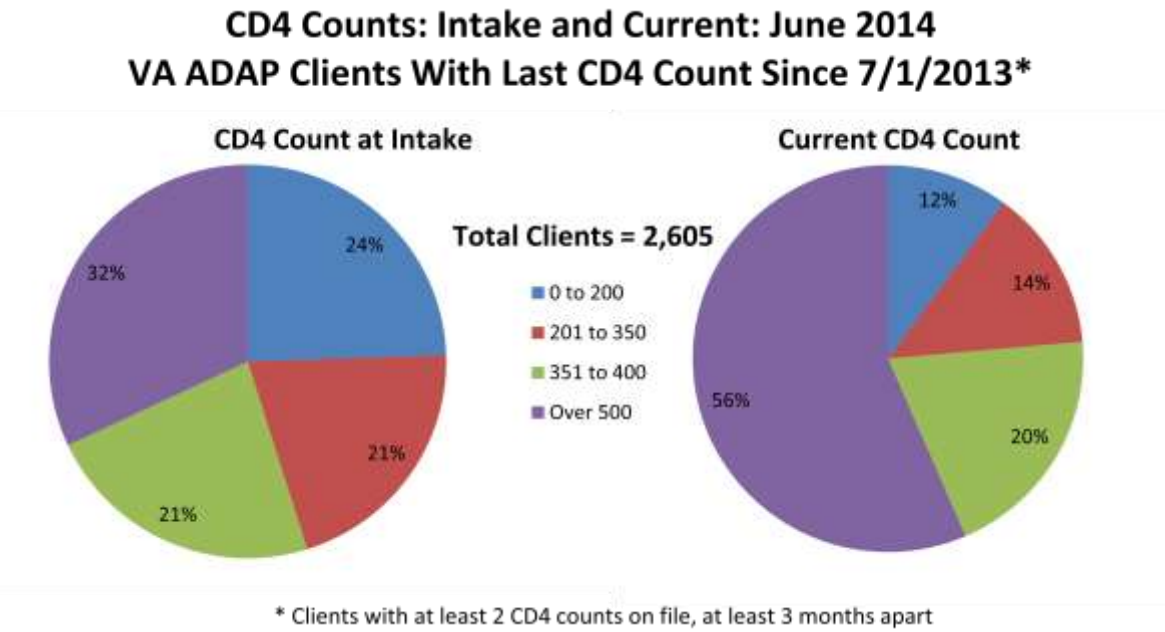



**Figure 5**

VDH has been awarded several million dollars in federal funds for new, highly visible national demonstration projects to increase early identification of HIV infection, facilitate linkage of newly diagnosed clients to care and improve retention in care, resulting in increased demand for medications through ADAP and, once enrolled, longer consistent periods of medication utilization due to better adherence and retention in care. Additionally, VDH has been expanding testing efforts throughout the state through a federally funded initiative. National estimates indicate about 18% of those people infected with HIV are unaware of their positive status. The goal of these efforts is to reduce that percentage and increase early entry into care. While these efforts increase utilization of ADAP, they also lead to clinically controlled HIV disease, which both reduces overall health care costs for clients and reduces transmission of HIV to others.

## Fiscal Status

The current GY 2014 ADAP services budget shows resources on hand of $39.5M. Federal funds make up 80% of current resources, including RW Part B formula-based funding and $11M in one-time awarded ADAP Emergency Relief Funding (ERF), which are competitive funds available to states with or at risk of implementing an ADAP waiting list. State funds support 14% of current ADAP resources, including the annual $2.6M ADAP appropriation, the $200,000 annual SPAP appropriation, and one-time reallocated funds from VDH. The remaining resources result from program revenue generated from rebates and Medicaid retroactive billing already collected.

As discussed in the "Projections" section of this report, certain unknown factors about insurance plans offered during the next open enrollment period impact whether existing resources will meet the current GY's need. Premium increases will require additional program resources, as new premium prices are effective January 2015. Medication formularies covered by insurance plans significantly impact whether resources will be able to meet client need. If certain highly utilized medications, including combination medications, are not included on insurance formularies, the ability for VA ADAP to provide those medications using current resources

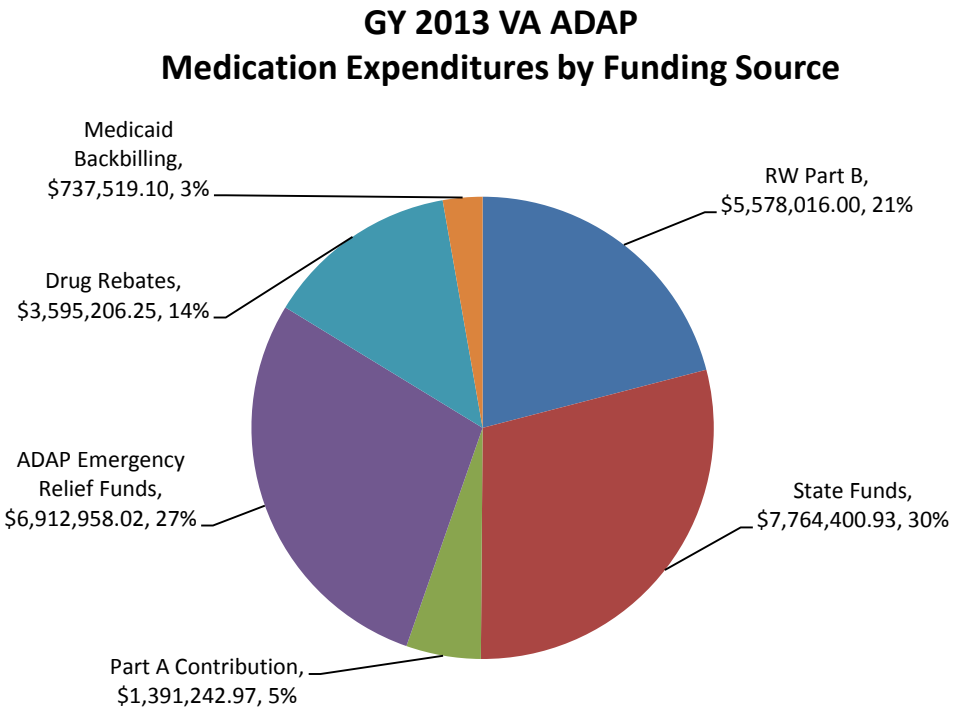
would require further assessment. If premium increases are no more than an average of 15% and if insurance formularies cover needed HIV medications in plans effective January 2015, then VA ADAP has adequate resources to avoid a medication waiting list for the remaining GY.

The largest funding source for VA ADAP services consists of federal RW Part B funds awarded through HRSA. Annual amounts fluctuate due to changes in Congressional appropriations and changes in living HIV cases nationally, as the award is formula based. 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 Purchase), with 18% supporting direct services and 12% supporting agency administration and program infrastructure. During the GY 2014 allocations process, VDH reduced funds to contractors by more than 54% and allocated those funds to ADAP services in GY 2014 to ensure an ADAP waiting list would not be implemented this year.

Reflected in the Figures 6 and 7 below, 21% of ADAP medication expenditures and 91% of insurance expenditures in GY 2013 were supported by federal funds. Federal funding included $4,984,251 in ADAP ERF awarded during that GY, in addition to a balance of $1,928,707 in ADAP ERF previously awarded from a prior application. Of note, ADAP ERF has been awarded on varying cycles by HRSA, and amounts in this report are being reported to synchronize with the RW GY (April 1, 2013 – March 31, 2014).

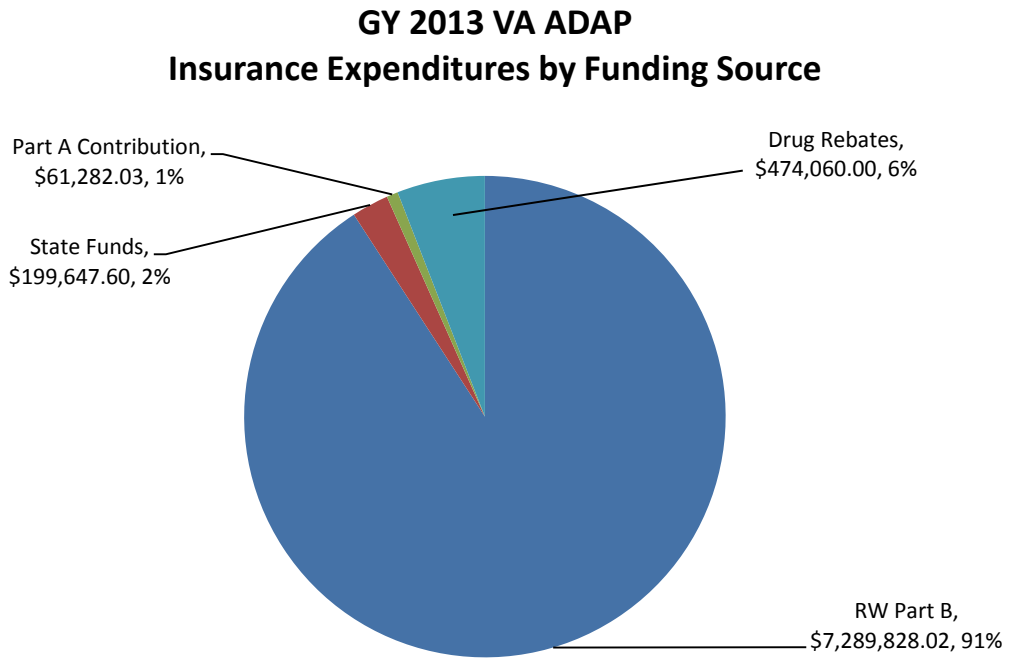
During GY 2013, both RW Part A grantees that serve urban jurisdictions in VA (i.e., the City of Norfolk and the Northern VA portion of the Washington, D.C. eligible metropolitan area) made a significant contribution to VA ADAP of $1,391,243, utilizing unspent grant balances at the end of the Part A budget period. Finally, state funds represented in Figure 6 reflect appropriations made in State Fiscal Year (FY) 2013 that were expended during the RW GY 2013.
During GY 2013, state contributions to VA ADAP totaled slightly over $7.7M. These funds were primarily used to purchase medications. With average monthly client costs for providing direct purchase medications at $852 per person ($10,224 annually), these state funds sustained an estimated 759 clients on direct purchase medications. A small portion of the state funds, under $200,000, supplemented funding needs for insurance support, serving 44 clients. Average monthly costs per client for insurance for GY13 were $860 before rebates, but were reduced to $382 per month per client ($4,585 annually) after accounting for the rebate revenue received during GY13 on medication copayments.

ADAP resources and expenditures are monitored on an ongoing basis and are reviewed weekly by a multidisciplinary team with monthly summaries reported to the Chief Deputy Commissioner of Public Health and Preparedness. This diligent monitoring and communication enabled assessment of resources and assisted with the elimination of the waiting list, which has allowed ADAP to serve more residents of the Commonwealth.




Grant Year April 1, 2013-March 31, 2014, 2013 Medication Expenditures $25,979,343.27

**Figure 6**




Grant Year April 1, 2013-March 31, 2014, 2013 Insurance Expenditures $8,024,817.65

**Figure 7**

*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. VDH leadership also uses this data to validate the number of clients served, prescriptions filled, and daily medication cost per client.

*Reduction of Federal Budget Due to Sequestration*
In accordance with the Budget Control Act of 2011, a series of spending cuts, called sequestration, cancelled approximately $85 billion in budgetary resources across the federal government for the remainder of the federal FY 2013. HRSA took steps to mitigate the effects of these cuts, but notified VDH that the RW GY 2013 award would be affected by an approximate 5% reduction. In June 2013, VDH received the final Notice of Grant Award (NOA) for RW Part B, which did reflect a one-time reduction of $1.2M. Sequestration did not impact the GY14 award.

## 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) are tracked monthly. The number of served clients (those actively receiving ADAP medications or insurance support) is the best predictor for ADAP costs. For GY 2013, 5,401 unduplicated clients received ADAP services with 3,698 receiving only direct medication services, 611 receiving only insurance services and 1,092 receiving both direct medication and insurance services (some clients access medications to avoid treatment disruption until insurance support is established). For GY 2014, 5,732 clients are projected to receive services, and 5,977 clients are projected for the subsequent year (which intersects with State FY 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 are satisified), client eligibility occurring throughout the year as a result of age or disability, as well as variations in MOOP 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 $4,550 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 2014 were released in late 2013 and the MOOP expenses (paid by VA ADAP) for those not receiving any tax subsidies was $6,350 per person annually. Projections were completed for GY14 and GY15 using the data available for the ACA plans from 2014, as 2015

cost structures are not yet available. For those receiving subsidy tax credits whose incomes are between 101% and 250% of the FPL, this MOOP expense 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 2014. The FPL distribution by program for clients enrolled in ADAP in June 2014 is illustrated in Figures 8 and 9. The majority of clients for both Direct Purchase ADAP (71%) and ACA (64%) 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, 72.2% are below 138% FPL and would be eligible for Medicaid expansion.

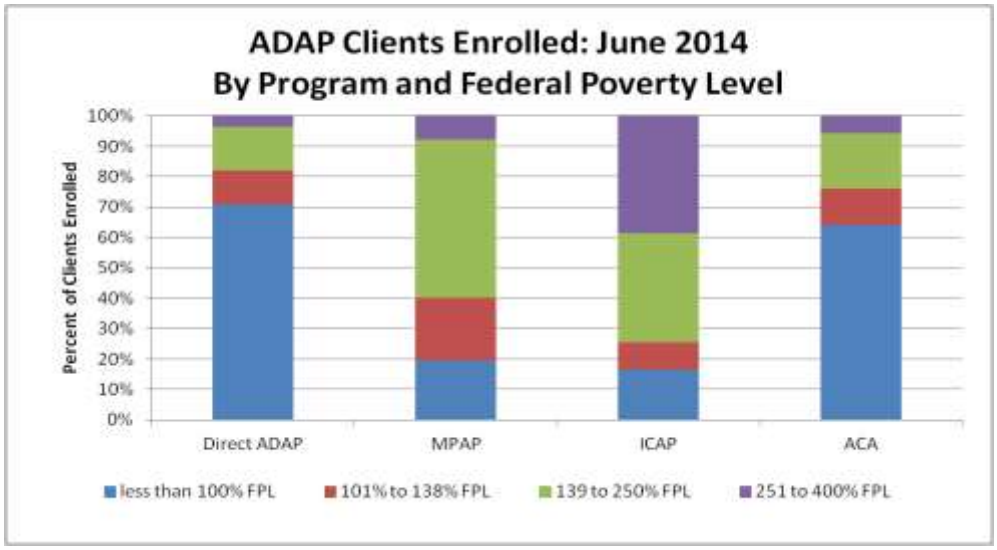



**Figure 8**

Using the 2014 ACA costs from the plans supported by VA ADAP, average annual costs for the population at or below 100% FPL would be $9,830 ($6,350 out of pocket, $3,480 premiums). This annual cost is lower than the average annual cost for a Direct Purchase ADAP client ($10,224), 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.

Estimates for each FPL using the ACA 2014 plan costs and other assumptions are depicted in the table below. The most cost effective portion of the population to insure under ACA is those with incomes between 101 and 250% FPL, as they receive both premium and cost sharing assistance, which translates into an estimated annual cost for VA ADAP of $6,933 before rebates. These

clients represent 30.2% of the current ADAP population enrolled in ACA. ADAP will continue to directly provide medications to an estimated 19.7% of the client population ineligible for insurance under ACA (for example, individuals with undocumented immigration status, individuals seeking insurance between open enrollment periods without a qualifying event or existing challenges with successfully enrolling into a plan).

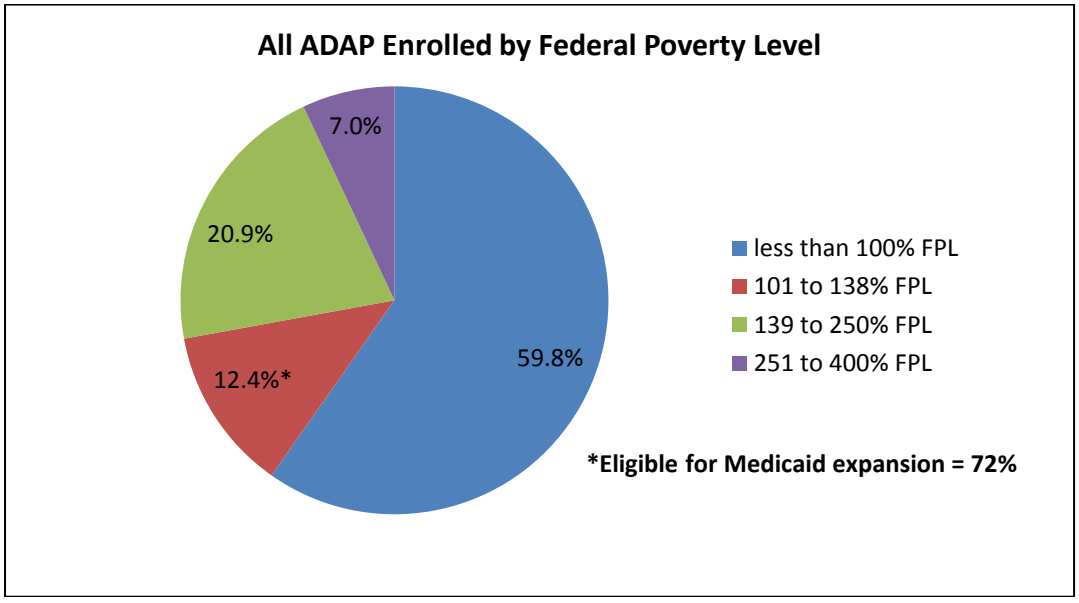



**Figure 9**

**Table 1. Estimates of ADAP Costs for ACA Insurance Plans by FPL**

| Federal Poverty Level | Premium | Cost Share Cap | Estimated Annual Cost | Percent Enrolled in ACA, June 2014 |
|---|---|---|---|---|
| At or Below 100% - No federal subsidization of premiums of cost shares | $3,480 | $6,350 | $9,830 | 64.1% |
| 101 to 250% - Federal subsidization of premiums and cost shares | $2,640 | $4,293 | $6,933 | 30.2% |
| 251 to 400% - Federal subsidization of premiums only | $2,796 | $6,350 | $9,146 | 5.6% |

*Rebates*

Rebates on medication cost shares have become an important source of revenue for VA ADAP over the past two years. These rebates are paid by pharmaceutical companies to state ADAPs through voluntary agreements. 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 costs so that federal dollars can be maximized for medication purchase. For example, some rebates may be used to fund certain services or administrative costs, allowing federal funds to be redirected to ADAP. Figure 10 illustrates cost share outlays and rebates received in GY13 (with rebate revenue lagging 3 months after the copayments that generated them), which demonstrates that VDH received $1.04 in rebates for each dollar of copayments expended.

While rebates are an essential piece of ADAP, 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.

In developing projections for ADAP for the next 18 to 24 months, rebates are calculated using a conservative estimate of eighty cents of rebate for each dollar of medication cost share outlay and assuming that rebates are lagged 3 months after the initial cost was paid. Projections are also done with and without rebate revenue, so that total cost outlays for the program are known.

**Insurance Copayment Costs and Rebate Revenue for April 2013 to March 2014, VA ADAP**

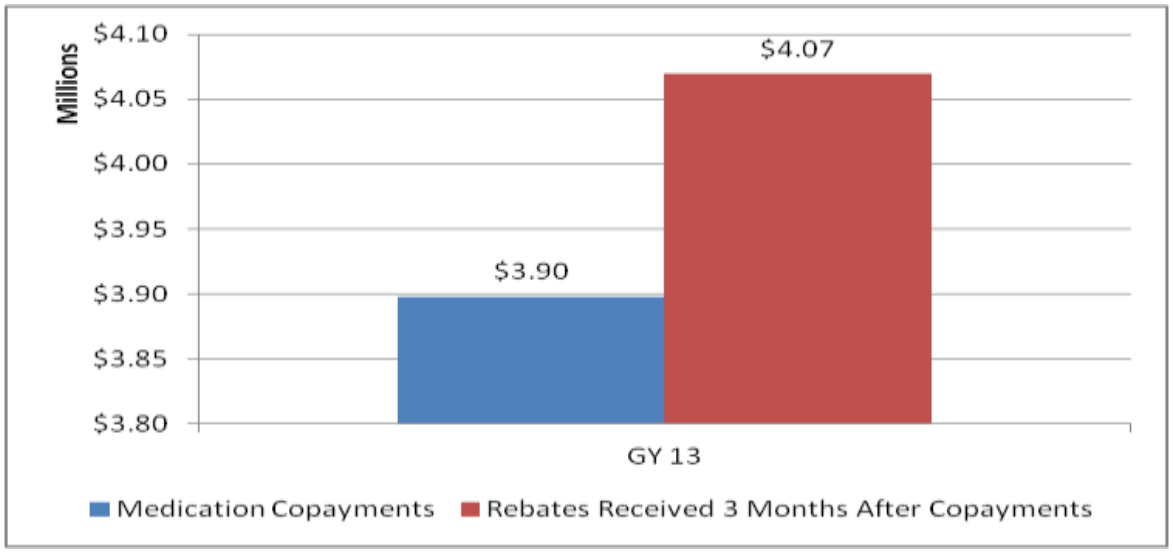



**Figure 10**

While rebates have become an important revenue source supporting ADAP sustainability, their future availability remains uncertain. Rebate terms are negotiated between the ADAP Crisis

Taskforce (a representative group of state ADAPs led by NASTAD) and pharmaceutical companies nationally. The outcome of upcoming negotiations will affect rebate amounts, with changes anticipated by January 1, 2015. Possibilities include a reduction of rebate amounts or elimination of rebates over time. Changes to current rebate terms could substantially change the ability to meet ongoing VA ADAP need.

*Cost Projections*

Figure 11 presents ADAP projections for the current and next RW GYs for five different scenarios. All costs associated with ACA plans for the next calendar year 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 (GY 2014). Therefore, substantial increases in costs could impact final GY 2014 quarter resource needs.

These projections assume continued program growth of approximately 41 new served clients per month, with 27 of these clients in Direct Purchase ADAP/ACA, 9 in Medicare D, and 5 in the private insurance continuation program. Because 2015 costs are unknown, insurance projections are based on current (2014) ACA plan costs (premiums and MOOP), with an additional scenario showing the impact of increased premiums. Program costs are shown both pre-rebates and post-rebates due to the uncertain future of rebate amounts.

The first scenario, "Direct ADAP for all persons," provides a benchmark by which to measure other scenarios. Without any insurance support or resulting rebates, total cost outlays are much higher under this scenario, at $44.2M and $49.1M in GY 2014 and GY 2015 for the same number of enrolled persons as other scenarios except Medicaid expansion. The number of persons served increases slightly from the other scenarios (except Medicaid expansion), as the projected utilization rate of Direct Purchase ADAP is higher than insurance programs (80% for Direct Purchase ADAP versus 60 to 65% of insured clients have filled prescriptions reported to VA ADAP on a monthly basis). Because VA ADAP does not receive data for insured persons once their MOOP is reached (and therefore ADAP is no longer making copayments), several months of prescription level data is not currently available. However, this missing data does not impact the cost projection. VA ADAP is working with its PBM, insurance carriers and federal partners to develop data sharing strategies to capture this missing information.

The second scenario, "Direct ADAP for all but MPAP," assumes that clients with Medicare Part D will continue to be served with funding through ADAP and SPAP, and all other clients will access medications through Direct Purchase ADAP. Program costs would be a pre-rebate $43.4M and $49.5M in GY 2014 and GY2015, and a post-rebate $41.9M and $47.7 for the same two years. Rebate revenue is generated from medication copayments for MPAP clients, contributing to cost effectiveness of this program, saving $1.5M in GY 2015 compared to the first scenario.

The third scenario is considered the most likely and shows an "increase of 15% in ACA premiums", based on preliminary discussions with multiple stakeholders who are monitoring national and state insurance trends. While information is limited, a premium increase is anticipated and would significantly impact projections and planning for ADAP sustainability.

This scenario assumes that those who are eligible for ACA will enroll between January and March of each year, leaving about 19.7% of ADAP clients not able to enroll in insurance and therefore utilizing directly purchased medications. The remaining 80.3% of clients would enroll into ACA plans by March 2015 and again during open enrollment for calendar year 2016. This scenario is more cost effective than the previous two scenarios, with an overall post-rebate cost of $34M in GY 2014 and $28.5M in GY 2015 (pre-rebate cost of $44M and $47.4M). The increase in premiums creates an additional $2M in cost per year. While VA ADAP does not play a role in regulation of premium increases, controls in this cost could substantially improve ADAP sustainability. Insurance carriers must obtain regulatory authorization from the Bureau of Insurance to increase premiums more than 10%, so ADAP costs will be reassessed after final premium prices are approved.

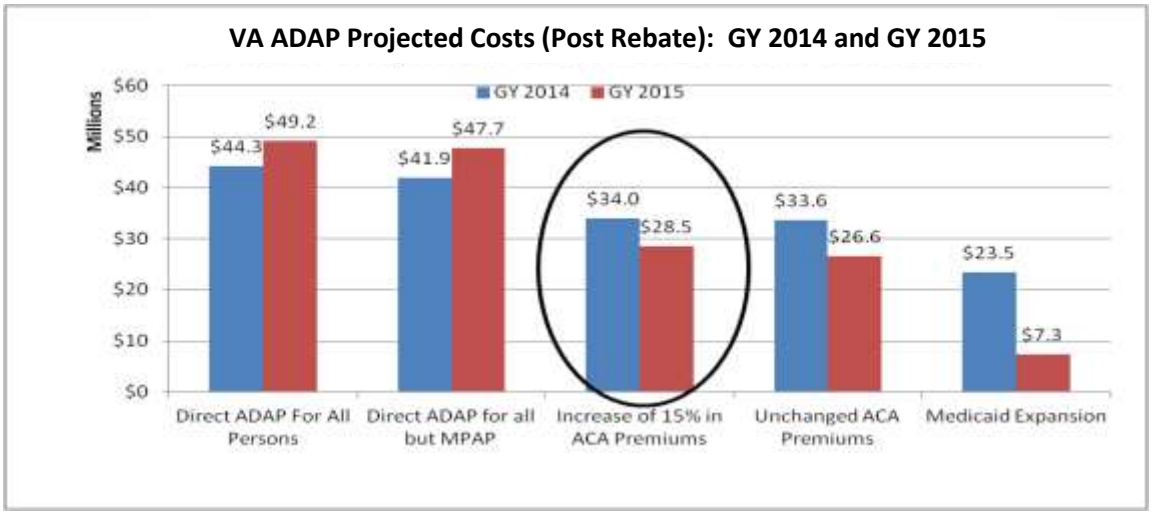



**Figure 11**

The fourth scenario, "unchanged ACA premiums," assumes that the costs for ACA plans remain stable in 2015 and 2016. This scenario results in initial ADAP outlays of $43.6M and $45.4M before rebates, but only $33.6M and $26.6M after rebates are received.

The fifth and last scenario, "Medicaid expansion", demonstrates cost savings if this change occurred on January 1, 2015. Over 80% of the Direct Purchase ADAP clients have incomes at or below 138% FPL and would be eligible for expanded Medicaid. In addition, 73% of the ACA enrolled population is also at or below 138% FPL. A smaller percentage of Medicare Part D clients (40%) and privately insured clients (25%) would be Medicaid eligible. Overall, 72.2 % of the ADAP enrolled population would be eligible for Medicaid expansion and the savings to ADAP in GY 2014 and GY 2015 would be large, with total costs after rebates reduced to $23.4M and $7.3M (pre-rebate costs of $33.5M and $13.3M).

Any scenario involving health insurance costs is dependent on inclusion of all necessary HIV medications on formularies offered through those plans. The DHHS provides evidence-based guidelines for the use of antiretroviral agents in HIV infected adults and adolescents (http://aidsinfo.nih.gov/). Certain medications, such as combination medications not covered by the some carriers in 2014, are recommended for first line treatment of patients with HIV disease. Selection of an appropriate antiretroviral regimen "should be individualized on the basis of

virologic efficacy, toxicity, pill burden, dosing frequency, drug to drug interaction potential, resistance testing results, comorbid conditions, and cost"[3]. There is no "one size fits all" medication regimen for HIV treatment. Exclusion of medications from coverage may compromise treatment options to achieve viral suppression. In addition, if plans do not cover commonly prescribed antiretroviral medications, cost effectiveness of insurance purchase will be significantly reduced. Complera® and Stribild® are two commonly prescribed combination medications that have not been covered on every insurance formulary in 2014. Purchasing those medications for insured clients would increase VA ADAP's cost by approximately $8.3M annually. The cost of supporting insurance premiums, medication cost shares as well as directly purchasing uncovered medications would result in a substantially more expensive program that would serve fewer clients, driving VA ADAP to consider when to cap services or implement a medication waiting list.

## 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 Virginia.

### *Eligibility and Utilization Monitoring*

VA ADAP will continue to monitor client eligibility and medication utilization across all ADAP service options 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 6 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 6 months, they and their medical provider are notified of ADAP disenrollment, unless mitigating factors are identified (such as a medically indicated treatment break). Clients may reapply to ADAP as needed, if circumstances change.

### *Insurance Continuation and Support*

Insurance purchase and support is now the predominant mechanism for providing medications to VA ADAP clients and will continue to serve an increasing proportion. It is the most cost effective option available at this time, with over two VA ADAP clients served through insurance support for the cost of serving one person through direct purchase of medications. Projections

[3] Panel on Antiretroviral Guidelines for Adults and Adolescents. Guidelines for the use of antiretroviral agents in HIV-1-infected adults and adolescents. Department of Health and Human Services. Available at http://aidsinfo.nih.gov/ContentFiles/AdultandAdolescentGL.pdf.

show a robust insurance support strategy will save VA ADAP $20.7M to $22.6M in GY15, compared with the cost of providing directly purchased medications for all clients. However, premium increases exceeding 15% and lack of insurance coverage for commonly prescribed antiretrovirals would decrease savings significantly, potentially jeopardizing VA ADAP's ability to serve all eligible clients. Although VA ADAP does not play a role in the regulatory control of insurance plan premium costs and formulary composition, the agency has provided extensive education to insurance carriers and other stakeholders, worked collaboratively across state agencies and leadership to dialogue about these challenges.

*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, beginning November 2014. Success of this effort will rely upon continuation of the extraordinary efforts that ADAP stakeholders (including medical providers, case managers, community based agencies, and consumers) showed during the inaugural open enrollment period.

Prior to the beginning of open enrollment, VA ADAP is working with the VDH Office of Licensure and Certification and the Bureau of Insurance to review plan details. An earlier assessment will allow 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 earlier will facilitate improved educational efforts to providers and clients, and identify possible coverage issues. VA ADAP is collaborating with other organizations, such as Virginia Commonwealth University, that share the common goal of enrolling clients to ACA insurance. This initiative aims to increase ACA plan enrollment in the Richmond metropolitan area. Although this initiative is not disease specific, VA ADAP's successes during the first open enrollment period resulted in the program's inclusion in this regional effort.

VA ADAP will continue engagement with the community to educate policy makers and other stakeholders about the necessity of ensuring access to all HIV antiretroviral medications. A change in HRSA's ADAP policy now allows the use of ADAP funds to support the costs of plans offering at least one drug per medication class. However, supporting plans with limited antiretroviral coverage may create barriers to effective treatment of HIV, potentially contributing to decreased adherence, disease progression, and development of viral resistance; in addition to the adverse financial impact to ADAP. VA ADAP will continue efforts to educate partners about the needs of low-income persons living with HIV/AIDS, including the need for affordable insurance coverage and medication formulary adequacy. VA ADAP is also working closely with the state supported HIV/AIDS Resource and Consultation Centers to provide education to 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.

*Maintaining Strong Community Partnerships*

Collaboration and communication that proved effective during the first open enrollment will be replicated in the upcoming months. Virginia Organizations Responding to AIDS (VORA) and pharmaceutical industry partners have reconvened statewide stakeholders meetings in preparation for the next open enrollment period. This group has 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 exchange of information necessary to improve access to medication for people living with HIV/AIDS.

*Pharmaceutical Manufacturer Rebates to ADAP*

Rebate revenue grew substantially during GY 2013 due to the successful enrollment of clients to ACA plans and the centralization of medication copayments for clients insured through private plans. Rebates make up 40% of national ADAP funding[4], and constituted 12% of the GY 2013 VA ADAP expenditures. Enrollment of all eligible ADAP clients during the second open enrollment period will result in additional revenue that will be directed to the support of premiums and cost shares for insured clients and direct medication purchase for the uninsured. Projections indicate rebate revenue could exceed $18M, if current rebate agreements continue and all eligible VA ADAP clients are enrolled into insurance. However, current rebate agreements expire in December 2014, and the future of ADAP rebates is uncertain. Early national discussions indicate either a reduction or partial elimination of ADAP rebates is likely. The outcome of national rebate negotiations will be monitored closely since significant reductions would cause an immediate need for additional ADAP funding.

*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.

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.

Data sharing within other units of the Division of Disease Prevention at VDH has helped to improve data 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 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 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 applied for a Special Projects of National Significance (SPNS) Health Information Technology grant, which would provide funding to improve reporting systems for both ADAP and RW services in the state. The proposed system would integrate reporting for ADAP and RW

[4] 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.

services and give providers a more flexible and responsive system with reports that could be customized at the contractor level.

*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. The AAC will be invaluable in providing first-hand experience with clients newly insured under the ACA, and guiding collaboration with an increased number of private providers who may begin caring for newly insured ADAP clients. The AAC's 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.

*Impact of Medicaid Expansion and Other Medicaid Options*

As illustrated in Figure 12, if Medicaid expands eligibility to serve persons at or below 138% FPL without the additional need to meet a category (such as aged, disabled or blind), then 72% of current VA ADAP clients would qualify. The benefit to clients would be significant, providing access to a wide scope of health care, medications, and supportive services beyond those related to HIV disease.

Costs to support insurance and medications through VA ADAP would significantly decrease, as would the number of clients. GY15 VA ADAP cost would fall to $7.3M as approximately 4,000 clients would transition to Medicaid. Cost savings would allow restoration of cuts made to services necessary for the health of low-income, insured and uninsured persons living with HIV/AIDS, for which funding was reduced by over 54% in GY 2014, and VA ADAP would be able to sustain services without the risk of capping services or implementing a waiting list.

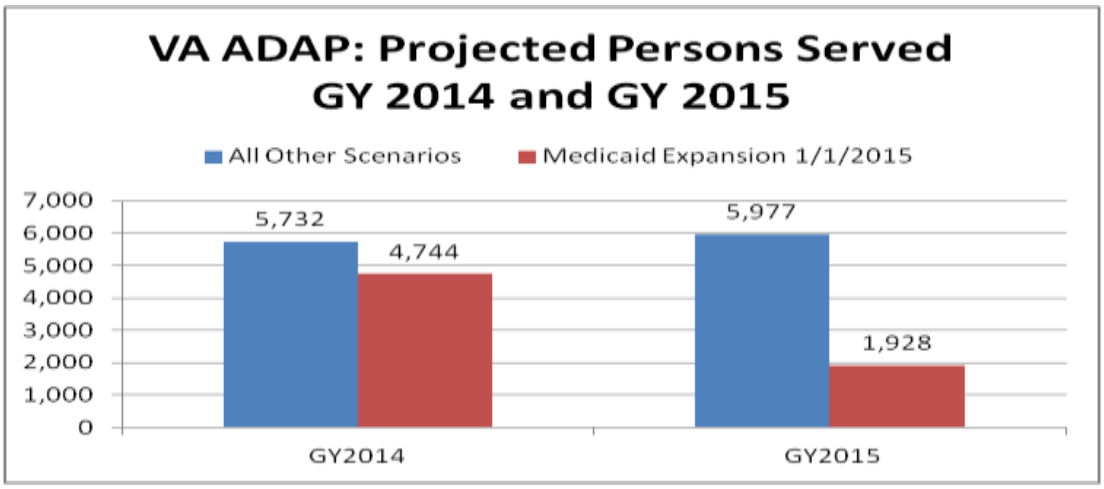



**Figure 12**

If Medicaid does not expand in the immediate future, an option to better serve persons who would otherwise be Medicaid eligible would be to seek a demonstration project waiver. Section 1115 Waiver of the Social Security Act, hereafter referred to as "1115," gives the Secretary of

Health and Human Services authority to approve experimental, pilot, or demonstration projects that promote the objectives of the Medicaid program. The purpose of these projects, which give states additional flexibility to design and improve their programs, is to demonstrate and evaluate policy approaches such as expanding eligibility to individuals who are not otherwise Medicaid eligible, providing services not typically covered by Medicaid and using innovative service delivery systems that improve care, increase efficiency, and reduce costs. These 1115 demonstration projects are approved for a five-year period and can be renewed, typically for an additional three years.

Creating disease-specific 1115 demonstrations projects is allowable, and the Centers for Medicare and Medicaid Services (CMS) has created a template for an HIV-specific waiver, located at http://medicaid.gov/Medicaid-CHIP-Program-Information/By-Topics/Waivers/1115/Downloads/Fillable-1115-Demo-10-12v2.pdf. Some states have successfully operated HIV-specific 1115 demonstration projects, including Maine, Massachusetts, and Washington, DC. While those states have now expanded Medicaid to serve clients previously covered under the demonstration projects, applications for new projects are still being accepted by CMS. If this action is supported, VDH would collaborate with the DMAS to assist with the application for an HIV-specific 1115 demonstration project.

*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 funding, and whether Medicaid expands. VA ADAP has identified $29.4M in reliably anticipated renewable federal and state funding for GY 2015. These resources include federal RW formula funding for ADAP, redirected RW service funding reallocated to ADAP, Medicaid retroactive billing recoveries, one quarter of rebates under current negotiated terms, and current state appropriations.

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 in availability or amount in future years. ADAP ERF has varied significantly over a four-year period, averaging $5.6M. Funds are competitively awarded and are not guaranteed year to year, contingent upon unspent national funds appropriated for other purposes. Funds awarded April 1, 2014 totaled $11M and were unusually high in relation to prior years (Year 1: $3M; Year 2: $3.5M; Year 3: $4.9M). The ADAP ERF competitive funding announcement was released August 11, 2014, and will provide up to 59 awards for amounts ranging from $100,000 to $11,000,000, pending availability of funds. The future of pharmaceutical industry rebates is unknown until upcoming national negotiations are completed.

If a worst case scenario of unavailable ADAP ERF and elimination of rebates occurs, then ADAP would face an unmet need of $18M for a program that would cost $47.4M (based on the third scenario “increase of 15% in ACA premiums” pre-rebate cost under the “Projections” section above). If an average ADAP ERF award is available ($6M) and new rebate terms provide a reduced amount ($7M), then ADAP unmet need would be reduced to approximately $5M. The unknown factors of ADAP ERF and rebates may result in greater need, but if these variables result in surplus funds, these could be returned to the source or applied to the

subsequent year's need through existing mechanisms (carrying over federal funds and purchasing medication inventory for future use).

## 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 adequate medication therapy that prevents viral replication and resistance. 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. Information about ACA insurance premium costs, medication formulary completeness, and Medicaid expansion will determine the next steps for continued sustainability of ADAP services. The Medicaid 1115 Waiver option may provide an alternative to serving the VA ADAP population if Medicaid does not expand in the Commonwealth.