

AIDS DRUG ASSISTANCE PROGRAM (ADAP)

**Fiscal Year 2017-18
May Revision Estimate**



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I. Program Overview

The California Department of Public Health (CDPH), Center for Infectious Diseases, Office of AIDS (OA), AIDS Drug Assistance Program (ADAP) provides access to life-saving medications for eligible California residents living with HIV, and will be providing assistance with covering costs related to HIV pre-exposure prophylaxis (PrEP) for clients at risk for acquiring HIV. ADAP services, including support for medications, health insurance premiums, and medical out-of-pocket costs, are provided to five groups of clients:

1. **Medication-only clients** are people living with HIV (PLWH) who do not have private insurance and are not enrolled in Medi-Cal or Medicare. ADAP covers the full cost of prescription medications on the ADAP formulary for these individuals. This group only receives services associated with medication costs.
2. **Medi-Cal share of cost (SOC) clients** are PLWH enrolled in Medi-Cal who have a SOC for Medi-Cal services. ADAP covers the SOC for medications for these clients. This group only receives services associated with medication costs.
3. **Private insurance clients** are PLWH who have some form of health insurance, including insurance purchased through Covered California, privately purchased health insurance, or employer-based health insurance; therefore, this group is sub-divided into three client sub-groups: Covered California clients, non-Covered California clients, and employer-based insurance clients. These groups receive services associated with medication costs, health insurance premiums, and medical out-of-pocket costs. Currently, employer-based insurance clients only receive medication services, but they will be offered health insurance premium and medical out-of-pocket cost services starting January 2018.
4. **Medicare Part D clients** are PLWH who are enrolled in Medicare and have purchased Medicare Part D plans for medication coverage. This group receives services associated with medication co-pays and Medicare Part D health insurance premiums. As part of this budget proposal, starting January 1, 2018, qualifying Medicare Part D clients will have the option for premium assistance with Medigap supplemental insurance policies, which cover medical out-of-pocket costs, or other medical out-of-pocket costs.
5. **PrEP clients** are individuals who are at risk for, but not infected with, HIV and have chosen to take PrEP as a way to prevent infection. The PrEP Assistance Program will start January 2018 and, as part of this budget proposal and accompanying trailer bill language, will cover both insured and uninsured clients. For insured clients, the PrEP Assistance Program will cover the gap between what the client's insurance plan and the manufacture's co-payment assistance program will pay towards medication costs. Both insured and uninsured PrEP Assistance Program clients will also receive services associated with PrEP-related medical out-of-pocket costs (see New Assumption # 1).

ADAP collects full rebate for prescriptions purchased for all client types listed above except Medi-Cal SOC and PrEP clients. As the primary payer, Medi-Cal has the right to claim federal mandatory rebate on prescriptions for Medi-Cal SOC clients. In order to

ensure duplicate rebate claims are not submitted to manufacturers by both programs, which is prohibited, ADAP does not invoice for rebates on these claims.

Historically, the majority of clients ADAP served were ADAP-only clients without health insurance because PLWH were unable to purchase affordable health insurance in the private marketplace. However, with the implementation of the Affordable Care Act (ACA), more ADAP clients have been able to access public and private health insurance coverage. ADAP clients are screened for Medi-Cal eligibility, and potentially eligible clients must apply. Clients who enroll in full-scope Medi-Cal are disenrolled from ADAP, because these clients have no SOC, drug co-pays or deductibles, and no premiums. All clients who obtain health coverage through Covered California or other health plans can remain in ADAP's medication program to receive assistance with their drug deductibles and co-pays for medications on the ADAP formulary. Eligible clients with health insurance can co-enroll in ADAP's health insurance assistance programs for assistance with their insurance premiums. Assisting clients with purchasing health insurance is more cost effective than paying the full cost of medications. In addition, assisting clients with purchasing and maintaining health insurance coverage improves the overall health of Californians living with HIV because clients have comprehensive health insurance and access to the full spectrum of medical care, rather than only HIV outpatient care and medications through the Ryan White (RW) system.

II. Estimate Overview

The ADAP Estimate for the 2017 May Revision provides a revised projection of Current Year [Fiscal Year (FY) 2016-17] and Budget Year (FY 2017-18) local assistance costs for the medication and health insurance programs for ADAP.

Table 1, page 5, shows the estimated ADAP local assistance expenditure need for the Current Year, and compares it to the amount reflected in the *2017-18 Governor's Budget*.

- For FY 2016-17, CDPH estimates that ADAP expenditures will be \$365.1 million, which is a \$2.6 million increase compared to the *2017-18 Governor's Budget*. The increase in expenditures is mainly due to an increase in medication-only clients and continuing increases in medication prices.
- For FY 2017-18, CDPH estimates that ADAP expenditures will be \$395.7 million, which is a \$13.5 million increase compared to the *2017-18 Governor's Budget*. OA estimates fewer clients transitioning from medication-only to private insurance associated with the proposed implementation of ADAP case management services (see Existing Assumption #1).

Table 2, page 5, shows the estimated ADAP rebate fund revenue for Current Year and Budget Year and compares them to the amount reflected in the *2017-18 Governor's Budget*.

- For FY 2016-17, CDPH estimates ADAP revenue will be \$298.8 million, which is a \$3.8 million decrease compared to the *2017-18 Governor's Budget*.
- For FY 2017-18, CDPH estimates ADAP revenue will be \$329.7 million, which is a \$24.7 million increase compared to the *2017-18 Governor's Budget*.

For FY 2016-17, the small decrease in revenue is due to estimated expenditures for 2016-Q3 and 2016-Q4 in the *2017-18 Governor's Budget* being less than actual expenditures, which are now available and result in a corresponding decrease in rebate.

For FY 2017-18, the increase in revenue is due mainly to the increase in the overall medication expenditures and an increase in the overall rebate percentage rate. See page 7 for additional revenue/rebate information.

California Department of Public Health AIDS Drug Assistance Program 2017 May Revision Table 1: Local Assistance (dollars in millions)								
Local Assistance	2017-18 Governor's Budget	Current Year FY 2016-17			2017-18 Governor's Budget	Budget Year FY 2017-18		
		2017 May Revision	\$ Change from 2017-18 Governor's Budget to 2017 May Revision	% Change from 2017-18 Governor's Budget to 2017 May Revision		2017 May Revision	\$ Change from 2017-18 Governor's Budget	% Change from 2017-18 Governor's Budget
Fund:								
Total Funds Requested	\$362.5	\$365.1	\$2.6	0.7%	\$382.2	\$395.7	\$13.5	3.5%
Federal Funds - Fund 0890	\$121.8	\$184.6	\$62.8	51.6%	\$117.4	\$111.4	-\$6.0	-5.1%
Rebate Funds - Fund 3080	\$240.7	\$180.5	-\$60.2	-25.0%	\$264.8	\$284.3	\$19.5	7.4%
Caseload	29,292	29,658	366	1.2%	30,994	32,003	1,009	3.3%

* Estimate numbers are rounded for presentation purposes; as a result, numbers may not total exactly.

Table 2: Rebate Fund Revenues (Fund 3080) 2017 May Revision (dollars in millions)								
Local Assistance	2017-18 Governor's Budget	Current Year FY 2016-17			2017-18 Governor's Budget	Budget Year FY 2017-18		
		2017 May Revision	\$ Change from 2017-18 Governor's Budget to 2017 May Revision	% Change from 2017-18 Governor's Budget to 2017 May Revision		2017 May Revision	\$ Change from 2017-18 Governor's Budget	% Change from 2017-18 Governor's Budget
Total Revenue Requested	\$302.6	\$298.8	-\$3.8	-1.3%	\$305.0	\$329.7	\$24.7	8.1%
Rebate Funds - Fund 3080	\$302.0	\$298.1	-\$3.8	-1.3%	\$304.3	\$329.1	\$24.7	8.1%
Interest Income	\$0.7	\$0.7	\$0.0	0.0%	\$0.7	\$0.7	\$0.0	0.0%

III. Overall Projections

A. Key influences on ADAP expenditures

- a. FY 2016-17: Compared to the *2017-18 Governor's Budget*, OA estimates that expenditures during FY 2016-17 will increase by 0.7 percent.
- b. FY 2017-18: Compared to the *2017-18 Governor's Budget*, OA estimates that expenditures during FY 2017-18 will increase by 3.5 percent. OA estimates significantly fewer clients transitioning from medication-only to private insurance associated with the proposed implementation of ADAP case management services (see Existing Assumption #1).

B. Expenditures

ADAP expenditures are broken out into two types: health care expenditures and enrollment/case management expenditures.

- a. Health care expenditures are estimated based on five client groups. Four of the client groups are PLWH: medication-only clients, Medi-Cal SOC clients, private insurance clients, and Medicare Part D clients. The fifth client group includes persons at risk for HIV who are receiving PrEP and are referred to as PrEP clients. Services the different client groups receive can include coverage of the following health care expenses: prescription medication costs for medications on the ADAP formulary (including deductibles, co-pays, and co-insurance); health insurance premiums; and medical out-of-pocket costs (e.g., deductibles and co-pays for physician visits, laboratory tests, etc). Expenditures are also shown by these different services for each client group. Estimated expenditures by client group are shown in Table 3. A detailed discussion of caseload and expenditures by client group and service type is in Section V on page 15.

CLIENT GROUP	HEALTH CARE EXPENDITURES	
	FY 2016-17	FY 2017-18
Medication-Only	\$304,977,994	\$308,864,703
Medi-Cal SOC	\$848,266	\$974,171
Private Insurance	\$32,142,670	\$55,890,180
Medicare Part D*	\$19,251,895	\$21,060,146
SUBTOTAL	\$357,220,825	\$386,789,200
PrEP	\$0	\$310,406
TOTAL	\$357,220,825	\$387,099,606

* Expenditures for Medicare Part D clients include Part D and Medigap premiums in FY 2017-18.

b. Enrollment/Case Management Expenditures

- Local ADAP enrollment services: Beginning in FY 2016-17, ADAP began allocating funds directly to ADAP enrollment sites based on ADAP's medication and insurance assistance enrollment numbers at each site. These funds may only be used for costs associated with enrolling and maintaining clients in ADAP. Local ADAP enrollment service cost estimates are approximately \$4.0 million annually for both FYs 2016-17 and 2017-18.
- Case management: In FY 2017-18, ADAP proposes allocating funds to ADAP enrollment sites that can provide case management services for ADAP clients who are not virally suppressed and/or who need assistance transitioning to private health coverage. ADAP estimates allocating approximately \$2.3 million for case management services in FY 2017-18 (see Existing Assumption #1 on page 12).
- Pharmacy Quality Incentive Program (QIP): In FY 2017-18, ADAP proposes allocating approximately \$2.3 million to pharmacies in the ADAP network that provide specific care and prevention measures identified by OA with the goal of improving health outcomes and reducing overall state costs (see Unchanged Assumption #2 on page 14).
- Contractor administrative fees: Administrative fees for the Pharmacy Benefits Manager (PBM) and Insurance and Medical Benefits Manager contractors are included in the medication and insurance assistance cost estimates. The new PBM contract does not allow the PBM to bill ADAP for non-approved transactions, effective July 1, 2016. ADAP paid \$3.9 million in total to the Enrollment Benefits Manager (EBM) contractor in FY 2016-17. According to the terms of the EBM contract, ADAP would have spent an additional \$550,000 for the remainder of FY 2016-17 and \$2.2 million in FY 2017-18; however, ADAP terminated this contract effective March 31, 2017, for material breaches of the contract, and has taken enrollment functions in-house. See New Assumption #2 on page 11 and Unchanged Assumption #1 on page 13.

C. Revenue

- a. ADAP Special Funds – ADAP receives both mandatory and voluntary supplemental rebates from drug manufacturers for ADAP drug expenditures. A six-month delay in rebate revenue exists because of the time required for billing the drug manufacturers and receipt of the rebate. Therefore, FY 2016-17 revenue estimates are based on actual rebates received for actual expenditures from January through June 2016, and estimated rebates received for actual expenditures from July through December 2016. FY 2017-18 revenue estimates

are based on estimated drug expenditures for the last two quarters of the current FY and the first two quarters of the budget FY.

- For FY 2016-17, OA estimates ADAP rebate revenues will decrease by 1.3 percent from \$302.6 million in the *2017-18 Governor's Budget* to \$298.8 million in the revised Current Year forecast.
- For FY 2017-18, OA estimates ADAP rebate revenues will increase by 8.1 percent from \$305.0 million in the *2017-18 Governor's Budget* to \$329.7 million in the revised Budget Year forecast.

For FY 2017-18, this estimate accounts for increased expenditures and an increase in the overall rebate percentage rate.

- b. Federal Funds – For FY 2016-17, federal fund expenditure authority increased by \$62.8 million compared to the 2017-18 Governor's Budget. The increase is due to a spending pattern shift in ADAP Earmark funds, a subcomponent of the federal RW Part B HIV Care grant. The ADAP Earmark funding is available to be utilized from April 1 to March 31 of any given year, which is known as the grant budget period. The first three months (April 1 through June 30) of the grant budget period fall into the current state FY and nine months (July 1 through March 31) fall into the state Budget Year. In prior years, ADAP primarily expended mandatory rebate funds during the months of April, May, and June. In FY 2016-17, ADAP has met the Health Resources and Services Administration (HRSA) requirement to spend mandatory rebate funds prior to federal funds and as a result plans on increasing spending of federal funds in April, May, and June 2017. In March 2017, ADAP received a partial Notice of Award for the 2017 ADAP Earmark funds. ADAP estimates spending \$87.8 million of the 2017 ADAP Earmark funds from April 1, 2017 to June 30, 2017. As reported in the 2017-18 November Estimate, additional federal fund expenditure authority includes \$75.9 million spent from July 1, 2016 to March 31, 2017 of 2016 ADAP Earmark funds, \$10.0 million spent from the 2016 RW Part B supplemental grant, and \$10.9 million spent from the 2015 ADAP Earmark carryover funds.

For FY 2017-18, ADAP's federal fund expenditure authority decreased by \$6.0 million compared to the 2017-18 Governor's Budget. The decrease is due to increased spending of the 2017 ADAP Earmark funding in FY 2016-17 (April 1, 2017 to June 30, 2017) leaving \$4.6 million to be spent in FY 2017-18 (July 1, 2017 to March 31, 2018). In March 2017, ADAP received a Notice of Award for the 2017 ADAP Emergency Relief grant in the amount of \$9.0 million. ADAP anticipates utilizing this funding in Budget Year after ADAP has met the HRSA spending requirement for mandatory rebates. Additionally, federal fund expenditure authority includes estimated 2017 RW Part B Supplemental grant funding in the amount of \$10.0 million and estimated 2018 ADAP Earmark funding in the amount of \$87.8 million for three months from April 1, 2018 to June 30, 2018. ADAP expects to receive a Notice of Award for the 2017 RW Part B Supplemental grant in September 2017 and for the 2018 ADAP Earmark funds

in March 2018. ADAP will update expenditure authority in the 2018-19 ADAP November Estimate and 2018-19 ADAP May Revision Estimate when notices are received.

- c. Match –HRSA requires grantees to have HIV-related non-HRSA expenditures. California’s HRSA match requirement for the 2017 Federal RW Part B Grant year (April 1, 2017 through March 31, 2018) is expected to be communicated at the end of May, 2017. OA anticipates the match requirement will be comparable to last year’s match requirement of \$65.3 million. OA will meet the match requirement using CDPH’s OA General Fund Support expenditures and local assistance expenditures for OA’s HIV Surveillance and Prevention Programs, as well as HIV-related expenditures from the California Department of Corrections and Rehabilitation.

IV. Assumption Projections

Below, we summarize the projected impact for each of the major fiscal assumptions.

New Assumptions/Premises

1. PrEP Assistance Program

As a result of a legislative augmentation in the 2016 Budget Act, CDPH received statutory and budgetary authority for ADAP to provide services to HIV-negative persons at risk for acquiring HIV by covering prescribed HIV PrEP medications on the ADAP formulary and related medical co-pays, co-insurance, and deductibles incurred by individuals accessing PrEP in California with annual incomes below 500 percent of the Federal Poverty Level (FPL). ADAP expected to implement this PrEP Assistance Program in the spring of 2017; however, given challenges with ADAP's enrollment system, OA now expects implementation will occur in January 2018.

For eligible insured clients, the PrEP Assistance Program will cover the gap between what health insurance and the manufacturer's co-payment assistance program will pay towards medication costs. CDPH has confirmed with the manufacturer, Gilead Sciences Inc., that for insured clients, Gilead will cover up to \$3,600 annually towards medication co-pays and deductibles, after which the CDPH PrEP Assistance Program would wrap around any remaining medication costs. The CDPH PrEP Assistance Program will also cover PrEP-related medical out-of-pocket costs for insured clients.

CDPH is proposing Trailer Bill Language to modify the California Health and Safety Code to clarify that the PrEP Assistance Program will pay for:

- 1) PrEP-related medical costs for uninsured clients; and
- 2) PrEP-related medical co-pays, co-insurance, deductibles, and drug costs not covered by a client's health insurance plan or the manufacturer's co-payment assistance program for insured clients.

With this change, uninsured clients who meet Gilead's income criteria of being at or below 500 percent of FPL, can get free drugs from Gilead's Patient Assistance Program until they can be navigated to more comprehensive health care coverage. Eligible uninsured clients will also be able to obtain assistance with PrEP-related medical costs through the CDPH PrEP Assistance Program.

In FY 2017-18, OA anticipates adding 450 clients to the PrEP Assistance Program (50 fewer clients than the 500 projected in the *2017-18 Governor's Budget*), resulting in \$311,000 in PrEP-related expenditures (\$87,000 in medication costs and \$224,000 in medical expenses). This amount is a decrease of \$91,701 from the \$401,701 in PrEP-related expenditures for FY 2017-18 projected in the *2017-18 Governor's Budget*. Of the 450 projected clients, OA projects that there will be a 50-50 split between insured and uninsured clients

enrolling into the PrEP Assistance Program. See section (V)(e) for details on PrEP Assistance Program expenditure estimates.

2. Termination of EBM Contract

Prior to July 1, 2016, ADAP's PBM contract included both pharmaceutical and enrollment services (see Unchanged Assumption #1). In April 2016, CDPH entered into two separate contracts: 1) a PBM contract (procured by the California Department of General Services, in collaboration with CDPH); and 2) an EBM contract. The intention of splitting the pharmaceutical and enrollment services was to increase competition among PBMs to achieve two specific goals: 1) to enhance client services and increase access to medications on the ADAP formulary; and 2) to lower overall program costs through savings in PBM administrative fees and drug reimbursement rates.

Effective April 1, 2016, ADAP entered into a three-year contract with a new EBM to develop and maintain a client eligibility portal to facilitate enrollment into ADAP and to provide customer service support to ADAP enrollment workers and clients via the EBM's Customer Support Team.

The contract with the new EBM was terminated effective March 31, 2017, for material breaches of contract. The decision was made in order to best serve the state's 29,000 ADAP clients. ADAP worked with a consulting firm to create a new ADAP enrollment system and has taken eligibility and enrollment functions in-house, including implementing a call center and a data processing center comprised of CDPH staff.

ADAP paid \$3.9 million in total to the EBM contractor in FY 2016-17. Termination of the EBM contract will result in local assistance cost-savings of \$550,000 in FY 2016-17 and \$2.2 million in FY 2017-18. State operation costs are not included in the ADAP Estimate. However, we expect an increase in state operation expenditures related to insourcing eligibility and enrollment functions of \$3.5 million in FY 2016-17 and \$4.2 million in FY 2017-18. These support costs will be covered by the ADAP Special Fund. Due to this shift in spending to state operations, there will be no EBM-related local assistance costs in FY 2017-18. Additional estimated one-time state operation costs of \$1.3 million that will impact the ADAP Special Fund in FY 2016-17 are related to material breaches of contract leading up to the EBM contract termination. These are costs that would have been incurred regardless of whether CDPH had taken enrollment and call center functions in-house. They are directly related to evaluating the security of the AJ Boggs enrollment portal not having a fully functioning enrollment system.

Existing Assumptions/Premises

1. ADAP Case Management Services

Providing enhanced services to medication-only clients and clients who are not virally suppressed through outreach and case management was a New Assumption in the FY 2017-18 November Estimate. By providing case management services, ADAP will be able to transition more medication-only clients to comprehensive health coverage. ADAP expects to allocate \$2.3 million to enrollment sites capable of conducting case management. Through the RW Program Compliance with Standards, Quality, and Timeliness Mandates Budget Change Proposal, ADAP has requested two full-time positions and \$251,000 in Special Fund support authority to establish an ADAP case management program.

A final rule introduced by the new federal administration entitled, "Patient Protection and Affordable Care Act; Market Stabilization," will shorten the dates for Covered California open enrollment from three months (from November 1, 2017 through January 31, 2018) to six weeks (from November 1, 2017 through December 15, 2017) for the benefit year starting January 1, 2018. ADAP expects to start implementing the case management program in July 2017; however, because of the shortened Covered California open enrollment period, OA is adjusting downward the projected number of clients that will transition from medication-only to private insurance during the 2017 open enrollment period. Medication-only clients proactively seeking to transition to private health coverage have already transitioned during the initial implementation of the ACA. OA anticipates that intensive outreach and case management is needed to help guide the remaining medication-only population to more comprehensive health coverage. As a result, cutting in half the open enrollment period results in cutting in half the number of clients able to be guided to comprehensive health insurance.

As a result of implementing this case management program, OA estimates 1,512 clients will transition from the medication-only client group to the private insurance client group. This is a decrease from the 2,948 clients projected in the *2017-18 Governor's Budget*. The estimated net savings for FY 2017-18 of \$30.4 million projected in the *2017-18 Governor's Budget* will be decreased by \$15.5 million to a net savings of \$14.9 million (\$23.3 million in drug expenditure savings, \$6.0 million in premium payments, \$108,000 in medical out-of-pocket costs, and \$2.3 million for case management services; rebate will not be impacted in FY 2017-18 because of the six-month delay in rebate collections).

2. Payment of Out-of-Pocket Medical Expenses for All OA-Health Insurance Premium Payment (OA-HIPP) Program Clients

ADAP currently pays private health insurance premiums and outpatient medical out-of-pocket costs for ADAP clients co-enrolled in OA-HIPP.

The 2016 Budget Act included funding authority to allow CDPH to pay health insurance premiums and medical out-of-pocket costs for all ADAP clients with health insurance, including those with employer-based insurance. Extending payment to include medical out-of-pocket costs and Medicare Part B premiums for clients co-enrolled in the Medicare Part D Premium Payment Program was an Existing Assumption in the *2017-18 Governor's Budget*.

ADAP expected to extend OA-HIPP services to clients with employer-based insurance in the spring of 2017; however, due to challenges with ADAP's enrollment system, implementation will likely be delayed until January 2018. There is no fiscal impact because of employer-based coverage in FY 2016-17. For FY 2017-18, ADAP projects an additional \$171,000 in premiums and out-of-pocket costs due to expanding service to individuals with employer-based coverage. This is a decrease from the \$1.1 million in additional premiums projected in the November Estimate.

In the *2017-18 Governor's Budget*, ADAP also proposed to implement coverage of Medicare Part B premiums and outpatient medical out-of-pocket costs, covered by Medigap policies, for ADAP clients co-enrolled in OA's Medicare Part D Premium Payment Program. However, ADAP has learned that Medicare Part B medical premiums are almost always automatically deducted from the individual's Social Security check and per federal RW statute, ADAP cannot directly reimburse an individual. As a result, ADAP is unable to implement this aspect of the program and has removed costs related to paying Medicare Part B premiums. ADAP will, however, move forward with implementing coverage for outpatient medical out-of-pocket costs or Medigap premiums (which pay medical out-of-pocket costs) for clients enrolled in OA's Medicare Part D Premium Payment Program. For FY 2017-18, ADAP projects \$270,000 in expenditures associated with outpatient medical out-of-pocket costs, including premiums for Medigap policies, for clients enrolled in OA's Medicare Part D Premium Payment Program.

Unchanged Assumptions/Premises

1. Anticipated Savings in ADAP PBM Fees

The projected savings in ADAP PBM fees was a New Assumption in the FY 2017-18 November Estimate.

Prior to July 1, 2016, ADAP's PBM contract included both pharmaceutical and enrollment services. The PBM was responsible for managing a pharmacy network of approximately 3,800 pharmacies throughout California that provided access to ADAP formulary drugs for ADAP clients, customer service support to ADAP enrollment workers and clients, and a web-based eligibility system. The former contract was executed on July 1, 2011 and expired on June 30, 2016.

Effective July 1, 2016, ADAP pays the new PBM, Magellan Rx Management, an approved transaction fee of \$1.75 per transition, a pharmacy dispensing fee of \$1.00 per transaction, and lower reimbursement rates for medications. The new PBM also

charges ADAP \$35.00 for each approved clinical Prior Authorization. The PBM costs include one-time costs of approximately \$3.0 million and on-going costs of approximately \$2.0 million annually.

In the previous PBM contract, ADAP paid an approved transaction fee of \$4.75, a pharmacy dispensing fee of \$4.05, and higher reimbursement rates for medications. ADAP also paid a \$2.00 fee for a non-approved transaction with a limit of no more than five non-approved transaction fees per prescription dispensed. In FY 2014-15, ADAP paid approximately \$1.75 million dollars in non-approved transaction fees. ADAP will not be charged non-approved transaction fees in the new PBM contract.

CDPH anticipates PBM savings of \$3.6 million in FY 2016-17 and \$3.9 million in FY 2017-18 due to lower dispensing and processing fees and the elimination of non-approved transaction fees.

2. ADAP Pharmacy QIP

The implementation of a QIP aimed at improving patient care, health outcomes, and patient satisfaction was a New Assumption in the FY 2017-18 November Estimate.

HRSA recommended that OA identify a quality improvement methodology and a service category to undertake quality improvement activities. In the 2017 RW Part B grant application, ADAP requested using \$2.3 million in ADAP Earmark funds to establish a pharmacy QIP. ADAP sent surveys to pharmacies within the ADAP network in mid February, 2017 to identify services provided within ADAP pharmacies that could benefit from quality improvement activities. Our PBM is currently compiling survey responses and will present the results to CDPH by late April, 2017. Based on the findings of the survey, ADAP will develop an incentive program to improve the quality of services provided.

Discontinued Major Assumptions

There are no Discontinued Major Assumptions.

V. Expenditure Details

A detailed breakdown of caseload and expenditures by client group and service type is shown below in Tables 4 and 5.

TABLE 4: ESTIMATED ANNUAL CASELOAD AND EXPENDITURES BY CLIENT GROUP AND SERVICE TYPE, FY 2016-17

CLIENT GROUP	CASELOAD		SERVICE TYPE EXPENDITURE			
	NUMBER	PERCENT	MEDICATIONS	INSURANCE PREMIUMS	MED OUT-OF-POCKET	TOTAL EXPENDITURE
Medication-Only	13,288	44.80%	\$304,977,994	\$0	\$0	\$304,977,994
Medi-Cal SOC	139	0.47%	\$848,266	\$0	\$0	\$848,266
Private insurance*	7,769	26.19%	\$12,626,068	\$18,673,191	\$843,410	\$32,142,670
Medicare Part D*	8,462	28.53%	18,915,167	\$336,729	\$0	\$19,251,895
SUBTOTAL	29,658	100.00%	\$337,367,495	\$19,009,920	\$843,410	\$357,220,825
PrEP	0	0.00%	\$0	\$0	\$0	\$0
TOTAL	29,658	100.00%	\$337,367,495	\$19,009,920	\$843,410	\$357,220,825

* Subgroup of 4,431 clients receiving assistance for premium payments and medical-out-of-pocket costs.

Estimate numbers are rounded for presentation purposes; as a result, numbers may not total exactly.

TABLE 5: ESTIMATED ANNUAL CASELOAD AND EXPENDITURES BY CLIENT GROUP AND SERVICE TYPE, FY 2017-18

CLIENT GROUP	CASELOAD		SERVICE TYPE EXPENDITURE			
	NUMBER	PERCENT	MEDICATIONS	INSURANCE PREMIUMS	MED OUT-OF-POCKET	TOTAL EXPENDITURE
Medication-Only	12,870	40.21%	\$308,864,703	\$0	\$0	\$308,864,703
Medi-Cal SOC	153	0.48%	\$974,171	\$0	\$0	\$974,171
Private insurance*	10,068	31.46%	\$17,359,777	\$36,802,391	\$1,728,012	\$55,890,180
Medicare Part D**	8,462	26.44%	20,012,246	\$778,349	\$269,550	\$21,060,146
SUBTOTAL	31,553	98.59%	\$347,210,897	\$37,580,740	\$1,997,562	\$386,789,200
PrEP	450	1.41%	\$86,625	\$0	\$223,781	\$310,406
TOTAL	32,003	100.00%	\$347,297,522	\$37,580,740	\$2,221,343	\$387,099,606

* Subgroup of 6,904 clients receiving assistance for premium payments and medical-out-of-pocket costs.

** Medical out-of-pocket costs for Medicare Part D clients include Medigap premiums.

a. Medication-only clients

This client group includes individuals who do not have private insurance and are not enrolled in Medi-Cal or Medicare Part D. ADAP covers the full cost of prescription medications for these individuals for medications on the ADAP formulary. This group only receives services associated with medication costs.

1. Medication Expenditures

- For FY 2016-17, OA estimates medication expenditures for medication-only clients will be \$305.0 million, which is a \$5.0 million increase compared to the *2017-18 Governor's Budget*. The increase in expenditures is mainly due to an increase in medication-only clients, as most eligible clients have transitioned to Medi-Cal Expansion, and the program enrollment is starting to increase at rates similar to pre-ACA implementation because the number of Californians living with HIV continues to rise each year due to new infections. Medication price increases also have a substantial impact.
 - For FY 2017-18, OA estimates medication expenditures for medication-only clients will be \$308.9 million, which is a \$11.0 million increase compared to the *2017-18 Governor's Budget*. The increase in FY 2017-18 expenditures compared to FY 2016-17 is mainly due to a decrease in the estimated number of clients that will transition to comprehensive health care coverage from ADAP case management services (Existing Assumption #1).
2. Health Insurance Premiums: There are no health insurance premium expenditures for medication-only clients.
 3. Medical Out-Of-Pocket Costs: There are no medical out-of-pocket cost expenditures for medication-only clients.

b. Medi-Cal SOC clients

This client group includes individuals enrolled in Medi-Cal who have a SOC for Medi-Cal services. This group receives services associated with medication costs.

1. Medication Expenditures

- For FY 2016-17, OA estimates medication expenditures for Medi-Cal SOC clients will be \$848,000, which is a \$119,000 increase compared to the *2017-18 Governor's Budget*. The increase in expenditures is due to higher SOC amounts associated with Medi-Cal clients enrolled in ADAP.
 - For FY 2017-18, OA estimates medication expenditures for Medi-Cal SOC clients will be \$974,000, which is a \$181,000 increase compared to the *2017-18 Governor's Budget*. The increase in FY 2017-18 from FY 2016-17 expenditures is due to rising costs associated with this client group.
2. Health Insurance Premiums: There are no health insurance premium expenditures for Medi-Cal SOC clients.
 3. Medical Out-Of-Pocket Costs: There are no medical out-of-pocket cost expenditures for Medi-Cal SOC clients.

c. Private insurance clients

This client group includes individuals who have some form of health insurance, including insurance purchased through Covered California, privately purchased

health insurance, or employer-based health insurance; therefore, this group is sub-divided into three client sub-groups: Covered California clients, non-Covered California clients, and employer-based insurance clients. These groups receive services associated with medication costs, health insurance premiums, and medical out-of-pocket costs. Currently, employer-based insurance clients only receive medication services, but they will be offered health insurance premium and medical out-of-pocket cost services starting January 2018.

1. Medication Expenditures

- For FY 2016-17, OA estimates medication expenditures for all private insurance clients will be \$12.6 million, which is a \$1.6 million increase compared to the *2017-18 Governor's Budget*. The increase in expenditures is due to higher than anticipated deductibles, co-pays, and co-insurance associated with private insurance clients.
- For FY 2017-18, OA estimates medication expenditures for all private insurance clients will be \$17.4 million, which is a \$2.4 million increase compared to the *2017-18 Governor's Budget*. The increase in FY 2017-18 expenditures is due to the same reason as above.

2. Health Insurance Premiums

- For FY 2016-17, OA estimates health insurance premium payment expenditures for all private insurance clients will be \$18.7 million, which is a \$1.3 million increase compared to the *2017-18 Governor's Budget*. Monthly premiums for both Covered California and non-Covered California clients increased with the 2017 open enrollment period.
- For FY 2017-18, OA estimates health insurance premium payment expenditures will be \$36.8 million, which is a \$7.3 million increase compared to the *2017-18 Governor's Budget* and a \$18.1 million increase compared to FY 2016-17. This increase is due to the transition of medication-only clients to private insurance due to ADAP case management services (Existing Assumption #1) as well as the annual increase in monthly premium.

3. Medical Out-Of-Pocket Costs

- For FY 2016-17, OA estimates medical out-of-pocket costs for all private insurance clients will be \$843,000, which is a \$595,000 decrease from the *2017-18 Governor's Budget*. Fewer clients than previously anticipated are utilizing this benefit.
- For FY 2017-18, OA estimates medical out-of-pocket costs will be \$1.7 million, which is a \$4.6 million decrease from the *2017-18 Governor's Budget*. Fewer clients than previously anticipated are expected to use this benefit in FY 2017-18; however, OA estimates that use of this benefit will continue to increase over time.

d. Medicare Part D clients

This client group includes individuals who are enrolled in Medicare and have purchased Medicare Part D plans for medication coverage. This group receives services associated with medication costs and Medicare Part D health insurance

premiums. As part of this proposal, starting January 2018, OA Medicare Part D Premium Payment Program clients will also be eligible for coverage of Medigap supplemental insurance premiums (which cover medical out-of-pocket costs) or outpatient medical out-of-pocket costs.

1. Medication Expenditures

- For FY 2016-17, OA estimates medication expenditures for Medicare Part D clients will be \$18.9 million, which is no change from the *2017-18 Governor's Budget*.
- For FY 2017-18, OA estimates medication expenditures for Medicare Part D clients will be \$20.0 million, which is also no change from the *2017-18 Governor's Budget*.

2. Health Insurance Premiums

- For FY 2016-17, OA estimates Medicare Part D premium payment expenditures will be \$337,000, which is an \$177,000 decrease from the *2017-18 Governor's Budget*. This is due to monthly premium payments beginning in January 2017; historically, premiums were paid annually usually in January of each calendar year.
- For FY 2017-18, OA estimates Medicare Part D premium payment expenditures will be \$778,000, which is a \$888,000 decrease compared to the *2017-18 Governor's Budget* due to the fact that ADAP is unable to cover Medicare Part B insurance.

3. Medical Out-Of-Pocket Costs

- For FY 2016-17, there will be no out-of-pocket costs for Medicare Part D clients.
- For FY 2017-18, OA estimates medical out-of-pocket costs will be \$270,000, including premiums for Medigap policies.

e. PrEP clients

This client group includes HIV-negative persons at risk for acquiring HIV who are taking PrEP. For insured clients, the PrEP Assistance Program will cover the gap between what the client's health insurance plan and the manufacturer's co-payment assistance program will pay towards medication costs, along with any PrEP-related medical out-of-pocket costs. Clients without health insurance will receive benefits related only to PrEP-related medical costs, as they will receive free drug from the manufacturer's free drug program. ADAP expects to implement this PrEP Assistance Program in January 2018. (New Assumption #1).

1. Medication Expenditures:

- For FY 2016-17, there will be no medication expenditures for this client group.
- For FY 2017-18, OA estimates medication expenditures will be \$87,000 for PrEP clients.

2. Health Insurance Premiums: Health insurance premium coverage is not currently included in the PrEP Assistance Program.

3. Medical Out-Of-Pocket Costs

- For FY 2016-17, OA there will be no medical out-of-pocket costs for PrEP clients.
- For FY 2017-18, OA estimates medical out-of-pocket costs will be \$224,000 for PrEP clients. From January through June 2018, ADAP estimates 75 clients per month enrolling in the PrEP Assistance Program with 50.0 percent uninsured and 50.0 percent insured. Estimated costs include one medical visit and one lab visit per quarter. For insured PrEP clients, the average monthly out-of-pocket cost of medical and lab visits was estimated at \$25 based on Covered California plans. This resulted in estimates of \$202,000 for medical costs for uninsured PrEP clients and \$22,000 for medical out-of-pocket costs for insured PrEP clients.

VI. Future Fiscal Issues

1. The HRSA 340B Drug Pricing Program Omnibus Guidance

The U.S. Department of Health and Human Services, HRSA administers section 340B of the Public Health Services Act, which is referred to as the “340B Drug Pricing Program.” Since 1992, HRSA has interpreted the statutory requirements of the 340B Drug Pricing Program (340B Program) through guidance published in the Federal Register. The 340B Program requires drug manufacturers to provide outpatient drugs to eligible covered entities at significantly reduced prices. The 340B Program allows covered entities to stretch finite federal resources to reach more eligible underserved/uninsured patients and provide additional comprehensive services.

Eligible covered entities include RW programs such as ADAP. California ADAP receives the 340B discount in the form of drug rebates, including collecting full rebate on claims for which ADAP only pays a portion of the drug cost (e.g., prescription co-pays), as is currently allowed by HRSA. These full rebates on partial pay claims are a vital part of ADAP’s annual budget.

On August 28, 2015, HRSA proposed new 340B Drug Pricing Program Omnibus Guidance in the Federal Register.

(<https://www.federalregister.gov/articles/2015/08/28/2015-21246/340b-drug-pricing-program-omnibus-guidance>). The proposed guidance would have limited ADAPs’ authority to collect full rebates on partial pay claims. The guidance proposed that the 340B discount on partial pay claims only be permitted if ADAP pays the premium on behalf of the client for the health insurance plan tied to the claim.

On January 30, 2017, the Office of Management and Budget withdrew the proposed 340B Omnibus Guidance. As such, OA projects there will be no fiscal impact in FYs 2016-17 or 2017-18.

2. Potential Increase in Federal Funds: 2017 RW Part B Supplemental Grant

In March 2017, HRSA released the funding opportunity announcement for the 2017 RW Part B Supplemental Grant. HRSA anticipates that approximately \$218.0 million will be available nationwide in 2017 RW Part B Supplemental funds. CDPH anticipates HRSA will award funds in September 2017. If awarded, these funds will be spent in the Budget Year.

The table below shows historically how much CDPH applied for the RW Part B Supplemental grants and how much was received:

Table 6: ADAP RW Part B Supplemental Funds		
Grant Budget Period	Application(s)	Funds Received
2010 (09/30/2010 - 09/29/2011)	\$3,700,000	\$2,659,865
2011 (09/30/2011 - 09/29/2012)	\$2,659,865	\$1,376,784
2012 (09/30/2012 - 09/29/2013)	\$2,659,865	\$2,129,954
2013 (09/30/2013 - 09/29/2014)	\$4,213,927	\$1,738,531
2014 (09/30/2014 - 09/29/2015)	\$2,000,000	\$2,000,000
2015 (09/30/2015 – 09/29/2016)	\$10,000,000	\$10,000,000
2016 (09/30/2016 – 09/29/2017)	\$10,000,000*	\$10,000,000*
*An additional \$8.7 million for HIV Care core medical and support services was received. Total supplemental funds received were \$18.7 million.		

3. New HIV Drugs

The following HIV drug may receive U.S. Food and Drug Administration (FDA) approval in the next few years:

- Bictegravir/emtricitabine/tenofovir alafenamide
This new HIV drug combines an integrase strand inhibitor (bictegravir) with two nucleoside reverse transcriptase inhibitors (emtricitabine and tenofovir alafenamide) and is in phase III trials. As of January 31, 2017, the manufacturer, Gilead Sciences Inc., has not submitted a New Drug Application (NDA) for this drug to the FDA.
- Darunavir/cobicistate/emtricitabine/tenofovir/alafenamide
This new HIV drug is a single tablet regimen for HIV treatment and is currently in phase III trials. As of January 31, 2017, the manufacturer Janssen Pharmaceutical has not submitted an NDA for this drug to the FDA.
- Dolutegravir/rilpivirine
This new HIV drug combines an integrase inhibitor (dolutegravir) with a non-nucleoside reverse transcriptase inhibitor (rilpivirine) into a single tablet maintenance regimen. This drug is currently in phase III trials. As of January 31, 2017, the manufacturer, GlaxoSmithKline PLC, has not submitted an NDA for this drug to the FDA.

If bictegravir/emtricitabine/tenofovir alafenamide, darunavir/cobicistate/emtricitabine/tenofovir/alafenamide, and/or dolutegravir/rilpivirine receive FDA approval and the ADAP Medical Advisory Committee approves addition to the ADAP formulary, OA will monitor pricing and supplemental rebates. If OA is able to determine that the drug costs will be cost neutral, ADAP will move forward with adding these drugs to the ADAP formulary.

VII. Fund Condition Statement

Table 7: Fund Condition Statement¹ (in thousands)					
Special Fund 3080: AIDS Drug Assistance Program Rebate Fund			FY 2015-16 Actuals	FY 2016-17 Estimate	FY 2017-18 Estimate
1	BEGINNING BALANCE		125,142	221,038	332,315
2	Prior Year Adjustment		499	0	0
3	Adjusted Beginning Balance		125,641	221,038	332,315
4	REVENUES, TRANSFERS AND OTHER ADJUSTMENTS				
5	Revenues				
6	4163000 Income From Surplus Money Investments (Interest)		623	650	650
7	4171400 Escheat - Unclaimed Checks, Warrants, Bonds, and Coupons		31	0	0
8	4172500 Miscellaneous Revenue		275,754	298,145	329,070
9	Total Revenues, Transfers, and Other Adjustments		276,408	298,795	329,720
10	Total Resources		402,049	519,833	662,035
11	EXPENDITURES AND EXPENDITURE ADJUSTMENTS				
12	Expenditures				
13	8880	FI\$Cal	2	1	2
14	4265	Department of Public Health			
15		State Operations ^{2,3}	1,567	6,954	6,779
16		Medication Local Assistance	165,067	160,670	244,475
17		Insurance Local Assistance	14,375	19,853	39,802
18	9900	Statewide General Administrative Expenditures		40	80
19	Total Expenditures and Expenditure Adjustments		181,011	187,518	291,138
20	FUND BALANCE		221,038	332,315	370,897
Row 6: Interest Actuals for FY 2015-16, Estimated for FYs 2016-17 and 2017-18			623,000	650,000	650,000
Miscellaneous Revenue					
Actual Rebate received July - Sept 2016 for Actual Expenditures from Jan - March 2016				81,714,879	
Actual Rebate received Oct - Dec 2016 for Actual Expenditures from Apr - June 2016				73,138,540	
Estimated Rebates received Jan - June 2017 for Actual Expenditures from July - Dec 2016				143,291,873	
Estimated Rebates to be received Jul - Dec 2017 for Estimated Expenditures from Jan - Jun 2017					173,833,572
Estimated Rebate to be received Jan - Jun 2018 for Estimated Expenditures from July - Dec 2017					155,235,955
Total Estimated FY 2016-17 Rebate Revenue				298,145,292	
Total Estimated FY 2017-18 Rebate Revenue					329,069,526

¹ Estimate numbers are rounded for presentation purposes; as a result, numbers may not total exactly.

² FY 2016-17 and FY 2017-18 include additional one time and on-going support expenditures described on page 11.

³ FY 2016-17 and FY 2017-18 include employee compensation adjustments – Item 9800.

VIII. Historical Program Data and Trends

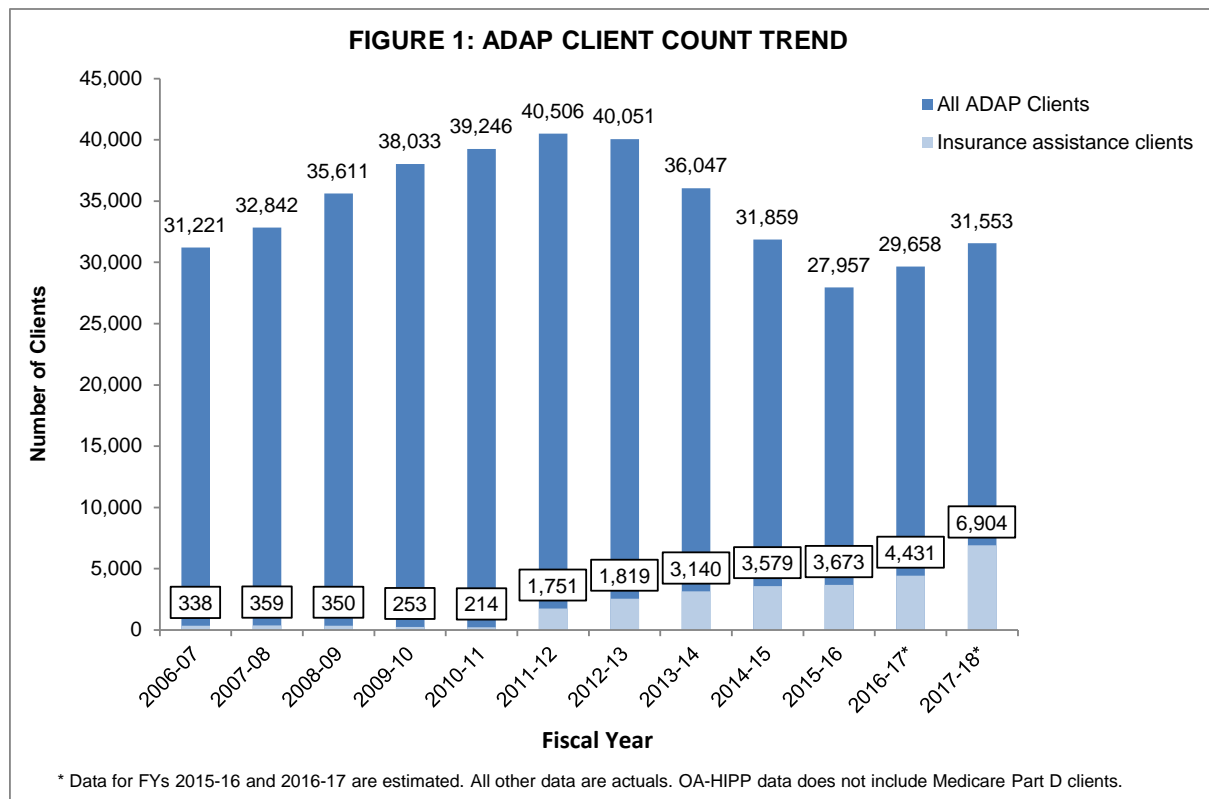
For all figures in this section, the data prior to FY 2016-17 is the observed historical data. Estimates for both FYs 2016-17 and 2017-18 are based on the overall projections and include all assumptions.

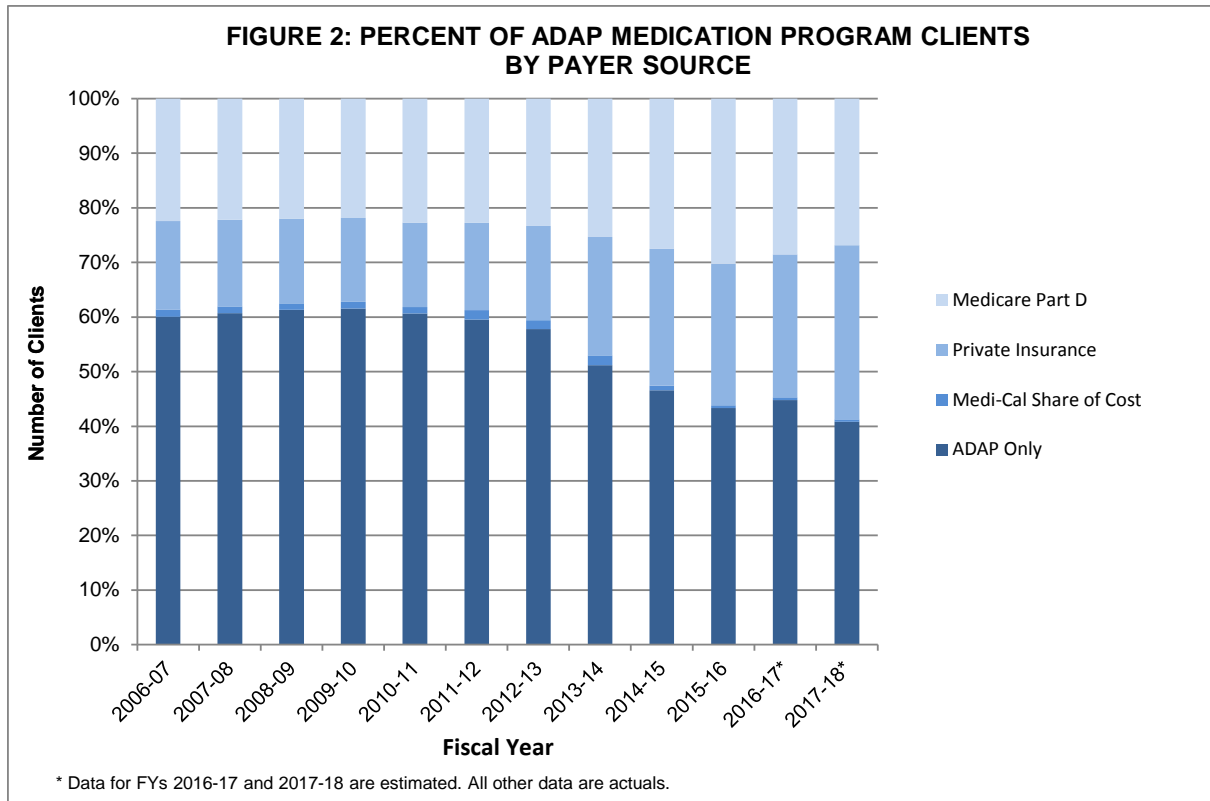
Figure 1 is a summary of total client counts in ADAP, excluding PrEP clients, by FY; the number of ADAP medication program clients who are also receiving insurance assistance is also shown.

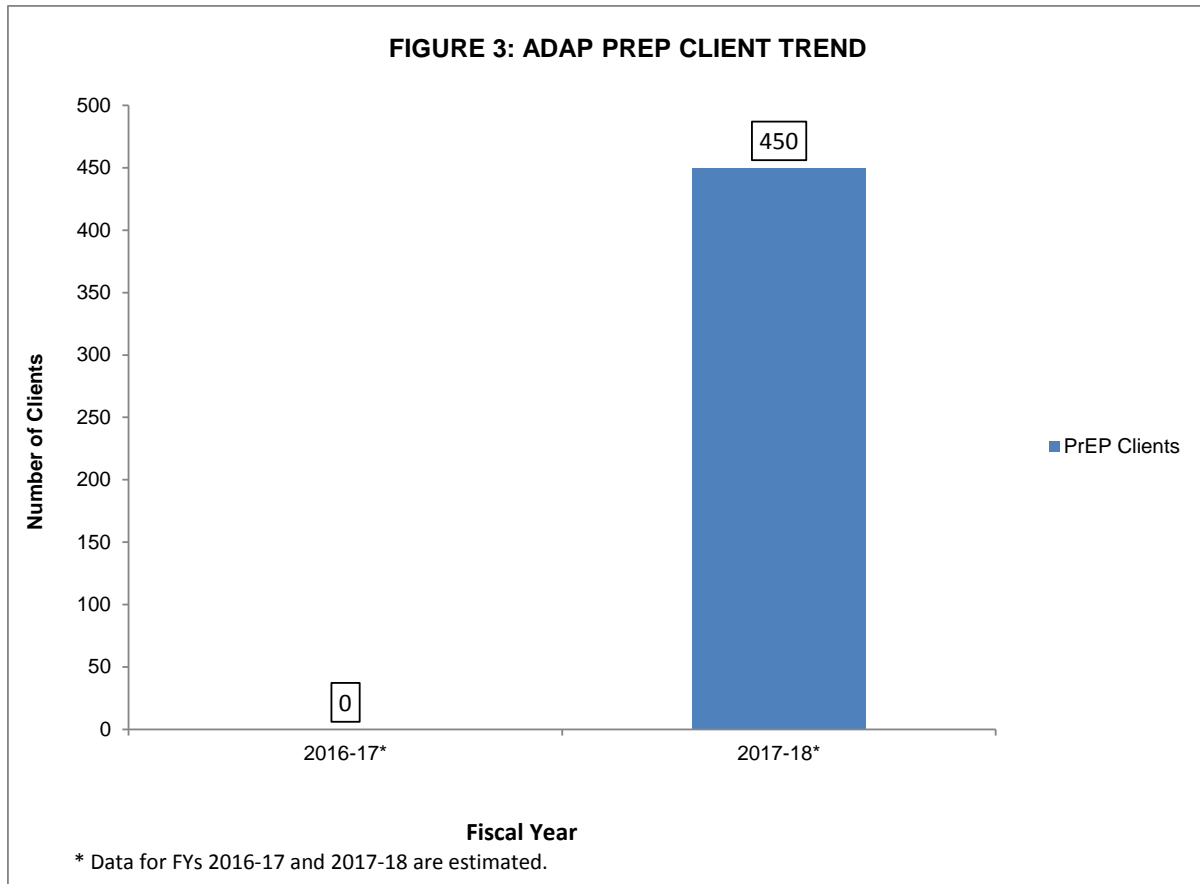
Figure 2 shows the proportion of ADAP medication program clients enrolled in the various payer groups by FY.

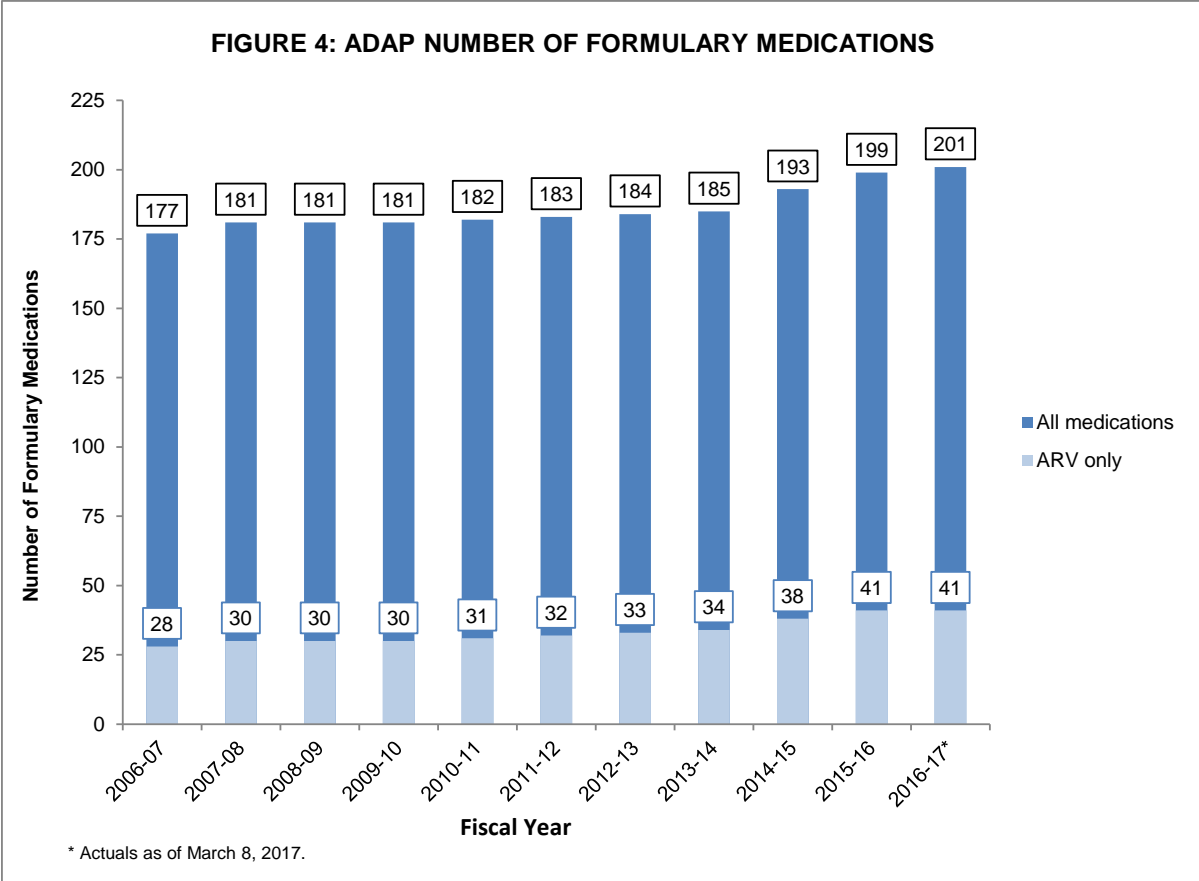
Figure 3 is a summary of estimated client counts in the PrEP Assistance Program by FY.

Figure 4 is the number of medications on the ADAP formulary by FY; the number of anti-retroviral medications is also shown.









- Elbasvir/grazoprevir (Zepatier™), a hepatitis C virus (HCV) medication for patients with genotypes 1 or 4, was added to the ADAP formulary on August 16, 2016.
- Sofosbuvir/velatasvir (Epclusa™), a pan genotypic HCV treatment, was added to the ADAP formulary on December 28, 2016.

IX. Current HIV Epidemiology in California

Approximately 126,000 PLWH in California at the end of 2014 had been diagnosed and reported to OA. However, OA estimates that 9.0 percent of all PLWH in California are unaware of their infection (as of the end of 2013, the latest data available). Therefore, OA estimates that there were approximately 139,000 PLWH in California as of the end of 2014. Since the epidemic began in 1981, approximately 100,000 Californians diagnosed with HIV have died, with over 1,500 dying in 2014 alone.

Of PLWH in California, approximately 42.0 percent are White; 33.7 percent are Hispanic/Latino; 18.2 percent are Black/African American; 3.8 percent are Asian; 1.7 percent are multi-racial; 0.4 percent are American Indian/Alaskan Native; and 0.2 percent are Native Hawaiian/Pacific Islander. While Whites and Hispanics/Latinos make up the largest percentage of PLWH in California, the rate of HIV among Blacks/African Americans is substantially higher (1,036 per 100,000 population, versus 356 per 100,000 among Whites, and 284 per 100,000 among Hispanics/Latinos).

Most of California's living HIV cases are attributed to male-to-male sexual transmission (66.1 percent); 9.0 percent of living cases are attributable to high-risk heterosexual contact (defined as contact with a sex partner or partners of the opposite gender who are either known to be HIV infected or known to be someone who injects drugs, has hemophilia, or is a man who has sex with other men); 7.3 percent to men who have sex with men who also inject drugs; 6.6 percent to injection drug use; 0.6 percent to perinatal exposure; and 10.0 percent to other or unknown sources, including other heterosexual contact.

There are approximately 5,000 new HIV cases reported in California each year. The number of PLWH in the state is expected to grow by approximately 3.0 percent each year for the next two years, and it is expected that this trend will continue for the foreseeable future until more progress is made in preventing new HIV infections. This increase is attributed to stable incidence rates and longer survival of those infected, primarily due to the effectiveness and availability of treatment.