AIDS DRUG ASSISTANCE PROGRAM (ADAP)

Fiscal Year 2019-20

May Revision Estimate

Karen L. Smith, MD, MPH
Director and State Public Health Officer

California Department of Public Health

California Department of Public Health

Table of Contents

I. Program Overview

The California Department of Public Health (Public Health), 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 provides 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.
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, medical out-of-pocket costs, and Medicare Part D health insurance premiums. Qualifying Medicare Part D clients have the option for premium assistance with Medigap supplemental insurance policies, which cover 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. For insured clients, the PrEP Assistance Program (PrEP-AP) pays for PrEP-related medical out-of-pocket costs and covers the gap between what the client's insurance plan and the manufacturer's co-payment assistance program pays towards medication costs. For uninsured clients, PrEP-AP only provides assistance with PrEP-related medical costs, as medication is provided free by the manufacturer's medication assistance program.

As a covered entity in the 340B Drug Pricing Program, ADAP collects rebate for a majority of prescriptions purchased for ADAP clients. ADAP does not collect rebate for prescriptions purchased for Medi-Cal SOC, nor PrEP-AP, clients. As the primary payer, Medi-Cal has the right to claim 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. ADAP also does not collect rebate on medication purchases for PrEP-AP clients because PrEP-AP is separate and distinct from ADAP and is not a 340B covered entity.

Historically, the majority of clients ADAP served were medication-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 dis-enrolled from ADAP, because these clients have no SOC, no 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 and medical out-of-pocket costs, which can only be paid for if ADAP pays the client's premium.
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 system.

II. Estimate Overview

The 2019-20 ADAP May Revision Estimate provides a revised projection of Current Year, Fiscal Year (FY) 2018-19, Local Assistance costs for medication, health insurance, medical out-of-pocket costs, ADAP enrollment sites, and administrative costs, along with projected Local Assistance costs for Budget Year, FY 2019-20.

Table 1, page 4, shows the estimated ADAP Local Assistance budget authority need for the Current Year, and compares it to the amount reflected in the 2019-20 Governor's Budget.

- For FY 2018-19, Public Health/OA estimates that the ADAP budget authority need will be $407.5 million, which is a $362,000 decrease in budget authority compared to the 2019-20 Governor's Budget. The net decrease is primarily due to a decrease in projected medication and medical out-of-pocket expenditures partially offset by projected increases in insurance premium and administrative expenditures (see key influences on ADAP expenditures on page 5 for more detail).

- For FY 2019-20, Public Health/OA estimates that the ADAP budget authority need will be $449.5 million, which is a $320,000 decrease in budget authority compared to the 2019-20 Governor's Budget. The net decrease is primarily due to a projected decrease in medication and medical out-of-pocket expenditures partially offset by a projected increase in insurance premium and administrative expenditures (see key influences on ADAP expenditures on page 5 for more detail).

Table 2, page 4, shows the estimated ADAP revenue for Current Year and Budget Year and compares them to the amount reflected in the 2019-20 Governor's Budget.

- For FY 2018-19, Public Health/OA estimates ADAP revenue will be $312.3 million, which is a $13.3 million decrease compared to the 2019-20 Governor's Budget. The decrease is primarily due to a decrease in projected medication expenditures (see revenue on page 7 for more detail).

- For FY 2019-20, Public Health/OA estimates ADAP revenue will be $378.9 million, which is a $79,000 decrease compared to the 2019-20 Governor's Budget. The decrease is primarily due to a decrease in projected medication expenditures (see revenue on page 7 for more detail).

California Department of Public Health
AIDS Drug Assistance Program
2019-20 May Revision Estimate
Table 1: Local Assistance Budget Authority
(In Thousands)

Local Assistance	2019-20 Governor's Budget	Current Year FY 2018-19			2019-20 Governor's Budget	Budget Year FY 2019-20		
		2019-20 May Revision Estimate	$ Change from 2019-20 Governor's Budget	% Change from 2019-20 Governor's Budget		2019-20 May Revision Estimate	$ Change from 2019-20 Governor's Budget	% Change from 2019-20 Governor's Budget
Total Funds Requested	**$407,878**	**$407,516**	**-$362**	**-0.1%**	**$449,789**	**$449,468**	**-$320**	**-0.1%**
Federal Trust Fund - Fund 0890	$129,143	$129,143	$0	0.0%	$135,138	$135,138	$0	0.0%
ADAP Rebate Fund - Fund 3080	$278,735	$278,373	-$362	-0.1%	$314,650	$314,330	-$320	-0.1%
Caseload	31,541	31,984	443	1.4%	33,457	34,628	1,171	3.5%

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

2019-20 May Revision Estimate
Table 2: ADAP Rebate Fund (Fund 3080) Revenues
(In Thousands)

Local Assistance	2019-20 Governor's Budget	Current Year FY 2018-19			2019-20 Governor's Budget	Budget Year FY 2019-20		
		2019-20 May Revision Estimate	$ Change from 2019-20 Governor's Budget	% Change from 2019-20 Governor's Budget		2019-20 May Revision Estimate	$ Change from 2019-20 Governor's Budget	% Change from 2019-20 Governor's Budget
Total Revenue Requested	**$325,632**	**$312,313**	**-$13,319**	**-4.1%**	**$378,988**	**$378,908**	**-$79**	**0.0%**
ADAP Rebate Fund - Fund 3080	$321,632	$308,313	-$13,319	-4.1%	$374,988	$374,908	-$79	0.0%
Interest Income	$4,000	$4,000	$0	0.0%	$4,000	$4,000	$0	0.0%

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

III. Overview Projections

A. Key influences on ADAP expenditures

a) FY 2018-19: Compared to the 2019-20 Governor's Budget, Public Health/OA estimates that FY 2018-19 expenditures will net decrease by 0.1 percent. The net decrease is primarily due to a decrease in projected medication expenditures for medication-only clients. The number of medication-only clients is projected to decrease due to transitioning to private insurance, or dis-enrollment from ADAP as a result of full-scope Medi-Cal eligibility. The net decrease is partially offset by an increase in projected insurance premium expenditures that is a result of an increase in private insurance clients utilizing premium assistance. Also, contributing to the change is higher than anticipated projected administrative expenditures from ADAP's insurance/medical benefits manager and to a lesser degree decreased projected medical out-of-pocket expenditures from private insurance clients (see expenditure detail on page 20).

b) FY 2019-20: Compared to the 2019-20 Governor's Budget, Public Health/OA estimates that FY 2019-20 expenditures will net decrease by 0.1 percent. The net decrease is primarily due to a decrease in projected medication expenditures for medication-only clients. The number of medication-only clients is projected to decrease due to transitioning to private insurance, or dis-enrollment from ADAP as a result of full-scope Medi-Cal eligibility. The net decrease is partially offset by an increase in projected insurance premium expenditures that are a result of an increase in private insurance clients utilizing premium assistance. Also, contributing to the change is higher than anticipated administrative expenditures from ADAP's insurance/medical benefits manager and to a lesser degree decreased projected medical out-of-pocket expenditures from the private insurance clients (see expenditure detail on page 21).

B. Expenditures

ADAP expenditures are broken out into two types: 1) variable expenditures consisting of health care expenditures and enrollment expenditures and 2) fixed expenditures.

a) Health Care and Enrollment Expenditures (Variable Expenditures)
- 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-AP 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 20.

- Local ADAP enrollment services: Beginning in FY 2016-17, Public Health/OA began allocating funds directly to ADAP enrollment sites based on ADAP services provided at each site. These funds may only be used for costs associated with enrolling and maintaining clients in ADAP. The total amount of funds for ADAP services performed is adjusted annually through the ADAP Estimate based on caseload and estimated services to be performed. Estimated expenditures for enrollment services are shown in Table 3. A description of the reimbursement methodology and detailed discussion of caseload and expenditures is included in Section V (B) on page 25.

TABLE 3: ESTIMATED VARIABLE EXPENDITURES BY CLIENT GROUP

CLIENT GROUP	EXPENDITURES	
	FY 2018-19	FY 2019-20
Medication-Only	$304,807,079	$315,972,368
Medi-Cal SOC	$1,071,494	$1,477,505
Private Insurance	$65,031,384	$87,982,784
Medicare Part D+	$23,838,377	$27,631,337
PrEP	$3,865,266	$7,309,358
SUBTOTAL	**$398,613,600**	**$440,373,352**
Enrollment Costs	$7,102,500	$7,745,000
TOTAL	**$405,716,100**	**$448,118,352**

+ Expenditures for Medicare Part D clients include Part D premiums, Part D medication co-pays, Part B medical out-of-pocket expenses, and Medigap premiums.

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

b) Fixed Expenditures

- Access, Adherence, and Navigation Program (AAN; formerly ADAP Case Management): In FY 2018-19 and FY 2019-20, Public Health/OA will be allocating funds to ADAP enrollment sites identified as having a large number of medication-only clients to provide navigation services to comprehensive health coverage and to provide assistance with achieving and maintaining viral suppression. Public

Health/OA will allocate $1.8 million for AAN in FY 2018-19 and $1.4 million in FY 2019-20 (see Existing Assumption #1 on page 14).

C. Revenue

a) ADAP Special Funds – ADAP receives both mandatory and voluntary supplemental rebates from drug manufacturers for ADAP medication expenditures. A six-month delay in rebate revenue exists because of the time required for billing the drug manufacturers and receipt of the rebate. FY 2018-19 revenue projections are based on actual and estimated rebates from actual medication expenditures from January through December 2018. FY 2019-20 revenue projections are based on estimated rebates from actual and estimated drug expenditures from January through December 2019.

- For FY 2018-19, Public Health/OA estimates ADAP rebate revenue will decrease by 4.1 percent from $325.6 million in the 2019-20 Governor's Budget to $312.3 million in the revised Current Year forecast. The decrease is primarily due to a decrease in projected medication expenditures from medication-only clients.

- For FY 2019-20, Public Health/OA estimates ADAP rebate revenue will decrease by less than 0.1 percent from $379 million in the 2019-20 Governor's Budget to $378.9 million in the revised Budget Year forecast. The decrease is primarily due to a decrease in projected medication expenditures from medication-only clients.

b) Federal Funds – for FY 2018-19, total federal fund budget authority will not change from the existing $129.1 million established in the 2019-20 Governor's Budget. Federal fund budget authority includes: the 2018 Ryan White Part B grant (ADAP Earmark) in the amount of $99.1 million (see Unchanged Assumption #2 on page 17), the 2018 Ryan White Part B Supplemental grant in the amount of $17 million (see Unchanged Assumption #3 on page 17), the 2018 ADAP Emergency Relief Funds grant (also called ADAP Shortfall Relief grant) in the amount of $11 million, and the 2017 Ryan White Part B grant carryover in the amount of $2 million (see Unchanged Assumption #4 on page 18).

For FY 2019-20, total federal fund budget authority will not change from the existing $135.1 million established in the 2019-20 Governor's Budget. Federal fund budget authority includes: estimated 2019 Ryan White Part B grant (ADAP Earmark) in the amount of $99.1 million, estimated 2019 Ryan White Part B Supplemental grant funding in the amount of $25 million, and 2019 ADAP Emergency Relief Funds grant (also called ADAP Shortfall Relief grant) funding in the amount of $11 million (see New Assumptions #1 on page 13).

Match – the Health Resources and Services Administration (HRSA) requires grantees to have HIV-related non-HRSA expenditures. California's HRSA match requirement for the 2019 Ryan White Part B grant year (April 1, 2019 through March 31, 2020) is $68.8 million. Public Health/OA will meet the match requirement using General Fund State Operations and Local Assistance expenditures from Public Health/OA's HIV Surveillance and Prevention Programs, as well as HIV-related expenditures from the California Department of Corrections and Rehabilitation.

IV. Assumptions

Future Fiscal Issues

New HIV Drugs

Background: The following HIV drug has received Food and Drug Administration (FDA) approval:

1. Dolutegravir/lamivudine (Dovato®)

On April 8, 2019, the FDA approved dolutegravir/lamivudine, a two-drug fixed-dose combination (FDC), for the treatment of HIV-1 infection in adults with no antiretroviral treatment history and with no known or suspected drug resistance to the individual components (dolutegravir and lamivudine). This is the first FDA-approved two-drug, fixed-dose, complete regimen for HIV treatment.

Background: The following HIV drugs may receive FDA approval in the next year:

1. PRO 140 (Leronlimab®)

PRO 140 is a humanized IgG4 monoclonal antibody that blocks HIV entry by binding to CCR5. Phase three clinical trials are evaluating this drug as a weekly injection for use as part of a regimen in people with highly drug resistant virus and limited treatment and for use as a monotherapy switch option for people with stable viral suppression. In a November 13, 2018 informational release, the manufacturer announced that the FDA has granted PRO 140 with a “fast track” designation, with the potential to be FDA approved during calendar year 2019.

2. Fostemsavir

Fostemsavir is an oral HIV attachment inhibitor that binds to gp120. It is being studied as a “salvage drug” for use in treatment-experienced people who develop intractable drug resistance to several classes of antiretroviral drugs. The manufacturer announced they expect to apply for FDA approval of this new salvage treatment during 2019.

3. Cabotegravir oral and long-acting (LA)

Cabotegravir is an HIV integrase strand transfer inhibitor (INSTI) being developed as both an oral tablet and LA injectable formulation. Injectable cabotegravir-LA is being developed as a single drug for HIV PrEP and as a component of a FDC (see #5 below) for treatment. Cabotegravir-LA has a very long half-life making intramuscular dosing every four to eight weeks possible. The oral formulation is being developed as a lead-in drug to assess for adverse reactions before patients switch to injections. The manufacturer has provided access to this medication in the United States. Phase three trials are ongoing with results expected in 2019. Plans for FDA submission are not publically known.

4. Cabotegravir/rilpivirine LA

Cabotegravir LA/rilpivirine LA is a two-drug FDC injectable formulation. Rilpivirine is a non-nucleoside reverse transcriptase inhibitor (NNRTI) and an oral tablet formulation is already FDA approved for HIV treatment. The cabotegravir LA/rilpivirine LA FDC is in phase three clinical trials with intramuscular dosing every four to eight weeks. Results are expected in 2019. Plans for FDA submission are not publically known.

5. Albuvirtide (Aikening®)

Albuvirtide is an HIV fusion inhibitor that binds to HIV's gp41 envelope protein similar to the mechanism of the FDA-approved enfuvirtide. Albuvirtide is formulated on a weekly intravenous infusion. It was approved for use in China in 2018 and one phase three clinical trial has been completed. Plans for FDA submission are not publically known.

Description of Change: If any of the above HIV drugs receive FDA approval and the ADAP Medication Advisory Committee (MAC) recommends their addition to the ADAP formulary, Public Health/OA will monitor pricing of each drug and if the ADAP Crisis Task Force (ACTF) has secured discounted pricing. If Public Health/OA is able to determine that the drugs do not represent a significant cost increase to the program, Public Health/OA will move forward with adding these drugs to the ADAP formulary.

Discretionary: No.

Reason for Adjustment/Change:

- As required by California Health and Safety Code (HSC) Section 120966, Public Health/OA must add an antiretroviral (ARV) drug to the formulary within 30 days of FDA approval if the drug has been recommended for addition by the MAC and its addition does not represent a significant cost increase to the program.

- If the net drug cost (after mandatory and negotiated supplemental rebates) and projected client utilization indicates a significant new cost to the program, the 30-day requirement no longer applies and Public Health/OA must determine whether the program has an adequate budget to fund the addition of the new drug. If not, Public Health/OA may seek additional budgetary authority through the Estimate process.

- Addition of new drugs to the ADAP formulary offers ADAP clients options for drugs that best work to optimize health efficacy.

Fiscal Impact and Fund Sources(s): The fiscal impact is unknown at this time. If any of the HIV drugs listed above receive FDA approval, Public Health/OA will monitor pricing and supplemental rebate negotiations. The funds impacted are the ADAP Rebate Fund (Fund 3080) and Federal Trust Fund (Fund 0890).

New PrEP Drugs

Background: Currently emtricitabine/tenofovir disoproxil fumarate (Truvada®) is the only drug approved by the FDA for the prevention of HIV. Additional HIV treatments are being evaluated for potential use for HIV prevention, while new drugs are also in clinical trials for use in HIV prevention.

The following PrEP drugs and devices may receive FDA approval in the next year:

1. Cabotegravir

Cabotegravir is an HIV INSTI being developed as both an oral tablet and LA injectable formulation. Injectable cabotegravir-LA dosed once every eight weeks is being developed as a single drug for HIV PrEP as a potential alternative to the daily oral dose of emtricitabine/tenofovir disoproxil fumarate. Cabotegravir for PrEP is currently in phase three trials. A timeline for FDA submission is not publically known.

2. Emtricitabine/tenofovir alafenamide (FTC/TAF; Descovy™)

Emtricitabine/tenofovir alafenamide is an FDA-approved FDC for the treatment of HIV. Clinical trials are ongoing to evaluate emtricitabine/tenofovir alafenamide for PrEP. Phase three trial results are anticipated to be completed in 2019.

3. Dapivirine vaginal ring

The dapivirine vaginal ring is made of silicone and contains the NNRTI dapivirine, which is slowly released. The ring can be worn for one month at a time. The ring releases dapivirine over the course of a month to protect against HIV. Two phase three clinical trials have been completed demonstrating a 30% reduction in HIV infection. The manufacturer has announced plans to submit to the FDA for approval. A timeline for FDA submission is not publically known.

Description of Change: If these HIV prevention drugs or devices receive FDA approval and the ADAP MAC recommends their addition to the ADAP formulary, Public Health/OA will monitor pricing of the new drugs. If Public Health/OA is able to determine that the drugs do not represent a significant cost to the program, Public Health/OA will move forward with adding these drugs to the ADAP and PrEP-AP formularies.

Discretionary: Yes.

Reason for Adjustment/Change:

- As provided by HSC 120972, eligible PrEP-AP persons have access to drugs listed on the ADAP drug formulary.

Fiscal Impact and Fund Source(s): The fiscal impact is unknown at this time. The fund impacted is the ADAP Rebate Fund (Fund 3080).

Expansion of PrEP Assistance Program (PrEP-AP)

Background: In the 2016 Budget Act Public Health/OA received statutory and budgetary authority to develop a PrEP-AP to provide services to HIV-negative persons 18 years of age or older at risk for acquiring HIV. The PrEP-AP was implemented on April 9, 2018, and is currently available to individuals with or without health insurance.

The 2018 Budget Act included $2 million ongoing to support proposals to modify the PrEP-AP by expanding eligibility and accessibility to the PrEP-AP for individuals 12 years of age or older, pursuant to HSC 120972 and authorized through Assembly Bill 1810 (Chapter 34, Statutes of 2018), and to enhance services to allow for the following: 1) payment of post-exposure prophylaxis (PEP) and related medical costs, 2) payment for up to 14 days of PEP and PrEP starter packs, regardless of whether PrEP-AP eligibility requirements are met, 3) up to 28 days of PEP medication for victims of sexual assault regardless of whether PrEP-AP eligibility requirements are met, 4) PrEP medication for insured clients without requiring use of the manufacturer's assistance program if it is not accepted by the client's health plan or pharmacy contracted by the health plan, 5) payment of insurance premiums for clients enrolled in the PrEP-AP if it will result in cost-savings to the state, and 6) the ability to consider insured individuals as uninsured for confidentiality or safety reasons.

Description of Change: Public Health/OA is pursuing a phased implementation strategy and has worked with stakeholders to prioritize implementation of enhancements to the PrEP-AP approved in the 2018 Budget Act. Phase one includes enhancement numbers 1, 2, and 4 above. Enhancement number 4 went live on March 1, 2019. Enhancement numbers 1 and 2 are currently in the planning stage. Public Health/OA projects implementation of all enhancements will take place over the next few years, and is dependent on timely execution of contracts, and on the ability of vendors to meet critical milestones.

Discretionary: No.

Reason for Adjustment/Change:

- Change to HSC Section 120972.

Fiscal Impact and Fund Source(s): Public Health/OA does not project a need for additional budget authority beyond the $2 million at this time; however, initial cost projections to enhance the PrEP-AP did not account for several enhancements approved in the 2018 Budget Act, including items numbers 3, 4, 5, and 6 listed above. Public Health/OA will provide future updates if projected costs cannot be absorbed within the existing $2 million budget authority. The fund impacted is the ADAP Rebate Fund (Fund 3080).

New Assumptions

Potential Change in Federal Funds: 2019 ADAP Emergency Relief Funds Grant (ADAP Shortfall Relief Grant)

Background: On June 25, 2018, HRSA released the funding opportunity announcement for the 2019 ADAP Emergency Relief Funds grant (ADAP Shortfall Relief grant). This award is intended for states/territories that demonstrate the need for additional resources to prevent, reduce, and/or eliminate ADAP waiting lists, including through implementation of cost-containment measures. California's cost-containment measures include maintaining data match agreements to ensure ADAP is the payer of last resort.

Description of Change: On October 23, 2018, ADAP applied to HRSA for the maximum amount of $11 million for the competitive 2019 ADAP Emergency Relief Funds grant. Public Health/OA received the notice of award on March 20, 2019, for the full $11 million.

The table below shows historically how much Public Health/OA applied for through the ADAP Emergency Relief Funds grant and how much was received:

Grant Budget Period	Application(s)	Funds Received
2015 (04/01/2015 – 03/31/2016)	$11,000,000	$6,441,447
2016 (04/01/2016 – 03/31/2017)	$11,000,000	$10,991,645
2017 (04/01/2017 – 03/31/2018)	$9,000,000	$9,000,000
2018 (04/01/2018 – 03/31/2019)	$11,000,000	$11,000,000
2019 (04/01/2019 – 03/31/2020)	$11,000,000	$11,000,000

Discretionary: Yes.

Reason for Adjustment/Change:

- The ADAP Emergency Relief Funds grant is a competitive funding opportunity and prior funding are not guarantees that funding will be provided in the future.

Fiscal Impact and Fund Source(s): The $11 million in funding received will be spent in FY 2019-20. Budget authority in the amount of $11 million has already been built into the baseline for FY 2019-20 and will not change. The fund impacted is the Federal Trust Fund (0890).

Existing Assumptions

Access, Adherence, and Navigation (AAN) Program

Background: Beginning in FY 2017-18, Public Health/OA began allocating funds to a select number of ADAP enrollment sites to navigate uninsured individuals to comprehensive health coverage and to support ADAP clients with achieving and maintaining viral suppression. Public Health/OA initially selected the top 19 sites with the largest ADAP medication-only client population to participate in the AAN Program. Of the 19 ADAP enrollment sites invited to participate, ten enrollment sites declined due to a variety of reasons. These reasons include lack of capacity and lack of infrastructure to bill for clients with private insurance. Additionally, financial disincentive due to reduced reimbursement rates from private insurance plans compared to higher reimbursement rates received for some Ryan White Part A funded ambulatory health services contributed to declining enrollment.

To align with the federal grant year and allow for the program to operate during an additional open enrollment period, Public Health/OA is in the process of amending program contracts to extend the contract end date from June 30, 2019 to March 31, 2020.

Also, because of lower than anticipated enrollment site participation, Public Health/OA is allocating an additional $120,000 in FY 2018-19 and $90,000 in FY 2019-20 to five of the ten participating enrollment sites identified as having the highest number of medication-only clients. The increased funding will be leveraged to add additional resources at these sites to navigate more clients to comprehensive health coverage.

Description of Change: Several unanticipated barriers resulted in a decrease in projections for client transition to comprehensive health coverage and estimated savings. Administrative barriers increased the time it took to review and process contract amendments, which were therefore not executed in time for the 2019 Covered California open enrollment period. Additionally, one enrollment site participating in the AAN program had difficulty filling a vacant Navigator position timely.

The following were also barriers identified by Navigators to enrolling clients into comprehensive health coverage: 1) client reluctance to enroll in private health coverage due to the elimination of the individual mandate; 2) concern with data privacy and public charge designation from clients without a social security number; 3) a lack of perceived need for private health coverage from clients with access to outpatient Ryan White services; and 4) clients declining to participate due to being enrolled in My Health LA, a no-cost health program for low-income, uninsured residents of Los Angeles County, which provides access to outpatient services, but limited access to HIV medication.

Discretionary: Yes.

Reason for Adjustment/Change:

- Unanticipated barriers to navigating clients to private insurance for the 2019 Covered California open enrollment period.

Fiscal Impact and Fund Source(s): Estimated net savings for FY 2018-19, $1.1 million from navigating 244 clients to comprehensive health insurance. Estimated net savings for FY 2019-20, $1.5 million from navigating 242 clients to comprehensive health insurance. No additional budget authority is needed. The funds impacted are the Federal Trust Fund (0890) and ADAP Rebate Fund (Fund 3080).

New HIV Drug

Background: The following HIV drug has received federal FDA approval:

1. Ibalizumab (Trogarzo®)

On March 6, 2018, the FDA approved ibalizumab (Trogarzo®), an HIV-1 inhibitor and long-acting monoclonal antibody for multi-drug resistant HIV-1 infection. Ibalizumab is administered intravenously once every 14 days by a trained medical professional and is used in combination with other ARV medications. The drug is indicated for adult patients who have tried multiple treatment options with current available therapies, but whose HIV infections cannot otherwise be successfully treated, including those with multidrug-resistant HIV.

On May 22, 2018, the ACTF announced that an agreement with the manufacturer of ibalizumab was reached for discounted pricing for this medication. Although Public Health/OA will be receiving reduced pricing, this new injectable is not cost neutral, and is projected to have a minor fiscal impact. Additionally, Public Health/OA is consulting with other Ryan White programs to determine how administration costs of this new injectable treatment can be covered.

On October 26, 2018, Public Health/OA was notified by HRSA that per the U.S Department of Health and Human Services' guidelines, ibalizumab has been deemed a new classification of ARV known as a CD4 Post-Attachment Inhibitor, which according to federal statute makes addition to the ADAP formulary compulsory for ADAPs nationwide.

Description of Change: Since the FY 2019-20 ADAP November Estimate, ADAP has revised estimated costs and client utilization of ibalizumab. The fiscal impact of ibalizumab was overestimated in the November Estimate.

Discretionary: No.

Reason for Adjustment/Change:

- Reduction in fiscal impact and client utilization.

- Statutory requirement. Section 2616(e) of the Public Health Service Act requires ADAPs maintain a formulary with at least one medication from each ARV drug class.

- Access to effective treatment for clients who have multi-drug resistant HIV.

Fiscal Impact and Fund Source(s): Estimated net expenditures for FY 2018-19 will be $132,000 for five clients. Estimated net expenditures for FY 2019-20 will be $1 million for 16 clients. The funds impacted are the ADAP Rebate Fund (Fund 3080) and Federal Trust Fund (Fund 0890).

Unchanged Assumptions/Premises

ADAP Special Fund State Operations Cost Adjustment - Interim ADAP Enrollment System (AES)/Project Approval Lifecycle (PAL)

Background: The interim AES was built as a basic solution while a permanent IT solution could be identified through the PAL process. In July 2018, during Stage 2 of the PAL process, the California Department of Technology (CDT) provided Public Health/OA with an approval and delegated authority for the project back to Public Health/OA. Public Health/OA is now beginning the project that will complete PAL process-identified enhancements that will finalize the establishment of a permanent IT ADAP Enrollment System.

For FY 2019-20 the total costs for the AES and PAL include: 1) $37,800 for adjustments in CDT staff costs for Independent Project Oversight Consulting, 2) $150,324 for Public Health/Information Technology Services Division (ITSD) staffing costs for PAL project management, 3) $40,000 for the newly identified costs for a consultant to assist Public Health/ITSD with independent verification and validation, 4) $233,333 for Project Development Cost – Enhancements completion, and 5) $2,800,000 for Maintenance and Operations costs for AES.

By the end of FY 2019-20, the enhancements identified via the PAL process are expected to be completed, making the interim AES the permanent IT solution. A budget change proposal will be completed for FY 2020-21 to establish ongoing for budget authority for ongoing Maintenance and Operations.

Description of Change: No change from the 2019-20 ADAP November Estimate.

Discretionary: Yes.

Reason for Adjustment/Change: N/A

Fiscal Impact and Fund Source(s): No additional budget authority is needed for FY 2019-20 beyond the $3.3 million approved in the 2019-20 Governor's Budget. The fund impacted is the ADAP Rebate Fund (Fund 3080).

Increase in Federal Funds: 2018 Ryan White Part B Grant

Background: In November 2017, Public Health/OA applied for the 2018 Ryan White Part B grant, the second year of the latest five-year funding cycle. The funding requested in the grant application totaled $137.5 million, of which $103 million was requested for the ADAP Branch, and $34.5 million requested by the HIV Care Branch.

In June 2018, upon receipt of the final notice of award for the 2018 Ryan White Part B grant, it was discovered that the total award was $140.2 million or $2.7 million above what Public Health/OA applied for. The $2.7 million in unanticipated funding is for ADAP Branch's Local Assistance.

Description of Change: No change from the FY 2019-20 ADAP November Estimate.

Discretionary: Yes.

Reason for Adjustment/Change: N/A

Fiscal Impact and Fund Source(s): No additional budget authority is needed for FYs 2018-19 and 2019-20 beyond the $2.7 million approved in the FY 2019-20 Governor's Budget. The fund impacted is the Federal Trust Fund (0890).

Decrease in Federal Funds: 2018 Ryan White Part B Supplemental Grant

Background: In March 2018, HRSA released a notice of funding opportunity for the 2018 Ryan White Part B Supplemental Grant. HRSA anticipates approximately $170 million will be available nationwide through the 2018 Ryan White Part B Supplemental grant.

In May 2018, Public Health/OA applied for the competitive 2018 Ryan White Part B Supplemental grant. Public Health/OA requested the maximum amount of $35 million, with $25 million specifically for ADAP to be used in FY 2018-19.

On September 20, 2018, Public Health/OA received a notice of award for $23.8 million, of which $17 million will be utilized by ADAP for medication expenditures. The below table shows Ryan White Part B Supplemental grant funds applied for and funds received, by grant budget period.

Grant Budget Period	Application(s)	Funds Received
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)	$18,700,000*	$18,700,000*
2017 (09/30/2017 – 09/29/2018)	$35,000,000**	$35,000,000**
2018 (09/30/2018 – 09/29/2019)	$35,000,000**	$23,766,000***

***Includes $8.7 million for HIV Care Branch and $10 million for ADAP.**
****Includes $10 million for HIV Care Branch and $25 million for ADAP.**
*****Includes $6.8 million for HIV Care Branch and $17 million for ADAP.**

Description of Change: No change from the FY 2019-20 ADAP November Estimate.

Discretionary: Yes.

Reason for Adjustment/Change: N/A

Fiscal Impact and Fund Source(s): No change in budget authority for FY 2018-19 beyond the $8 million decrease reflected in the 2019-20 Governor's Budget. The fund impacted is the Federal Trust Fund (0890).

Increase in Federal Funds: 2017 Ryan White Part B Grant Carryover

Background: The Ryan White Part B grant is the largest of the three federal grants that OA/ADAP receives funding for. The grant's budget period runs from April 1st to March 31st. The grant is shared between Public Health/OA's HIV Care Branch and ADAP Branch, and is broken into three main sub-components: Base, Minority AIDS Initiative (MAI), and ADAP Earmark. Funding for Base and MAI is utilized by the HIV Care Branch and ADAP. Earmark funding is utilized by the ADAP Branch. Funding from the Ryan White Part B grant that is not fully expended by the end of the federal grant period can be carried over to the next grant period with approval from HRSA. Public Health/OA can generally determine how carryover funding is utilized, with the exception of MAI funding, which must be utilized solely by the HIV Care Branch. Carryover funding from the Base and the ADAP Earmark are always utilized by the ADAP Branch due to administrative limitations that prevent the HIV Care Branch from timely utilization of carryover funds, as carryover funding must be expended by March 31 of any given year.

On July 30, 2018, Public Health/OA finalized closing the 2017 Ryan White Part B grant with HRSA. Upon closure of the grant there remained $2.1 million in unspent funding. Broken down by sub-component, Base had $659,000, MAI had $42,000, and the ADAP Earmark had $1.4 million, in carryover funding. On October 26, 2018, Public Health/OA received a notice of award for $2.1 million, the same amount that was applied for and broken down by sub-component in the same way listed above. ADAP will utilize the Base ($659,000) and ADAP Earmark ($1.4 million) portions.

Description of Change: No change from the 2019-20 ADAP November Estimate.

Discretionary: Yes.

Reason for Adjustment/Change: N/A

Fiscal Impact and Fund Source(s): No additional budget authority is needed for FY 2018-19 beyond the $2 million approved in the 2019-20 Governor's Budget. The fund impacted is the Federal Trust Fund (Fund 0890).

Discontinued Assumptions/Premises

Payment of Out-of-Pocket Medical Expenses for All OA-HIPP Clients

Why is Change Needed/ Reason for Adjustment: Previously approved in the FY 2017-18 ADAP November Estimate. This assumption was included in the FY 2017-18 ADAP November Estimate as a result of a legislative augmentation in the 2016 Budget Act. This assumption is included in the base estimate.

Increase in Funding to ADAP Enrollment Sites

Why is Change Needed/ Reason for Adjustment: Previously approved in the FY 2018-19 ADAP November Estimate. This assumption was included in the FY 2018-19 ADAP November Estimate as a result of a legislative augmentation in the 2017 Budget Act. This assumption is included in the base estimate.

V. Expenditure Details

A. A detailed breakdown of caseload and expenditures by client group and service type is shown below in Tables 6 through 11.

TABLE 6: FY 2018-19 - May Revision Estimated Caseload and Variable Expenditures

CLIENT GROUP	CASELOAD		SERVICE TYPE EXPENDITURE				
	NUMBER	PERCENT	MEDICATIONS	INSURANCE PREMIUMS	MED OUT-OF-POCKET COST	ADDITIONAL ADMIN COSTS	TOTAL EXPENDITURE
Medication-Only	12,809	40.0%	$304,212,565	$0	$0	$594,514	$304,807,079
Medi-Cal SOC	118	0.4%	$1,066,008	$0	$0	$5,486	$1,071,494
Private insurance*	9,883	30.9%	$20,519,154	$41,605,792	$1,410,384	$1,496,053	$65,031,384
Medicare Part D*+	7,683	24.0%	$19,926,137	$1,343,701	$1,405,591	$1,162,947	$23,838,377
PrEP	1,490	4.7%	$385,213	$0	$395,053	$3,085,000	$3,865,266
SUBTOTAL	**31,984**	**100.0%**	**$346,109,078**	**$42,949,494**	**$3,211,029**	**$6,344,000**	**$398,613,600**
Enrollment Site Costs	0	0.0%	$0	$0	$0	$7,102,500	$7,102,500
TOTAL	**31,984**	**100.0%**	**$346,109,078**	**$42,949,494**	**$3,211,029**	**$13,446,500**	**$405,716,100**

*** Subgroup of 8,949 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 and Medicare Part B medical out-of-pocket expenses.

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

TABLE 7: FY 2018-19 - November Estimated Caseload and Variable Expenditures

CLIENT GROUP	CASELOAD		SERVICE TYPE EXPENDITURE				
	NUMBER	PERCENT	MEDICATIONS	INSURANCE PREMIUMS	MED OUT-OF-POCKET COST	ADDITIONAL ADMIN COSTS	TOTAL EXPENDITURE
Medication-Only	12,882	40.8%	$307,592,866	$0	$0	$426,166	$308,019,032
Medi-Cal SOC	134	0.4%	$1,089,470	$0	$0	$4,434	$1,093,904
Private insurance*	9,807	31.1%	$20,220,298	$39,193,744	$1,916,540	$854,262	$62,184,844
Medicare Part D*+	7,712	24.4%	$20,271,173	$1,434,584	$1,399,006	$671,738	$23,776,501
PrEP	1,007	3.2%	$461,976	$0	$489,213	$3,150,166	$4,101,355
SUBTOTAL	**31,541**	**100.0%**	**$349,635,784**	**$40,628,328**	**$3,804,759**	**$5,106,766**	**$399,175,637**
Enrollment Site Costs	0	0.0%	$0	$0	$0	$6,902,500	$6,902,500
TOTAL	**31,541**	**100.0%**	**$349,635,784**	**$40,628,328**	**$3,804,759**	**$12,009,266**	**$406,078,137**

*** Subgroup of 8,843 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 and Medicare Part B medical out-of-pocket expenses.

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

TABLE 8: FY 2018-19 - Difference Between May Revision and November Estimates

CLIENT GROUP	CASELOAD		SERVICE TYPE EXPENDITURE				
	NUMBER	PERCENT	MEDICATIONS	INSURANCE PREMIUMS	MED OUT-OF-POCKET COST	ADDITIONAL ADMIN COSTS	TOTAL EXPENDITURE
Medication-Only	-72	-16.3%	-$3,380,300	$0	$0	$168,348	-$3,211,953
Medi-Cal SOC	-16	-3.6%	-$23,462	$0	$0	$1,052	-$22,410
Private insurance*	76	17.3%	$298,856	$2,412,048	-$506,156	$641,791	$2,846,540
Medicare Part D*+	-29	-6.5%	-$345,036	-$90,883	$6,586	$491,209	$61,875
PrEP	483	109.1%	-$76,763	$0	-$94,160	-$65,166	-$236,089
SUBTOTAL	**443**	**100.0%**	**-$3,526,706**	**$2,321,166**	**-$593,730**	**$1,237,234**	**-$562,036**
Enrollment Site Costs	0	0.0%	$0	$0	$0	$200,000	$200,000
TOTAL	**443**	**100.0%**	**-$3,526,706**	**$2,321,166**	**-$593,730**	**$1,437,234**	**-$362,036**

*** Subgroup increased 106 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 and Medicare Part B medical out-of-pocket expenses.

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

TABLE 9: FY 2019-20 - May Revision Estimated Caseload and Variable Expenditures

CLIENT GROUP	CASELOAD		SERVICE TYPE EXPENDITURE				
	NUMBER	PERCENT	MEDICATIONS	INSURANCE PREMIUMS	MED OUT-OF-POCKET COST	ADDITIONAL ADMIN COSTS	TOTAL EXPENDITURE
Medication-Only	12,580	36.3%	$315,378,783	$0	$0	$593,586	$315,972,368
Medi-Cal SOC	136	0.4%	$1,471,091	$0	$0	$6,414	$1,477,505
Private insurance*	10,687	30.9%	$25,839,557	$58,584,847	$2,011,467	$1,546,913	$87,982,784
Medicare Part D*+	7,683	22.2%	$21,370,782	$1,717,372	$3,431,095	$1,112,087	$27,631,337
PrEP	3,542	10.2%	$2,564,143	$0	$1,651,215	$3,094,000	$7,309,358
SUBTOTAL	**34,628**	**100.0%**	**$366,624,356**	**$60,302,219**	**$7,093,777**	**$6,353,000**	**$440,373,352**
Enrollment Site Costs	0	0.0%	$0	$0	$0	$7,745,000	$7,745,000
TOTAL	**34,628**	**100.0%**	**$366,624,356**	**$60,302,219**	**$7,093,777**	**$14,098,000**	**$448,118,352**

*** Subgroup of 11,373 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 and Medicare Part B medical out-of-pocket expenses.

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

TABLE 10: FY 2019-20 - November Estimated Caseload and Variable Expenditures

CLIENT GROUP	CASELOAD		SERVICE TYPE EXPENDITURE				
	NUMBER	PERCENT	MEDICATIONS	INSURANCE PREMIUMS	MED OUT-OF-POCKET COST	ADDITIONAL ADMIN COSTS	TOTAL EXPENDITURE
Medication-Only	12,653	37.8%	$320,675,902	$0	$0	$426,087	$321,101,989
Medi-Cal SOC	134	0.4%	$1,271,698	$0	$0	$4,513	$1,276,211
Private insurance*	10,752	32.1%	$25,640,823	$53,226,343	$3,472,228	$888,647	$83,228,041
Medicare Part D*+	7,712	23.0%	$22,034,765	$1,663,474	$2,778,617	$637,353	$27,114,211
PrEP	2,207	6.6%	$1,641,752	$0	$1,628,246	$2,688,140	$5,958,138
SUBTOTAL	**33,457**	**100.0%**	**$371,264,941**	**$54,889,818**	**$7,879,091**	**$4,644,740**	**$438,678,590**
Enrollment Site Costs	0	0.0%	$0	$0	$0	$7,460,000	$7,460,000
TOTAL	**33,457**	**100.0%**	**$371,264,941**	**$54,889,818**	**$7,879,091**	**$12,104,740**	**$446,138,590**

*** Subgroup of 11,324 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 and Medicare Part B medical out-of-pocket expenses.

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

TABLE 11: FY 2019-20 - Difference Between May Revision and November Estimates

CLIENT GROUP	CASELOAD		SERVICE TYPE EXPENDITURE				
	NUMBER	PERCENT	MEDICATIONS	INSURANCE PREMIUMS	MED OUT-OF-POCKET COST	ADDITIONAL ADMIN COSTS	TOTAL EXPENDITURE
Medication-Only	-72	-6.2%	-$5,297,120	$0	$0	$167,499	-$5,129,621
Medi-Cal SOC	2	0.2%	$199,393	$0	$0	$1,901	$201,294
Private insurance*	-65	-5.6%	$198,734	$5,358,504	-$1,460,761	$658,266	$4,754,743
Medicare Part D*+	-29	-2.5%	-$663,984	$53,898	$652,478	$474,734	$517,126
PrEP	1,335	114.1%	$922,391	$0	$22,970	$405,860	$1,351,221
SUBTOTAL	**1,170**	**100.0%**	**-$4,640,585**	**$5,412,402**	**-$785,314**	**$1,708,260**	**$1,694,763**
Enrollment Site Costs	0	0.0%	$0	$0	$0	$285,000	$285,000
TOTAL	**1,170**	**100.0%**	**-$4,640,585**	**$5,412,402**	**-$785,314**	**$1,993,260**	**$1,979,763**

*** Subgroup increased 49 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 and Medicare Part B medical out-of-pocket expenses.

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

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 2018-19, Public Health/OA estimates medication expenditures for medication-only clients will be $304.2 million, which is a $3.4 million decrease compared to the 2019-20 Governor's Budget. The decrease in expenditures is primarily due to increased medication savings from fewer medication-only clients as a result of dis-enrolling medication-only clients whom are eligible for full-scope Medi-Cal and clients transitioning to private insurance with a partial offset for higher medication prices.
   - For FY 2019-20, Public Health/OA estimates medication expenditures for medication-only clients will be $315.4 million, which is a $5.3 million decrease compared to the 2019-20 Governor's Budget. This decrease is due to the same reasons listed above.
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 only receives services associated with medication costs.

1. Medication Expenditures:
   - For FY 2018-19, Public Health/OA estimates medication expenditures for Medi-Cal SOC clients will be $1.1 million, which is a $23,000 decrease compared to the 2019-20 Governor's Budget. The decrease in expenditures is due to a smaller caseload offset by higher SOC amounts for medications.
   - For FY 2019-20, Public Health/OA estimates medication expenditures for Medi-Cal SOC clients will be $1.5 million, which is a $199,000 increase compared to the 2019-20 Governor's Budget. The increase in expenditures is due to a slightly higher caseload and higher SOC amounts for medications.
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.

1. Medication Expenditures:
   - For FY 2018-19, Public Health/OA estimates medication expenditures for all private insurance clients will be $20.5 million, which is a $299,000 increase compared to the 2019-20 Governor's Budget. The increase in expenditures is due to a slightly higher caseload than previously anticipated.
   - For FY 2019-20, Public Health/OA estimates medication expenditures for all private insurance clients will be $25.8 million, which is a $199,000 increase compared to the 2019-20 Governor's Budget. This increase is due to continuing growth in private insurance caseload.
2. Health Insurance Premiums:
   - For FY 2018-19, Public Health/OA estimates health insurance premium payment expenditures for all private insurance clients will be $41.6 million, which is a $2.4 million increase compared to the 2019-20 Governor's Budget. This increase is due to higher overall caseload than previously anticipated and higher premiums for Covered California clients.
   - For FY 2019-20, Public Health/OA estimates health insurance premium payment expenditures will be $58.6 million, which is a $5.4 million increase compared to the 2019-20 Governor's Budget. This increase is due to the same reasons listed above.
3. Medical Out-Of-Pocket Costs:
   - For FY 2018-19, Public Health/OA estimates medical out-of-pocket costs for all private insurance clients will be $1.4 million, which is a $506,000 decrease compared to the 2019-20 Governor's Budget. The decrease is due to lower than projected service utilization.
   - For FY 2019-20, Public Health/OA estimates medical out-of-pocket costs will be $2.0 million, which is a $1.5 million decrease compared to the 2019-20 Governor's Budget. This decrease is due the same reason listed above.

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, medical out-of-pocket costs, Medicare Part D health insurance premiums, and assistance with Medigap premiums, which cover medical out-of-pocket costs.

1. Medication Expenditures:
   - For FY 2018-19, Public Health/OA estimates medication expenditures for Medicare Part D clients will be $19.9 million, which is a $345,000

decrease compared to the 2019-20 Governor's Budget. The decrease in expenditures is due to slightly fewer than anticipated clients with Medicare Part D plans in the medication assistance program and slightly lower than anticipated deductibles and co-insurance.

- For FY 2019-20, Public Health/OA estimates medication expenditures for Medicare Part D clients will be $21.4 million, which is a $664,000 decrease compared to the 2019-20 Governor's Budget. This decrease is due to the same reasons listed above.

2. Health Insurance Premiums:
   - For FY 2018-19, Public Health/OA estimates Medicare Part D premium payment expenditures will be $1.3 million, which is a $91,000 decrease compared to the 2019-20 Governor's Budget. This decrease is due to lower than anticipated Medicare Part D premiums.
   - For FY 2019-20, Public Health/OA estimates Medicare Part D premium payment expenditures will be $1.7 million, which is a $54,000 increase compared to the 2019-20 Governor's Budget. This increase is due to a slightly higher than anticipated caseload.
3. Medical Out-Of-Pocket Costs:
   - For FY 2018-19, Public Health/OA estimates medical out-of-pocket costs will be $1.4 million, which is a $7,000 increase compared to the 2019-20 Governor's Budget. This minimal increase is due to higher than previously projected caseload offset by lower than previously projected monthly costs for paying Medicare Part B medical out-of-pocket costs, including premiums for Medigap policies.
   - For FY 2019-20, Public Health/OA estimates medical out-of-pocket costs will be $3.4 million, which is a $652,000 million increase compared to the 2019-20 Governor's Budget. This increase is due to both a larger caseload and higher monthly costs than previously projected.

e. PrEP clients

This client group includes HIV-negative persons at risk for acquiring HIV who are taking PrEP. For insured clients, PrEP-AP covers the gap between what the client's health insurance plan and the manufacturer's medication co-payment assistance program will pay towards medication costs, along with any PrEP-related medical out-of-pocket costs. Clients without health insurance receive benefits related only to PrEP-related medical costs, as PrEP medication is received free from the manufacturer's medication assistance program.

1. Medication Expenditures:
   - For FY 2018-19, Public Health/OA estimates medication expenditures for PrEP-AP will be $385,000, which is a $77,000 decrease compared to the 2019-20 Governor's Budget. This decrease is primarily due to lower than anticipated caseload who are accessing medication expenditures.
   - For FY 2019-20, Public Health/OA estimates medication expenditures will be $2.6 million, which is a $922,00 increase compared to the 2019-20

Governor's Budget. This increase is due to higher than anticipated medication expenditures for insured PrEP clients.

2. Health Insurance Premiums: There are no health insurance premium expenditures for PrEP-AP clients.
3. Medical Out-Of-Pocket Costs:
   - For FY 2018-19, Public Health/OA estimates medical out-of-pocket costs will be $395,000 for PrEP clients, which is a $94,000 decrease compared to the 2019-20 Governor's Budget. This decrease is primarily due to less than anticipated client enrollment.
   - For FY 2019-20, Public Health/OA estimates medical out-of-pocket costs will be $1.7 million for PrEP-AP clients, which is a $23,000 increase compared to the 2019-20 Governor's Budget. This slight increase is due to higher than anticipated costs for uninsured clients offset by lower than anticipated costs for insured clients.

B. ADAP Enrollment Services

a. The reimbursement methodology used to determine service payment to enrollment sites is unchanged from the 2019-20 Governor's Budget. The reimbursement methodology includes payment of a floor amount to all ADAP enrollment sites with at least one ADAP enrollment during the fiscal year and the ADAP enrollment services listed below. Payment is made for each ADAP enrollment service performed with total payment dependent on total volume. Public Health/OA updated projected enrollment numbers, resulting in an estimate of $7.1 million in enrollment costs for FY 2018-19 and $7.7 million in enrollment costs for FY 2019-20.

   1. Floor Amount:
      - For FY 2018-19, Public Health/OA estimates reimbursement of $955,000 for 191 enrollment sites.
      - For FY 2019-20, Public Health/OA estimates reimbursement of $1 million for 201 enrollment sites.
   2. New Medication Enrollment:
      - For FY 2018-19, Public Health/OA estimates reimbursement of $500,000 from 5,000 clients enrolling into ADAP at some point throughout the fiscal year.
      - For FY 2019-20, Public Health/OA estimates reimbursement at $600,000 from 6,000 clients enrolling into ADAP at some point throughout the fiscal year.
   3. Bi-annual Self-Verification:
      - For FY 2018-19, Public Health/OA estimates reimbursement of $900,000 from 30,000 clients recertifying into ADAP at some point throughout the fiscal year.
      - For FY 2019-20, Public Health/OA estimates reimbursement of $900,000 from 30,000 clients recertifying into ADAP at some point throughout the fiscal year.

4. ADAP Annual Re-Enrollment:
   - For FY 2018-19, Public Health/OA estimates reimbursement of $3 million from 30,000 clients re-enrolling into ADAP at some point throughout the fiscal year.
   - For FY 2019-20, Public Health/OA estimates reimbursement of $3 million from 30,000 clients re-enrolling into ADAP at some point throughout the fiscal year.
5. New Insurance Assistance Enrollment:
   - For FY 2018-19, Public Health/OA estimates reimbursement of $715,000 from 2,600 clients enrolling into one of the two Public Health/OA's insurance assistance programs at some point throughout the fiscal year.
   - For FY 2019-20, Public Health/OA estimates reimbursement of $715,000 from 2,600 clients enrolling into one of the two Public Health/OA's insurance assistance programs at some point throughout the fiscal year.
6. Insurance Assistance Annual Re-Enrollment:
   - For FY 2018-19, Public Health/OA estimates reimbursement of $813,000 from 6,500 clients re-enrolling into one of the two Public Health/OA's insurance assistance programs at some point throughout the fiscal year.
   - For FY 2019-20, Public Health/OA estimates reimbursement of $1.1 million from 9,000 clients re-enrolling into one of the two Public Health/OA's insurance assistance programs at some point throughout the fiscal year.
7. New PrEP Enrollment:
   - For FY 2018-19, Public Health/OA estimates reimbursement of $200,000 from 2,000 clients enrolling into PrEP-AP at some point throughout the fiscal year.
   - For FY 2019-20, Public Health/OA estimates reimbursement of $200,000 from 2,000 clients enrolling into PrEP-AP at some point throughout the fiscal year.
8. PrEP Re-Enrollment:
   - For FY 2018-19, Public Health/OA estimates reimbursement of $20,000 from 200 clients re-enrolling into PrEP-AP at some point throughout the fiscal year.
   - For FY 2019-20, Public Health/OA estimates reimbursement of $200,000 from 2,000 clients re-enrolling into PrEP-AP at some point throughout the fiscal year.

VI. Historical Program Data and Trends

For all figures in this section, the data prior to FY 2018-19 is the observed historical data. Estimates for FY 2018-19 and FY 2019-20 are based on the overall projections and include all assumptions.

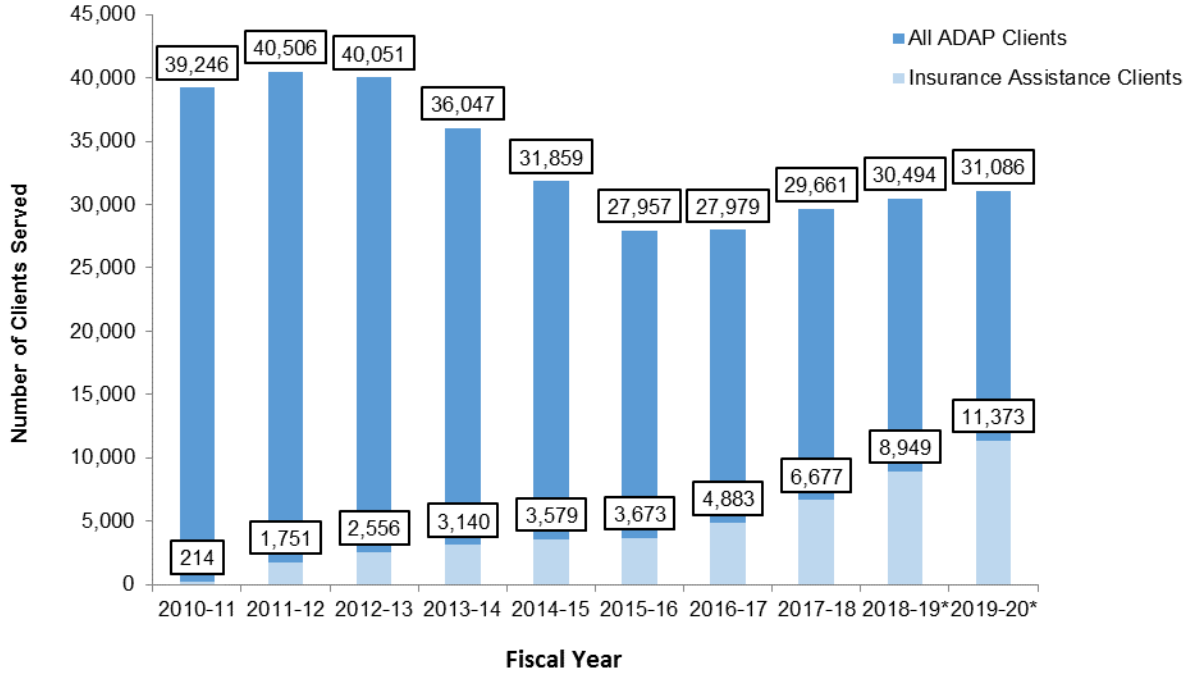
Figure 1 is a summary of total client counts in ADAP by FY, excluding PrEP clients. The number of ADAP medication program clients who are also receiving insurance assistance is also shown.

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

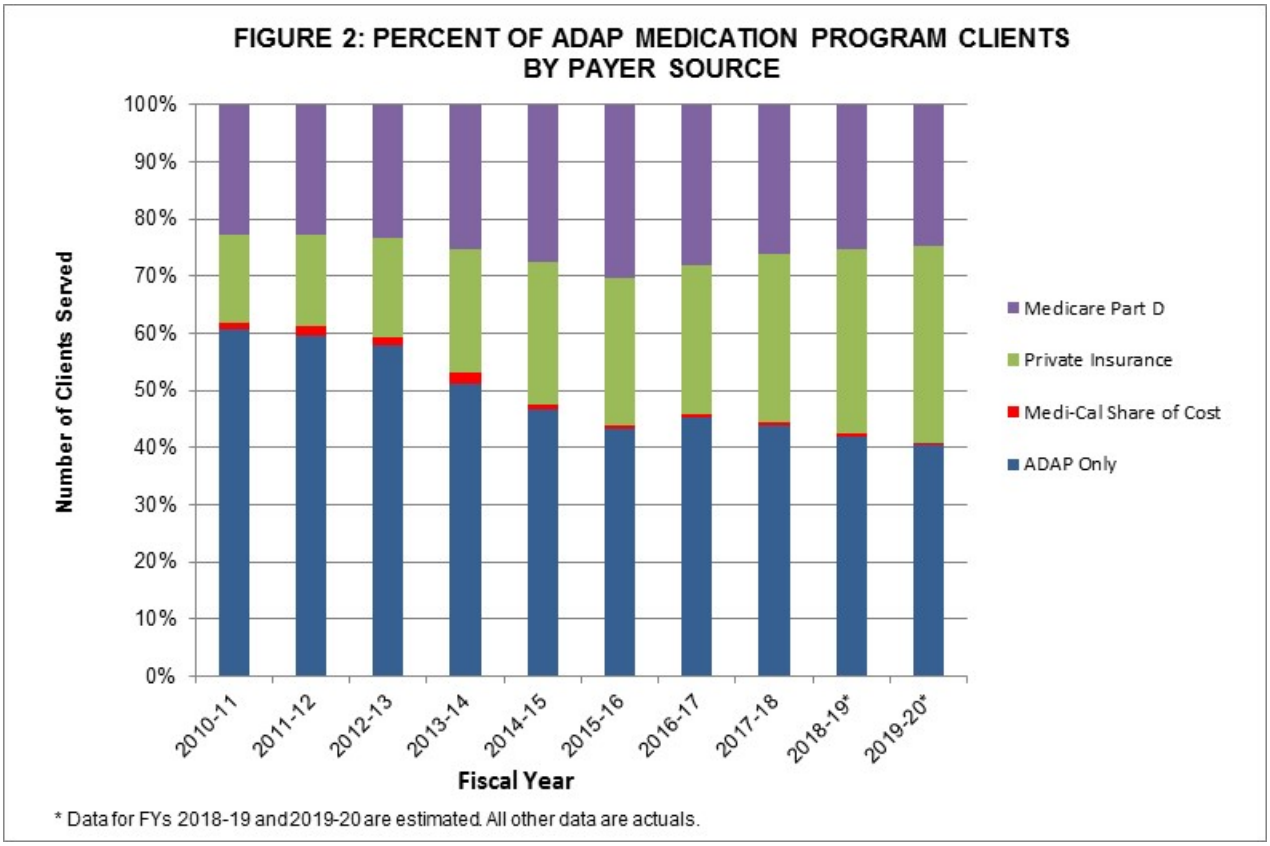
Figure 3 is a summary of estimated client counts in PrEP Assistance Program by FY.

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

FIGURE 1: ADAP CLIENT COUNT TREND

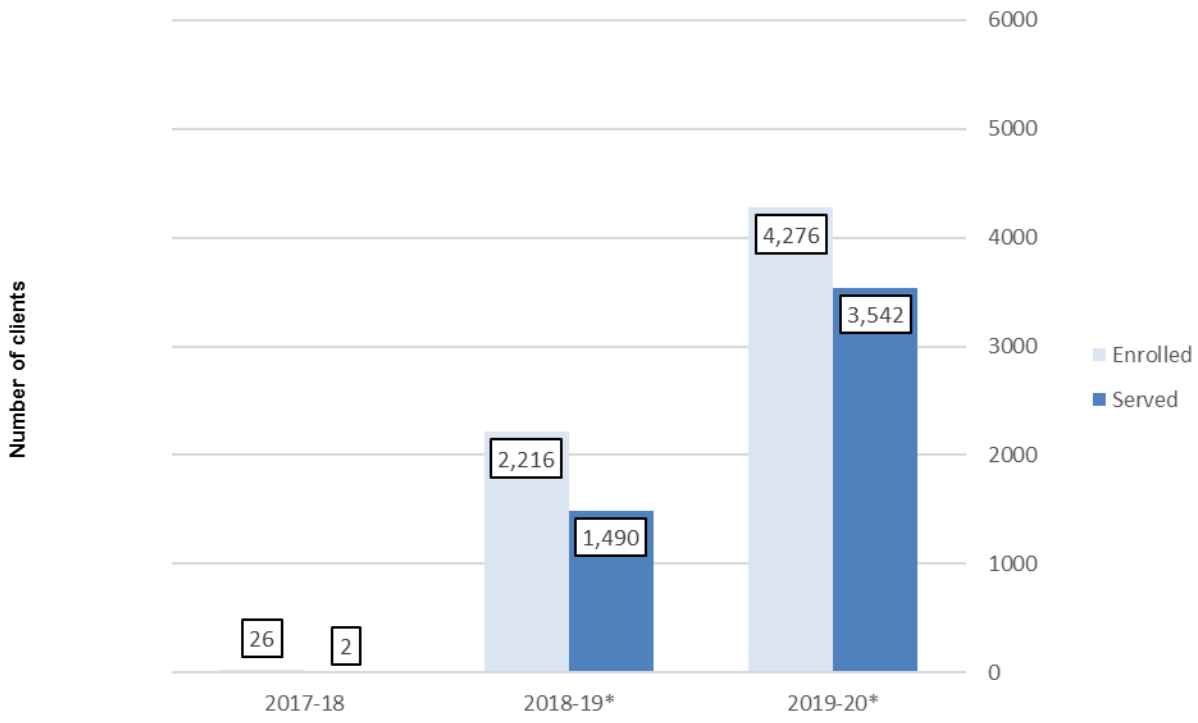


* Data for FYs 2018-19 and 2019-20 are estimated. All other data are actuals.



Note: In Figures 1 and 2, all client counts represent the number of clients served who incur program costs. Enrolled clients who do not incur program costs are excluded from these counts.

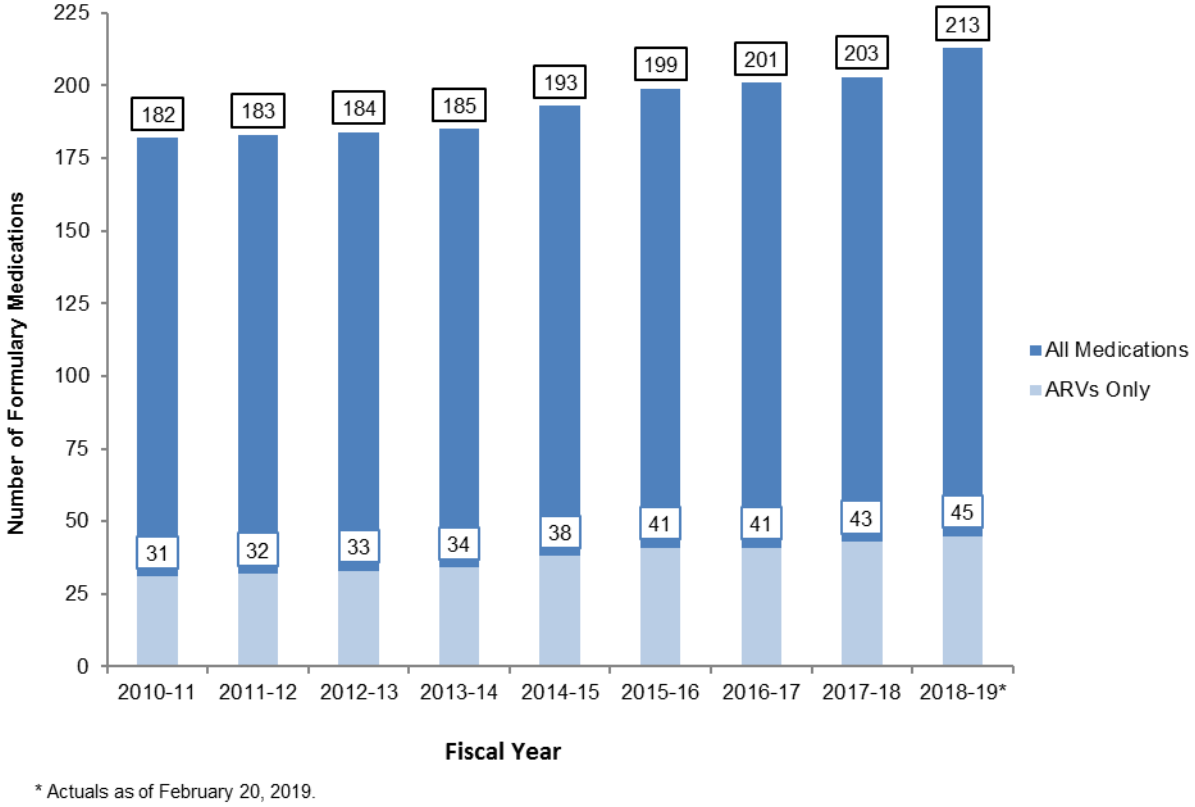
FIGURE 3: ADAP PREP CLIENT TREND



* Data for FYs 2018-19 and 2019-20 are estimated.

Note: In Figure 3, both clients served and enrolled are displayed.

FIGURE 4: NUMBER OF MEDICATIONS ON ADAP FORMULARY



* Actuals as of February 20, 2019.

Additions to the ADAP Formulary

- Efavirenz/lamivudine/tenofovir DF (Symfi™), a FDC ARV, was added to the formulary on March 8, 2019.
- Lamivudine/tenofovir disoproxil fumarate (Cimduo™), a FDC ARV, was added to the formulary on March 8, 2019.
- Darunavir/cobicistat/emtricitabine/tenofovir alafenamide (Symtuza™), a FDC ARV, was added to the formulary on March 1, 2019.

Removal from the ADAP Formulary

- Elvitegravir (Vitekta™), an ARV , was removed from the ADAP formulary on February 12, 2019.
- Ombitasvir/paritaprevir/ritonavir (Technivie™), a hepatitis C drug, was removed from the ADAP formulary on February 12, 2019.
- Ombitasvir/paritaprevir/ritonavir tablets with dasabuvir (Viekira Pak™), a hepatitis C drug, was removed from the ADAP formulary on February 12, 2019.

VII. Current HIV Epidemiology in California

Approximately 135,000 people in California at the end of 2017 had been diagnosed with HIV and reported to CDPH/OA. However, CDPH/OA estimates that 12 percent of all PLWH in California are unaware of their infection. Therefore, CDPH/OA estimates that there were approximately 153,000 PLWH in California as of the end of 2017. Since the epidemic began in 1981, approximately 100,000 Californians diagnosed with HIV have died, with over 1,800 dying in 2017 alone.

Of the approximately 135,000 people living with diagnosed HIV (PLWDH) in California, approximately 39.1 percent are White; 36.1 percent are Hispanic/Latinx; 17.2 percent are Black/African American; 4.0 percent are Asian; 3.1 percent are multi-racial; 0.3 percent are American Indian/Alaskan Native; and 0.2 percent are Native Hawaiian/Pacific Islander. While Whites and Hispanics/Latinxs make up the largest percentage of PLWDH in California, the rate of HIV among Blacks/African Americans is substantially higher (1,019 per 100,000 population, versus 348 per 100,000 among Whites, and 312 per 100,000 among Hispanics/Latinxs).

Most of California's living HIV cases are attributed to male-to-male sexual transmission (67.7 percent); 8.7 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); 6.9 percent to men who have sex with men who also inject drugs; 5.9 percent to injection drug use; 0.6 percent to perinatal exposure; and 10.3 percent to other or unknown sources, including other heterosexual contact.

There are approximately 4,800 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.