

**AIDS DRUG ASSISTANCE PROGRAM  
(ADAP)**

**Fiscal Year 2019-20**

**November Estimate**



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# California Department of Public Health

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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.
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, 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 November 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 2018 Budget Act.

- For FY 2018-19, CDPH/OA estimates that the ADAP budget authority need will be \$407.9 million, which is a \$26.2 million decrease in budget authority compared to the 2018 Budget Act. The decrease is primarily due to a decrease in projected medication expenditures (see key influences on ADAP expenditures on page 5 for more detail) and less than expected funding from the 2018 Ryan White Part B Supplemental grant (see New Assumption #3 on page 13).
- For FY 2019-20, CDPH/OA estimates that the ADAP budget authority need will be \$449.8 million, which is a \$15.7 million increase in budget authority compared to the 2018 Budget Act. The increase is primarily due to an increase in projected medication and insurance premium 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 2018 Budget Act.

- For FY 2018-19, CDPH/OA estimates ADAP revenue will be \$325.6 million, which is a \$830,000 decrease compared to the 2018 Budget Act. The decrease is primarily due to a decrease in projected medication expenditures (see revenue on page 7 for more detail).
- For FY 2019-20, CDPH/OA estimates ADAP revenue will be \$379 million, which is a \$52.5 million increase compared to the 2018 Budget Act. The increase is primarily due to an increase in medication expenditures (see revenue on page 7 for more detail).

**California Department of Public Health  
AIDS Drug Assistance Program  
2019-20 November Estimate  
Table 1: Local Assistance  
(In Thousands)**

Local Assistance	2018 Budget Act	Current Year FY 2018-19			2018 Budget Act	Budget Year FY 2019-20		
		2019-20 November Estimate	\$ Change from 2018 Budget Act	% Change from 2018 Budget Act		2019-20 November Estimate	\$ Change from 2018 Budget Act	% Change from 2018 Budget Act
<b>Fund:</b>								
<b>Total Funds Requested</b>	<b>\$434,076</b>	<b>\$407,878</b>	<b>-\$26,198</b>	<b>-6.0%</b>	<b>\$434,076</b>	<b>\$449,789</b>	<b>\$15,713</b>	<b>3.6%</b>
Federal Funds - Fund 0890	\$132,438	\$129,143	-\$3,295	-2.5%	\$132,438	\$135,138	\$2,700	2.0%
Rebate Funds - Fund 3080	\$301,638	\$278,735	-\$22,902	-7.6%	\$301,638	\$314,650	\$13,013	4.3%
<b>Caseload</b>	<b>30,864</b>	<b>31,541</b>	<b>677</b>	<b>2.2%</b>	<b>30,864</b>	<b>33,457</b>	<b>2,593</b>	<b>8.4%</b>

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

**Table 2: Rebate Fund Revenues (Fund 3080)  
2019-20 November Estimate  
(In Thousands)**

Local Assistance	2018 Budget Act	Current Year FY 2018-19			2018 Budget Act	Budget Year FY 2019-20		
		2019-20 November Estimate	\$ Change from 2018 Budget Act	% Change from 2018 Budget Act		2019-20 November Estimate	\$ Change from 2018 Budget Act	% Change from 2018 Budget Act
<b>Total Revenue Requested</b>	<b>\$326,462</b>	<b>\$325,632</b>	<b>-\$830</b>	<b>-0.3%</b>	<b>\$326,462</b>	<b>\$378,988</b>	<b>\$52,526</b>	<b>16.1%</b>
Rebate Funds - Fund 3080	\$324,462	\$321,632	-\$2,830	-0.9%	\$324,462	\$374,988	\$50,526	15.6%
Interest Income	\$2,000	\$4,000	\$2,000	100.0%	\$2,000	\$4,000	\$2,000	100.0%

### III. Overview Projections

#### A. Key influences on ADAP expenditures

- a) FY 2018-19: Compared to the 2018 Budget Act, CDPH/OA estimates that FY 2018-19 expenditures will decrease by 6 percent. The 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 number of private insurance clients is increasing at a rate higher than the decrease in medication-only clients, which explains why the overall client count is increasing. Also, contributing to the decrease in budget authority is less than anticipated funding from the 2018 Ryan White Part B Supplemental grant (see New Assumption #3 on page 13).
- b) FY 2019-20: Compared to the 2018 Budget Act, CDPH/OA estimates that FY 2019-20 expenditures will increase by 3.6 percent. The increase is primarily due to an increase in projected medication expenditures for medication-only clients, and an increase in insurance premium expenditures for private insurance clients. Despite enrollment for medication-only clients decreasing, increased medication prices more than offsets the decreased client count.

#### 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 18.

- Local ADAP enrollment services: Beginning in FY 2016-17, CDPH/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 22.

<b>TABLE 3: ESTIMATED VARIABLE EXPENDITURES BY CLIENT GROUP</b>		
<b>CLIENT GROUP</b>	<b>EXPENDITURES</b>	
	<b>FY 2018-19</b>	<b>FY 2019-20</b>
Medication-Only	\$308,019,032	\$321,101,989
Medi-Cal SOC	\$1,093,904	\$1,276,211
Private Insurance	\$62,184,844	\$83,228,041
Medicare Part D*	\$23,776,501	\$27,114,211
PrEP	\$4,101,355	\$5,958,138
<b>SUBTOTAL</b>	<b>\$399,175,637</b>	<b>\$438,678,590</b>
Enrollment Site Costs	\$6,902,500	\$7,460,000
<b>TOTAL</b>	<b>\$406,078,137</b>	<b>\$446,138,590</b>
+ 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 (formerly ADAP Case Management): In FY 2018-19 and FY 2019-20, CDPH/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. CDPH/OA will allocate \$1.8 million for Access, Adherence, and Navigation in FY 2018-19 and \$1.4 million in FY 2019-20 (see Existing Assumption #2 on page 16).
- Pharmacy Quality Incentive Program (QIP): In FY 2019-20, ADAP will allocate approximately \$2.3 million to pharmacies in the ADAP network that provide specific care and prevention measures identified by CDPH/OA with the goal of improving health outcomes and reducing overall state costs.

## 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 estimated rebates from actual and estimated medication expenditures from January through December 2018. FY 2019-20 revenue projections are based on estimated rebates from estimated drug expenditures from January through December 2019.
- For FY 2018-19, CDPH/OA estimates ADAP rebate revenue will decrease by 0.3 percent from \$326.5 million in the 2018 Budget Act to \$325.6 million in the revised Current Year forecast. The decrease is primarily due to a decrease in projected medication expenditures for medication-only clients, but is offset by an increase in medication expenditures by private insurance clients and increasing interest income.
  - For FY 2019-20, CDPH/OA estimates ADAP rebate revenue will increase by 16.1 percent from \$326.5 million in the 2018 Budget Act to \$379 million in the revised Budget Year forecast. The increase is primarily caused by an increase in medication expenditures for medication-only and private insurance clients due to increasing medication prices and more private insurance clients.
- b) Federal Funds – for FY 2018-19, total federal fund expenditures will decrease by \$3.3 million to \$129.1 million compared to the 2018 Budget Act. Federal fund budget authority includes: the 2018 Ryan White Part B grant (ADAP Earmark) in the amount of \$99.1 million, which received a funding increase of \$2.7 million (see New Assumption #1 on page 12), 2018 Ryan White Part B Supplemental grant in the amount of \$17 million, which received a funding decrease of \$8 million (see New Assumption #3 on page 13), the 2018 ADAP Shortfall Relief grant (formerly ADAP Emergency Relief grant) in the amount of \$11 million, and the 2017 Ryan White Part B grant carryover in the amount of \$2 million (see New Assumption #4 on page 14).

For FY 2019-20, total federal fund expenditures will increase by \$2.7 million to \$135.1 million compared to the 2018 Budget Act. 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 Fund grant funding in the amount of \$11 million.

Match – the Health Resources and Services Administration (HRSA) requires grantees to have HIV-related non-HRSA expenditures. California’s HRSA match requirement for the 2018 Ryan White Part B grant year (April 1, 2018 through March 31, 2019) is \$69.5 million. CDPH/OA will meet the match requirement using CDPH/OA General Fund State Operations expenditures and Local Assistance expenditures for CDPH/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 drugs have received federal Food and Drug Administration (FDA) approval:

1. Lamivudine/tenofovir disoproxil fumarate (Cimduo™)

On February 28, 2018, the FDA approved 300 mg lamivudine and 300 mg tenofovir disoproxil fumarate (Cimduo™), two nucleoside analog reverse transcriptase inhibitors, as a once daily single-tablet combination regimen for the treatment of HIV-1 infection, in combination with other antiretroviral (ARV) medications.

2. Darunavir/cobicistat/emtricitabine/tenofovir alafenmaide (Symtuza™)

On July 17, 2018, the FDA approved this HIV combination drug, which combines a protease inhibitor (darunavir), a pharmacokinetic enhancer (cobicistat), a nucleoside reverse transcriptase inhibitor (emtricitabine), and a nucleotide reverse transcriptase inhibitor (tenofovir alafenamide). The FDA approved darunavir/cobicistat/emtricitabine/tenofovir alafenmaide as a complete once daily, single-tablet treatment regimen for patients infected with HIV-1.

3. Doravirine/lamivudine/tenofovir disoproxil fumarate (Delstrigo™)

On August 30, 2018, the FDA approved this fixed-dose single tablet regimen combining an investigational non-nucleoside reverse transcriptase inhibitor (doravirine) and two nucleoside analog reverse transcriptase inhibitors (lamivudine and tenofovir disoproxil fumarate).

4. Doravirine (Pifeltro™)

On August 30, 2018, the FDA approved this investigational non-nucleoside reverse transcriptase inhibitor for use in the treatment of HIV-1 infection in combination with other ARV drugs.

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

1. PRO 140

This is a new class of HIV/AIDS drug currently in phase III clinical trials. It is intended to protect healthy cells from HIV infection and is a monoclonal antibody targeted against the CCR5 receptor. The manufacturer met with the FDA on June 22, 2018, and based on FDA feedback, is continuing to gather safety and efficacy data. There is no indication as to when a New Drug Application (NDA) might be submitted.

2. Dolutegravir/lamivudine

This drug entered phase III clinical trials on February 8, 2018. This two-drug regimen acts as a potential equivalent treatment alternative from the combination regimens of three or more drugs for HIV-1 treatment. The manufacturer is exploring how HIV treatment can reduce the number of drugs a patient is exposed to while maintaining the same level of efficacy achieved with multi-drug regimens. An NDA was submitted to the FDA on October 17, 2018.

### 3. Fostemsavir

This is a new experimental attachment inhibitor under development. It is being studied for use in treatment-experienced people with resistance to several classes of antiretroviral drug.

### 4. Cabotegravir/rilpivirine

This drug is starting phase III clinical trials investigating cabotegravir with rilpivirine, non-nucleoside reverse transcriptase inhibitor as a long-acting (given every eight weeks) two-drug regimen for the treatment for HIV. Initial results of the phase III trial are expected in 2019.

Description of Change: The ADAP Medical Advisory Committee (MAC) voted to recommend the addition of Cimduo™, Symtuza™, Pifeltro™, and Delstrigo™, to the ADAP drug formulary. CDPH/OA will conduct a cost analysis for the four approved drugs once it is determined if the ADAP Crisis Task Force (ACTF) is able to secure discounted pricing for these new treatment options. If any of the remaining HIV drugs receive FDA approval and the ADAP MAC recommends their addition to the ADAP formulary, CDPH/OA will monitor pricing of each drug. If CDPH/OA is able to determine that the drugs do not represent a significant cost increase to the program, CDPH/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, CDPH/OA must add an 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 CDPH/OA must determine whether the program has an adequate budget to fund the addition of the new drug. If not, CDPH/OA may seek additional budgetary authority through the Estimate process.
- Addition of new drugs to the ADAP formulary offers ADAP clients options of drugs that best work to optimize health efficacy.

Fiscal Impact and Fund Source(s): The fiscal impact is unknown at this time. If any of the HIV drugs listed above receive FDA approval, CDPH/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 Pre-Exposure Prophylaxis (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 drug may receive FDA approval in the next year:

#### 1. Cabotegravir

This new drug is an integrase strand transfer inhibitor being developed as a long-acting injectable and a potential alternative to the daily oral dose of Truvada® for the prevention of HIV. This new drug is currently in phase III trials.

Description of Change: If this HIV prevention drug receives FDA approval and the ADAP MAC recommends its addition to the ADAP formulary, CDPH/OA will monitor pricing of the new drug. If CDPH/OA is able to determine that the drug does not represent a significant cost to the program, CDPH/OA will move forward with adding this drug to the ADAP and PrEP-AP formularies.

Discretionary: Yes

#### Reason for Adjustment/ Change:

- This is the first new drug under development specifically indicated for the prevention of HIV infection.
- 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 Pre-Exposure Prophylaxis Assistance Program (PrEP-AP)**

Background: As a result of a legislative augmentation in the 2016 Budget Act, CDPH/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. PrEP-AP was implemented on April 9, 2018 and is currently available to individuals with or without health insurance.

Description of Change: CDPH/OA received a \$2 million legislative augmentation through the 2018 Budget Act to support proposals to modify PrEP-AP by expanding eligibility and accessibility to PrEP-AP for individuals 12 years of age or older, pursuant to HSC 120972 and authorized through AB 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 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.

Discretionary: No

Reason for Adjustment/ Change:

- Change to HSC Section 120972.

Fiscal Impact and Fund Source(s): No additional budget authority beyond the \$2 million legislative augmentation is needed at this time; however, initial cost projections to enhance PrEP-AP did not account for several enhancements approved in the 2018 Budget Act, including items numbers 3, 4, 5, and 6 listed above. CDPH/OA will provide future updates if projected costs cannot be absorbed within the existing \$2 million in budget authority. The fund impacted is the ADAP Rebate Fund (Fund 3080).

### **New Assumptions**

#### **Increase in Federal Funds: 2018 Ryan White Part B Grant**

Background: In November 2017, CDPH/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.

Description of Change: 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 CDPH/OA applied for. The \$2.7 million in unanticipated funding is for ADAP Branch's Local Assistance.

Discretionary: Yes

Reason for Adjustment/ Change:

- Unanticipated funding received.

Fiscal Impact and Fund Source(s): Increase of \$2.7 million Local Assistance in FY 2018-19 and FY 2019-20. The fund impacted is the Federal Trust Fund (0890).

## **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 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.

Description of Change: On May 22, 2018, the ACTF announced that an agreement with the manufacturer of ibalizumab was reached for discounted pricing for this medication. Although CDPH/OA will be receiving reduced pricing, this new injectable is not cost neutral, and is projected to have a moderate fiscal impact. Additionally, CDPH/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, CDPH/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.

Discretionary: No

Reason for Adjustment/ Change:

- 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 \$2.3 million for 6 clients. Estimated net expenditures for FY 2019-20 will be \$13.3 million for 16 clients. The funds impacted are the ADAP Rebate Fund (Fund 3080) and Federal Trust Fund (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.

Description of Change: In May 2018, CDPH/OA applied for the competitive 2018 Ryan White Part B Supplemental grant. CDPH/OA requested the maximum amount of \$35 million, with \$25 million specifically for ADAP to be used in Fiscal Year (FY) 2018-19. On September 20, 2018, CDPH/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.

Table 1: Ryan White Part B Supplemental Funds		
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.		

Discretionary: Yes

Reason for Adjustment/ Change:

- The Ryan White Part B Supplemental grant is a competitive funding opportunity.
- Prior funding awards are not guarantees that funding will be provided in the future.

Fiscal Impact and Fund Source(s): Decrease of \$8 million Local Assistance in FY 2018-19. 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 1<sup>st</sup> to March 31<sup>st</sup>. The grant is shared between CDPH/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. CDPH/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.

Description of Change: On July 30, 2018, CDPH/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, CDPH/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.

Discretionary: Yes

Reason for Adjustment/ Change:

- Fully leverage federal funding.

Fiscal Impact and Fund Source(s): Increase of \$2 million Local Assistance in FY 2018-19. The fund impacted is the Federal Trust Fund (Fund 0890).

### **Existing Assumptions**

#### **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, interim solution while a permanent IT solution could be identified via the PAL process. The California Department of Technology (CDT) and CDPH Information Technology Services Division (ITSD) are currently working collaboratively to identify a long-term IT solution for the AES. See Attachment A.

Description of Change: There are no changes in the budget authority for FY 2018-19 from what was approved in the 2018 Budget Act as a one-time augmentation. CDPH/OA is updating this assumption to include projected costs for FY 2019-20, and requests budget authority to maintain the interim AES. For FY 2019-20 the total cost for the PAL project includes: 1) \$37,800 for adjustments in CDT staff costs for Independent Project Oversight Consulting, 2) \$150,324 for ITSD staffing costs for PAL project management, 3) \$40,000 for the newly identified costs for a consultant to assist 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 ADAP PAL is expected to be completed, making the interim AES the permanent IT solution.

Discretionary: Yes

Reason for Adjustment/ Change:

- There is currently no budget authority established for FY 2019-20.

Fiscal Impact and Fund Source(s): For FY 2018-19, no additional budget authority is needed. Estimated State Operations expenditures for FY 2019-20 total \$3.3 million and additional budget authority is needed. The fund impacted is the ADAP Rebate Fund (Fund 3080).

### **Access, Adherence, and Navigation (AAN) Program**

Background: Beginning in FY 2017-18, CDPH/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. CDPH/OA selected the top 19 sites with the largest ADAP medication-only client population to participate in the Access, Adherence, and Navigation Program. Of the 19 ADAP enrollment sites invited to participate, eight enrollment sites declined due to a variety of reasons, including lack of capacity, 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, and lack of infrastructure to bill for clients with private insurance. CDPH/OA is currently awaiting a response from one site.

Description of Change:

To align with the federal grant year and allow for the program to operate during an additional open enrollment period, CDPH/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, CDPH/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. However, due to current processing times needed to review and execute contracts, the amendments may not be fully executed in time for the 2019 Covered California open enrollment period, which would decrease estimated savings.

Discretionary: Yes

Reason for Adjustment/ Change:

- Offset costs due to lower than anticipated enrollment site participation in the Access, Adherence, and Navigation Program.
- Maximize the number of clients transitioned to comprehensive health coverage.

Fiscal Impact and Fund Source(s): Estimated net savings for FY 2018-19, \$5.1 million (\$7.9 million in medication expenditure savings, less \$944,000 in additional premium payments, less \$126,000 in additional medical out-of-pocket costs, and less \$1.8 million in enrollment site payments) from navigating 496 clients to comprehensive health insurance. Estimated net savings for FY 2019-20, \$5.4 million (\$8.2 million in medication expenditure savings, less \$1 million in additional premium payments, less \$397,000 in additional medical out-of-pocket costs, and less \$1.4 million in enrollment site payments) from navigating 486 clients to comprehensive medical insurance. No additional budget authority is needed. The funds impacted are the Federal Trust Fund (Fund 0890) and ADAP Rebate Fund (Fund 3080).

### **Unchanged Assumptions/Premises**

List:

1. Payment of Out-of-Pocket Medical Expenses for All OA-HIPP Clients
2. Increase in Funding to ADAP Enrollment Sites

### **Discontinued Assumptions/Premises**

There are no Discontinued Assumptions.

**V. Expenditure Details**

A. 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 VARIABLE EXPENDITURES BY CLIENT GROUP AND SERVICE TYPE, FY 2018-19							
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
<b>SUBTOTAL</b>	<b>31,541</b>	<b>100.0%</b>	<b>\$349,635,784</b>	<b>\$40,628,328</b>	<b>\$3,804,759</b>	<b>\$5,106,766</b>	<b>\$399,175,637</b>
Enrollment Site Costs	0	0.0%	\$0	\$0	\$0	\$6,902,500	\$6,902,500
<b>TOTAL</b>	<b>31,541</b>	<b>100.0%</b>	<b>\$349,635,784</b>	<b>\$40,628,328</b>	<b>\$3,804,759</b>	<b>\$12,009,266</b>	<b>\$406,078,137</b>
* Subgroup of 9,645 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 5: ESTIMATED ANNUAL CASELOAD AND VARIABLE EXPENDITURES BY CLIENT GROUP AND SERVICE TYPE, FY 2019-20							
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
<b>SUBTOTAL</b>	<b>33,457</b>	<b>100.0%</b>	<b>\$371,264,941</b>	<b>\$54,889,818</b>	<b>\$7,879,091</b>	<b>\$4,644,740</b>	<b>\$438,678,590</b>
Enrollment Site Costs	0	0.0%	\$0	\$0	\$0	\$7,460,000	\$7,460,000
<b>TOTAL</b>	<b>33,457</b>	<b>100.0%</b>	<b>\$371,264,941</b>	<b>\$54,889,818</b>	<b>\$7,879,091</b>	<b>\$12,104,740</b>	<b>\$446,138,590</b>
* Subgroup of 12,664 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, CDPH/OA estimates medication expenditures for medication-only clients will be \$307.6 million, which is a \$30.5 million decrease compared to the 2018 Budget Act. 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 Medical and clients transitioning to private insurance with a partial offset for higher medication prices.
  - For FY 2019-20, CDPH/OA estimates medication expenditures for medication-only clients will be \$320.7 million, which is a \$13.1 million increase compared to the revised projection for FY 2018-19. This increase 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 receives services associated with medication costs.

1. Medication Expenditures
  - For FY 2018-19, CDPH/OA estimates medication expenditures for Medi-Cal SOC clients will be \$1.1 million, which is a \$92,000 increase compared to the 2018 Budget Act. The increase in expenditures is due to higher medication costs as a result of higher SOC amounts with no change to caseload.
  - For FY 2019-20, CDPH/OA estimates medication expenditures for Medi-Cal SOC clients will also be \$1.3 million, which is a \$182,000 increase compared to the revised projection for FY 2018-19. As in FY 2018-19, the increase in expenditures is due to similar caseload with 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, CDPH/OA estimates medication expenditures for all private insurance clients will be \$20.2 million, which is a \$1.8 million increase compared to the 2018 Budget Act. The increase in expenditures is due to more clients transitioning to private insurance.
- For FY 2019-20, CDPH/OA estimates medication expenditures for all private insurance clients will be \$25.6 million, which is a \$5.4 million increase compared to the revised projection for FY 2018-19. This increase is due to continuing growth in private insurance caseload.

2. Health Insurance Premiums

- For FY 2018-19, CDPH/OA estimates health insurance premium payment expenditures for all private insurance clients will be \$39.2 million, which is a \$1.5 million decrease compared to the 2018 Budget Act. The increase in clients will be offset by lower premiums than previously estimated.
- For FY 2019-20, CDPH/OA estimates health insurance premium payment expenditures will be \$53.2 million, which is a \$14.0 million increase compared to the revised projection for FY 2018-19. This increase is due to the same client transition stated above and an increase in premium costs.

3. Medical Out-Of-Pocket Costs

- For FY 2018-19, CDPH/OA estimates medical out-of-pocket costs for all private insurance clients will be \$1.9 million, which is a \$25,000 decrease compared to the 2018 Budget Act. The decrease is due to lower than projected service utilization.
- For FY 2019-20, CDPH/OA estimates medical out-of-pocket costs will be \$3.5 million, which is a \$1.6 million increase compared to the revised projection for FY 2018-19. The increase is due to a growing insurance population and a projected increase in service utilization.

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, CDPH/OA estimates medication expenditures for Medicare Part D clients will be \$20.3 million, which is a \$862,000 decrease compared to the 2018 Budget Act. The decrease in expenditures is due to fewer than anticipated clients with Medicare Part D

plans in the medication assistance program and lower than anticipated deductibles and co-insurance.

- For FY 2019-20, CDPH/OA estimates medication expenditures for Medicare Part D clients will be \$22.0 million, which is a \$1.8 million increase compared to the revised projection for FY 2018-19. This increase is due to an increase in deductibles and co-insurance from prior year.

## 2. Health Insurance Premiums

- For FY 2018-19, CDPH/OA estimates Medicare Part D premium payment expenditures will be \$1.4 million, which is a \$171,000 increase compared to the 2018 Budget Act. This change is due to a higher than anticipated increase in Medicare Part D clients for whom ADAP pays Medicare Part D premiums.
- For FY 2019-20, CDPH/OA estimates Medicare Part D premium payment expenditures will be \$1.7 million, which is a \$229,000 increase compared to the revised projection for FY 2018-19. This increase is due to the same reason as above.

## 3. Medical Out-Of-Pocket Costs

- For FY 2018-19, CDPH/OA estimates medical out-of-pocket costs will be \$1.4 million, which is a \$967,000 increase compared to the 2018 Budget Act. This increase is due to higher than previously projected monthly costs for paying Medicare Part B medical out-of-pocket costs, including premiums for Medigap policies.
- For FY 2019-20, CDPH/OA estimates medical out-of-pocket costs will be \$2.8 million, which is a \$1.4 million increase compared to the revised projection for FY 2018-19. This increase is due to both a larger caseload and higher monthly costs.

## 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, CDPH/OA estimates medication expenditures for PrEP-AP will be \$462,000, which is a \$179,000 increase compared to the FY 2018 Budget Act. This increase is primarily due to higher than anticipated drug expenditures, offset by less than anticipated client enrollment.
- For FY 2019-20, CDPH/OA estimates medication expenditures will be \$1.6 million, which is a \$1.2 million increase compared to the revised

projection for FY 2018-19. This increase is due to increased caseload as the program continues to grow.

2. Health Insurance Premiums: Health insurance premium coverage is not included in PrEP-AP.
3. Medical Out-Of-Pocket Costs
  - For FY 2018-19, CDPH/OA estimates medical out-of-pocket costs will be \$489,000 for PrEP clients, which is a \$228,000 decrease compared to the 2018 Budget Act. This decrease is primarily due to less than anticipated client enrollment.
  - For FY 2019-20, CDPH/OA estimates medical out-of-pocket costs will be \$1.6 million for PrEP-AP clients, which is a \$1.2 million increase compared to the revised projection for FY 2018-19. This increase is due to increased caseload as the program continues to grow.

## B. ADAP Enrollment Services

- a. The reimbursement methodology used to determine service payment to enrollment sites is unchanged from the 2018 Budget Act. 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. CDPH/OA updated projected enrollment numbers, resulting in an estimate of \$6.9 million in enrollment costs for FY 2018-19 and \$7.5 million in enrollment costs for FY 2019-20.

1. Floor Amount
  - For FY 2018-19, CDPH/OA estimates reimbursement of \$965,000 for 193 enrollment sites.
  - For FY 2019-20, CDPH/OA estimates reimbursement of \$1 million for 200 enrollment sites.
2. New Medication Enrollment
  - For FY 2018-19, CDPH/OA estimates reimbursement of \$400,000 from 4,000 clients enrolling into ADAP at some point throughout the fiscal year.
  - For FY 2019-20, CDPH/OA estimates reimbursement at \$400,000 from 4,000 clients enrolling into ADAP at some point throughout the fiscal year.
3. Bi-annual Self-Verification
  - For FY 2018-19, CDPH/OA estimates reimbursement of \$900,000 from 30,000 clients recertifying into ADAP at some point throughout the fiscal year.
  - For FY 2019-20, CDPH/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, CDPH/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, CDPH/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, CDPH/OA estimates reimbursement of \$715,000 from 2,600 clients enrolling into one of the two CDPH/OA's insurance assistance programs at some point throughout the fiscal year.
  - For FY 2019-20, CDPH/OA estimates reimbursement of \$715,000 from 2,600 clients enrolling into one of the two CDPH/OA's insurance assistance programs at some point throughout the fiscal year.
6. Insurance Assistance Annual Re-Enrollment
  - For FY 2018-19, CDPH/OA estimates reimbursement of \$813,000 from 6,500 clients re-enrolling into one of the two CDPH/OA's insurance assistance programs at some point throughout the fiscal year.
  - For FY 2019-20, CDPH/OA estimates reimbursement of \$1.1 million from 9,000 clients re-enrolling into one of the two CDPH/OA's insurance assistance programs at some point throughout the fiscal year.
7. New PrEP Enrollment
  - For FY 2018-19, CDPH/OA estimates reimbursement of \$80,000 from 800 clients enrolling into PrEP-AP at some point throughout the fiscal year.
  - For FY 2019-20, CDPH/OA estimates reimbursement of \$120,000 from 1,200 clients enrolling into PrEP-AP at some point throughout the fiscal year.
8. PrEP Re-Enrollment
  - For FY 2018-19, CDPH/OA estimates reimbursement of \$30,000 from 300 clients re-enrolling into PrEP-AP at some point throughout the fiscal year.
  - For FY 2019-20, CDPH/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

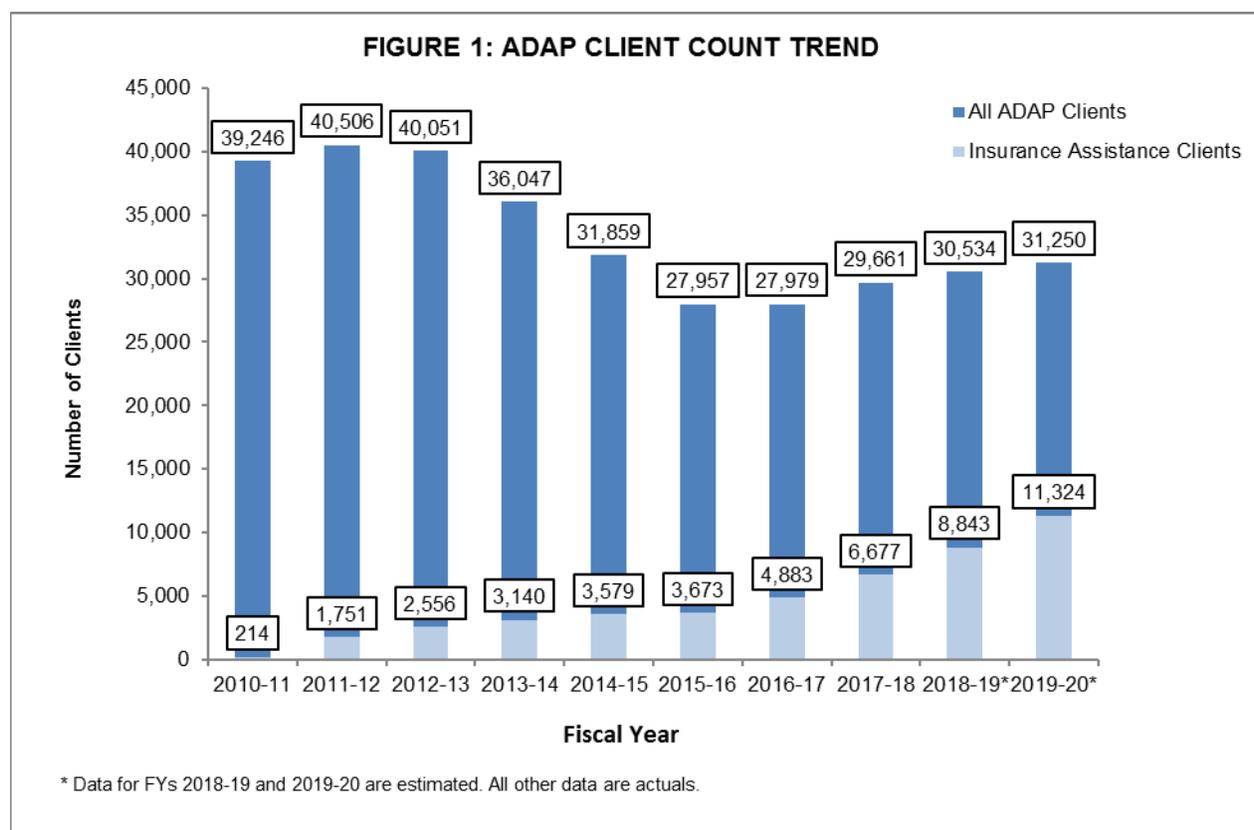
For all figures in this section, the data prior to FY 2018-19 is the observed historical data. Estimates for FY 2018-19 and FY 2019-20 are based on the overall projections and include all assumptions.

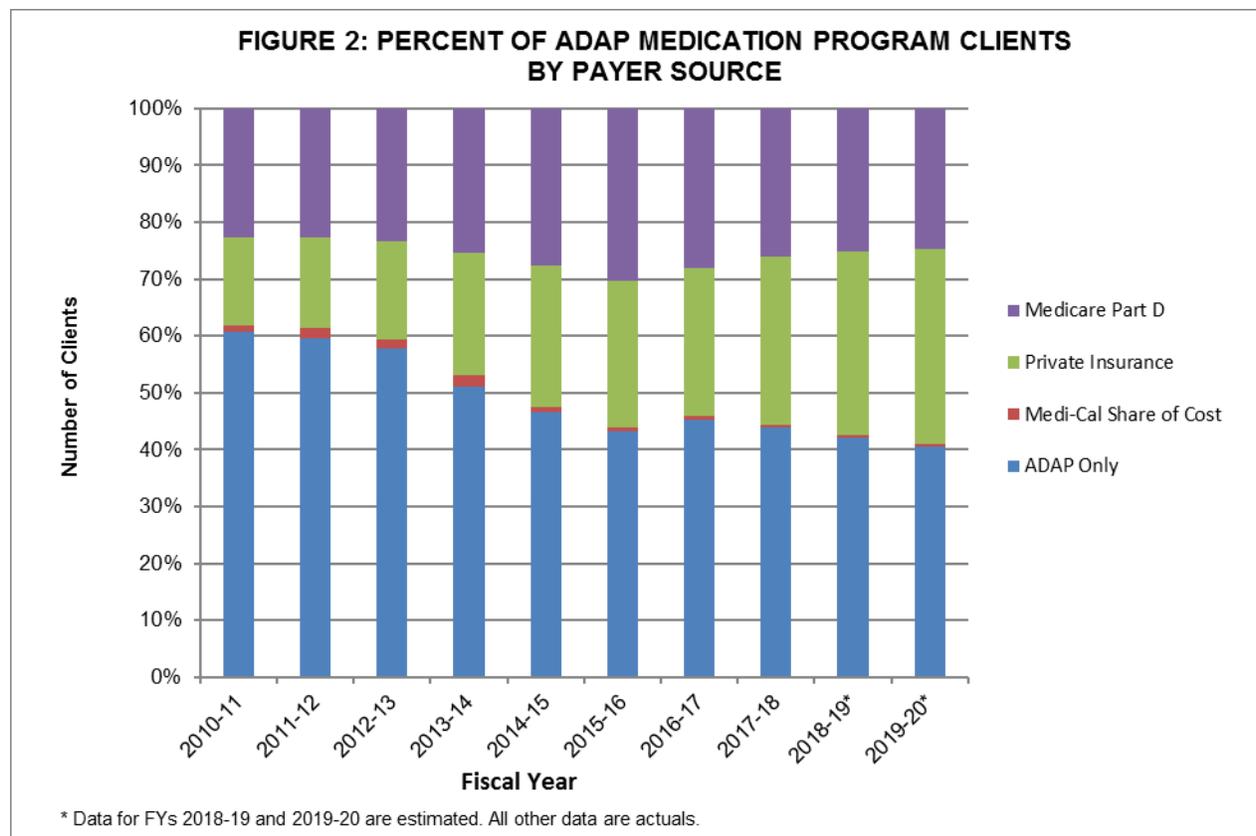
Figure 1 is a summary of total client counts in ADAP by FY, excluding PrEP clients. The number of ADAP medication program clients who are also receiving insurance assistance is also shown.

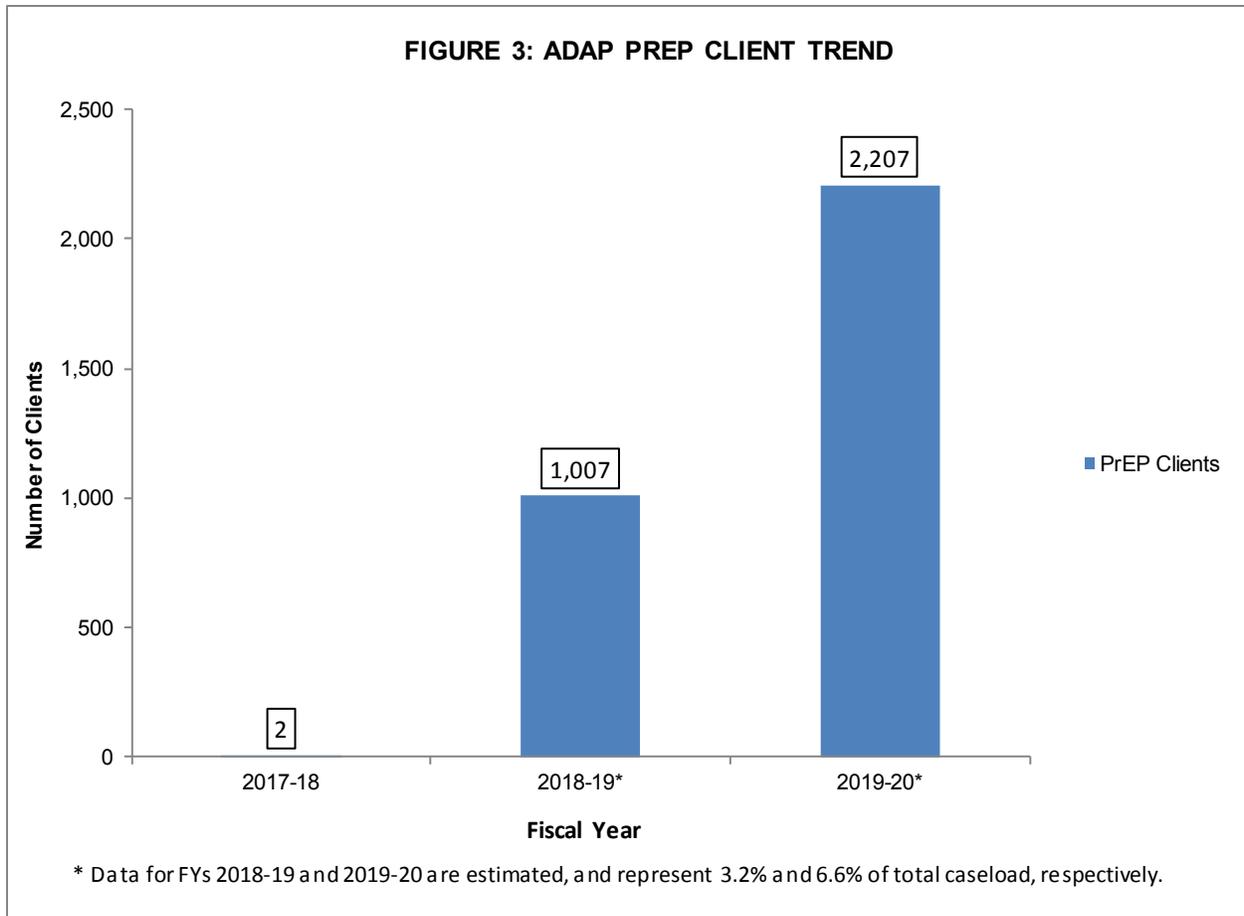
Figure 2 shows the proportion of ADAP medication program clients enrolled in the various payer groups by FY.

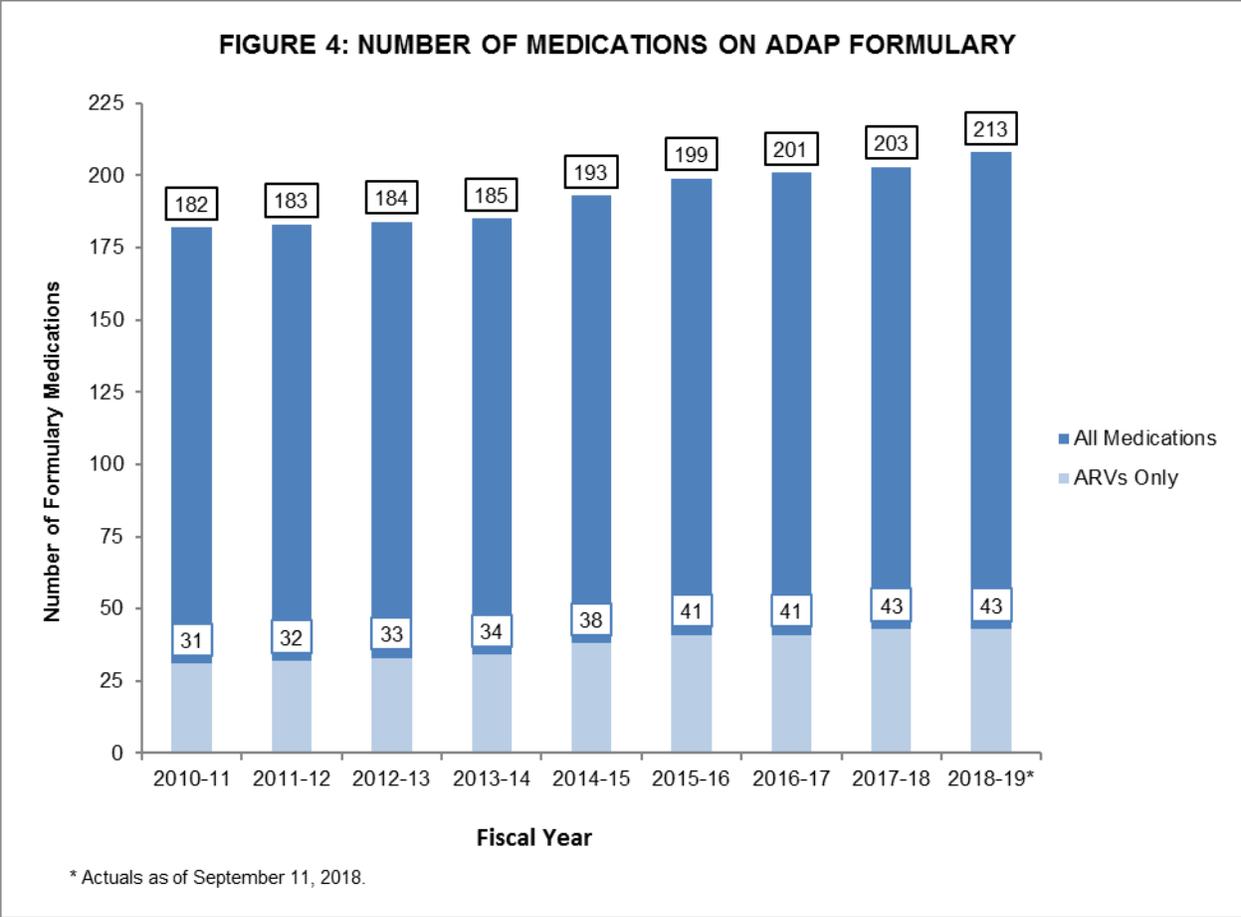
Figure 3 is a summary of estimated client counts in PrEP Assistance Program by FY.

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









- Simeprevir (Olysio®) was removed from the ADAP formulary on May 25, 2018.
- Crofelermer (Mytesi®) was added to the ADAP formulary on June 14, 2018.
- Hepatitis B recombinant (HEPLISAV-B) vaccine was added to the ADAP formulary on November 12, 2018.
- Influenza vaccine was added to the ADAP formulary on November 12, 2018.
- Measles, mumps, and rubella (MMR) vaccine was added to the ADAP formulary on November 12, 2018.
- Tetanus, diphtheria, and pertussis (TDAP) vaccine was added to the ADAP formulary on November 12, 2018.
- Varicella-zoster (Herpes) vaccine was added to the ADAP formulary on November 12, 2018.

## VII. Current HIV Epidemiology in California

Approximately 132,000 PLWH in California at the end of 2016 had been diagnosed and reported to CDPH/OA. However, CDPH/OA estimates that 13 percent of all PLWH in California are unaware of their infection. Therefore, CDPH/OA estimates that there were approximately 151,000 PLWH in California as of the end of 2016. Since the epidemic began in 1981, approximately 100,000 Californians diagnosed with HIV have died, with over 1,700 dying in 2016 alone.

Of PLWH in California, approximately 40.3 percent are White; 35.3 percent are Hispanic/Latino; 17.5 percent are Black/African American; 3.9 percent are Asian; 2.5 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/Latinos make up the largest percentage of PLWH in California, the rate of HIV among Blacks/African Americans is substantially higher (1,023 per 100,000 population, versus 352 per 100,000 among Whites, and 303 per 100,000 among Hispanics/Latinos).

Most of California's living HIV cases are attributed to male-to-male sexual transmission (66.7 percent); 8.8 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); 7.0 percent to men who have sex with men who also inject drugs; 6.0 percent to injection drug use; 0.6 percent to perinatal exposure; and 11.0 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.

**California Department of Public Health  
Status Update of the Project Approval Lifecycle and the  
AIDS Drug Assistance Program Enrollment System  
January 10, 2019**

**Request:** The California Department of Public Health/Office of AIDS (CDPH/OA) is requesting \$3.3 million in 2019-20 from the AIDS Drug Assistance Program Rebate Fund to cover costs to support the implementation of the ADAP Enrollment System (AES). The increased funding will cover costs for enhancements (\$233,000), maintenance and operations (\$2.8 million), and increased Project Approval Lifecycle (PAL) costs (\$228,000).

**Background:** Due to the early contract termination with the ADAP Enrollment Benefits Manager for material breaches of contract in March 2017, CDPH/OA implemented an interim AES with minimal functionality to prevent disruption of client services and lapses in client care (refer to the FY 2017-18 May Revision Estimate, page 11). Since then, CDPH/OA has been using the Interim AES to manage client eligibility and to exchange information with the Pharmacy Benefits Manager and the Insurance and Medical Benefits Manager. CDPH/OA, in collaboration with CDPH/Information Technology Services Division (ITSD), is conducting a PAL project to establish a permanent solution for the AES, which can be considered in three distinct phases: (1) Interim AES development; (2) PAL implementation; and (3) AES long-term solution. On July 26, 2018, CDPH/OA received Stage 2 Approval from the California Department of Technology (CDT) to implement a PAL project that would enable CDPH/OA to use the interim AES as the basis for the long-term system, after an assessment of business needs and alternatives. During the alternatives' analysis, CDPH/OA and CDT determined that enhancing the interim AES offered the highest benefit to future ADAP Enrollment Benefits System support.

**Funding Authority and Expenditures:** Approximately \$11.7 million from the AIDS Drug Assistance Program Rebate Fund is available for the Interim AES and PAL process from FY 2016-17 through FY 2018-19. This amount includes \$2.7 million (all for AES) in FY 2016-17, \$4.6 million in FY 2017-18 (\$4.3 million for AES and \$303,000 for PAL), and \$4.4 million (\$3.9 million for AES and \$472,000 for PAL) in FY 2018-19. The 2019 Governor's Budget includes a request for \$3.3 million in 2019-20 from the AIDS Drug Assistance Program Rebate Fund. As of November 2018, CDPH/OA has expended approximately \$8.1 million in Interim AES development and operations costs and PAL process costs.

**Status:** Currently, CDPH/OA is using the Interim AES for ADAP eligibility management needs. Additionally, the AES PAL portion of the project is within scope, budget, and will start the final stage in early January 2019. Once the PAL project is complete, the Interim AES will become the long-term solution, development for core operations will be complete, and the system will transition into maintenance and operations. Baseline PAL documentation will be updated to reflect changes as needed.