

# **AIDS DRUG ASSISTANCE PROGRAM (ADAP)**

## **Estimate Package**

**2014-15 May Revision**



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## **EXECUTIVE SUMMARY**

The California Department of Public Health (CDPH), Center for Infectious Diseases, Office of AIDS (OA), AIDS Drug Assistance Program (ADAP) 2013 Budget Act appropriation is \$406.3 million. For the *2014-15 May Revision*, CDPH is requesting an increase of \$27.9 million in federal funds, an increase of \$37.6 million in rebate funds, and a decrease in reimbursement funds of \$58.0 million due to a surplus in fiscal year (FY) 2013-14. For FY 2014-15, ADAP estimates a budget increase of \$24.8 million when compared to the revised current year budget of \$413.8 million.

The budget for ADAP, which includes insurance assistance programs, does not include General Fund for FY 2013-14 or FY 2014-15.

### **Expenditure Forecast**

Unadjusted expenditure estimates for the *2014-15 May Revision* were derived from a linear regression model. The 36-month data set for this estimate used actual expenditures from April 2011 through February 2014, and estimated expenditures for March 2014. Estimates were adjusted based on the assumptions listed on page 9. This methodology assumes a linear increase in expenditures over time. However, the increase in expenditures is no longer occurring due to two key policy changes recently implemented: 1) the movement of ADAP clients into the Low Income Health Program (LIHP) through December 31, 2013; and 2) beginning January 1, 2014, the movement of ADAP clients to Medi-Cal Expansion and Covered California due to the implementation of the Patient Protection and Affordable Care Act (PPACA).

To address this limitation, pre-regression adjustments were made for LIHP, Medi-Cal Expansion, and OA's Pre-Existing Condition Insurance Plan (OA-PCIP) premium payment program. The adjustments add the monthly savings realized to date back into the data points in the regression as if LIHP, Medi-Cal Expansion, and OA-PCIP were never in effect. Covered California savings were negligible at this time and disregarded as a pre-regression adjustment. This methodology maintains the integrity of the linear regression model, and allows OA to estimate the full impact of each assumption. Pre-regression adjustments were also made to account for reduced Pharmacy Benefits Manager (PBM) transaction fees and reimbursement rates (July 2011); increased split fee savings (July 2011) and savings due to expanding OA-Health Insurance Premium Payment (HIPP) program (July 2011). Post-regression adjustments were conducted for the addition of new hepatitis C virus (HCV) drugs (New Assumption 1, page 10), 2014 Medi-Cal Expansion (Existing Assumption 1, page 11), Covered California (Existing Assumption 2, page 13), OA-PCIP (Existing Assumption 3, page 15), additional PBM Costs (Existing Assumption 4, page 16), LIHP (Unchanged Assumption 1, page 18), and Cal MediConnect (Unchanged Assumption 7, page 18).

For FY 2013-14, total estimated expenditures of \$413.8 million are \$7.5 million more than the Budget Act authority of \$406.3 million. However, there is no General Fund need for local assistance because ADAP will use all mandatory rebate funds available

in FY 2013-14 due to the federal Health Resources and Services Administration's (HRSA) requirement to spend mandatory rebate funds prior to spending federal funds. ADAP also estimates spending an additional \$27.9 million in federal funds and returning \$58.0 million of reimbursement funds to the California Department of Health Care Services (DHCS), when compared to the FY 2013-14 Budget Act.

FY 2014-15 estimated expenditures of \$438.5 million are \$24.8 million more than FY 2013-14 revised estimated expenditures of \$413.8 million primarily due to costs associated with adding new HCV drugs to the ADAP formulary.

### **Revenue Forecast**

Payments of ADAP expenditures are made from three fund sources: 1) federal funds; 2) rebate funds; and 3) reimbursements from DHCS as a result of funding available through the Safety Net Care Pool (SNCP). (See Appendix B: Fund Sources for funding details on page 31.)

Major changes from the *2014-15 Governor's Budget*:

- An increase in the drug rebate rate from 65 to 67 percent based on the past four quarters of actual rebates received (see page 37).
- For FY 2014-15, ADAP will utilize \$53.6 million of the \$58.9 million reimbursement funds available from DHCS which increases reimbursement expenditure authority by \$2.5 million.

For FY 2013-14, ADAP total resources are anticipated to increase by \$9.5 million compared to the *2014-15 Governor's Budget*. In addition, due to HRSA's recent requirement to spend mandatory rebates prior to spending federal funds, ADAP will maintain a special fund reserve with supplemental rebate funds.

For FY 2014-15, resources are anticipated to increase by \$20.2 million compared to the *2014-15 Governor's Budget* due to an increase in expenditures and an increase in federal funds.

### 1. FISCAL COMPARISON TABLES

**Table 1a: Expenditure Comparison: FY 2013-14 in 2014-15 May Revision to 2013-14 Budget Act (000's)**

	FY 2013-14 in 2014-15 May Revision					2013-14 Budget Act					Difference				
	Total	Reimbursement	Federal	State	ADAP Special Fund	Total	Reimbursement	Federal	State	ADAP Special Fund	Total	Reimbursement	Federal	State	ADAP Special Fund
<b>Local Assistance Funding</b>	<b>\$413,767</b>	<b>\$8,315</b>	<b>\$107,071</b>		<b>\$298,380</b>	<b>\$406,289</b>	<b>\$66,339</b>	<b>\$79,141</b>		<b>\$260,809</b>	<b>\$7,477</b>	<b>(\$58,024)</b>	<b>\$27,930</b>		<b>\$37,571</b>
ADAP Expenditure Estimate	\$397,552	\$4,578	\$107,071		\$285,903	\$389,146	\$62,302	\$79,141		\$247,703	\$8,406	(\$57,724)	\$27,930		\$38,200
<b>Prescription Costs</b>	<b>\$390,634</b>	<b>\$2,477</b>	<b>\$105,759</b>		<b>\$282,398</b>	<b>\$383,076</b>	<b>\$58,951</b>	<b>\$78,484</b>		<b>\$245,643</b>	<b>\$7,559</b>	<b>(\$56,473)</b>	<b>\$27,275</b>		<b>\$36,758</b>
Basic Prescription Costs	\$534,031	\$2,477	\$105,759		\$425,795	\$563,626	\$58,951	\$78,484		\$426,191	(\$29,594)	(\$56,473)	\$27,275		(\$396)
Addition of Hep C Drugs															
2014 Medi-Cal Expansion Impact	(\$71,588)				(\$71,588)	(\$74,076)				(\$74,076)	\$2,488				\$2,488
Covered California Impact	(\$1,154)				(\$1,154)	(\$3,709)				(\$3,709)	\$2,554				\$2,554
LHP Impact	(\$69,009)				(\$69,009)	(\$100,256)				(\$100,256)	\$31,247				\$31,247
QA-PCIP Impact	(\$1,645)				(\$1,645)	(\$2,510)				(\$2,510)	\$865				\$865
Effect of Cal MediConnect on ADAP	(\$1)				(\$1)						(\$1)				(\$1)
<b>PBM Operational Costs</b>	<b>\$6,917</b>	<b>\$2,100</b>	<b>\$1,312</b>		<b>\$3,505</b>	<b>\$6,071</b>	<b>\$3,351</b>	<b>\$657</b>		<b>\$2,062</b>	<b>\$847</b>	<b>(\$1,251)</b>	<b>\$655</b>		<b>\$1,442</b>
Basic PBM Costs	\$9,437	\$2,100	\$1,312		\$6,024	\$7,979	\$3,351	\$657		\$3,971	\$1,458	(\$1,251)	\$655		\$2,053
Addition of Hep C Drugs															
2014 Medi-Cal Expansion Impact	(\$1,268)				(\$1,268)	(\$1,174)				(\$1,174)	(\$94)				(\$94)
Covered California Impact	(\$20)				(\$20)	(\$59)				(\$59)	\$38				\$38
Additional PBM Costs	\$20				\$20	\$538				\$538	(\$518)				(\$518)
LHP Impact	(\$1,222)				(\$1,222)	(\$1,174)				(\$1,174)	(\$48)				(\$48)
QA-PCIP PBM Impact	(\$29)				(\$29)	(\$40)				(\$40)	\$11				\$11
Effect of Cal MediConnect on ADAP	(\$)				(\$)						(\$)				(\$)
LHU Administration	\$2,000				\$2,000	\$2,000				\$2,000					
Insurance Assistance Program: Medicare Part D	\$1,000				\$1,000	\$1,000				\$1,000					
Insurance Assistance Program: OA-PCIP	\$652	\$172			\$480	\$649	\$127			\$522	\$3	\$45			(\$42)
Insurance Assistance Program: OA-HIPP	\$12,562	\$3,565	\$1,500		\$8,997	\$13,494	\$3,910	\$1,494		\$9,584	(\$932)	(\$345)	\$6		(\$587)
<b>Support/Administration Funding</b>	<b>\$2,502</b>		<b>\$1,174</b>	<b>\$411</b>	<b>\$917</b>	<b>\$2,444</b>		<b>\$1,116</b>	<b>\$411</b>	<b>\$917</b>	<b>\$57</b>			<b>\$57</b>	

**Table 1b: Expenditure Comparison: FY 2013-14 in 2014-15 May Revision to FY 2013-14 in 2014-15 Governor's Budget (November Estimate) (000's)**

	FY 2013-14 in 2014-15 May Revision					2013-14 in 2014-15 Governor's Budget (November Estimate)					Difference				
	Total	Reimbursement	Federal	State	ADAP Special Fund	Total	Reimbursement	Federal	State	ADAP Special Fund	Total	Reimbursement	Federal	State	ADAP Special Fund
<b>Local Assistance Funding</b>	<b>\$413,767</b>	<b>\$8,315</b>	<b>\$107,071</b>		<b>\$298,380</b>	<b>\$419,036</b>	<b>\$8,315</b>	<b>\$103,488</b>		<b>\$307,232</b>	<b>(\$5,269)</b>	<b>\$</b>	<b>\$3,583</b>		<b>(\$8,852)</b>
ADAP Expenditure Estimate	\$397,552	\$4,578	\$107,071		\$285,903	\$401,400	\$4,233	\$103,488		\$293,679	(\$3,848)	\$345	\$3,583		(\$7,776)
<b>Prescription Costs</b>	<b>\$390,634</b>	<b>\$2,477</b>	<b>\$105,759</b>		<b>\$282,398</b>	<b>\$394,416</b>	<b>\$2,118</b>	<b>\$102,223</b>		<b>\$290,075</b>	<b>(\$3,781)</b>	<b>\$359</b>	<b>\$3,536</b>		<b>(\$7,676)</b>
Basic Prescription Costs	\$534,031	\$2,477	\$105,759		\$425,795	\$540,201	\$2,118	\$102,223		\$435,860	(\$6,169)	\$359	\$3,536		(\$10,064)
Addition of Hep C Drugs															\$
2014 Medi-Cal Expansion Impact	(\$71,588)				(\$71,588)	(\$72,733)				(\$72,733)	\$1,145				\$1,145
Covered California Impact	(\$1,154)				(\$1,154)	(\$1,587)				(\$1,587)	\$433				\$433
LHP Impact	(\$69,009)				(\$69,009)	(\$69,778)				(\$69,778)	\$769				\$769
QA-PCIP Impact	(\$1,645)				(\$1,645)	(\$1,686)				(\$1,686)	\$40				\$40
Effect of Cal MediConnect on ADAP	(\$1)				(\$1)	(\$1)				(\$1)					\$
<b>PBM Operational Costs</b>	<b>\$6,917</b>	<b>\$2,100</b>	<b>\$1,312</b>		<b>\$3,505</b>	<b>\$6,984</b>	<b>\$2,115</b>	<b>\$1,265</b>		<b>\$3,604</b>	<b>(\$67)</b>	<b>(\$14)</b>	<b>\$47</b>		<b>(\$100)</b>
Basic PBM Costs	\$9,437	\$2,100	\$1,312		\$6,024	\$9,490	\$2,115	\$1,265		\$6,109	(\$53)	(\$14)	\$47		(\$85)
Addition of Hep C Drugs Impact															\$
2014 Medi-Cal Expansion Impact	(\$1,268)				(\$1,268)	(\$1,288)				(\$1,288)	\$20				\$20
Covered California Impact	(\$20)				(\$20)	(\$28)				(\$28)	\$8				\$8
Additional PBM Costs	\$20				\$20	\$103				\$103	(\$83)				(\$83)
LHP Impact	(\$1,222)				(\$1,222)	(\$1,263)				(\$1,263)	\$41				\$41
QA-PCIP PBM Impact	(\$29)				(\$29)	(\$30)				(\$30)	\$1				\$1
Effect of Cal MediConnect on ADAP	(\$)				(\$)	(\$)				(\$)					\$
LHU Administration	\$2,000				\$2,000	\$2,000				\$2,000					\$
Insurance Assistance Program: Medicare Part D	\$1,000				\$1,000	\$1,000				\$1,000					\$
Insurance Assistance Program: OA-PCIP	\$652	\$172			\$480	\$495	\$131			\$364	\$157	\$42			\$116
Insurance Assistance Program: OA-HIPP	\$12,562	\$3,565	\$1,500		\$8,997	\$14,141	\$3,952	\$1,500		\$10,189	(\$1,578)	(\$387)			(\$1,192)
<b>Support/Administration Funding</b>	<b>\$2,502</b>		<b>\$1,174</b>	<b>\$411</b>	<b>\$917</b>	<b>\$2,502</b>		<b>\$1,174</b>	<b>\$411</b>	<b>\$917</b>					

Table 1c: Expenditure Comparison: 2014-15 May Revision to FY 2013-14 in 2014-15 May Revision (000's)

	2014-15 May Revision					FY 2013-14 in 2014-15 May Revision					Difference				
	Total	Reimbursement	Federal	State	ADAP Special Fund	Total	Reimbursement	Federal	State	ADAP Special Fund	Total	Reimbursement	Federal	State	ADAP Special Fund
<b>Local Assistance Funding</b>	<b>\$438,536</b>	<b>\$53,645</b>	<b>\$106,290</b>		<b>\$278,601</b>	<b>\$413,767</b>	<b>\$8,315</b>	<b>\$107,071</b>		<b>\$298,380</b>	<b>\$24,770</b>	<b>\$45,330</b>	<b>(\$781)</b>		<b>(\$19,779)</b>
ADAP Expenditure Estimate	\$422,643	\$51,964	\$106,290		\$264,388	\$397,552	\$4,578	\$107,071		\$285,903	\$25,091	\$47,387	(\$781)		(\$21,514)
Prescription Costs	\$415,289	\$49,164	\$104,985		\$261,141	\$390,634	\$2,477	\$105,759		\$282,398	\$24,655	\$46,687	(\$774)		(\$21,258)
Basic Prescription Costs	\$583,305	\$49,164	\$104,985		\$429,156	\$534,031	\$2,477	\$105,759		\$425,795	\$49,273	\$46,687	(\$774)		\$3,361
Addition of Hep C Drugs	\$30,566				\$30,566						\$30,566				\$30,566
2014 Medi-Cal Expansion Impact	(\$187,833)				(\$187,833)	(\$71,588)				(\$71,588)	(\$116,245)				(\$116,245)
Covered California Impact	(\$10,735)				(\$10,735)	(\$1,154)				(\$1,154)	(\$9,581)				(\$9,581)
LHHP Impact						(\$69,009)				(\$69,009)	\$69,009				\$69,009
OA-PCIP Impact						(\$1,645)				(\$1,645)	\$1,645				\$1,645
Effect of Cal MediConnect on ADAP	(\$13)				(\$13)	(\$1)				(\$1)	(\$13)				(\$13)
<b>PBM Operational Costs</b>	<b>\$7,354</b>	<b>\$2,800</b>	<b>\$1,306</b>		<b>\$3,248</b>	<b>\$6,917</b>				<b>\$3,505</b>	<b>\$437</b>	<b>\$2,800</b>	<b>\$1,306</b>		<b>(\$257)</b>
Basic PBM Costs	\$9,677	\$2,800	\$1,306		\$5,571	\$9,437	\$2,100	\$1,312		\$6,024	\$240	\$700	(\$7)		(\$453)
Addition of Hep C Drugs Impact	\$541				\$541						\$541				\$541
2014 Medi-Cal Expansion Impact	(\$3,326)				(\$3,326)	(\$1,268)				(\$1,268)	(\$2,058)				(\$2,058)
Covered California Impact	(\$190)				(\$190)	(\$20)				(\$20)	(\$170)				(\$170)
Additional PBM Costs	\$652				\$652	\$20				\$20	\$633				\$633
LHHP Impact						(\$1,222)				(\$1,222)	\$1,222				\$1,222
OA-PCIP PBM Impact						(\$29)				(\$29)	\$29				\$29
Effect of Cal MediConnect on ADAP	(\$)				(\$)	(\$)				(\$)	(\$)				(\$)
LHJ Administration	\$2,000				\$2,000	\$2,000				\$2,000					
Insurance Assistance Program: Medicare Part D	\$1,000				\$1,000	\$1,000				\$1,000					
Insurance Assistance Program: OA-PCIP						\$652	\$172			\$480	(\$652)	(\$172)			(\$480)
Insurance Assistance Program: OA-HIPP	\$12,893	\$1,681	\$1,500		\$11,213	\$12,562	\$3,565	\$1,500		\$8,997	\$331	(\$1,885)			\$2,216
<b>Support/Administration Funding</b>	<b>\$2,502</b>		<b>\$1,174</b>	<b>\$411</b>	<b>\$917</b>	<b>\$2,502</b>		<b>\$1,174</b>	<b>\$411</b>	<b>\$917</b>					

Table 1d: Expenditure Comparison: 2014-15 May Revision to 2014-15 Governor's Budget (November Estimate) (000's)

	2014-15 May Revision					2014-15 Governor's Budget					Difference				
	Total	Reimbursement	Federal	State	ADAP Special Fund	Total	Reimbursement	Federal	State	ADAP Special Fund	Total	Reimbursement	Federal	State	ADAP Special Fund
<b>Local Assistance Funding</b>	<b>\$438,536</b>	<b>\$53,645</b>	<b>\$106,290</b>		<b>\$278,601</b>	<b>\$409,622</b>	<b>\$51,126</b>	<b>\$98,727</b>		<b>\$259,769</b>	<b>\$28,914</b>	<b>\$2,519</b>	<b>\$7,563</b>		<b>\$18,832</b>
ADAP Expenditure Estimate	\$422,643	\$51,964	\$106,290		\$264,388	\$392,980	\$49,651	\$98,727		\$244,602	\$29,663	\$2,313	\$7,563		\$19,786
Prescription Costs	\$415,289	\$49,164	\$104,985		\$261,141	\$386,143	\$47,003	\$97,519		\$241,621	\$29,147	\$2,161	\$7,465		\$19,520
Basic Prescription Costs	\$583,305	\$49,164	\$104,985		\$429,156	\$587,280	\$47,003	\$97,519		\$442,758	(\$3,975)	\$2,161	\$7,465		(\$13,602)
Addition of Hep C Drugs	\$30,566				\$30,566						\$30,566				\$30,566
2014 Medi-Cal Expansion Impact	(\$187,833)				(\$187,833)	(\$189,896)				(\$189,896)	\$2,063				\$2,063
Covered California Impact	(\$10,735)				(\$10,735)	(\$11,227)				(\$11,227)	\$492				\$492
LHHP Impact															
OA-PCIP Impact															
Effect of Cal MediConnect on ADAP	(\$13)				(\$13)	(\$15)				(\$15)	\$2				\$2
<b>PBM Operational Costs</b>	<b>\$7,354</b>	<b>\$2,800</b>	<b>\$1,306</b>		<b>\$3,248</b>	<b>\$6,838</b>	<b>\$2,649</b>	<b>\$1,208</b>		<b>\$2,981</b>	<b>\$516</b>	<b>\$152</b>	<b>\$98</b>		<b>\$267</b>
Basic PBM Costs	\$9,677	\$2,800	\$1,306		\$5,571	\$10,180	\$2,649	\$1,208		\$6,323	(\$503)	\$152	\$98		(\$752)
Addition of Hep C Drugs Impact	\$541				\$541						\$541				\$541
2014 Medi-Cal Expansion Impact	(\$3,326)				(\$3,326)	(\$3,363)				(\$3,363)	\$37				\$37
Covered California Impact	(\$190)				(\$190)	(\$199)				(\$199)	\$9				\$9
Additional PBM Costs	\$652				\$652	\$220				\$220	\$432				\$432
LHHP Impact															
OA-PCIP PBM Impact															
Effect of Cal MediConnect on ADAP	(\$)				(\$)	(\$)				(\$)					
LHJ Administration	\$2,000				\$2,000	\$2,000				\$2,000					
Insurance Assistance Program: Medicare Part D	\$1,000				\$1,000	\$1,000				\$1,000					
Insurance Assistance Program: OA-PCIP															
Insurance Assistance Program: OA-HIPP	\$12,893	\$1,681	\$1,500		\$11,213	\$13,642	\$1,475	\$1,500		\$12,167	(\$748)	\$206			(\$954)
<b>Support/Administration Funding</b>	<b>\$2,502</b>		<b>\$1,174</b>	<b>\$411</b>	<b>\$917</b>	<b>\$2,502</b>		<b>\$1,174</b>	<b>\$411</b>	<b>\$917</b>					

TABLE 2a: Resource Comparison: FY 2013-14 in 2014-15 May Revision to 2013-14 Budget Act (000's)

	FY 2013-14 in 2014-15 May Revision					2013-14 Budget Act					Difference				
	Total	Reimbursement	Federal	State	ADAP Special Fund	Total	Reimbursement	Federal	State	ADAP Special Fund	Total	Reimbursement	Federal	State	ADAP Special Fund
<b>Available Resources</b>	<b>\$401,558</b>	<b>\$8,315</b>	<b>\$108,245</b>	<b>\$411</b>	<b>\$284,587</b>	<b>\$419,395</b>	<b>\$66,339</b>	<b>\$80,258</b>	<b>\$411</b>	<b>\$272,387</b>	<b>(\$17,837)</b>	<b>(\$58,024)</b>	<b>\$27,987</b>		<b>\$12,200</b>
Basic Rebate Revenues	\$284,467				\$284,467	\$325,376				\$325,376	(\$40,909)				(\$40,909)
Income from Surplus Money Investments	\$120				\$120	\$120				\$120					
Federal Fund ADAP Earmark	\$98,380		\$98,380			\$91,296		\$91,296			\$7,084		\$7,084		
2013 ADAP Emergency Relief Funds	\$10,761		\$10,761			(\$13,775)		(\$13,775)			\$24,536		\$24,536		
2013 ADAP Supplemental	\$7,713		\$7,713			\$2,737		\$2,737			\$4,977		\$4,977		
2013 ADAP Earmark Funds Utilized in FY 2012-13	(\$2,912)		(\$2,912)								(\$2,912)		(\$2,912)		
2013 Federal funds (Surplus/Carryover)	(\$5,697)		(\$5,697)								(\$5,697)		(\$5,697)		
General Funds	\$411			\$411		\$411			\$411						
LIHP Impact						(\$52,677)				(\$52,677)	\$52,677				\$52,677
OA-PCIP Impact						(\$432)				(\$432)	\$432				\$432
Adjustments															
Safety Net Care Pool Funds	\$53,561	\$53,561				\$66,339	\$66,339								
Safety Net Care Pool Funds (Surplus Funds)	(\$45,246)	(\$45,246)									(\$45,246)	(\$45,246)			

TABLE 2b: Resource Comparison: FY 2013-14 in 2014-15 May Revision to FY 2013-14 in 2014-15 Governor's Budget (November Estimate) (000's)

	FY 2013-14 in 2014-15 May Revision					FY 2013-14 in 2014-15 Governor's Budget (November Estimate)					Difference				
	Total	Reimbursement	Federal	State	ADAP Special Fund	Total	Reimbursement	Federal	State	ADAP Special Fund	Total	Reimbursement	Federal	State	ADAP Special Fund
<b>Available Resources</b>	<b>\$401,558</b>	<b>\$8,315</b>	<b>\$108,245</b>	<b>\$411</b>	<b>\$284,587</b>	<b>\$392,048</b>	<b>\$8,315</b>	<b>\$104,662</b>	<b>\$411</b>	<b>\$278,659</b>	<b>\$9,510</b>	<b>\$</b>	<b>\$3,583</b>		<b>\$5,927</b>
Basic Rebate Revenues	\$284,467				\$284,467	\$278,539				\$278,539	\$5,927				\$5,927
Income from Surplus Money Investments	\$120				\$120	\$120				\$120					
Federal Fund ADAP Earmark	\$98,380		\$98,380			\$98,380		\$98,380			\$		\$		
2013 ADAP Emergency Relief Funds	\$10,761		\$10,761					\$10,761			\$10,761				
2013 ADAP Supplemental	\$7,713		\$7,713			\$7,713		\$7,713							
2013 ADAP Earmark Funds Utilized in FY 2012-13	(\$2,912)		(\$2,912)			(\$2,912)		(\$2,912)			(\$)				
2013 Federal funds (Surplus/Carryover)	(\$5,697)		(\$5,697)			(\$9,096)		(\$9,096)			\$3,399		\$3,399		
General Funds	\$411			\$411		\$411			\$411						
LIHP Impact															
OA-PCIP Impact															
Adjustments						(\$184)		(\$184)			\$184		\$184		
Safety Net Care Pool Funds	\$53,561	\$53,561				\$66,339	\$66,339								
Safety Net Care Pool Funds (Surplus Funds)	(\$45,246)	(\$45,246)				(\$58,024)	(\$58,024)				\$12,778	\$12,778			

**TABLE 2c: Resource Comparison: 2014-15 May Revision to FY 2013-14 in 2014-15 May Revision (000's)**

	2014-15 May Revision					FY 2013-14 in 2014-15 May Revision					Difference				
	Total	Reimbursement	Federal	State	ADAP Special Fund	Total	Reimbursement	Federal	State	ADAP Special Fund	Total	Reimbursement	Federal	State	ADAP Special Fund
<b>Available Resources</b>	<b>\$432,330</b>	<b>\$53,645</b>	<b>\$107,464</b>	<b>\$411</b>	<b>\$270,810</b>	<b>\$401,558</b>	<b>\$8,315</b>	<b>\$108,245</b>	<b>\$411</b>	<b>\$284,587</b>	<b>\$30,772</b>	<b>\$45,330</b>	<b>(\$781)</b>		<b>(\$13,777)</b>
Basic Rebate Revenues	\$270,690				\$270,690	\$284,467				\$284,467	(\$13,777)				(\$13,777)
Income from Surplus Money Investments	\$120				\$120	\$120				\$120					
Federal Fund ADAP Earmark	\$98,306		\$98,306			\$98,380		\$98,380			(\$75)		(\$75)		
2013 & 2014 ADAP Emergency Relief Funds	\$4,449		\$4,449			\$10,761		\$10,761			(\$6,312)		(\$6,312)		
2013 & 2014 ADAP Supplemental	\$2,971		\$2,971			\$7,713		\$7,713			(\$4,742)		(\$4,742)		
2013 Ryan White Part B Supplemental	\$1,739		\$1,739								\$1,739		\$1,739		
General Funds	\$411			\$411		\$411			\$411						
Safety Net Care Pool Funds	\$58,949	\$58,949				\$53,561	\$53,561				\$5,388	\$5,388			
Safety Net Care Pool Funds (Surplus)	(\$5,304)	(\$5,304)				(\$45,245)	(\$45,245)				\$39,942	\$39,942			

**TABLE 2d: Resource Comparison: 2014-15 May Revision to 2014-15 Governor's Budget (November Estimate) (000's)**

	2014-15 May Revision					2014-15 Governor's Budget					Difference				
	Total	Reimbursement	Federal	State	ADAP Special Fund	Total	Reimbursement	Federal	State	ADAP Special Fund	Total	Reimbursement	Federal	State	ADAP Special Fund
<b>Available Resources</b>	<b>\$432,330</b>	<b>\$53,645</b>	<b>\$107,464</b>	<b>\$411</b>	<b>\$270,810</b>	<b>\$412,125</b>	<b>\$51,126</b>	<b>\$99,901</b>	<b>\$411</b>	<b>\$260,687</b>	<b>\$20,206</b>	<b>\$2,519</b>	<b>\$7,563</b>		<b>\$10,123</b>
Basic Rebate Revenues	\$270,690				\$270,690	\$260,567				\$260,567	\$10,123				\$10,123
Income from Surplus Money Investments	\$120				\$120	\$120				\$120					
Federal Fund ADAP Earmark	\$98,306		\$98,306			\$98,306		\$98,306			\$		\$		
2013 & 2014 ADAP Emergency Relief Funds	\$4,449		\$4,449								\$4,449		\$4,449		
2013 & 2014 ADAP Supplemental	\$2,971		\$2,971								\$2,971		\$2,971		
2013 Ryan White Part B Supplemental	\$1,739		\$1,739			\$1,739		\$1,739							
General Funds	\$411			\$411		\$411			\$411						
Adjustments						(\$143)		(\$143)			\$143		\$143		
Safety Net Care Pool Funds	\$58,949	\$58,949				\$53,645	\$53,645								
Safety Net Care Pool Funds (Surplus)	(\$5,304)	(\$5,304)				(\$2,519)	(\$2,519)				(\$2,784)	(\$2,784)			

## 2. ASSUMPTIONS

### Estimate Methodology

Unadjusted expenditure estimates for the *2014-15 May Revision* were derived from a linear regression model utilizing a 36-month data set of actual expenditures from April 2011 through February 2014 and estimated March 2014 data. The estimates were adjusted based on the assumptions listed below.

For purposes of the *2014-15 May Revision*, expenditure and revenue adjustments were made to the Fund Condition Statement (FCS) (Table 9, page 20) to reflect the estimated impact of one New Assumption, five Existing Assumptions, and seven Unchanged Assumptions, including:

FY Impact		
2013-14	2014-15	<b>New Assumption</b> (page 10)
	X	1. Addition of Hepatitis C Virus (HCV) Drugs Simeprevir and Sofosbuvir to the ADAP Formulary.
		<b>Existing (Significantly Changed) Assumptions</b> (page 11)
X	X	1. 2014 Medi-Cal Expansion.
X	X	2. Covered California: Impact of the PPACA Insurance Requirement on ADAP and OA-HIPP.
X		3. OA-PCIP Implementation.
X	X	4. Additional Pharmacy Benefit Manager Costs.
X	X	5. Federal Funding Issue: Ryan White (RW) Grant Adjustments.
		<b>Unchanged Assumptions*</b> (page 18)
X		1. Impact of Low Income Health Program on ADAP.
X	X	2. Change in Methodology: Adjust Linear Regression Expenditure Methodology.
X	X	3. Reimbursement of Federal Funding through SNCP.
*	*	4. Cross Match of RW Client Data with Franchise Tax Board Data.
X		5. Using Non-RW funds to Pay OA-HIPP Premiums for LIHP-eligible OA-HIPP Clients.
X	X	6. Increased Rebate Percentage.
X	X	7. Effect of Cal MediConnect.

\*Assumption unchanged but fiscal outcome impacted by the revised expenditure estimate for all except for Unchanged Assumption 4.

## New Assumptions

### 1. Addition of Hepatitis C Virus (HCV) Drugs Simeprevir and Sofosbuvir to the ADAP Formulary

Janssen Research and Development, LLC and Gilead have each developed new HCV medications. The U.S. Food and Drug Administration (FDA) approved simeprevir (Olysio), developed by Janssen, on November 22, 2013 and approved sofosbuvir (Sovaldi), developed by Gilead, on December 6, 2013. Both drugs were approved as new therapies to treat chronic HCV. On January 24, 2014, the ADAP Medical Advisory Committee (MAC) voted to recommend that both simeprevir and sofosbuvir be added to the ADAP formulary, citing the large burden of HCV co-infection among HIV-infected patients with its resulting impact on mortality (about 5 percent of deaths among all persons living with HIV/AIDS in California are currently due to HCV), and the tremendous improvement in HCV cure rate that these new drugs offer over current HCV therapy.

Twelve percent of Californians living with HIV are estimated to be co-infected with HCV based on matching the 2011 California Chronic Viral Hepatitis Registry surveillance data with the 2011 California HIV/AIDS surveillance data. Applying this 12 percent co-infection rate to the estimated 37,873 ADAP client population in FY 2014-15 yields an estimated 4,545 ADAP clients co-infected with HCV in FY 2014-15. Based on expert opinion from consultation with a number of HIV/HCV co-treatment experts in California, OA estimates that only 10 percent (454) of HCV co-infected ADAP clients will receive treatment with the new HCV therapies in FY 2014-15. The estimated per client expenditures for treatment with the new HCV drugs will vary based on the HCV genotype of the clients who receive treatment, as recommended treatment varies by genotype. OA has had discussions with the ADAP MAC on establishing prior authorization criteria for these new HCV drugs that would make the new drugs available to those most in need and most likely to benefit from HCV treatment by prioritizing treatment for ADAP clients with more advanced liver disease. OA will finalize its prior authorization criteria prior to June 30, 2014.

Based on the anticipated number of ADAP clients who will receive HCV treatment in FY 2014-15 and the distribution of HCV genotypes within the population, the initial estimated expenditures for adding the new HCV drugs to the ADAP formulary in FY 2014-15 are **\$31,106,995**, excluding rebate. Rebate is unknown at this time because manufacturers must keep rebate amounts confidential as required by contract agreements with the 340B Prime Vendors. To estimate rebate, ADAP applied the historical average of 23 percent used to invoice drug manufacturers for rebate before adjusting for different insurance coverage groups. To date, both Gilead and Janssen are not providing voluntary supplemental rebate to ADAPs throughout the country for sofosbuvir and simeprevir, respectively. The usual six-month delay in rebate collections was taken into account, which results in more "up front" costs for any policy change resulting in new drug expenditures. The final cost estimate for adding both drugs to the ADAP formulary in FY 2014-15 is

**\$26,092,263.** Provision of this treatment is subject to available resources and the authorization criteria developed by OA.

In addition to the costs of the new HCV drugs, treatment guidelines recommend concurrent usage with pegylated interferon and/or ribavirin for most clients. These costs have been included in Table 3.

TABLE 3: ESTIMATED EXPENDITURES FOR NEW HCV DRUGS USED IN CONJUNCTION WITH PEGYLATED INTERFERON AND/OR RIBAVIRIN BY COVERAGE GROUP, FY 2014-15				
COVERAGE GROUP	CLIENTS	TOTAL EXPEND\$	REBATE	ADJUSTED NET EXPEND\$
ADAP Only	262	\$27,721,102	\$7,130,334	\$20,590,768
Medi-Cal	7	\$538,063	\$0	\$538,063
Private Insurance	79	\$1,562,970	\$2,138,329	-\$575,359
Medicare	106	\$1,284,860	\$760,801	\$524,059
<b>TOTAL</b>	<b>454</b>	<b>\$31,106,995</b>	<b>\$10,029,465</b>	<b>\$21,077,530</b>
<b>TOTAL WITH REBATE DELAY</b>			<b>\$5,014,733</b>	<b>\$26,092,263</b>

Methodological detail for developing this estimate can be found in Appendix F, starting on page 48.

### **Existing (Significantly Changed) Assumptions**

#### **1. 2014 Medi-Cal Expansion**

Effective January 1, 2014, Medi-Cal expanded coverage for individuals between 19 and 64 years old, including individuals without disabilities, with income less than 138 percent of the federal poverty level (FPL). For a single individual, the qualifying income would be less than \$15,856 (based on 2013 FPL) and for a family size of four, the allowable income would be approximately \$32,499. Medi-Cal Expansion coverage is free for those who qualify and clients will have no out-of-pocket health care expenses.

In December 2013, OA disseminated written guidance to ADAP Enrollment Workers (EWs) regarding the eligibility criteria and enrollment process for Medi-Cal Expansion, and in January 2014 conducted training for all ADAP EWs that described the process for screening potentially eligible ADAP clients for Medi-Cal Expansion.

For the *2014-15 Governor's Budget*, OA estimated savings due to transitioning the following four groups of clients to Medi-Cal Expansion starting on January 1, 2014:

- A. ADAP-only clients who previously transitioned to LIHP or who were eligible for their county LIHP but did not have time to transition to LIHP before January 1, 2014 (Group 1, identified as ADAP to LIHP clients);
- B. ADAP-only clients potentially eligible for Medi-Cal Expansion who exceeded the LIHP upper limits of their residing counties or were from counties that did not implement LIHP (Group 2, identified as ADAP to Medi-Cal Expansion clients);
- C. Current OA-PCIP clients; and
- D. OA-HIPP clients eligible for Medi-Cal Expansion.

For the *2014-15 May Revision*, OA updated the assumption's components (client shift, reduced expenditures, and reduced rebate revenue) using actual January and February 2014 data. The estimate that 70 percent of eligible ADAP clients (Groups 1-4) would transition to Medi-Cal Expansion in FY 2013-14 used in the *2014-15 Governor's Budget* was retained, because it produced a reasonably accurate estimate based on actual data through February 2014. The 70 percent adjustment factor was applied to initial expenditure savings and to potentially eligible clients, which covers all the potential disparities in data used to determine eligibility, including income and immigration status. With the adjustment factor, this represented a final FY 2013-14 estimated savings of \$108,300 in premiums for 70 clients and \$72.9 million in drug expenditures for 5,260 clients outlined in Table 4, below. Due to the six-month delay in rebate collections, the impact of rebate loss will be reflected in FY 2014-15.

CLIENT GROUP	PREMIUM SAVINGS\$	DRUG EXPEND SAVINGS\$	TOTAL CLIENTS
Group 1 (ADAP to LIHP)	\$0	\$72,352,287	5,140
Group 2 (ADAP to MCE)	\$0	\$249,966	23
Group 3 (OA-PCIP)	\$0	\$219,946	27
Group 4 (OA-HIPP)	\$108,300	\$33,179	70
EXPENDITURE SAVINGS\$, FY 2013-14	\$108,300	\$72,855,378	5,260
LOSS REBATE REVENUE, FY 2013-14	\$0	\$0	5,260
NET SAVINGS\$, FY 2013-14	\$108,300	\$72,855,378	5,260

For FY 2014-15, OA applied the same 90 percent adjustment factor for both expenditures and clients as in the *2014-15 Governor's Budget*. Thus, net savings for Medi-Cal Expansion were estimated at \$2.5 million in premiums and

\$127.0 million in net drug savings (\$191.2 million in drug expenditure savings with \$64.2 million in rebate loss) for 9,369 clients, (Table 5, below).

TABLE 5: SUMMARY OF MEDI-CAL EXPANSION SAVINGS, FY 2014-15			
CLIENT GROUP	PREMIUM SAVINGS\$	DRUG EXPEND SAVINGS\$	TOTAL CLIENTS
Group 1 (ADAP to LIHP)	\$0	\$177,357,386	8,298
Group 2 (ADAP to MCE)	\$0	\$12,138,409	676
Group 3 (OA-PCIP)	\$0	\$895,493	34
Group 4 (OA-HIPP)	\$2,506,360	\$767,849	361
EXPENDITURE SAVING\$, FY 2014-15	\$2,506,360	\$191,159,138	9,369
LOSS REBATE REVENUE, FY 2014-15	\$0	\$64,198,588	9,369
NET SAVING\$, FY 2014-15	\$2,506,360	\$126,960,550	9,369

## **2. Covered California: Impact of the PPACA Insurance Requirement on ADAP and OA-HIPP**

Covered California is offering four levels of coverage: platinum, gold, silver, and bronze. The coverage for each level is exactly the same, but the client can choose to pay a higher monthly premium and have lower deductibles/co-pays (platinum) or pay a lower monthly premium and have higher deductibles/co-pays (bronze). Legal California residents who earn between 138-400 percent FPL will be eligible for tax credits which can be taken immediately and will reduce the client's portion of the monthly premium.

OA will continue to encourage ADAP clients who earn between 138-200 percent FPL and are applying for health insurance coverage through Covered California to purchase a silver policy because these clients will be eligible for additional cost-sharing subsidies that will significantly lower their monthly premium and out-of-pocket health care expenses. This will ensure that OA is paying the lowest possible monthly premium, while simultaneously providing the client with most cost effective comprehensive health insurance policy. OA will also continue to inform ADAP clients who earn between 201 percent FPL and \$50,000 that purchasing a platinum policy will result in the lowest out-of-pocket costs.

In November 2013, HRSA conducted a comprehensive site visit of OA's RW Part B (including ADAP and OA-HIPP) Program. In the site visit report, HRSA recommended that OA consider and pursue mechanisms to pay client out-of-pocket medical expenses for clients who choose to purchase insurance through Covered

California. Developing and implementing the administrative capacity to pay out-of-pocket medical expenses, in addition to premiums for eligible OA-HIPP clients, will remove the financial disincentive currently present for ADAP-only clients to obtain private health insurance. This policy change will encourage more ADAP clients to enroll in coverage through Covered California, which will result in an overall reduction in ADAP expenditures. This policy change will also improve the overall health of Californians living with HIV/AIDS because clients will have comprehensive health insurance and ready access to the full continuum of care, rather than only HIV care and medications through the RW system. This assumption requires Trailer Bill Language to amend Section 120955 (i) of the California Health and Safety Code to clarify that OA has the authority to pay for cost sharing (co-pays) for medical expenses.

OA is moving forward to develop and publish a Request for Proposals or Invitation to Bid to solicit applications from vendors who have the capacity to pay out-of-pocket medical expenses and premiums. After a vendor is selected, a contract will need to be developed and executed before the Third-Party Administrator could begin providing services. Due to the time necessary to complete these processes, OA anticipates payment of out-of-pocket medical expenses and premiums to begin in January 2016 (FY 2015-16), and the correlating effect on client shift, reduction in ADAP expenditures and change to rebate revenue will be reflected in the *2015-16 Governor's Budget*.

For the *2014-15 Governor's Budget*, OA assumed that only 2.8 percent of eligible ADAP-only clients would enroll in Covered California in FY 2013-14 based on ADAP's experience of enrolling ADAP-only clients into PCIP. ADAP-only clients who choose to enroll in Covered California will have new client out-of-pocket expenses (medical visit deductibles and co-pays for medical visits) that uninsured ADAP clients who receive care at RW-funded clinics do not currently incur.

For the *2014-15 May Revision*, OA updated the assumption's components (client shift, reduced expenditures, and reduced rebate revenue) using actual data for January and February for adjustments for impact numbers. The estimate that 2.8 percent of eligible ADAP-only clients would co-enroll in Covered California and OA-HIPP in FY 2013-14 used in the *2014-15 Governor's Budget* was retained because it produced a reasonably accurate estimate based on actual data through February 2014. OA factored in administrative costs of \$724,180 in FY 2013-14 to modify and automate processes and reduce application processing timelines in anticipation of the increased demand for premium payment assistance and the corresponding workload. Final savings were \$1.6 million before administrative costs, which reduced the savings by \$724,180 for final net savings of \$848,489.

TABLE 6: COVERED CALIFORNIA, FY 2013-14 (ALL CLIENT GROUPS)				
LINE ITEM	CLIENTS	EXPEND\$	REBATE REVENUE	NET
Premiums	227	\$260,452	\$0	\$260,452
Drug Deduct & Co-Pays	227	\$36,214	\$0	\$36,214
Averted Drug Expend\$	227	-\$1,934,964	-65,630	-\$1,869,335
<b>SUBTOTAL</b>	<b>227</b>	<b>-1,638,298</b>	<b>-\$65,630</b>	<b>-\$1,572,669</b>
<b>TOTAL WITH ADMIN</b>	<b>227</b>	<b>\$724,180</b>	<b>\$0</b>	<b>-\$848,489</b>

For FY 2014-15, OA increased the estimated percent of eligible ADAP-only clients who would co-enroll in Covered California and OA-HIPP from 2.8 percent to 7.2 percent, which was the same adjustment factor used in the *FY 2014-15 Governor's Budget*. Initial net savings for Covered California were estimated at \$10.0 million. OA factored in cost estimates of \$100,000 associated with maintaining and modifying current data systems to help manage the OA-HIPP workload, resulting in a final net savings of \$9.9 million.

TABLE 7: COVERED CALIFORNIA, FY 2014-15 (ALL CLIENT GROUPS)				
LINE ITEM	CLIENTS	EXPEND\$	REBATE REVENUE	NET
Premiums	539	\$1,045,822	\$0	\$1,045,822
Drug Deduct & Co-Pays	539	\$187,243	\$0	\$187,243
Averted Drug Expend\$	539	-\$11,212,417	\$0	-\$11,212,417
<b>SUBTOTAL</b>	<b>539</b>	<b>-\$9,979,352</b>	<b>\$0</b>	<b>-\$9,979,352</b>
<b>TOTAL WITH ADMIN</b>	<b>539</b>	<b>\$100,000</b>	<b>\$0</b>	<b>-\$9,879,352</b>

### 3. OA-PCIP Implementation

OA-PCIP was implemented in November 2011 to pay monthly PCIP premiums for eligible clients living with HIV. Clients who co-enroll in OA-PCIP and ADAP also receive assistance with drug deductibles and co-pays for drugs on the ADAP formulary. OA-PCIP was implemented as a cost-containment measure, since it is

more cost-effective to pay monthly insurance premiums and medication deductibles and co-pays than to pay the full cost of the clients' HIV-related drugs.

PCIP was originally designed to sunset after December 31, 2013. However, the Centers for Medicare and Medicaid Services (CMS) granted PCIP transitional coverage up to four months, through April 30, 2014, to people currently enrolled in PCIP who had not yet secured other health insurance coverage. This transitional coverage was designed to allow PCIP enrollees more time to review marketplace plan options and purchase health insurance. Beginning in December 2013, OA contacted each PCIP client on a monthly basis to determine if they acquired other health insurance. OA paid PCIP premiums for OA-PCIP clients who had not obtained other health coverage, thus preventing lapse in coverage.

PCIP premiums are generally paid one month in advance. Using actual premiums from July 2013 to March 2014 and estimated data for April 2014, and actual drug deductibles and co-pays for July 2013 to February 2014 and estimated data for March and April 2014, OA estimates savings from the first ten months of FY 2013-14 to be \$562,353 (\$652,272 in premium costs, \$1.7 million in drug expenditure savings, and \$459,917 from loss of rebate revenue from state PCIP expenditures from January to June 2013, in which no rebate was collected). Since federal PCIP allows rebate, there is no change to rebate revenue for drug expenditures in FY 2013-14. Of the \$652,272 need for PCIP premiums, OA will use \$172,265 in reimbursement funds for OA-PCIP clients potentially eligible for LIHP/Medi-Cal Expansion since the program cannot use RW or rebate funds for these expenditures. The remainder will be paid using the ADAP Rebate Fund.

TABLE 8: SUMMARY OF PCIP CHANGES, FY 2013-14					
ISSUE	PREMIUMS	DRUG EXPEND\$	REBATE REVENUE	TOTAL ESTIMATE	CLIENTS
<b>TOTAL</b>	<b>\$652,272</b>	<b>-\$1,674,542</b>	<b>-\$459,917</b>	<b>-\$562,353</b>	<b>194</b>
Reimbursement funds for premiums	\$172,265				51
SF for premiums	\$480,007				143

#### **4. Additional Pharmacy Benefit Manager Costs**

In November 2013, HRSA conducted a comprehensive site visit of OA's RW Part B Program. One of the findings stated that final ADAP eligibility determinations are not verified by OA. Currently, ADAP EWs are trained on ADAP's policies and procedures, enroll eligible clients in ADAP and maintain secure client files at local ADAP enrollment sites. OA staff conduct site visits to monitor ADAP enrollment sites and review client files. However, due to the large number of ADAP clients, OA staff review at least 10, but no more than 50 files per site visit. HRSA recommends that OA develop a centralized electronic system with uploading capability that will allow a secondary review of all applications to ensure that data are accurate and

interpretation of supporting documentation is consistent with eligibility criteria to address the risk of potential program fraud or abuse.

For the *2014-15 Governor's Budget*, ADAP reflected additional ADAP PBM costs due to the increased workload associated with implementing the federal HRSA mandate to conduct six-month ADAP client eligibility re-certification and modifying the ADAP application to capture additional client information for HRSA's mandated ADAP Data Report and OA-HIPP. ADAP anticipated that the amended contract would be executed by January 2014. However, OA is finalizing the contract amendment to include the additional tasks mentioned below.

OA has been working with ADAP's PBM to allow OA staff and ADAP EWs the ability to add, store, view, and delete scanned client eligibility documents. OA staff will also have the ability to view, add, edit, delete, and approve or deny EW and enrollment site information. The system will also be modified to allow OA staff the ability to make ADAP eligibility determinations. Once the contract is executed and all the ADAP client files are scanned, OA staff will no longer need to travel to local ADAP enrollment sites to review a subset of client files to assess compliance with ADAP's policies because the final eligibility determination will be made by OA. These changes will result in one-time set-up fees of \$289,000.

Also, the initial contract amendments did not include a cost of \$10,000 for modifying the PBM's enrollment module to accommodate new fields associated with the HRSA ADAP Report or costs of \$35,000 for modifying the PBM's system to allow OA access to view, edit, process, and track OA-HIPP enrollment application information.

It is anticipated that the amended contract will be executed by May 2014, at which time the six-month ADAP client eligibility re-certification process will begin at an estimated cost of \$19,873 for FY 2013-14 (based on one month of the estimated six-month re-certification costs). In FY 2014-15 ADAP will incur full ongoing cost for ADAP client six-month re-certification at \$238,472 annually. In FY 2014-15, ADAP anticipates one-time costs of \$414,000 for required modifications to the PBM's systems to meet the terms of the amended contract. ADAP estimates total expenditures in FY 2014-15 of \$652,472.

## **5. Federal Funding Issue: RW Grant Adjustments**

In November 2013, CDPH applied for the 2014 ADAP Emergency Relief Fund (ERF) Grant. These funds are for states to address "cost-cutting" or "cost-saving" measures and are to be used in conjunction with the RW HIV/AIDS Treatment Program's Part B ADAP funds. CDPH requested the maximum amount of \$11.0 million. On March 12, 2014, HRSA issued a partial 2014 ADAP ERF Notice of Award (NoA) for \$3,238,367, and on April 14, 2014, HRSA issued another NoA for the 2014 ADAP ERF with an additional \$1,210,476, for a total of \$4,448,843. The budget period is from April 1, 2014 to March 31, 2015; OA will use these funds for ADAP expenditures in the budget year.

In December 2013, CDPH applied for the 2014 ADAP Supplemental Grant. These funds are for states with demonstrated severe need to purchase medications. CDPH requested \$7.7 million for the 2014 ADAP Supplemental Grant. On March 20, 2014, HRSA issued the 2014 ADAP Supplemental NoA for \$2,971,412 with a budget period of April 1, 2014 to March 31, 2015. OA will use these funds for drug expenditures in the budget year.

### **Unchanged Assumptions**

These items were included in the *2014-15 Governor's Budget* as Major Assumptions. For the *2014-15 May Revision*, fiscal outcomes were impacted by the revised expenditure estimate to all except for Unchanged Assumption 4 and are reflected in the FCS on page 20; there were no changes made to the estimate methodology.

1. Impact of LIHP on ADAP was approved as a Major Assumption in November 2013. There are no changes to this assumption except that additional savings from LIHP back-billing for San Francisco and Los Angeles Counties are expected, but the amounts are unknown as they are based on LIHP reimbursement rates.
2. Change in Methodology to adjust the Linear Regression Expenditures to include two other pre-regression adjustments (OA-PCIP and LIHP) in FY 2014-15 was approved as a Major Assumption in November 2013. There are no changes to this assumption.
3. Reimbursement of federal funding through SNCP was approved as a Major Assumption in November 2013. For FY 2014-15, ADAP will utilize \$53.6 million of the \$58.9 million reimbursement funds available from DHCS, which increases reimbursement expenditure authority by \$2.5 million from the *2014-15 Governor's Budget*.
4. Cross Match of RW Client Data with Franchise Tax Board (FTB) Data to share tax data with ADAP was approved as a Major Assumption in November 2013. This assumption requires Trailer Bill Language (TBL) to add Section 120962 of the California Health and Safety Code and Section 19548.2 of the Revenue and Taxation Code to allow sharing of FTB tax data with OA. There are no changes to this assumption.
5. Using Non-RW funds to Pay OA-HIPP Premiums for LIHP-eligible OA-HIPP Clients was approved as a Continuing Assumption in November 2013. There are no changes to this assumption.
6. Increased Rebate Percentage was approved as a Continuing Assumption in November 2013. ADAP increased the drug rebate rate from 65 to 67 percent based on the past four quarters of actual rebates received.
7. Effect of Cal MediConnect was approved as a Major Assumption in November 2013. OA anticipates no significant fiscal impact on ADAP in FYs 2013-14 and 2014-15. There are no changes to this assumption. OA will continue to monitor Cal MediConnect's implementation and will provide estimates in future estimate packages if necessary.

**Discontinued Assumptions** - There are no Discontinued Assumptions.

### 3. FUND CONDITION STATEMENT

The Fund Condition Statement (FCS) (Table 9, page 20) shows the status of the ADAP Rebate Fund (3080) for FY 2012-13, FY 2013-14, and FY 2014-15, and all the factors that impact the fund including revenues, expenditures, revenue collection rate, interest earned, and assumptions.

For FY 2013-14, the revenue estimate is based on:

- A. Actual rebates (\$152,096,875) collected for expenditures during January through June 2013;
- B. Estimated rebates (\$132,369,791) calculated by applying 67 percent rebate collection rate (44 percent for mandatory rate and 23 percent for supplemental rebate) (Unchanged Assumption 6, page 18) to actual expenditures from July to December 2013; and
- C. It is estimated there will be an additional amount of approximately \$120,000 of revenue from interest earned.

For FY 2014-15, the revenue estimate (\$270,690,125) was developed by applying the 67 percent rebate collection rate to projected expenditures (based on one-half of the linear regression from FYs 2013-14 and 2014-15 and adjusted for assumptions) for January to December 2014. It is estimated that there will be an additional amount of \$120,000 of revenue from interest earned.

To determine funding need, OA estimated expenditures based on a revised linear regression adjusted for expenditure projections, determined all ADAP costs, and applied all available rebate funds to ensure compliance with HRSA's new requirements to utilize all mandatory rebate funds prior to spending federal funds. OA then applied remaining fund sources, including federal funds and reimbursements.

The budget for ADAP, which includes insurance assistance programs, does not include General Fund for local assistance in FY 2013-14 or FY 2014-15.

**MAY REVISION FUND CONDITION STATEMENT**

Table 9: FUND CONDITION STATEMENT (in thousands)				FY 2012-13 Actuals	FY 2013-14 Estimate	FY 2014-15 Estimate
Special Fund 3080 AIDS Drug Assistance Program Rebate Fund						
1	BEGINNING BALANCE			5,036	29,494	14,780
2	Prior Year Adjustment			8,642	0	0
3	Adjusted Beginning Balance			13,678	29,494	14,780
4	REVENUES, TRANSFERS AND OTHER ADJUSTMENTS					
5	Revenues					
6	150300 Income From Surplus Money Investments (Interest)			113	120	120
7	161400 Miscellaneous Revenue			302,198	284,467	270,690
8	Total Revenues, Transfers, and Other Adjustments			302,311	284,587	270,810
9	Total Resources			315,989	314,081	285,590
10	EXPENDITURES AND EXPENDITURE ADJUSTMENTS					
11	Expenditures					
12	8880	FISCAL		5	4	4
13	0840	State Controllers Office		2	0	0
15	4265	Department of Public Health				
16		State Operations		1,061	917	917
17		ADAP Local Assistance		275,780	287,903	266,388
18		OA-PCIP, OA-HIPP, and Medicare Part D Local Assistance		9,647	10,477	12,213
19						
20	Total Expenditures and Expenditure Adjustments			286,495	299,301	279,522
21	FUND BALANCE			29,494	14,780	6,068

Row 6: Interest Actuals for FY 2012-13, Estimated for FYs 2013-14 and 2014-15

112,669	120,000	120,000
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**Miscellaneous Revenue**

Actual Mandatory and Supplemental Rebate received from July - Sept 2013 from Expenditures for Jan - Mar 2013	79,447,459
Actual Mandatory and Supplemental Rebate received from Oct - Dec 2013 from Expenditures for April - June 2013	72,649,416
Estimated Rebate to be received Jan - June 2014 from Actual Expenditures from July - Dec 2013 (\$197,566,852 x 67% avg rebate rate) (UA 6)	
Estimated Mandatory Rebate Revenue (\$197,566,852 x 44% avg Mand Rebate Rate)	86,929,415
Estimated Supplemental Rebate Revenue (\$197,566,852 x 23% avg Supp Rebate Rate)	45,440,376
Estimated Rebate to be received Jul - Dec 2014 from Estimated Expenditures for Jan - Jun 2014 (\$196,029,659 x 67% avg rebate rate) (UA 6)	
1/2 LR FY 2013-14	
EA 1	271,734,149
EA 2	-72,855,378
EA 3	-1,174,570
Sum	196,029,659
Estimated Mandatory Rebate Revenue (\$196,029,659 x 44% avg Mand Rebate Rate)	86,253,050
Estimated Supplemental Rebate Revenue (\$196,029,659 x 23% avg Supp Rebate Rate)	45,086,821
Estimated Rebate to be received Jan - Jun 2015 from Estimated Expenditures for July - Dec 2014 (\$200,500,776 x 67% avg rebate rate) (UA 6)	
1/2 LR FY 2014-15	
EA 1	296,490,825
EA 2	-90,800,591
Sum	200,500,776
Estimated Mandatory Rebate Revenue (\$200,500,776 x 44% avg Mand Rebate Rate) + NA 1 rebate adj \$5,014,733	93,235,075
Estimated Supplemental Rebate Revenue (\$200,500,776 x 23% avg Supp Rebate Rate)	46,115,179
<b>Total Miscellaneous Revenue:</b>	<b>284,466,665</b>
	<b>270,690,124</b>

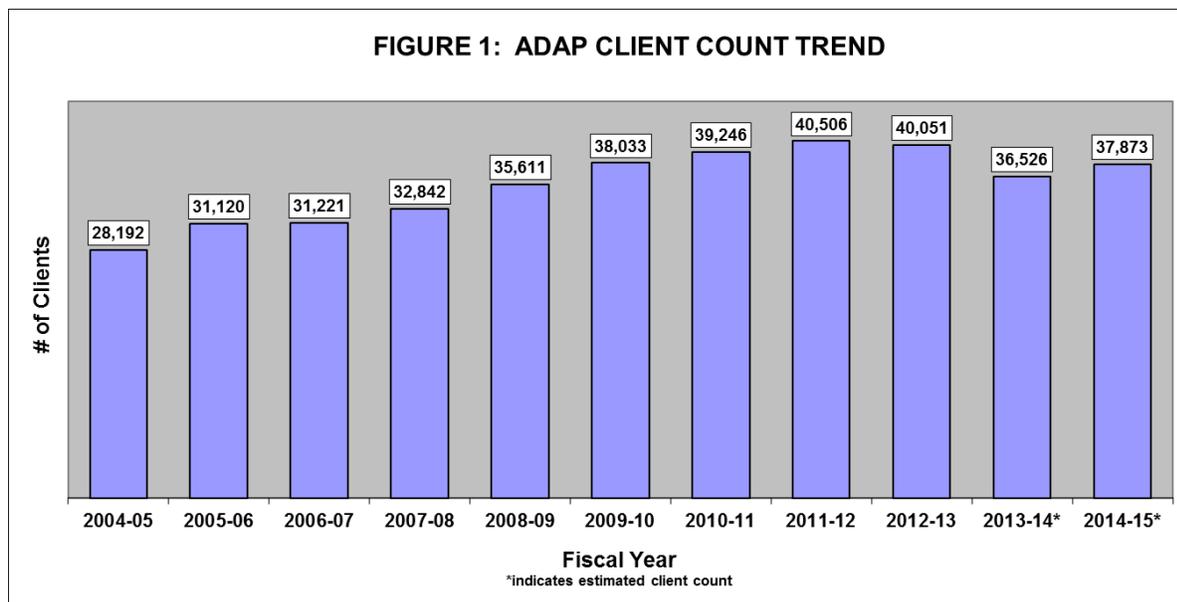
	FY 2013-14 Estimate	FY 2014-15 Estimate
<b>ADAP EXPENDITURES</b>		
<b>ADAP Expenditure Projection:</b> FYs 2013-14 and 2014-15, Linear Regression	543,468,297	592,981,649
<b>Adjustments to ADAP Expenditure Projection:</b>		
Addition of Hepatitis C Drugs to the ADAP Formulary (NA 1)	0	31,106,995
2014 Medi-Cal Expansion (EA 1)	-72,855,378	-191,159,138
Covered California: Impact of the PPACA Insurance Requirement on ADAP and OA-HIPP (EA 2)	-1,174,570	-10,925,174
Impact of the LIHP Counties on ADAP (UA 1)	-70,231,219	0
OA-PCIP Implementation (EA 3)	-1,674,542	0
Additional PBM Costs (EA 4)	19,873	652,472
Effect of the Cal MediConnect Program on ADAP (UA 7)	-562	-13,523
<b>Subtotal: ADAP Expenditure Projection after Adjustments</b>	<b>397,551,899</b>	<b>422,643,281</b>
Need for Local Health Jurisdictions (LHJ)	2,000,000	2,000,000
<b>Total: Projected Need for ADAP</b>	<b>399,551,899</b>	<b>424,643,281</b>
<b>Total Special Fund 3080 Available for ADAP Expenditures</b>	<b>-302,682,668</b>	<b>-272,456,427</b>
Non-Add: Special Fund Need for Local Health Jurisdictions	2,000,000	2,000,000
Special Fund 3080 (Supplemental) Reserve	14,779,872	6,067,970
<b>Table 17: Total: Special Fund 3080 Need for ADAP Expenditures</b>	<b>-287,902,797</b>	<b>-266,388,457</b>
<b>Reimbursement Funds (Safety Net Care Pool) from DHCS</b>	<b>-53,560,700</b>	<b>-58,948,538</b>
Reimbursement Need for OA-HIPP	3,737,657	1,680,606
Reimbursement Funds available for ADAP	-49,823,043	-57,267,932
Non-Add: Reimbursement Need for ADAP expenditures that are not allowable under RW (BY only)	4,190,269	4,431,729
Reimbursement Adjustment	387,461	
Surplus Reimbursement Funds	45,245,313	5,303,594
<b>Total: Reimbursement Need for ADAP Expenditures</b>	<b>-4,577,730</b>	<b>-51,964,338</b>
<b>Federal Fund ADAP Earmark</b>	<b>97,206,303</b>	<b>97,131,700</b>
2013 & 2014 Ryan White ADAP Supplemental	7,713,428	2,971,412
2013 ADAP Earmark Funds utilized in FY 2012-13	-2,912,359	0
2013 Ryan White Part B Supplemental	0	1,738,531
2013 & 2014 ADAP Emergency Relief Funds	10,761,268	4,448,843
Surplus Federal Funds/Carryover	-5,697,268	0
<b>Total: Federal Fund Need for ADAP Expenditures</b>	<b>-107,071,372</b>	<b>-106,290,486</b>

<b>PREMIUM EXPENDITURES</b>	<b>FY 2013-14 Estimate</b>	<b>FY 2014-15 Estimate</b>
<b>OA-PCIP Expenditure Projection</b>	<b>652,272</b>	<b>0</b>
Non-Add: OA-PCIP Premiums for LIHP-eligible OA-PCIP Clients (EA 3)	172,265	0
<b>Subtotal: OA-PCIP Expenditure Projection</b>	<b>652,272</b>	<b>0</b>
<b>OA-HIPP Expenditure Projection:</b>	<b>13,910,230</b>	<b>15,853,713</b>
Non-Add: Medi-Cal Expansion (EA 1)	2,111,874	4,186,966
2014 Medi-Cal Expansion (EA 1)	-108,300	-2,506,360
Covered California: Impact of the PPACA Insurance Requirement on OA-HIPP (EA 2)	260,452	1,045,822
Non-Add: OA-HIPP Premiums for LIHP-eligible OA-HIPP Clients (UA 5)	1,561,818	0
<b>Subtotal: OA-HIPP Expenditure Projection</b>	<b>14,062,382</b>	<b>14,393,175</b>
<b>Total: Projected Expenditures for OA-PCIP and OA-HIPP Premiums</b>	<b>14,714,654</b>	<b>14,393,175</b>
Local Assistance Medicare Part D Premiums	1,000,000	1,000,000
<b>Total: Projected Need for OA-Insurance Assistance Programs</b>	<b>15,714,654</b>	<b>15,393,175</b>
<b>Special Fund 3080 Appropriation for OA Insurance Assistance Programs</b>	<b>-11,553,153</b>	<b>-13,166,961</b>
Non-Add: Local Assistance Medicare Part D Premiums	-1,000,000	-1,000,000
Special Fund 3080 Adjustment	1,076,156	954,392
<b>Row 18: Special Fund 3080 Projected Need for Insurance Assistance Programs</b>	<b>-10,476,997</b>	<b>-12,212,569</b>
<b>Reimbursement (Safety Net Care Pool) Appropriation for OA Insurance Assistance Programs</b>	<b>-4,082,625</b>	<b>-1,474,605</b>
Reimbursement Need for OA-PCIP and OA-HIPP expenditures that are not allowable under RW	3,737,657	1,680,606
Reimbursement Surplus/Additional Need	344,968	-206,001
<b>Reimbursement (Safety Net Care Pool) Need for OA Insurance Assistance Programs</b>	<b>-3,737,657</b>	<b>-1,680,606</b>
<b>Federal Fund Appropriation for OA Insurance Assistance Programs (RW Part B Base Funds)</b>	<b>-1,500,000</b>	<b>-1,500,000</b>

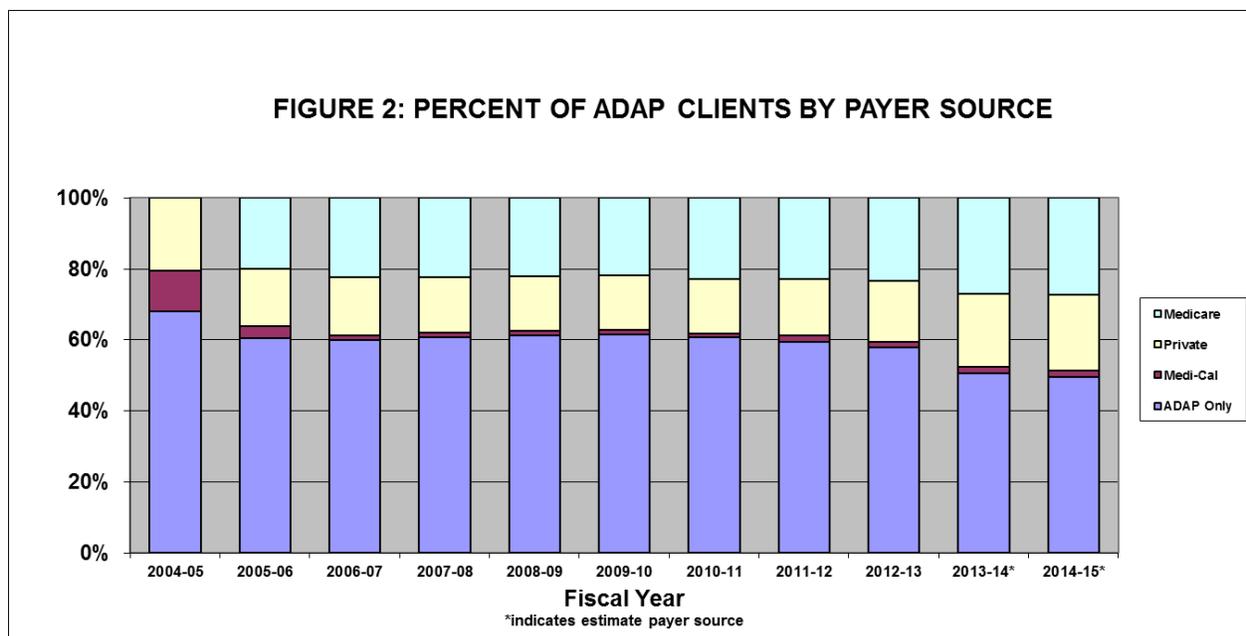
#### 4. HISTORICAL PROGRAM DATA AND TRENDS\*

(\*Data for FY 2013-14 and FY 2014-15 are estimated, all other data are actuals)

For all figures and tables in Section 4, the data prior to FY 2013-14 is the observed historical data. To develop client and prescription estimates for FY 2013-14 and FY 2014-15, OA used a regression model similar to the one used for expenditure estimates. These estimates were then adjusted in the following figures and tables to take into account client, expenditure, and prescription adjustments due to Medi-Cal Expansion, Covered California, and LIHP (Existing Assumption 1, Existing Assumption 2, and Unchanged Assumption 1, as applicable).

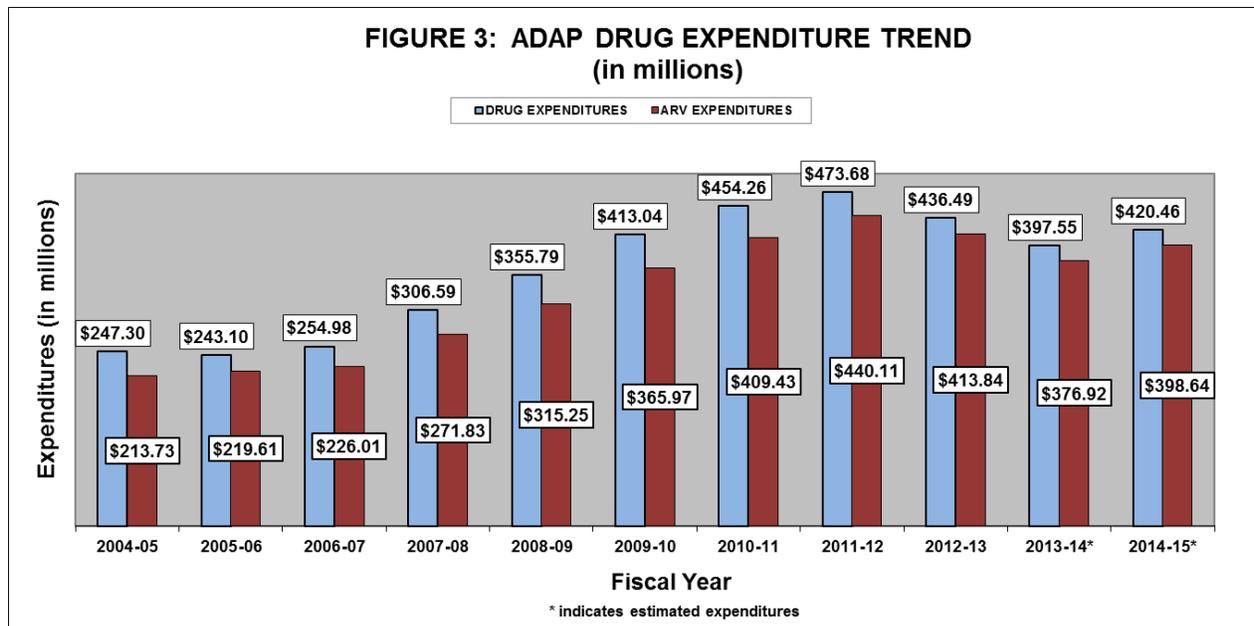


Note: Clients shifting out of ADAP due to Medi-Cal Expansion in FY 2013-14 are still considered to be ADAP clients for FY 2013-14; they will no longer be clients in FY 2014-15. LIHP clients who shifted out of ADAP and successfully transitioned to Medi-Cal Expansion will no longer be ADAP clients in FY 2013-14 or FY 2014-15. LIHP Health Care Coverage Initiative clients who do not qualify for Medi-Cal Expansion will come back to the ADAP program in FY 2013-14 and FY 2014-15, either as ADAP-only clients (if they do not purchase insurance through Covered California), or as ADAP private insurance clients (if they do purchase insurance through Covered California).

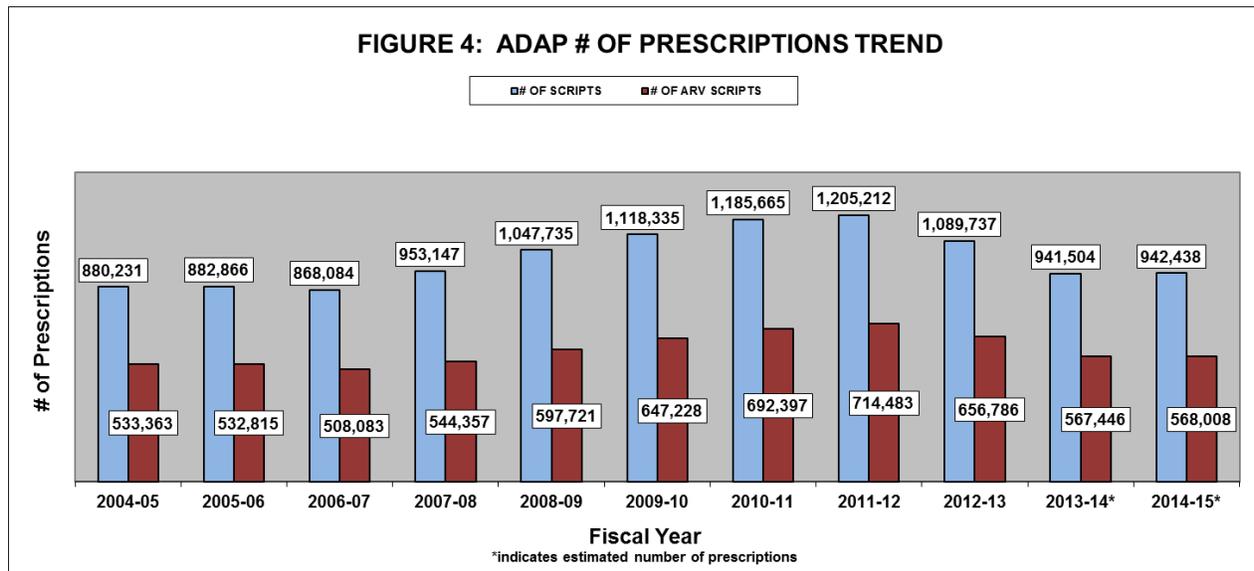


Note: For Figure 2 and Table 10, the actual percentage of ADAP clients by payer source/coverage group in FY 2012-13 was applied to the estimated client counts in FY 2013-14 and FY 2014-15 to estimate the percentage of clients by payer source. These percentages were then adjusted to account for the shift of ADAP-only clients to private insurance due to Covered California, Existing Assumption 2.

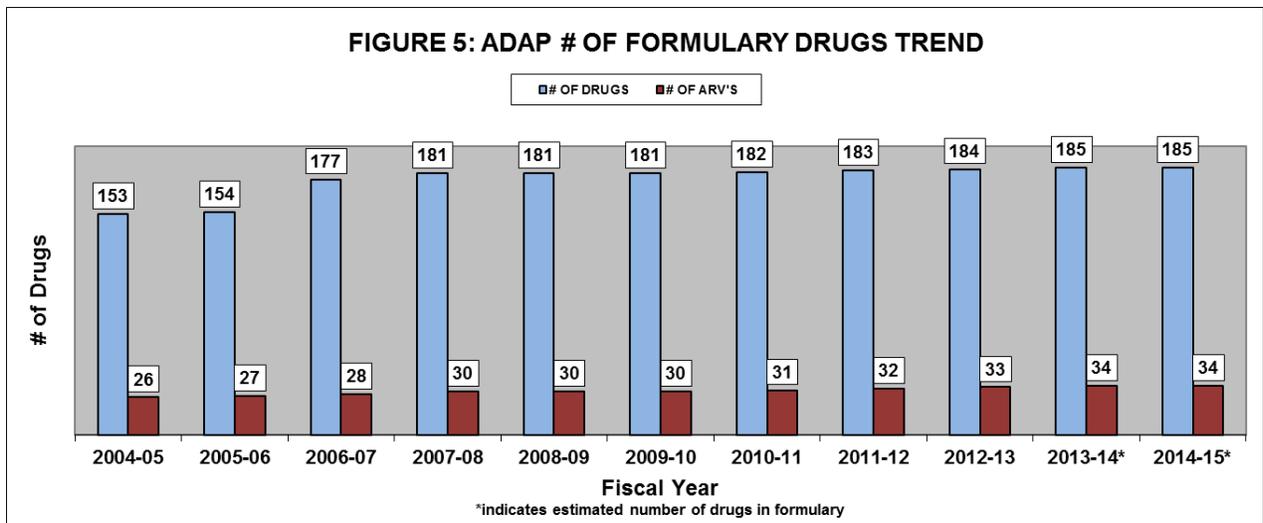
Coverage Group	FY 2013-14		FY 2014-15	
	Clients	Percent	Clients	Percent
ADAP-only	18,475	50.58%	18,738	49.48%
Medi-Cal	672	1.84%	704	1.86%
Private Insurance	7,539	20.64%	8,115	21.43%
Medicare	9,840	26.94%	10,315	27.24%
<b>TOTALS</b>	<b>36,526</b>	<b>100.00%</b>	<b>37,873</b>	<b>100.00%</b>



Note: Drug expenditures do not include annual administrative support for local health jurisdictions, Medicare Part D, OA-HIPP, or OA-PCIP premium payments. For these costs, see the FCS on page 20.



Note: To estimate the number of antiretroviral (ARV) prescriptions, OA used the percentage of ARV prescriptions in FY 2012-13 and applied it to the estimated drug prescriptions in FYs 2013-14 and 2014-15.



**APPENDIX A: EXPENDITURE AND REVENUE ESTIMATE METHODS****Updated Expenditure Estimate for FY 2013-14**

<b>TABLE 11: LINEAR REGRESSION MODEL FOR MAY REVISION FOR FY 2013-14 COMPARED TO 2013-14 GOVERNOR'S BUDGET</b>			
<b>MAY REVISION</b>	<b>GOVERNOR'S BUDGET</b>	<b>CHANGE FROM PREVIOUS EST (\$)</b>	<b>CHANGE FROM PREVIOUS EST (%)</b>
\$543,468,297	\$549,874,133	-\$6,405,836	-1.17

**Updated Expenditure Estimate for FY 2014-15**

<b>TABLE 12: LINEAR REGRESSION MODEL FOR MAY REVISION FOR FY 2014-15 COMPARED TO 2013-14 GOVERNOR'S BUDGET</b>			
<b>MAY REVISION</b>	<b>GOVERNOR'S BUDGET</b>	<b>CHANGE FROM PREVIOUS EST (\$)</b>	<b>CHANGE FROM PREVIOUS EST (%)</b>
\$592,981,649	\$597,602,503	-\$4,620,854	-0.77%

**Linear Regression Model – Expenditure Estimates**

The linear regression methodology is similar to the method used to estimate expenditures for FYs 2013-14 and 2014-15 in the *2014-15 Governor's Budget* with two changes: 1) OA used the updated range of actual expenditures, from April 2011 through February 2014; and 2) OA estimated March 2014 expenditures by: a) taking the invoiced expenditures for the first full week of March (March 3–March 9); b) calculating the daily expenditure rate for the two-day invoice (March 1–March 2) and seven-day invoice (March 3–March 9); and c) applying that daily expenditure rate to the remaining days of the month. As in the *2014-15 Governor's Budget*, six pre-regression adjustments were made for reduced PBM transaction fees and reimbursement rates, increased split fee savings, OA-HIPP expansion savings, OA-PCIP savings, and LIHP savings. There was no longer a need for adjusting for the elimination of ADAP services in jails, and PBM (approved) transaction fees were increased from \$4 to \$4.75. Unlike the *2014-15 Governor's Budget*, there was also a pre-regression adjustment for Medi-Cal Expansion savings, and there was no longer a need for adjusting for ADAP counting towards True-out-of-Pocket (TroOP). Covered California savings through March 2014 were negligible at this time and disregarded as a pre-regression adjustment. Using a more recent set of actual expenditure data to predict future expenditures allowed OA to “fine tune” previous estimates.

Figure 6, below, shows ADAP historic expenditures by month used in the linear regression model. The regression line (red) represents the best-fitting straight line for estimating the expenditures:

- During normal growth periods, a linear regression model should accurately predict expenditures (the red regression line goes straight through the data points).
  - During low growth periods, a linear regression model would overestimate expenditures (the red regression line goes over the data points).
  - During high growth periods, a linear regression model using the point estimate would underestimate expenditures (the red regression line goes under the data points).
- Thus, given the recent relatively high growth expenditure period beginning in FY 2007-08 (not shown in the figure), and the desire to not underestimate the need for ADAP to utilize the ADAP Rebate Fund to address increasing expenditures, OA continues to use the upper bound of the 95 percent confidence interval (CI) around the point estimate (blue line) for regression estimates. This is the same strategy used during the previous estimate development.

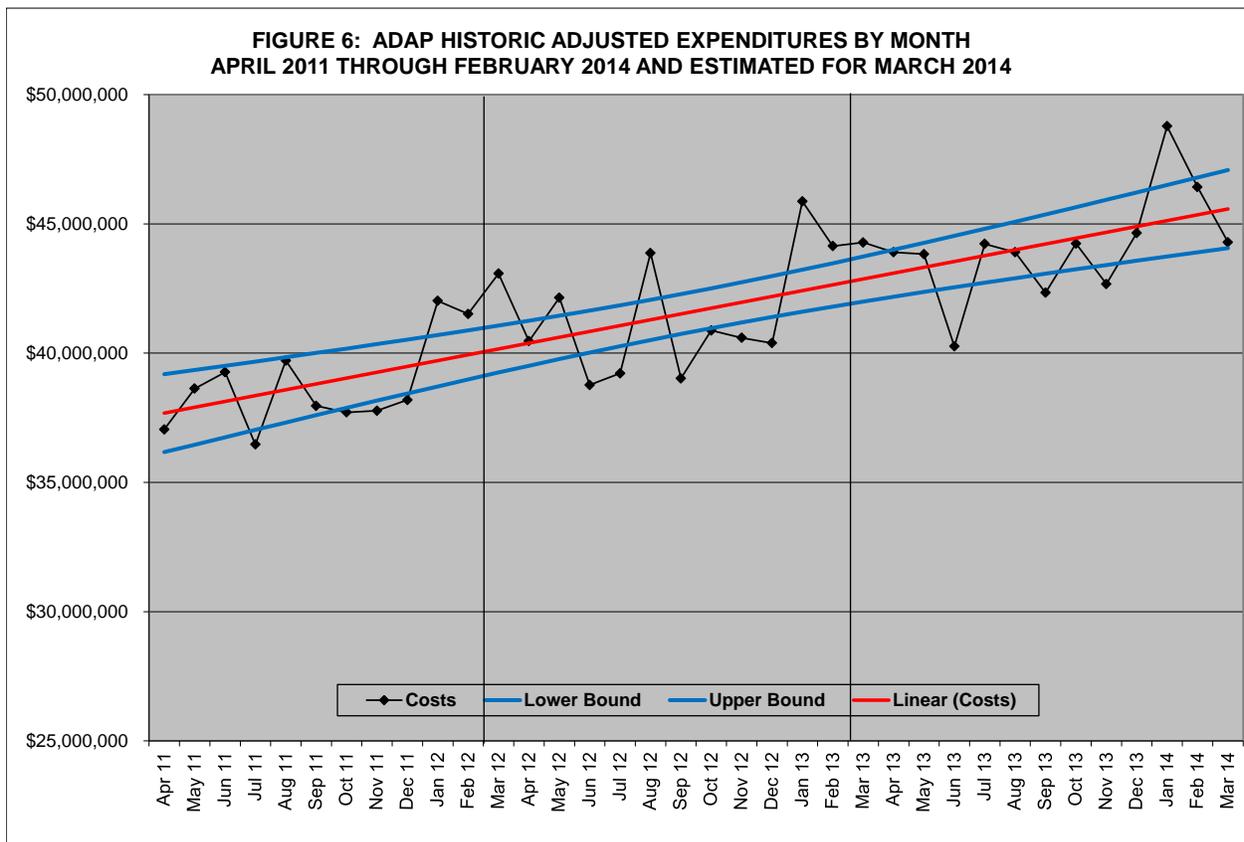


Table 13 displays historic drug expenditures by FY, annual change, and percent change.

<b>TABLE 13: ADAP HISTORIC AND PROJECTED DRUG EXPENDITURES</b>			
(*Data for FY 2013-14 and FY 2014-15 are projected, all other data are actuals)			
<b>Fiscal Year</b>	<b>Expenditures</b>	<b>Annual Change in Expenditures</b>	<b>Pct Annual Change</b>
1997-98	\$86,674,336	N/A	N/A
1998-99	\$98,924,742	\$12,250,405	14.13%
1999-00	\$119,465,151	\$20,540,409	20.76%
2000-01	\$144,913,504	\$25,448,353	21.30%
2001-02	\$167,709,426	\$22,795,922	15.73%
2002-03	\$187,854,138	\$20,144,712	12.01%
2003-04	\$220,101,760	\$32,247,622	17.17%
2004-05	\$247,299,716	\$27,197,956	12.36%
2005-06	\$243,096,942	-\$4,202,774	-1.70%
2006-07	\$254,977,392	\$11,880,450	4.89%
2007-08	\$306,590,832	\$51,613,440	20.24%
2008-09	\$355,786,400	\$49,195,569	16.05%
2009-10	\$413,035,251	\$57,248,851	16.09%
2010-11	\$454,426,055	\$41,390,804	10.02%
2011-12	\$473,684,504	\$19,258,449	4.24%
2012-13	\$436,497,134	-\$37,187,370	-7.85%
2013-14*	\$397,551,899	-\$38,945,235	-8.92%
2014-15*	\$422,643,281	\$25,091,382	6.31%
<b>Total Average</b>	<b>FY 97-98 to 14-15</b>	<b>\$19,429,848</b>	<b>10.41%</b>

Note: Drug costs include administrative costs at the pharmacy and PBM level. Drug costs do not include annual administrative support for local health jurisdictions, Medicare Part D, OA-HIPP, or OA-PCIP premium payments. For these costs, see FCS (Table 9, page 20).

Notes: In FY 2005-06, ADAP expenditures decreased for the first time due to the enrollment of ADAP clients in Medicare Part D, starting in January 2006. This also resulted in a lower than average increase in expenditures in FY 2006-07. The annual percentage increase in expenditures has decreased in FYs 2010-11 and 2011-12 because of the elimination of jail clients and the changes to TrOOP in FY 2010-11. Additionally, the decrease for FY 2012-13 are mainly due to LIHP, while for FY 2013-14, the decrease is mainly due to LIHP, Medi-Cal Expansion, and Covered California.

### **ADAP Rebate Revenue Estimate Method**

In general, to forecast future revenue, the rebate revenue estimate method applies an expected revenue collection rate to actual drug expenditures and projected drug expenditures (based on a linear regression and adjusted for the impact of assumptions). Using the most recent four quarters of actual rebates collected, the expected revenue collection rate is 67 percent. Revenue development for a given FY is based on actual rebates collected and actual expenditures, if available, and/or projected drug expenditures (based on linear regression). A six-month delay is necessary to take into account the time required for billing the drug manufacturers and receipt of the rebate.

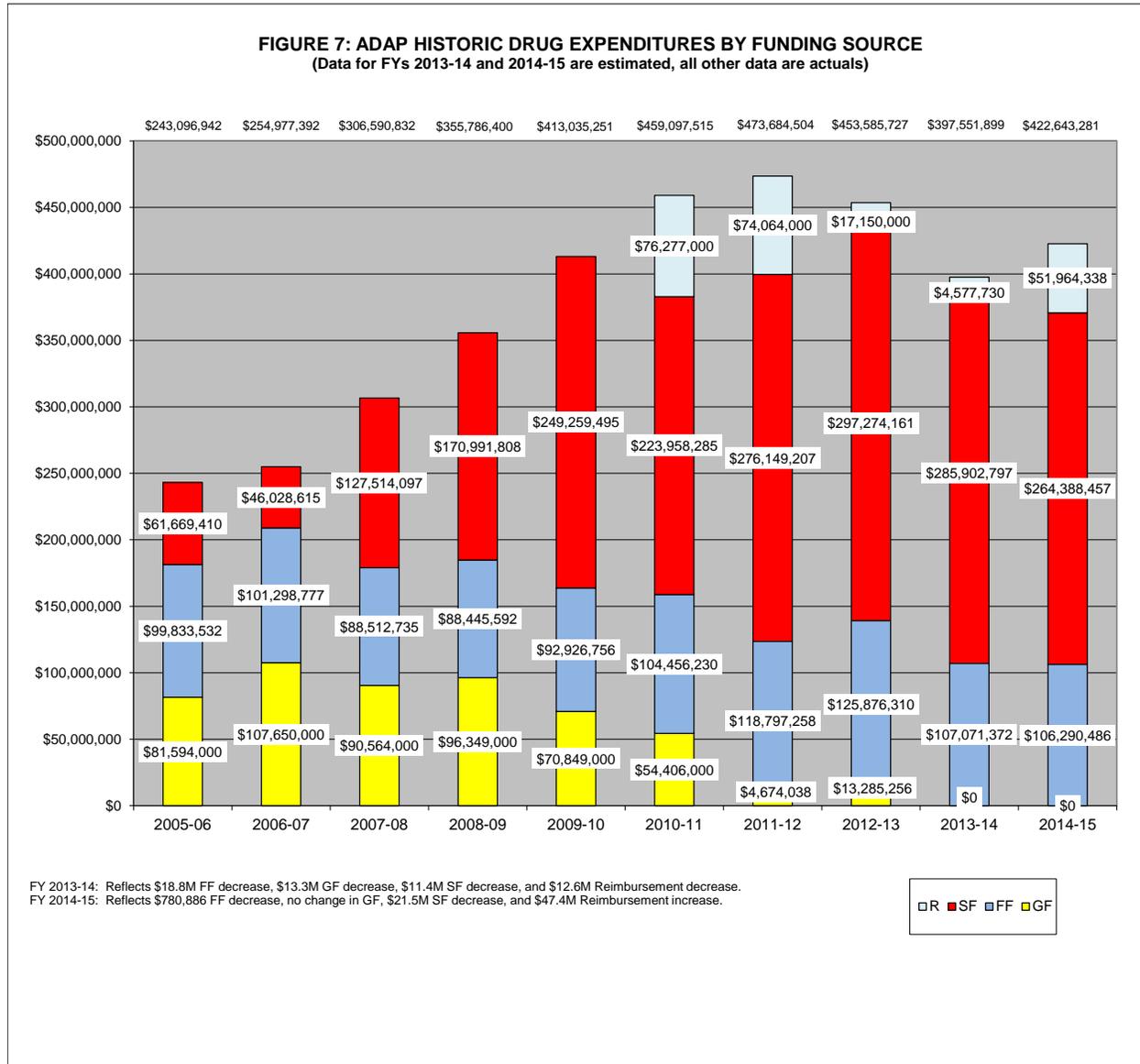
Therefore, revenue estimates are based on drug expenditures for the last two quarters of the previous FY and the first two quarters of the current FY.

The method used to project revenues for the *2014-15 May Revision* is similar to the method used for the *2014-15 Governor's Budget*. Revenue estimates for FY 2013-14 in the *2014-15 May Revision* included: actual rebates (\$152,096,875) collected for the period January through June 2013 and estimated rebates calculated by applying the 67 percent expected rebate collection rate to actual drug expenditures from July to December 2013 (\$132,369,791).

For FY 2014-15, the revenue estimate (\$270,690,125) was developed by applying the 67 percent expected rebate collection rate to projected drug expenditures (based on a linear regression and adjusted for expenditure savings) for the period January through December 2014. OA also applied revenue impact from New Assumption 1 to prevent overestimating rebate revenue.

It should be noted that the revenue estimate method uses average expenditures for each six-month period and does not directly take into account the seasonal behavior of expenditures. Historical data show that drug expenditures are lower in the first half of the FY (July through December) compared to the second half of the FY.

### APPENDIX B: FUND SOURCES



**General Fund**

The local assistance budget for ADAP, which includes insurance assistance programs, will not include General Fund for FY 2013-14 or FY 2014-15.

**Federal Fund**

Federal funding from the annual HRSA grant award through RW includes both “Base” funding and “ADAP Earmark” funding. The Base award from the grant provides funds for care and support programs within OA. The Part B Earmark award must be used for ADAP-related services only. The RW award is predicated upon the State of California meeting Maintenance of Effort (MOE) and match requirements. Non-compliance with these requirements will result in withholding a portion (match) or the entire (MOE) Part B federal grant award to California.

In the *2013-14 May Revision*, OA requested an additional \$15.0 million in federal fund expenditure authority in FY 2012-13 to utilize some of the available 2013 RW Part B award. Since OA spent \$2,912,359 of the \$15.0 million in FY 2012-13, the remainder was spent in FY 2013-14.

ADAP received three 2013 Supplemental awards: 1) RW ADAP Supplemental Award for \$7,713,428; 2) RW Part B Supplemental award for \$1,738,531; and 3) ADAP ERF award for \$10,761,268. ADAP will use these funds for drug expenditures.

On March 12, 2014, HRSA issued the NoA for the 2014 ADAP ERF Grant. OA received \$3,238,367. On April 14, 2014, HRSA issued another NoA for the 2014 ADAP ERF with an additional \$1,210,476, for a total of \$4,448,843. ADAP will use these funds for drug expenditures in the budget year.

On March 20, 2014, HRSA issued the NoA for partial 2014 RW Part B Grant funding based on: (1) HRSA’s budget projections; (2) estimated total budget amounts using 2013 program funding award levels; and, (3) specialized reporting requirements. These funds are expected to cover continuation costs beginning April 1, 2013 until full 2014 funding levels have been determined; at that time a revised NoA will be issued to reflect final funding amounts. California’s 2014 ADAP Earmark partial award totaled \$28,136,738, or 29 percent of the 2013 California ADAP Earmark award. This NoA also included 2014 ADAP Supplemental funds of \$2,971,412. ADAP will use these funds for drug expenditures.

**Match**

HRSA requires grantees to have HIV-related non-HRSA expenditures. California’s 2013 HRSA match requirement for FY 2013-14 funding is \$65,314,468. OA will meet the match requirement by using General Fund expenditures from OA’s Surveillance Program and support, as well as the California Department of Corrections and Rehabilitation, and the California HIV/AIDS Research Program.

Note: California's 2014 HRSA match requirement was not identified in the partial 2014 RW Part B Grant NoA issued by HRSA on March 20, 2014.

## **MOE**

HRSA requires grantees to maintain HIV-related expenditures at a level that is not less than the prior FY. California's MOE target, based on FY 2012-13 estimated expenditures at the time of the Year 2014 HRSA grant application, is \$502,476,676. Expenditures included in California's MOE calculations are not limited to OA programs, and include HIV-related expenditures for all state agencies able to report General Fund expenditures specific to HIV-related activities such as care, treatment, prevention, and surveillance. In 2009, HRSA stated that expenditures from rebate funds may be used towards the MOE requirement. On November 16, 2012, HRSA released a policy letter affirming that drug rebates can be used for either the federal match or MOE requirement, but not both.

## **Reimbursement**

On February 1, 2010, CMS approved DHCS's proposed amendment to the Special Terms and Conditions, amended October 5, 2007. The amendment incorporates federal flexibilities to expand DHCS's ability to claim additional state expenditures to utilize federal funding under SNCP. DHCS used certified public expenditures from various programs, including ADAP, to claim federal funds. ADAP estimates utilizing \$8.3 million of the \$53.6 million SNCP funds available for ADAP in FY 2013-14 due to ADAP's requirement to spend mandatory rebate funds prior to spending federal funds. For FY 2014-15, ADAP estimates utilizing \$53.6 million of the \$58.9 million SNCP funds available for ADAP. DHCS informed OA that SNCP funds are not restricted and may be used for expenditures not allowable under the RW Payer of Last Resort provision. Thus, in FY 2013-14 and FY 2014-15, OA will utilize SNCP funds to cover the costs associated with clients eligible for other public assistance programs, including Medi-Cal and LIHP, and to cover the costs of transaction fees invoiced by ADAP's PBM contractor for the administrative costs associated with managing prescription transactions that are ultimately identified as not eligible for ADAP payment.

## **ADAP Rebate Fund 3080**

The use of this fund is established under both state law and federal funding guidance. The ADAP Rebate Fund was legislatively established in 2004 to support the provision of ADAP services. California Health and Safety Code Section 120956, which established the ADAP Rebate Fund, states in part:

“... (b) All rebates collected from drug manufacturers on drugs purchased through the ADAP implemented pursuant to this chapter and, not withstanding Section 16305.7 of the Government Code, interest earned on

these moneys shall be deposited in the fund exclusively to cover costs related to the purchase of drugs and services provided through ADAP...”

ADAP receives both mandatory and voluntary supplemental rebates for drugs dispensed to ADAP clients; the original rebate law required by California Health and Safety Code Section 120956, subsequent federal (Medicaid) rebate law, and the subsequent nationally negotiated voluntary ADAP rebate established with individual drug manufacturers. Though these rebates constitute a significant part of the annual ADAP budget, the exact amount of rebate to be collected on an annual basis varies due to a number of factors, including quarterly changes in the federal calculation for the mandatory rebate due on the part of the manufacturer, and the “voluntary” nature of the supplemental rebates.

Supplemental rebates (rebates beyond those required by the federal Medicaid rebate law) are negotiated on an ongoing basis by the ADAP Crisis Task Force (ACTF). ACTF is a national rebate negotiating coalition working on behalf of all state ADAPs. ACTF enters into voluntary, confidential supplemental rebate agreements with drug manufacturers.

Though these agreements are entered into in good faith by both parties, there is no guaranteed continuation of the voluntary supplemental rebate. The agreements are generally entered into for an average term of one to two years, but the drug manufacturer or the program can cancel the voluntary supplemental rebate agreement at any time with a 30-day written notice. Additionally, the rebate agreements are highly confidential and any unauthorized disclosure could invalidate the agreements, resulting in serious national implications for all state ADAPs.

Supplemental rebate agreements are in place for almost all the ARVs on the ADAP formulary through the end of calendar year 2014. One manufacturer declined to extend its agreement beyond December 31, 2013, because its two ARV drugs have a very small and declining market share of ARV sales, and two agreements have been extended to the end of 2015. ACTF plans on meeting with manufactures in July 2014 to discuss the feasibility of extending agreements beyond 2014. ACTF agreements are a significant source of rebate revenue, as ARV drugs represent 95 percent of all ADAP drug expenditures in FY 2012-13.

## **1. Additional Rebate Percentage**

The mandatory federal Medicaid 340B rebate is based on a percentage of the average manufacturers price (AMP), plus penalties for any price increases that exceed the inflation rate for the Consumer Price Index (CPI). Since both the AMP and the federally mandated Medicaid 340B rebate are confidential and not publicized, the resulting rebate amount is also unknown to ADAP. ACTF negotiations usually result in an additional voluntary, supplemental rebate based on a percentage of AMP. For example, if the current mandatory 340B rebate for brand drugs is 23 percent of AMP, and ACTF has negotiated a supplemental rebate of

2 percent of AMP from manufacturer X for drug Y, then ADAP receives a total rebate of 25 percent of AMP for that drug.

## 2. “Price Freeze” Rebates

The “price freeze” option is another type of voluntary rebate offered by some manufacturers to compensate ADAP for commercial price increases. Currently, of the available ARV medications on the ADAP formulary, 19 are subject to a price freeze rebate. Eighteen of these drugs represented 60 percent of ADAP’s drug expenditures in FY 2012-13 (the 19th ARV was not added until September 2013). If the manufacturers impose a price increase that exceeds CPI (inflation rate) while the ADAP price freeze is in effect, the program reimburses retail pharmacies at the new higher price. Though this initially results in higher expenditures for the program, these price freeze agreements eventually offset the cost by increased rebates subsequently received and deposited in the rebate fund.

### ADAP Rebate Invoicing

ADAP invoices the manufacturers for drug rebates on a quarterly basis (see Table 14, page 37 consistent with both federal drug rebate law and drug industry standards. All ADAPs are required to invoice drug manufacturers within 90 days of the end of a given calendar year quarter (e.g., January through March, April through June, etc.) in compliance with federal requirements. ADAP mails drug rebate invoices approximately 30 to 60 days after the end of the quarter. For example, the January through March quarter invoice is sent out by the end of May. The time between the end of the billing quarter and the mailing of the invoice is necessary to generate and confirm the accuracy of the rebate invoices.

### Timeframe for Receipt of Rebates

Federal HRSA guidance on ADAP rebate indicates that drug manufacturers are to pay rebate invoices from ADAP within 90 days of receipt. Federal Medicaid rebate law requires that drug manufacturers pay drug rebates within 30 days of receipt of a rebate invoice. The majority of large drug manufacturers have generally paid rebates close to the Medicaid payment timeframe, usually within 30 to 60 days from the date of invoicing, while the majority of smaller manufacturers are more closely following the HRSA timeframe of 90 days when processing ADAP rebate invoices. Due to the above invoicing requirements and rebate payment timeframes, ADAP receives drug rebates anywhere from five to eight months after program expenditures. Consequently, rebates due on expenditures in the second half of a given FY may not be received until the subsequent FY.

Rebate fund budget authority for local health jurisdictions and premium payments is requested as follows:

- \$2 million in FY 2013-14 and FY 2014-15 to local health jurisdictions to help offset the costs of ADAP enrollment and eligibility screening for clients at enrollment sites located throughout the state. Annual allocations are based on the number of ADAP clients enrolled during the previous calendar years;
- \$1 million for the Medicare Part D Premium Payment Program in both FYs. This program assists eligible clients in paying their Part D monthly premiums, allowing them to receive the Part D benefit;
- \$480,007 to cover premium payments for OA-PCIP in FY 2013-14 only; and
- \$8,996,990 and \$11,212,569 to cover premium payments for OA-HIPP in FYs 2013-14 and 2014-15, respectively.

**TABLE 14: HISTORIC ADAP REBATE REVENUE COLLECTION PERCENTS BY QUARTER**

<b>FY-QTR</b>	<b>Drugs Purchased</b>	<b>Rebate Received</b>	<b>Received / Purchased</b>
2002/03-Q1	\$46,263,616	\$10,136,693	21.91%
2002/03-Q2	\$46,714,748	\$10,257,857	21.96%
2002/03-Q3	\$47,028,955	\$10,146,224	21.57%
2002/03-Q4	\$47,846,818	\$10,846,426	22.67%
2003/04-Q1	\$51,607,688	\$12,275,494	23.79%
2003/04-Q2	\$51,732,389	\$15,045,513	29.08%
2003/04-Q3	\$56,857,403	\$17,801,378	31.31%
2003/04-Q4	\$59,904,280	\$19,249,713	32.13%
2004/05-Q1	\$61,533,761	\$19,334,264	31.42%
2004/05-Q2	\$60,894,584	\$18,691,016	30.69%
2004/05-Q3	\$61,680,181	\$19,176,357	31.09%
2004/05-Q4	\$63,191,190	\$15,847,186	25.08%
2005/06-Q1	\$63,433,758	\$21,866,164	34.47%
2005/06-Q2	\$62,536,173	\$20,624,121	32.98%
2005/06-Q3	\$58,562,814	\$26,768,577	45.71%
2005/06-Q4	\$58,564,197	\$25,095,840	42.85%
2006/07-Q1	\$60,334,084	\$24,791,394	41.09%
2006/07-Q2	\$58,609,374	\$24,489,071	41.78%
2006/07-Q3	\$67,474,884	\$32,724,197	48.50%
2006/07-Q4	\$68,559,050	\$31,734,710	46.29%
2007/08-Q1	\$68,797,779	\$33,524,051	48.73%
2007/08-Q2	\$71,581,717	\$35,262,749	49.26%
2007/08-Q3	\$81,926,045	\$44,200,318	53.95%
2007/08-Q4	\$84,285,291	\$39,834,969	47.26%
2008/09-Q1	\$82,366,671	\$36,272,892	44.04%
2008/09-Q2	\$85,997,429	\$38,043,925	44.24%
2008/09-Q3	\$93,564,283	\$46,300,283	49.48%
2008/09-Q4	\$93,858,017	\$40,827,251	43.50%
2009/10-Q1	\$98,508,463	\$44,718,090	45.40%
2009/10-Q2	\$95,842,924	\$44,131,629	46.05%
2009/10-Q3	\$109,578,075	\$55,921,629	51.03%
2009/10-Q4	\$109,105,789	\$55,287,500	50.67%
2010/11-Q1	\$108,993,239	\$56,542,481	51.88%
2010/11-Q2	\$109,126,234	\$60,632,240	55.56%
2010/11-Q3	\$117,756,733	\$69,854,403	59.32%
2010/11-Q4	\$118,549,848	\$67,571,808	57.00%
2011/12-Q1	\$113,894,685	\$65,608,229	57.60%
2011/12-Q2	\$113,441,625	\$66,278,515	58.43%
2011/12-Q3	\$126,356,874	\$83,124,919	65.79%
2011/12-Q4	\$119,991,320	\$73,630,805	61.36%
2012/13-Q1	\$113,135,974	\$73,360,369	64.84%
2012/13-Q2	\$107,160,900	\$70,016,626	65.34%
2012/13-Q3	\$111,981,513	\$79,447,459	70.95%
2012/13-Q4	\$104,158,746	\$72,649,416	69.75%

Note: The Rebate Received column ties back to the quarter in which the drugs were purchased.

TABLE 15: COMPARISON OF REVENUE BETWEEN 2014-15 May Revision and 2014-15 Governor's Budget						
UPDATED ESTIMATE FOR FY 2013-14						
Expenditure Period	Available Data	May Revision	Available Data	Governor's Budget	Change (\$)	Change (%)
Jan - Mar 2013	Actual Rebates	\$79,447,459	Actual Rebates	\$79,418,673	\$28,786	0.04%
Apr - Jun 2013	Actual Rebates	\$72,649,416	Actual Expenditures @65%	\$67,703,185	\$4,946,231	7.31%
Jul- Dec 2013	Actual Expenditures @67%	\$132,369,791	Estimated Expenditures @65%	\$131,417,427	\$952,364	0.72%
<b>Subtotal Revenue</b>		\$284,466,665		\$278,539,285	\$5,927,380	2.13%
Interest		\$120,000		\$120,000	\$0	0.00%
<b>Total Revenue</b> (see Table 9, Fund Condition Statement)		\$284,586,665		\$278,659,285	\$5,927,380	2.13%
UPDATED ESTIMATE FOR FY 2014-15						
Expenditure Period	Available Data	May Revision	Available Data (Expenditure Period)	Governor's Budget	Change (\$)	Change (%)
Jan - Jun 2014	Estimated Expenditures @67%	\$131,339,871	Estimated Expenditures @65%	\$129,545,375	\$1,794,496	1.39%
Jul - Dec 2014	Estimated Expenditures @67%	\$139,350,253	Estimated Expenditures @65%	\$131,024,663	\$8,325,590	6.35%
<b>Adjustment</b>				-\$3,000		
<b>Subtotal Revenue after Adjustments</b>		\$270,690,124		\$260,567,038	\$10,123,086	3.89%
Interest		\$120,000		\$120,000	\$0	0.00%
<b>Total Revenue</b> (see Table 9, Fund Condition Statement)		\$270,810,124		\$260,687,038	\$10,123,086	3.88%

**Note:** When actual rebate data are not available, revenue projection methodology is based on a percentage of actual expenditures (if available) or estimated expenditures. This method does not take into account the seasonal fluctuations between the first half of the FY (when expenditures are lower) and the second half (when expenditures are higher).

## APPENDIX C: POTENTIAL FUTURE FISCAL ISSUES

ADAP continues to monitor policy issues and drugs that have the potential to impact the fiscal condition of ADAP. These issues can occur within the state and federal arenas, as well as in the private sector. Because the future fiscal impact may be difficult to estimate, ADAP assesses the status of these issues on an ongoing basis. These issues are summarized below:

### 1. Potential Savings Due to Cross Match of RW Client Data to Medi-Cal Eligibility Data Systems (MEDS)

#### Background:

Federal requirements stipulate that RW grant funds are to be used solely as a payer of last resort. To minimize the possibility of paying for medications that should be billed to Medi-Cal or other third-party payers such as Medicare Part D and Covered California, OA is working on an interagency agreement with DHCS that will allow for a monthly cross match of RW and MEDS client data. CDPH and DHCS have agreed on a blind match proposal that ensures client confidentiality and are in the process of developing the agreement.

#### Description of Change:

This cross match between RW client data and MEDS client data, once implemented, will identify RW clients who are also Medi-Cal clients and if they have a Share of Cost (SOC). Clients identified as enrolled in Medi-Cal with no SOC and who do not have Medicare will be terminated from ADAP with a notation made that they are enrolled in Medi-Cal. When these clients arrive at an ADAP pharmacy to get their medications, the medications will be billed to Medi-Cal rather than to ADAP. To the extent allowable under Medi-Cal, OA will also re-coup any prior ADAP expenditures for these clients through a pharmacy back-billing process by the ADAP PBM contractor.

#### Discretionary? Y/N:

No. RW funds by statute may not be used for any item or service for which payment has been made or can reasonably be expected to be made by another payment source (Sections 2605(a)(6), 2617(b)(7)(F), 2664(f)(1), and 2671(i) of the Public Health Service Act).

#### Reason for Adjustment/Change:

- Federal mandate; and
- Due to the large number of ADAP clients, ADAP cannot manually screen all clients for third-party payers each month.

#### Fiscal Impact (Range) and Fund Source(s):

Increased ADAP savings (fiscal +); fiscal range is unknown at this time.

## 2. Carry Forward Request for Unspent 2013 RW Federal Grant Funds

### Background:

On November 16, 2012, HRSA released a policy letter stating that due to regulations that govern federally funded grants, including Part B and ADAP awards, grantees are required to spend 340B rebate funds prior to drawing down Federal RW grant funds. If not all available dollars are projected to be spent at the end of the Federal RW Grant year, the federal fund balance will be returned to HRSA and a carry forward request can be submitted for unspent federal funds.

### Description of Change:

OA did not utilize all 2013 RW Grant funds. Thus, CDPH will submit a carry forward request for these unused funds. The carry forward will request that the unobligated federal fund balance, due to rebate funds being spent first, be carried forward to spend in the next Federal RW Grant budget period (April 1, 2014 - March 31, 2015). If awarded, ADAP will use these funds for drug expenditures and health insurance premium payments.

### Discretionary? Y/N:

Yes.

### Reason for Adjustment/Change:

- Due to available 340B rebate funds, OA did not utilize all 2013 RW funds by the end of the grant year.
- A carry forward request will not guarantee funding in the subsequent grant year.

### Fiscal Impact (Range) and Fund Source(s):

Up to approximately \$7.2 million in additional federal funds.

## 3. Possible FDA Approval of Elvitegravir

### Background:

Elvitegravir is an investigational antiretroviral (ARV) medication that is in the integrase inhibitor class, currently in Phase III clinical trials. If approved, elvitegravir will offer a once-daily dosing option for integrase inhibitors, as compared to the currently available raltegravir, which requires dosing twice daily. Once FDA approved, there may be a shift from current raltegravir users to elvitegravir because of the longer dosing interval. In addition, patients may switch from once-daily protease inhibitors (PI) and non-nucleoside reverse transcriptase inhibitors once daily integrase inhibitor is available. This drug is part of the "Quad" (elvitegravir/cobicistat/emtricitabine/tenofovir) formulation that was FDA approved on August 27, 2012. The manufacturer, Gilead, originally submitted a New Drug Application (NDA) to the FDA for elvitegravir on June 27, 2012. Elvitegravir had been given priority review status by the FDA and was expected to be on the market by May 2013; however, on April 29, 2013, Gilead announced that the company received a Complete Response Letter (CRL) from the FDA stating that the FDA was

unable to approve the application for elvitegravir, citing deficiencies in documentation and validation of certain quality testing procedures and methods. Gilead has worked with the FDA to address the questions raised on CRL and on April 21, 2014, the company announced that the FDA had accepted the refiling of the NDA for their drug.

Description of Change:

On average, ARV drugs may receive FDA approval within six months of NDA acceptance.

Discretionary? Y/N:

No. California Health and Safety Code Section 120966.

Reason for Adjustment/Change:

- As required by law, ADAP must add a new ARV to the formulary within 30 days of FDA approval if its addition does not represent a cost increase to the program and the drug has been recommended for addition by the ADAP MAC.
- 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.

Fiscal impact (Range) and Fund Sources(s):

If approved, ADAP will monitor pricing and supplemental rebate negotiations closely.

4. Possible FDA Approval of Cobicistat

Background:

Cobicistat is an ARV being developed both as a pharmacokinetic booster for the integrase inhibitor elvitegravir and as a booster for PIs. This drug is also part of the previously discussed "Quad" formulation. The manufacturer, Gilead, submitted an NDA to the FDA on June 28, 2012, and cobicistat was expected to be on the market by May 2013; however, on April 29, 2013, Gilead announced that the company received a CRL from the FDA regarding the application for cobicistat. The letter stated that the FDA was unable to approve the application for cobicistat, citing deficiencies in documentation and validation of certain quality testing procedures and methods. Gilead has worked with the FDA to address the questions raised in the CRL and on April 21, 2014, the company announced that the FDA had accepted the refiling of the NDA for cobicistat.

Description of Change:

On average, ARV drugs may receive FDA approval within six months of NDA acceptance.

Discretionary? Y/N:

No. California Health and Safety Code Section 120966.

Reason for Adjustment/Change:

- As required by law, ADAP must add a new ARV to the formulary within 30 days of FDA approval if its addition does not represent a cost increase to the program and the drug has been recommended for addition by the ADAP MAC.
- 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.

Fiscal impact (Range) and Fund Sources(s):

If approved, ADAP will monitor pricing and supplemental rebate negotiations closely.

5. Possible FDA Approval of Fixed-Dose Darunavir with CobicistatBackground:

On April 1, 2014 Janssen Research and Development, LLC (Janssen) announced that the manufacturer submitted a NDA to the FDA for approval of a once-daily fixed-dose ARV combination tablet containing darunavir, a protease inhibitor developed by Janssen, with cobicistat, an investigational pharmacokinetic enhancer or boosting agent, developed by Gilead Sciences, Inc. (Gilead) for use in combination with other human immunodeficiency virus (HIV-1) medicines. The announcement did not indicate that Janssen received priority status for the combination drug from the FDA; therefore, a market availability date is difficult to estimate. Janssen announced the license agreement with Gilead for the development of the once-daily tablet fixed-dose combination product of darunavir and cobicistat in June 2011.

Darunavir is indicated for treatment of HIV-1 in treatment-naive and treatment-experienced adult patients with no darunavir resistance-associated mutations. Darunavir is currently always taken with ritonavir, a boosting agent, with food and in combination with other HIV medicines. If approved, the new fixed-dose darunavir/cobicistat combination tablet will be marketed under a new brand name and will, for the first time, offer an additional therapeutic option that eliminates the need to take a boosting agent in a separate tablet with darunavir.

Description of Change:

Janssen filed the NDA for this new combination drug on April 1, 2014.

Discretionary? Y/N:

No. California Health and Safety Code Section 120966.

Reason for Adjustment/Change:

- As required by law, ADAP must add a new ARV to the formulary within 30 days of FDA approval if its addition does not represent a cost increase to the program and the drug has been recommended for addition by the ADAP MAC.

- 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.

Fiscal impact (Range) and Fund Sources(s):

If approved, ADAP will monitor pricing and supplemental rebate negotiations closely.

## APPENDIX D: CURRENT HIV/AIDS EPIDEMIOLOGY IN CALIFORNIA

### HIV Prevalence

Prevalence reflects the number of people who are currently infected with HIV, and thus, who could qualify for ADAP currently or sometime in the future. California estimates that about 152,600 persons were living with HIV/AIDS in California at the end of 2013. This estimate includes people who are HIV positive but are not yet diagnosed, by applying a national estimate of those unaware of their infection status developed by the Centers for Disease Control and Prevention (CDC). CDC estimates 15.8 percent of all HIV-infected persons are unaware of their infection. <sup>[1]</sup>

Living HIV/AIDS cases in California are estimated to be 43.3 percent White, 17.8 percent African American, 33.1 percent Latino, 3.9 percent Asian/Pacific Islander, 0.4 percent American Indian/Alaskan Native, and 1.3 percent Multi-racial. The results of a CDC algorithm that estimates the distribution of living cases with respect to mode of HIV exposure applied to California data show most (64.5 percent) of California's estimated living HIV/AIDS cases are attributed to male-to-male sexual transmission, 12.9 percent to heterosexual transmission, 11.7 percent to injection drug use, 9.9 percent to men who have sex with men who also inject drugs, 0.5 percent to perinatal exposure, and 0.5 to other or unknown sources.

The number of living HIV/AIDS cases in the state is expected to grow by approximately 2 percent (with a range of 2,800–5,400) each year for the next two years, and it is expected that this increasing trend will continue for the foreseeable future. This increase is attributed to stable incidence rates and longer survival of those infected, primarily due to the effectiveness and availability of treatment.

<sup>[1]</sup> Monitoring selected national HIV prevention and care objectives by using HIV surveillance data—United States and six dependent areas, 2011. *HIV Surveillance Supplemental Report* 2013;18 [No. 5]. Available at <http://www.cdc.gov/hiv/library/reports/surveillance/> Published Oct 2013. Accessed March 4, 2014.

## **HIV Incidence**

Incidence is a measure of new infections over a specified period of time (typically a year), and thus provides an indication of the future need for ADAP support.

California has implemented HIV incidence surveillance using a CDC-developed algorithm based on HIV surveillance data and testing of remnant samples. The estimates of HIV incidence in California for 2009–2011 based on the data and methodology provided by CDC are as follows:

- 2009: Estimated infections = 4,964 (95 percent CI 4,117–5,811);
- 2010: Estimated infections = 4,949 (95 percent CI 4,129–5,770); and
- 2011: Estimated infections = 5,275 (95 percent CI 4,275–6,275).

Surveillance data are dynamic and may change over time. Additionally, the number of tested samples increases with time, leading to more precise incidence estimates. Therefore, estimates from 2011 should be considered preliminary and will likely change as additional data become available. Data from the HIV incidence surveillance system will be used to revise and update California incidence estimates on an annual basis.

**APPENDIX E: SENSITIVITY ANALYSIS****FY 2013-14**

ADAP conducted a sensitivity analysis exploring the impact on total expenditures by increasing and decreasing the number of clients and the expenditures per client (\$/client). For this sensitivity analysis, ADAP started with the estimated total drug expenditures for FY 2013-14 using the upper bound of the 95 percent CI from the linear regression model and subtracted cost/savings for all assumptions impacting drug expenditures.

For these factors, clients and expenditures per client, ADAP created scenarios ranging from negative 3 percent to positive 3 percent, in 1 percent intervals. Those scenarios labeled as “Hi” represent 3 percent, “Med” represent 2 percent, and “Lo” represents a 1 percent change. The left column in Table 16, below, lists the seven (including no change) scenarios for changes in \$/client, starting with the best case scenario {3 percent decrease in \$/client, Hi(-)} and finishing with the worst case scenario {3 percent increase in \$/client, Hi(+)}. The seven scenarios for changes in client counts are listed across the table.

<b>\$/ Client Scenarios</b>	<b>Number of Client Scenarios</b>						
	<b>Hi (-) CI</b>	<b>Med (-) CI</b>	<b>Lo (-) CI</b>	<b>Zero Change in Clients</b>	<b>Lo (+) CI</b>	<b>Med (+) CI</b>	<b>Hi (+) CI</b>
<b>Hi (-): Best</b>	\$374,177,393	\$378,013,817	\$381,850,242	\$385,686,667	\$389,523,092	\$393,359,517	\$397,195,942
<b>Med (-)</b>	\$378,013,817	\$381,889,793	\$385,765,769	\$389,641,745	\$393,517,720	\$397,393,696	\$401,269,672
<b>Lo (-)</b>	\$381,850,242	\$385,765,769	\$389,681,295	\$393,596,822	\$397,512,348	\$401,427,875	\$405,343,401
<b>Zero Change in \$/ Client</b>	\$385,686,667	\$389,641,745	\$393,596,822	\$397,551,899	\$401,506,976	\$405,462,053	\$409,417,131
<b>Lo (+)</b>	\$389,523,092	\$393,517,720	\$397,512,348	\$401,506,976	\$405,501,604	\$409,496,232	\$413,490,860
<b>Med (+)</b>	\$393,359,517	\$397,393,696	\$401,427,875	\$405,462,053	\$409,496,232	\$413,530,411	\$417,564,590
<b>Hi (+): Worst</b>	\$397,195,942	\$401,269,672	\$405,343,401	\$409,417,131	\$413,490,860	\$417,564,590	\$421,638,319

The center cell highlighted in light blue shows the revised estimated expenditures for FY 2013-14, using the 95 percent CI from the linear regression model and adjusted for all assumptions. The best case scenario, which is a 3 percent decrease in \$/client coupled with a 3 percent decrease in the number of clients, results in an estimate of \$374.2 million (top left cell, light green). The worst case scenario, a 3 percent increase in \$/client coupled with a 3 percent increase in number of clients, results in an estimate of \$421.6 million (bottom right cell, red). The table provides a range of values to assist in projecting the total expenditures for FY 2013-14.

**FY 2014-15**

Below is the sensitivity analysis for FY 2014-15, using the same logic that was used for FY 2013-14. In this sensitivity analysis, ADAP adjusted for several assumptions that impacted ADAP's FY 2014-15 total expenditures and total client count. Similar to the FY 2013-14 sensitivity analysis, we started with the estimated total drug expenditures for FY 2014-15 using the upper bound of the 95 percent CI from the linear regression model. ADAP then subtracted savings for all assumptions. The "baseline," or center cell, highlighted in light blue below, reflects all adjustments to the linear regression expenditure projection. Table 17, below, provides a range of values to assist in projecting the total expenditures for FY 2014-15.

TABLE 17: SENSITIVITY ANALYSIS FOR FISCAL YEAR 2014-15 EXPENDITURES' ESTIMATE USING LINEAR REGRESSION MODEL							
\$ / Client Scenarios	Number of Client Scenarios						
	Hi (-) CI	Med (-) CI	Lo (-) CI	Zero Change in Clients	Lo (+) CI	Med (+) CI	Hi (+) CI
<b>Hi (-): Best</b>	\$397,792,835	\$401,871,504	\$405,950,173	\$410,028,842	\$414,107,510	\$418,186,179	\$422,264,848
<b>Med (-)</b>	\$401,871,504	\$405,992,221	\$410,112,938	\$414,233,655	\$418,354,372	\$422,475,088	\$426,595,805
<b>Lo (-)</b>	\$405,950,173	\$410,112,938	\$414,275,703	\$418,438,468	\$422,601,233	\$426,763,998	\$430,926,763
<b>Zero Change in \$ / Client</b>	\$410,028,842	\$414,233,655	\$418,438,468	\$422,643,281	\$426,848,094	\$431,052,907	\$435,257,720
<b>Lo (+)</b>	\$414,107,510	\$418,354,372	\$422,601,233	\$426,848,094	\$431,094,955	\$435,341,817	\$439,588,678
<b>Med (+)</b>	\$418,186,179	\$422,475,088	\$426,763,998	\$431,052,907	\$435,341,817	\$439,630,726	\$443,919,635
<b>Hi (+): Worst</b>	\$422,264,848	\$426,595,805	\$430,926,763	\$435,257,720	\$439,588,678	\$443,919,635	\$448,250,593

## APPENDIX F: ASSUMPTION METHODOLOGY

### New Assumptions

#### 1. Addition of Hepatitis C Drugs Simeprevir and Sofosbuvir to the ADAP Formulary

Additional costs for adding two newly-FDA-approved hepatitis C drugs, simeprevir (trade name Olysio) and sofosbuvir (trade name Sovaldi), to the ADAP formulary were estimated as follows:

- a. Based on the estimated ADAP clients in FY 2014-15, multiplied 12 percent co-infection rate for HIV and hepatitis C from a 2011 match of HIV/AIDS and hepatitis C surveillance data (12 percent of 37,873 = 4,544).
- b. Of the co-infected clients, ADAP estimated that 10 percent would receive HCV treatment in FY 2014-15 (10 percent of 4,544 clients = 454). This 10 percent estimate is based on expert opinion from consultation with a number of HIV/HCV co-treatment experts in California. Barriers to treating a higher percentage of HIV/HCV co-infected patients in FY 2014-15 include patients not knowing that they can or should be treated for HCV or not feeling that this is a priority, serious medical co-morbidities that make curing HCV not a priority, lack of providers with HCV expertise, and limited capacity for treating the large number of HIV/HCV co-infected patients among providers with HCV expertise. As explained on page 10, ADAP clients with advanced liver disease will be prioritized for HCV treatment within available resources.
- c. HCV treatment is based on the HCV genotype of the treated patient. The distribution of HCV genotypes in the United States HCV-infected population is shown in Table 18, page 49. HCV drug treatment and duration is based on recommendations for treating HIV/HCV co-infected patients published by the American Association for the Study of Liver Diseases and the Infectious Diseases Society of America (<http://hcvguidelines.org>, accessed March 12, 2014). Treatment costs are separated by genotype and interferon eligibility. Treatment cost includes only costs for sofosbuvir and/or simeprevir, and does not include costs for pegylated interferon and/or ribavirin, which are already on ADAP's formulary and are recommended to be used in conjunction with sofosbuvir and/or simeprevir. Initial estimated total expenditures for FY 2014-15 are \$34.4 million (\$44.6 million in drug expenditures and \$10.3 million in rebate), assuming all clients are ADAP-only.

GENOTYPE	GENOTYPE PERCENT	INTERFERON ELIGIBLE	TREATMENT AND DURATION IN WEEKS	NUMBER OF CLIENTS	EXPEND\$	REBATE	NET COST\$
1	77.6%	Eligible (90%)	SOF X 12 wks	317	\$27,343,926	\$6,289,103	\$21,054,823
		Ineligible (10%)	SOF X 24 wks (5%)	18	\$3,038,214	\$698,789	\$2,339,425
			SOF + SMV X 12 wks (5%)	18	\$2,719,195	\$625,415	\$2,093,780
2	14.6%	N/A	SOF X 12 wks	67	\$5,731,793	\$1,318,312	\$4,413,480
3	6.5%	N/A	SOF X 24 wks	29	\$5,078,754	\$1,168,113	\$3,910,641
4	1.2%	Eligible (50%)	SOF X 12 wks	3	\$236,722	\$54,446	\$182,276
		Ineligible (50%)	SOF X 24 wks	3	\$473,443	\$108,892	\$364,551
<b>TOTAL</b>	<b>100.00%</b>			<b>454</b>	<b>\$44,622,047</b>	<b>\$10,263,071</b>	<b>\$34,358,976</b>

SOF = sofosbuvir and SMV = simeprevir.  
 For SOF, \$28,728 for 4-week or \$86,184 for 12-week treatment per client before rebate.  
 For SMV, \$22,695 for 4-week or \$68,085 for 12 week treatment per client before rebate.  
 For 18 clients on both SOF and SMV, SOF expenditures = \$1,519,107 and SMV expenditures = \$1,200,088 before rebate.

d. For final expenditures, ADAP estimated the impact of different coverage groups based on FY 2012-13 client and expenditure per prescription data. That is, 57.8 percent of clients were ADAP-only, 1.6 percent were Medi-Cal, 17.3 percent were private insurance, and 23.3 percent were Medicare Part D. Before rebate, the average expenditure per full treatment course was \$98,286 (\$44.6 million / 454 clients). Final ADAP-only expenditures of \$25.8 million were calculated by multiplying the average expenditure per treatment by the number of clients who were ADAP-only (57.8 percent of 454 = 262 clients; and \$98,286 X 262 clients = \$25.8 million). Based on FY 2012-13 data, the other coverage groups were calculated as a percentage of ADAP-only expenditure per prescription (Medi-Cal = 68.2 percent, private insurance = 18.8 percent, and Medicare Part D = 11.5 percent), and expenditures were calculated accordingly (for private insurance, 17.3 percent of 454 = 79 clients; 18.8 percent of \$98,286 = \$18,479; and \$18,479 X 79 clients = \$1.5 million).

e. Rebate was calculated at 23 percent of ADAP-only expenditures, except for Medi-Cal in which there was no rebate, for a total of \$8.0 million (for ADAP-only, 23 percent of \$25.8 million = \$5.9 million; and for private insurance, \$98,286 X 79 clients X 23 percent = \$1.8 million). Additionally, the six-month delay in rebate collections will result in more “up front” costs for a final estimate of **\$24.9 million**.

Individual net costs per drug were calculated as \$24,051,900 for sofosbuvir and \$870,488 for simeprevir.

f. In addition to the cost of new HCV drugs, treatment guidelines recommend concurrent usage with pegylated interferon and ribavirin for most clients. In Table 18, the interferon eligible clients for genotype 1 and 4 would have additional costs for

both of these drugs. For genotypes 2 and 3, there would be additional costs only for ribavirin. Expenditures by coverage were computed in the same manner as sofosbuvir and simeprevir in step d, along with appropriate rebate return percentages.

<b>TABLE 19: ESTIMATED EXPENDITURES FOR NEW HEP C DRUGS BY COVERAGE GROUP, FY 2014-15</b>				
<b>COVERAGE GROUP</b>	<b>CLIENTS</b>	<b>TOTAL EXPEND\$</b>	<b>REBATE</b>	<b>ADJUSTED NET EXPEND\$</b>
ADAP Only	262	\$25,764,272	\$5,925,782	\$19,838,489
Medi-Cal	7	\$500,081	\$0	\$500,081
Priv Insure	79	\$1,452,640	\$1,777,094	-\$324,454
Medicare	106	\$1,194,162	\$274,657	\$919,505
<b>TOTAL</b>	<b>454</b>	<b>\$28,911,155</b>	<b>\$7,977,534</b>	<b>\$20,933,621</b>
<b>TOTAL WITH REBATE DELAY</b>			<b>\$3,988,767</b>	<b>\$24,922,388</b>

In addition to the cost of new HCV drugs, treatment guidelines recommend concurrent usage with pegylated interferon and/or ribavirin for most clients. In Table 18, the interferon eligible clients for genotype 1 and 4 would have additional costs for both of these drugs. For genotypes 2 and 3, there would be additional costs only for ribavirin. Expenditures by coverage were computed in the same manner as sofosbuvir and simeprevir in step d, along with appropriate rebate return percentages.

<b>TABLE 20: ESTIMATED EXPENDITURES FOR PEG-INTERFERON AND RIBAVIRIN BY COVERAGE GROUP, FY 2014-15</b>				
<b>COVERAGE GROUP</b>	<b>CLIENTS</b>	<b>TOTAL EXPEND\$</b>	<b>REBATE</b>	<b>ADJUSTED NET EXPEND\$</b>
ADAP Only	240	\$1,956,830	\$1,204,552	\$752,278
Medi-Cal	7	\$37,982	\$0	\$37,982
Private Insurance	72	\$110,330	\$361,235	-\$250,905
Medicare	97	\$90,698	\$486,144	-\$395,446
<b>TOTAL</b>	<b>416</b>	<b>\$2,195,840</b>	<b>\$2,051,931</b>	<b>\$143,909</b>
<b>TOTAL WITH REBATE DELAY</b>			<b>\$1,025,966</b>	<b>\$1,169,875</b>

- f. Final costs for sofosbuvir and simeprevir, including concurrent treatment with pegylated interferon and/or ribavirin in applicable clients, were computed by summing up the expenditures, rebate, and adjusted net expenditures in Tables 19 and 20.

<b>TABLE 21: ESTIMATED EXPENDITURES FOR NEW HCV DRUGS AND PEGYLATED INTERFERON AND RIBAVIRIN BY COVERAGE GROUP, FY 2014-15</b>				
<b>COVERAGE GROUP</b>	<b>CLIENTS</b>	<b>TOTAL EXPEND\$</b>	<b>REBATE</b>	<b>ADJUSTED NET EXPEND\$</b>
ADAP Only	262	\$27,721,102	\$7,130,334	\$20,590,768
Medi-Cal	7	\$538,063	\$0	\$538,063
Private Insurance	79	\$1,562,970	\$2,138,329	-\$575,359
Medicare	106	\$1,284,860	\$760,801	\$524,059
<b>TOTAL</b>	<b>454</b>	<b>\$31,106,995</b>	<b>\$10,029,465</b>	<b>\$21,077,530</b>
<b>TOTAL WITH REBATE DELAY</b>			<b>\$5,014,733</b>	<b>\$26,092,263</b>