

**AIDS DRUG ASSISTANCE PROGRAM
(ADAP)
November 2009
Estimate Package**

2010-11 GOVERNOR'S BUDGET



**Mark B Horton, MD, MSPH
Director**

**CALIFORNIA
DEPARTMENT OF PUBLIC HEALTH**

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1. FISCAL COMPARISON TABLES

TABLE 1a: Expenditure Comparison: FY 2009-10 November Estimate to FY 2009-10 Budget Act (000's)												
	2009-10 November Estimate				2009-10 Appropriation				Difference			
	Total	Federal	State	Rebate Fund	Total	Federal	State	Rebate Fund	Total	Federal	State	Rebate Fund
Local Assistance Funding	\$419,896	\$92,927	\$70,849	\$256,120	\$414,033	\$92,927	\$70,849	\$250,257	\$5,863	\$0	\$0	\$5,863
Drug Expenditure Estimate	417,763	92,927	70,849	253,987	412,033	92,927	70,849	248,257	5,730	0	0	5,730
Prescription Costs	405,297	90,046	69,137	246,114	399,894	85,458	69,698	244,738	5,403	4,588	-561	1,376
Basic Prescription Costs	405,297	90,046	69,137	246,114	399,894	85,458	69,698	244,738	5,403	4,588	-561	1,376
Eliminate Services to County Jails	0	0	0	0	0	0	0	0	0	0	0	0
PBM Operational Costs	12,466	2,881	1,712	7,873	12,139	7,469	1,151	3,519	327	-4,588	561	4,354
Basic PBM Costs	12,966	2,881	2,212	7,873	12,639	7,469	1,651	3,519	327	-4,588	561	4,354
Administrative Reduction	-500	0	-500	0	-500	0	-500	0	0	0	0	0
Eliminate Services to County Jails	0	0	0	0	0	0	0	0	0	0	0	0
LHJ Administration	1,000	0	0	1,000	1,000	0	0	1,000	0	0	0	0
Medicare Part D	1,000	0	0	1,000	1,000	0	0	1,000	0	0	0	0
Tropism Assay*	133	0	0	133	0	0	0	0	133	0	0	133
Support/Administration Funding	\$2,648	\$1,178	\$411	\$1,059	\$2,560	\$1,178	\$218	\$1,164	\$88	\$0	\$193	-\$105

TABLE 1b: Expenditure Comparison: FY 2010-11 November Estimate to FY 2009-10 Budget Act (000's)												
	2010-11 Governor's Budget				2009-10 Appropriation				Difference			
	Total	Federal	State	Rebate Fund	Total	Federal	State	Rebate Fund	Total	Federal	State	Rebate Fund
Local Assistance Funding	\$462,128	\$92,927	\$158,311	\$210,890	\$414,033	\$92,927	\$70,849	\$250,257	\$48,095	\$0	\$87,462	-\$39,367
Drug Expenditure Estimate	459,995	92,927	158,311	208,757	412,033	92,927	70,849	248,257	47,962	0	87,462	-39,500
Prescription Costs	446,061	90,046	153,888	202,127	399,894	85,458	69,698	244,738	46,167	4,588	84,190	-42,611
Basic Prescription Costs	456,950	90,046	163,118	203,786	399,894	85,458	69,698	244,738	57,056	4,588	93,420	-40,952
Eliminate Services to County Jails	-10,889	0	-9,230	-1,659	0	0	0	0	-10,889	0	-9,230	-1,659
PBM Operational Costs	13,934	2,881	4,423	6,630	12,139	7,469	1,151	3,519	1,795	-4,588	3,272	3,111
Basic PBM Costs	14,782	2,881	5,218	6,683	12,639	7,469	1,651	3,519	2,143	-4,588	3,567	3,164
Administrative Reduction	-500	0	-500	0	-500	0	-500	0	0	0	0	0
Eliminate Services to County Jails	-348	0	-295	-53	0	0	0	0	-348	0	-295	-53
LHJ Administration	1,000	0	0	1,000	1,000	0	0	1,000	0	0	0	0
Medicare Part D	1,000	0	0	1,000	1,000	0	0	1,000	0	0	0	0
Tropism Assay*	133	0	0	133	0	0	0	0	133	0	0	133
Support/Administration Funding	\$2,657	\$1,178	\$411	\$1,068	\$2,560	\$1,178	\$218	\$1,164	\$97	\$0	\$193	-\$96

TABLE 1c: Expenditure Comparison: FY 2010-11 November Estimate to FY 2009-10 November Estimate (000's)												
	2010-11 Governor's Budget				2009-10 November Estimate				Difference			
	Total	Federal	State	Rebate Fund	Total	Federal	State	Rebate Fund	Total	Federal	State	Rebate Fund
Local Assistance Funding	\$462,128	\$92,927	\$158,311	\$210,890	\$419,896	\$92,927	\$70,849	\$256,120	\$42,232	\$0	\$87,462	-\$45,230
Drug Expenditure Estimate	459,995	92,927	158,311	208,757	417,763	92,927	70,849	253,987	42,232	0	87,462	-45,230
Prescription Costs	446,061	90,046	153,888	202,127	405,297	90,046	69,137	246,114	40,764	0	84,751	-43,987
Basic Prescription Costs	456,950	90,046	163,118	203,786	405,297	90,046	69,137	246,114	51,653	0	93,981	-42,328
Eliminate Services to County Jails	-10,889	0	-9,230	-1,659	0	0	0	0	-10,889	0	-9,230	-1,659
PBM Operational Costs	13,934	2,881	4,423	6,630	12,466	2,881	1,712	7,873	1,468	0	2,711	-1,243
Basic PBM Costs	14,782	2,881	5,218	6,683	12,966	2,881	2,212	7,873	1,816	0	3,006	-1,190
Administrative Reduction	-500	0	-500	0	-500	0	-500	0	0	0	0	0
Eliminate Services to County Jails	-348	0	-295	-53	0	0	0	0	-348	0	-295	-53
LHJ Administration	1,000	0	0	1,000	1,000	0	0	1,000	0	0	0	0
Medicare Part D	1,000	0	0	1,000	1,000	0	0	1,000	0	0	0	0
Tropism Assay*	133	0	0	133	133	0	0	133	0	0	0	0
Support/Administration Funding	\$2,657	\$1,178	\$411	\$1,068	\$2,648	\$1,178	\$411	\$1,059	\$9	\$0	\$0	\$9

*Tropism Assay is a laboratory test required to demonstrate clinical indication for one of the antiretroviral agents covered by ADAP. These costs were not displayed separately in prior estimates but the amount is reflected within Rebate Fund drug expenditures (2009-10 Appropriation).

TABLE 2a: Resource Comparison: FY 2009-10 November Estimate to FY 2009-10 Budget Act (000's)

	2009-10 November Estimate				2009 -10 Appropriation				Difference			
	Total	Federal	State	Rebate Fund	Total	Federal	State	Rebate Fund	Total	Federal	State	Rebate Fund
Available Resources	\$349,665	\$94,105	\$71,260	\$184,300	\$348,586	\$94,105	\$71,067	\$183,414	\$1,079	\$0	\$193	\$886
Basic Rebate Revenues	182,300	0	0	182,300	180,414	0	0	180,414	1,886	0	0	1,886
Income from Surplus Money Investments	2,000	0	0	2,000	3,000	0	0	3,000	-1,000	0	0	-1,000
Federal Funds	94,105	94,105	0	0	94,105	94,105	0	0	0	0	0	0
General Fund	71,260	0	71,260	0	71,067	0	71,067	0	193	0	193	0
Eliminate Services to County Jails	0	0	0	0	0	0	0	0	0	0	0	0

TABLE 2b: Resource Comparison: FY 2010-11 November Estimate to FY 2009-10 Budget Act (000's)

	2010-11 Governor's Budget				2009-10 Appropriation				Difference			
	Total	Federal	State	Rebate Fund	Total	Federal	State	Rebate Fund	Total	Federal	State	Rebate Fund
Available Resources	\$457,584	\$94,105	\$158,722	\$204,757	\$348,586	\$94,105	\$71,067	\$183,414	\$108,998	\$0	\$87,655	\$21,343
Basic Rebate Revenues	204,469	0	0	204,469	180,414	0	0	180,414	24,055	0	0	24,055
Income from Surplus Money Investments	2,000	0	0	2,000	3,000	0	0	3,000	-1,000	0	0	-1,000
Federal Funds	94,105	94,105	0	0	94,105	94,105	0	0	0	0	0	0
General Fund	168,247	0	168,247	0	71,067	0	71,067	0	97,180	0	97,180	0
Eliminate Services to County Jails	-11,237	0	-9,525	-1,712	0	0	0	0	-11,237	0	-9,525	-1,712

TABLE 2c: Resource Comparison: FY 2010-11 November Estimate to FY 2009-10 November Estimate (000's)

	2010-11 Governor's Budget				2009-10 November Estimate				Difference			
	Total	Federal	State	Rebate Fund	Total	Federal	State	Rebate Fund	Total	Federal	State	Rebate Fund
Available Resources	\$457,584	\$94,105	\$158,722	\$204,757	\$349,665	\$94,105	\$71,260	\$184,300	\$107,919	\$0	\$87,462	\$20,457
Basic Rebate Revenues	204,469	0	0	204,469	182,300	0	0	182,300	22,169	0	0	22,169
Income from Surplus Money Investments	2,000	0	0	2,000	2,000	0	0	2,000	0	0	0	0
Federal Funds	94,105	94,105	0	0	94,105	94,105	0	0	0	0	0	0
General Fund	168,247	0	168,247	0	71,260	0	71,260	0	96,987	0	96,987	0
Eliminate Services to County Jails	-11,237	0	-9,525	-1,712	0	0	0	0	-11,237	0	-9,525	-1,712

2. MAJOR ASSUMPTIONS

Estimate Methodology for Information Only

Expenditure and revenue estimates for Fiscal Year (FY) 2010-11 were derived from a linear regression model as used in the FY 2009-10 Estimate. The *May Revision* model used a data set beginning January 2006 to February 2009. The data set for the FY 2010-11 *November Estimate* includes data through July 2009. Expenditure and revenue adjustments were made to estimate the impact of the new major assumption that discontinues ADAP services in county jails. To estimate the expenditure and revenue impact from eliminating ADAP in jails, the percentage of expenditures and revenue associated with jail services in FY 2007-08 was calculated. This percentage was then applied to the unadjusted FY 2010-11 expenditure and revenue estimates to estimate the expected contribution of jail services on FY 2010-11 expenditures and revenues. These amounts were subtracted from the unadjusted FY 2010-11 expenditure and revenue estimates to arrive at the final adjusted estimates.

Methodologies for developing the previous estimates (*May Revision* for FY 2009-10 and Governor's Budget FY 2009-10) also included an alternative percent change model (for reference only). The percent change model is not included in the FY 2010-11 estimate since the linear regression model provides the more reliable estimates at this time.

New Major Assumption

1. Discontinue ADAP services in county jails - ADAP began serving inmates in county jails in 1994 due to the increasing fiscal impact on local health jurisdictions in meeting their mandate to provide medical services to their incarcerated populations. Thirty-six local jails participated in ADAP in FY 2008-09, servicing 1,862 clients. In FY 2010-11, it is projected that 2,027 incarcerated individuals would have been served by ADAP should this reduction have not occurred. The impact of this change in ADAP coverage will increase the fiscal burden at the county level. Both the Government Code (Section 29602) and the Penal Code (Sections 4011et seq. and 4015[a]) address the issue of providing medical care to inmates in local jails. These codes specifically provide that local health jurisdictions (LHJs) are primarily liable for inmate care in the jails.

Change from Prior Estimate: This is a new major assumption for FY 2010-11. This assumption requires trailer bill language (TBL) to amend (HSC 120955 (a)(1)) to specifically address eligibility of individuals while incarcerated in county jails.

Revised Major Assumptions

There are no Revised Major Assumptions.

Discontinued Major Assumptions

Medi-Cal Policy Change 163: New Qualified Aliens (NQAs) and Permanently Residing Under Color of Law (PRUCOL) immigrants and Amnesty Aliens
A Medi-Cal policy change made this assumption unnecessary.

Modified Assumption

1. Decrease Interest Earned on Special Fund (SF) 3080 - The Budget Act of FY 2009-10 estimated interest income at \$3 million for FY 2009-10. Actual interest earned for FY 2008-

09 was \$2.1 million. Since interest rates have declined due to the economic downturn, and there will be less money in the fund to accumulate interest, the estimate has been reduced for both FYs 2009-10 and 2010-11 to \$2 million annually.

Change from Prior Estimate: This is a modified assumption for FY 2010-11 that will also impact FY 2009-10 revenues. This change will result in decreased revenues.

3. FUND CONDITION STATEMENT

The Fund Condition Statement (FCS), (see Table 3, page 5) shows the status of the ADAP SF for FYs 2008-09, 2009-10, and 2010-11 and all the factors that impact the fund including revenue, expenditures, and changes to the revenue collection rate and interest earned.

For FYs 2009-10 and 2010-11, the FCS was developed using a revenue collection rate of 46 percent of actual expenditures for January to June 2009 and projected expenditures from July 2009 to December 2010. Actual revenue (rebate collections) is shown for FY 2008-09. Projected expenditures were based on the linear regression methodology using actual expenditure data for the period January 2006 to July 2009. (For a detailed comparison of estimated revenues for FY 2009-10 as shown in the *November Estimate* and in the previous estimate for the FY 2009-10 Budget Act, see Table 9, page 11.)

Effective with the FY 2009-10 Budget Act, projected ADAP expenditures reflect a permanent \$25 million General Fund (GF) reduction to overall ADAP expenditures, restored by \$25 million SF, and a \$500,000 GF reduction to the Pharmacy Benefits Management (PBM) contract administrative costs.

For FY 2009-10, there is an increase in expenditures due to revised and updated client caseload and expenditure estimates based on linear regression which result in more rebate revenue.

For FY 2010-11, the Governor's Budget reflects a net increase in ADAP funding of \$48,095,000. This is the result of a \$97 million GF increase related to increased caseload and increased cost of prescription drugs (\$59.3 million GF) as well as an increase to backfill a projected shortfall (and maintain a prudent five-percent reserve) in the ADAP Rebate Fund (\$37.7 million GF). This increase is partially offset by \$9.5 million GF savings and \$1.7 million SF savings resulting from the proposed elimination of ADAP services to county jails, effective July 1, 2010. Thus, the net GF augmentation proposed for ADAP in FY 2010-11 is \$87.5 million.

NOVEMBER ESTIMATE FUND CONDITION STATEMENT

TABLE 3: FUND CONDITION STATEMENT (in thousands)		FY 2008-09 actuals	FY 2009-10 estimate	FY 2010-11 estimate
Special Fund 3080 AIDS Drug Assistance Program Rebate Fund				
1	BEGINNING BALANCE	80,356	91,183	18,116
2	Prior Year Adjustment	23,938	0	0
3	Adjusted Beginning Balance	104,294	91,183	18,116
4	REVENUES, TRANSFERS AND OTHER ADJUSTMENTS			
5	Revenues			
6	150300 Income From Surplus Money Investments	2,106	2,000	2,000
7	161400 Miscellaneous Revenue	157,852	182,300	202,757
8	Total Revenues, Transfers, and Other Adjustments	159,958	184,300	204,757
9	Total Resources	264,252	275,483	222,873
10	EXPENDITURES AND EXPENDITURE ADJUSTMENTS			
11	Expenditures			
	8880 FISCAL			1
12	0840 State Controllers Office	1	23	57
13	4260 Department of Health Care Service (State Ops)	0	165	159
14	4265 Department of Public Health			
15	State Operations	1,158	1,059	1,068
16	Local Assistance	171,910	256,120	210,890
17				
18				
19	Total Expenditures and Expenditure Adjustments	173,069	257,367	212,175
20	FUND BALANCE	91,183	18,116	10,698

Row 6: Estimates based on actual interest earned for FY 2008-09 (lower than expected). FY 2009-10 through FY 2010-2011 estimated at \$2M per year.

	2,000,000	2,000,000
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Miscellaneous Revenue

Actual expenditures for Jan - June 2009
Estimated expenditures for July - Dec 2009

	187,422,300
	208,881,488

Estimated expenditures for Jan - June 2010
Estimated expenditures for July - Dec 2010

	208,881,488
	235,616,072

Estimated expenditures for Jan - June 2011
Estimated expenditures for July - Dec 2011

Estimated Calendar Year Expenditures

	396,303,788	444,497,560
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Estimated revenue at 46% rebate collection rate on 396,303,788
Estimated revenue at 46% rebate collection rate on 444,497,560

	182,299,742	
		204,468,878

Revenue Impact: Eliminate Services to Jails

	-1,712,458
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Row 7: Projection of Total Revenue after Cost Containment

	182,299,742	202,756,420
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Linear Regression Expenditure Projection
Administrative Reduction to PBM Contract
Subtotal: Local Assistance Expenditure Estimate
Expenditure Impact: Eliminate Services to Jails
Subtotal: Expenditure Projection after Cost Containment
Less: Federal Fund Appropriation (Earmark)
Less: General Fund Appropriation
SF Balance After Strategies (Need)
Additional Need (Reserve - 5% of SF Expenditures)

	418,262,976	471,732,143
	-500,000	-500,000
	417,762,976	471,232,143
		-11,237,140
	417,762,976	459,995,003
	-92,926,756	-92,926,756
	-70,849,000	-70,849,000
		-76,764,000
		-10,698,000
		-87,462,000

General Fund Augmentation
Special Fund 3080 need to meet Expenditure Estimate

	253,987,220	208,757,247
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Local Assistance LHJ
Local Assistance Medicare Part D
Tropism Assay

	1,000,000	1,000,000
	1,000,000	1,000,000
	132,623	132,623

Row 16: Total Special Fund Need

	256,119,843	210,889,870
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4. HISTORICAL PROGRAM DATA AND TRENDS

(*Data for FYs 2009-10 and 2010-11 are estimated, all other data actual)

All data represent actuals except FYs 2009-10 and 2010-11 data which are estimates derived from the following methods: 1) for the clients and prescription estimates (figures 1, 2 and 4), the January 2006 linear regression model with monthly clients and prescriptions as data points, respectively, was used; for the drugs estimate (figure 3), we applied the percentage of prescriptions/drugs in FY 2008-09 to the FYs 2009-10 and 2010-11 prescription estimate. Note that the reduction in the estimated number of ADAP clients due to the elimination of ADAP in jails is accounted for in the figures below for FY 2010-11.

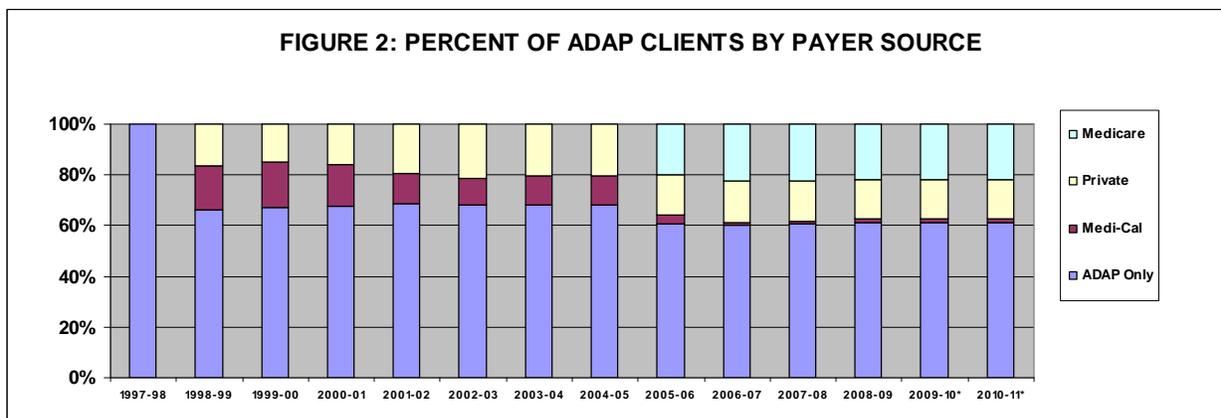
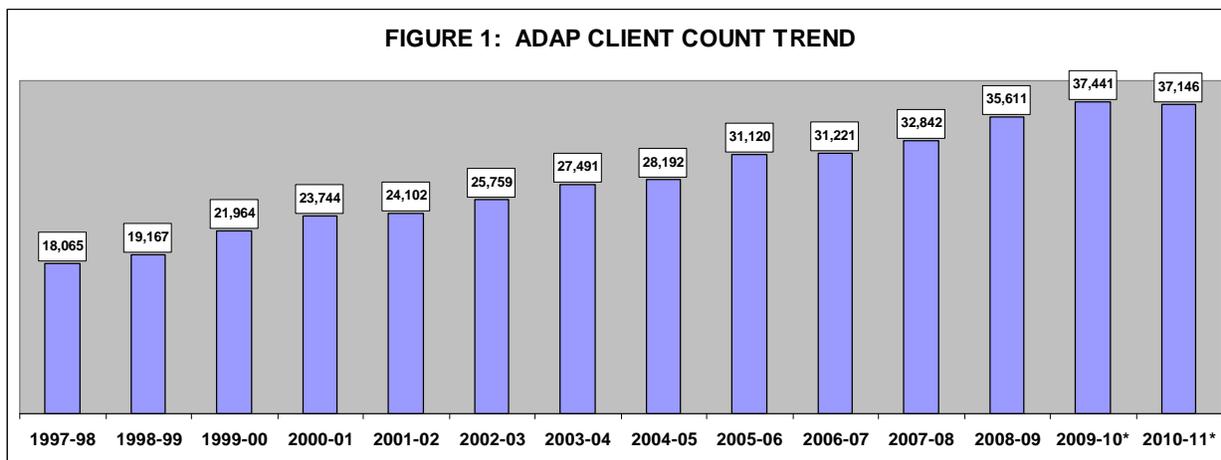
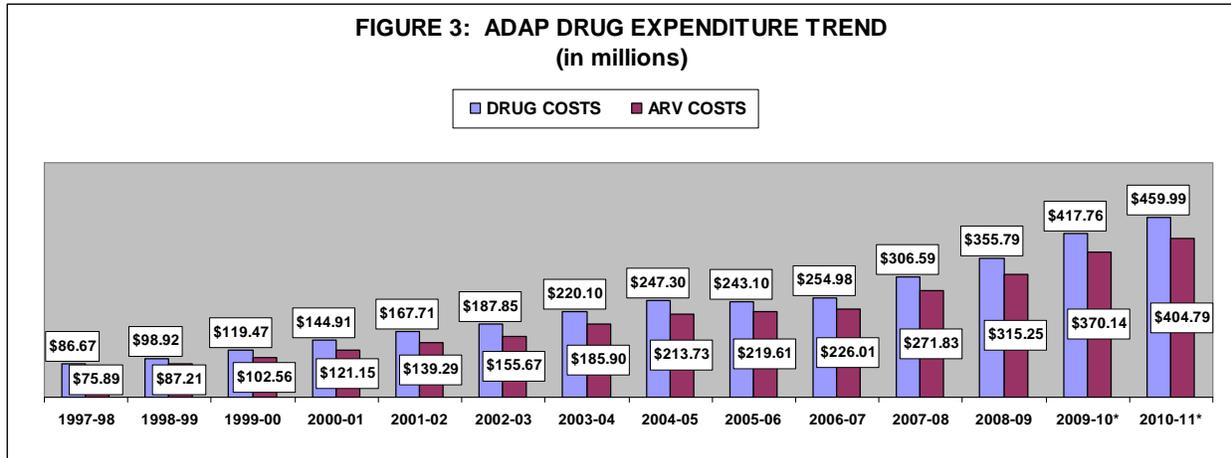
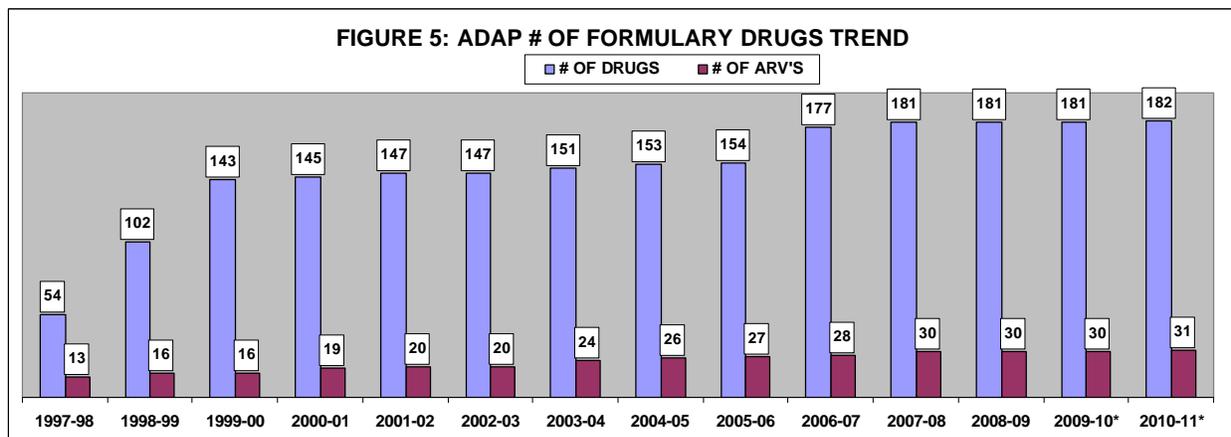
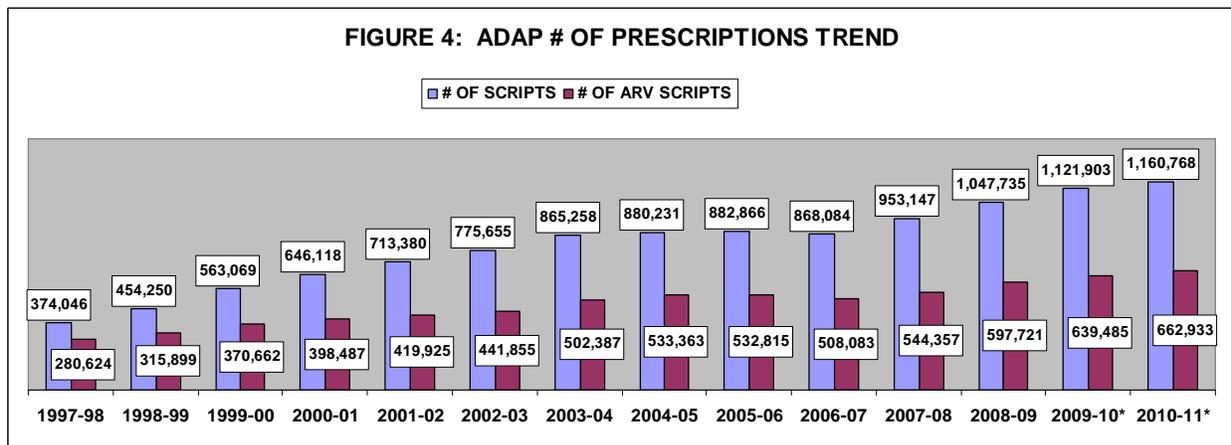


TABLE 4: ESTIMATED ADAP CLIENTS BY COVERAGE GROUP

COVERAGE GROUP	FY 2009-10*		FY 2010-11*	
	CLIENTS	PERCENT	CLIENTS	PERCENT
ADAP	22,970	61.35%	22,006	59.24%
Medi-Cal	434	1.16%	454	1.22%
Private Insurance	5,815	15.53%	6,084	16.38%
Medicare	8,222	21.96%	8,602	23.16%
TOTAL	37,441	100.00%	37,146	100.00%



Note: Non-drug expenditures including Tropism Assay (laboratory test required to demonstrate clinical indication for one of the antiretroviral (ARV) agents covered by ADAP; \$132,623 in FY 2008-09 and \$42,708 to date in FY 2009-10), and annual administrative support of \$1 million for Local Health Jurisdictions (LHJs) and Medicare Part D premium payments of \$1 million are *not* displayed here. Drug costs *do* include administrative costs at the pharmacy (\$4.05 per transaction) and PBM (\$6.00 per transaction) level.



Vicriviroc is the second drug in the CCR5 inhibitors class of ARV drugs which may be filed with the FDA within the first half of 2010 and approved in following months. If approved, ADAP's number of formulary drugs would be 182 in FY 2010-11.

APPENDIX A: EXPENDITURE AND REVENUE ESTIMATE METHODS

Drug Expenditure Estimates

Updated Expenditure Estimate for FY 2009-10

TABLE 5: LINEAR REGRESSION MODEL FOR NOVEMBER ESTIMATE, FY 2009-10 (ACTUAL DATA JANUARY 2006 THROUGH JULY 2009)			
Revised Estimate	Estimate from Budget Act 2009-10	Change from Previous Estimate (\$)	Change from Previous Estimate (%)
\$418,262,976	\$412,533,061	\$5,729,915	1.39%

New Expenditure Estimate for FY 2010-11

TABLE 6: LINEAR REGRESSION MODEL FOR NOVEMBER ESTIMATE, FY 2010-11 (ACTUAL DATA JANUARY 2006 THROUGH JULY 2009)			
November Estimate FY 2010-11	Estimate from Budget Act 2009-10	Change from Previous Estimate (\$)	Change from Previous Estimate (%)
\$471,732,143	\$412,533,061	\$59,199,082	14.35%

Linear Regression Model – Expenditure Estimates

The Linear Regression methodology is the same as that used to develop the FY 2009-10 Budget Act expenditure estimate. Updated data points include actual expenditures from January 2006 through July 2009 (as opposed to January 2006 through February 2009 for the FY 2009-10 Budget Act) to maximize its predictive accuracy. Thus, five more data points (expenditures from March 2009 through July 2009) were added to the data set for a total of 43 data points.

Figure 6, page 9 shows ADAP historic expenditures by month. The (thick straight black) regression line represents the best fitting straight line for estimating the expenditures:

- During normal growth periods, a Linear Regression Model should accurately predict expenditures (the black regression line goes straight through the data points).
- During low growth periods, a Linear Regression Model would overestimate expenditures (the black regression line goes over the data points). Thus, for the single low growth period in the past, we elected to use an alternative model, the percent change model (for more information on the history of the projection model see Appendix I).
- During high growth periods, a Linear Regression Model using the point estimate would underestimate expenditures (the black regression line goes under the data points). Thus, given the recent relatively high growth expenditure period beginning in 2007-08, and the desire not to underestimate the need for ADAP to utilize the ADAP SF to address increasing expenditures, we continue to use the upper bound of the 95 percent confidence interval

around the point estimate for our regression estimates. This is the same strategy used for the FY 2009-10 budget estimates.

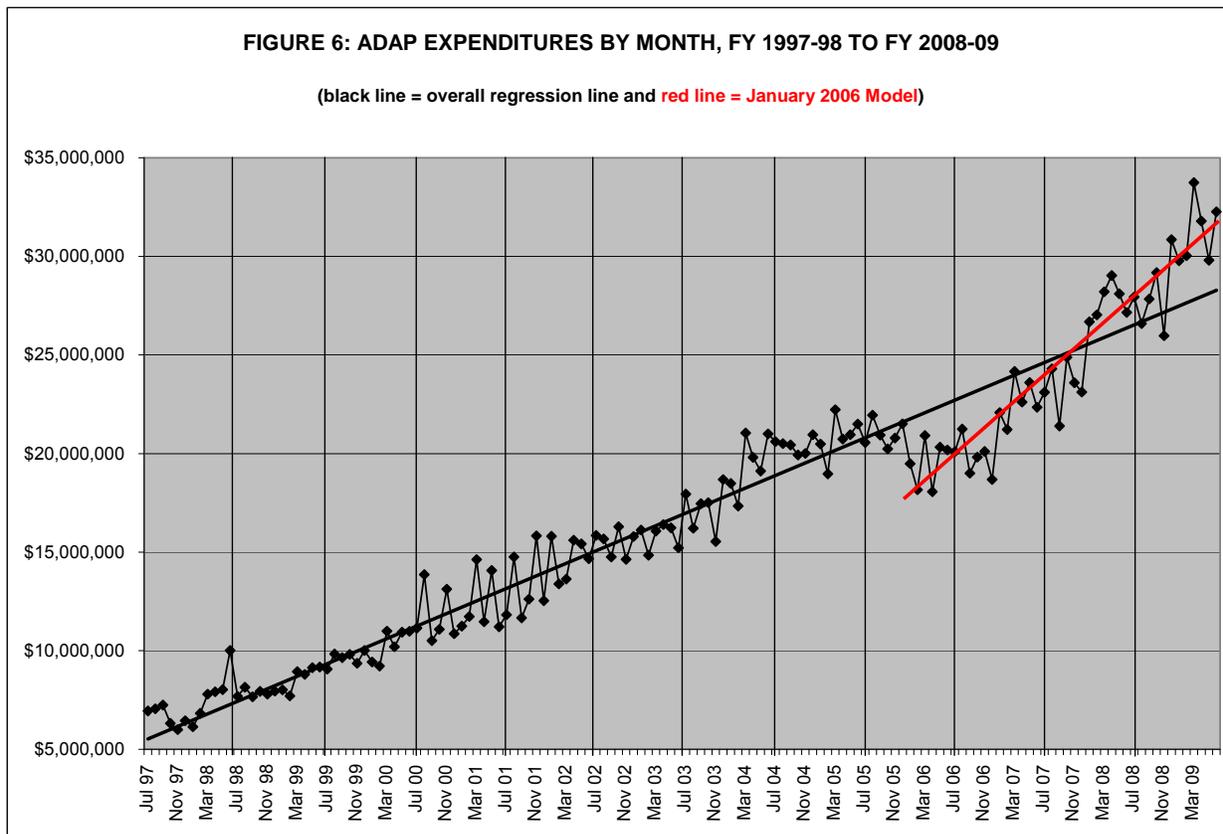


Table 7 shows historic drug expenditures by FY, annual change and percent change.

Fiscal Year	Expenditures	Annual Change in Expenditures	Pct Annual Change
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%
Total Average	98-99 to 08-09	\$24,464,733	13.90%

Note: Non-drug expenditures including Tropism Assay (\$132,623 in FY 2008-09 and \$42,708 to date in FY 2009-10), and annual administrative support of \$1 million for Local Health Jurisdictions (LHJs) and Medicare Part D premium payments of \$1 million are *not* displayed here. Drug costs *do* include administrative costs at the pharmacy and PBM level.

Program Expenditure Estimate for FY 2010-11

In addition to the drug expenditure estimates noted in Table 7, page 9, total estimated program costs include:

1. Tropism Assay \$132,623
2. Administrative support for LHJs \$1 million
3. Medicare Part D premium payments \$1 million
4. The reduction to the Pharmacy Management Benefit contract of \$500,000.
5. Elimination of services in jails (\$11,237,140)

Thus, total FY 2010-11 program expenditures are estimated at \$462,127,626. The \$11.2 million reduction was estimated by applying the percentage of jail expenditures in FY 2007-08 to the unadjusted FY 2010-11 expenditure estimate and subtracting this amount from the initial FY 2010-11 estimate.

ADAP Rebate Revenue

FY-QTR	\$ Drugs Purchased	Received in Rebate \$	Received / Purchased
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	\$18,691,012	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	\$20,612,704	32.96%
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	\$36,270,311	44.04%
2008/09-Q2	\$85,997,429	\$38,033,298	44.23%
2008/09-Q3	\$93,564,283	\$45,375,093	48.50%

46.32%

ADAP Rebate Revenue Estimate Method

The rebate revenue estimate methodology applies the expected revenue collection rate (46 percent) to estimated or actual expenditures (whichever is more current) to forecast future revenue. Estimated revenue for the FY is based on drug expenditures for the last two quarters of the previous FY and the first two quarters of the current FY to take into account the time required for billing and collection. For example, the *November Estimate 2010-11*, updates revenue projections for FY 2009-10 using actual expenditures from January to June 2009 (last half of FY 2008-09) and estimates expenditures from July to December 2009 (the first half of FY 2009-10). The revenue estimate for FY 2010-11 uses estimated expenditures for the period January - June 2010 (last half of FY 2009-10) and estimated expenditures from July to December 2010 (first half of FY 2010-11).

Revenue estimates for *May Revision FY 2010-11* will use updated data from these time periods and include actual rebates collected, actual expenditures, and updated expenditure estimates. It should be noted that the current revenue estimate method uses average expenditures for each six-month period and does not take into account the seasonal behavior of expenditures that historical data now show. That is, historical data now show that drug expenditures are lower in the first half of the FY (July to December) compared to the second.

While the elimination of services to county jails reduces expenditures, it also results in an associated reduction in rebate revenue collected. The methodology used to calculate the reduction in rebate revenue is based on the percentage of revenue associated with jail services in FY 2007-08. This percentage was applied to estimated revenue from the first half of FY 2010-11 and subtracted from the initial rebate estimate. Revenue from the last half of FY 2009-10 would be exempt from this adjustment because elimination of jail services will begin in July 2010.

TABLE 9: COMPARISON OF REBATE REVENUE* BETWEEN NOVEMBER ESTIMATE FY 2010-11 AND Budget Act 2009-10						
UPDATED ESTIMATE FOR FY 2009-10						
Expenditure Period	Available Data	Updated Per November Estimate FY 2009-10	Available Data	Budget Act FY 2009-10	Change (\$)	Change (%)
Jan - Jun 2009	Actual Expenditures @ 46%	\$86,214,258	Estimate Expenditures @ 46%	\$85,531,370	\$682,888	0.80%
Jul - Dec 2009	Estimated Expenditures @ 46%	\$96,085,484	Estimate Expenditures @ 46%	\$94,882,604	\$1,202,880	1.27%
Subtotal Revenue		\$182,299,742		\$180,413,974	\$1,885,769	1.05%
Interest		\$2,000,000		\$3,000,000	-\$1,000,000	-33.33%
Total Revenue (see Table 3, Fund Condition Statement)		\$184,299,742		\$183,413,974	\$885,769	0.48%
ESTIMATE FOR FY 2010-11						
Expenditure Period	Available Data	November Estimate FY 2010-11	Available Data	FY 2009-10 (Updated)	Change (\$)	Change (%)
Jan - Jun 2010	Estimated Expenditures @ 46%	\$96,085,484	Actual Expenditures @ 46% (Jan-Jun 2009)	\$86,214,258	\$9,871,226	11.45%
Jul - Dec 2010	Estimated Expenditures @ 46%	\$108,383,393	Estimated Expenditures @ 46% (Jul-Dec 2009)	\$96,085,484	\$12,297,909	12.80%
Subtotal Revenue		\$204,468,878		\$182,299,742	\$22,169,135	12.16%
FY 2010-11	Reduction: Elimination of Services to Jails	-\$1,712,458			-\$1,712,458	N/A
Interest		\$2,000,000		\$2,000,000	\$0	0.00%
Total Revenue (see Table 3, Fund Condition Statement)		\$204,756,420		\$184,299,742	\$20,456,677	11.10%

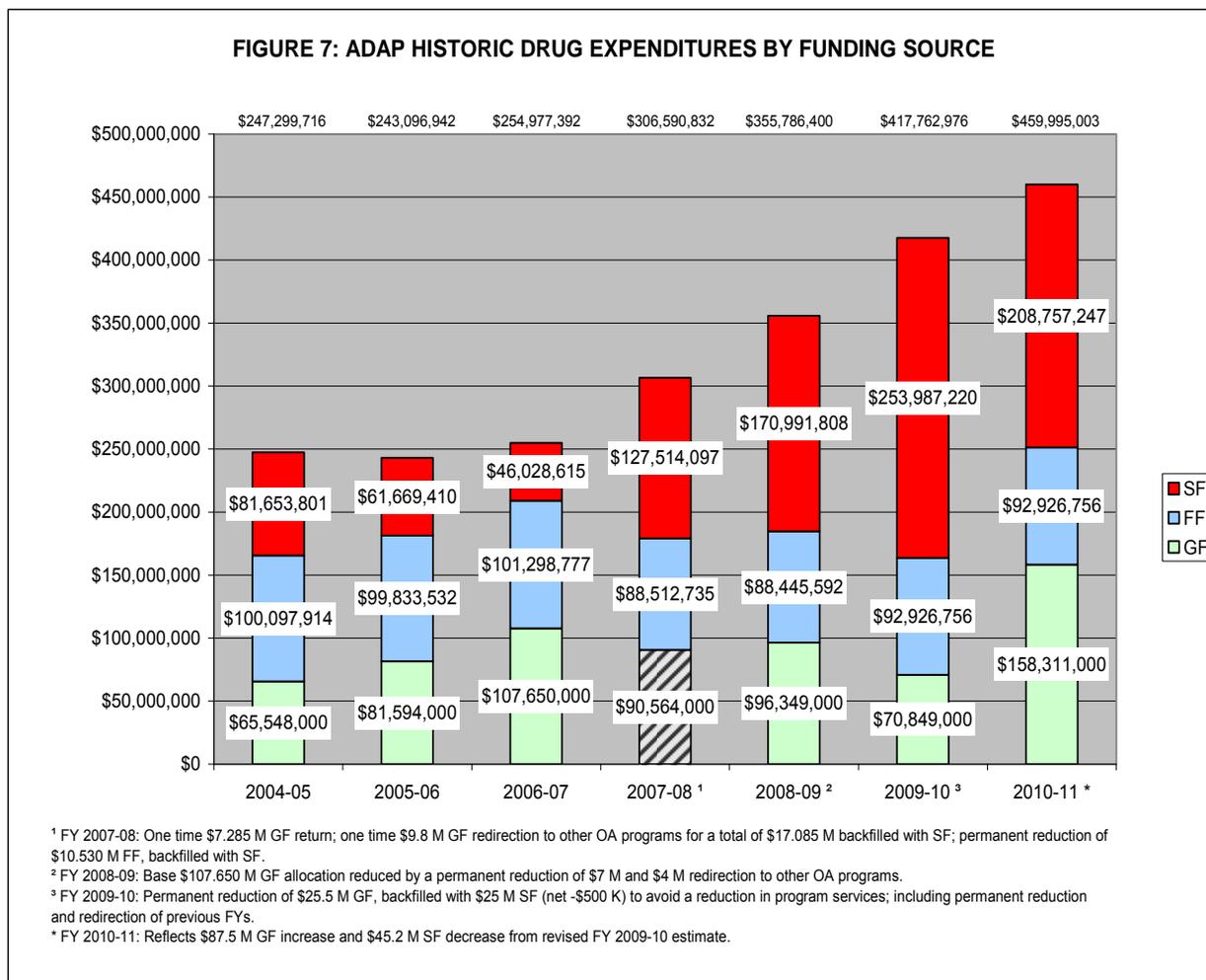
*Note: When actual rebate data are not available, revenue projection methodology bases revenue first on estimated and then actual expenditures. This method does not take into account the seasonal fluctuations between the first half of the FY (when expenditures are lowest) and the second half (when expenditures are highest).

APPENDIX B: FUND SOURCES

Payment of ADAP expenditures are made from three fund sources:

1. State GF
2. Federal funding from the Health Resources and Services Administration (HRSA) through the Ryan White HIV/AIDS Treatment Modernization Act of 2006 (RW), Part B, ADAP Earmark grant. The ADAP program has secured an award for the period April 1, 2009 - March 31, 2010. A four year extension to RW legislation for the period April 1, 2010 - March 31, 2014 has been enacted.
3. ADAP SF consists of both mandatory and voluntary rebates from manufacturers with products on the ADAP formulary.

Figure 7 (below) shows the amount and proportions of the three funding sources and the additional funding need for FY 2010-11:



General Fund

ADAP's GF allocation is used for prescription drugs for eligible clients and is the only source of funding used by ADAP to meet the Medi-Cal Share of Cost (SOC) for eligible clients, prescription expenditures for Medicare Part D clients, and a portion of the transaction fees invoiced by ADAP's PBM contractor to pay for the administrative costs associated with managing prescription transactions that are ultimately identified as not eligible for ADAP payment.

GF redirections and reductions: in FY 2007-08, due to cost saving associated with Medicare Part D and ADAP's eligibility screening enhancements and effective rebate collection system, the program returned \$7.285 million on a one-time basis to the State's GF, redirected \$9.8 million in GF to other Office of AIDS (OA) programs, and increased ADAP SF authority by \$17.085 million to back fill these redirections. In FY 2008-09, the GF incurred a permanent reduction of \$7 million; in FY 2009-10, the Budget Act included a \$25.5 million GF reduction backfilled with \$25 million from the SF.

For FY 2010-11, the Governor's Budget reflects a net increase in ADAP funding of \$48,095,000. This is the result of a \$97 million GF increase related to increased caseload and increased cost of prescription drugs (\$59.3 million GF) as well as an increase to backfill a projected shortfall (and maintain a prudent five-percent reserve) in the ADAP Rebate Fund (\$37.7 million GF). This increase is partially offset by \$9.5 million GF savings and \$1.7 million SF savings resulting from the proposed elimination of ADAP services to county jails, effective July 1, 2010. Thus, the net GF augmentation proposed for ADAP in FY 2010-11 is \$87.5 million.

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 the OA. The Part B Earmark 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.

Match

HRSA requires grantees to have HIV-related non-HRSA expenditures of at least one half of the HRSA grant award. Since California's 2009 HRSA grant award is \$128,263,422, the match requirement for FY 09-10 funding is \$64,131,711. California has met this requirement every year using General Fund.

Maintenance of Effort (MOE)

HRSA requires grantees to maintain HIV-related expenditures at a level that is not less than the prior fiscal year. California's MOE target, based on FY 2007-08 expenditures at the time of the HRSA grant application, is \$495,741,243. 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 GF expenditures specific to HIV-related activities such as care, treatment, prevention, and surveillance. SF expenditures may be used towards the MOE requirement.

Federal Fund redirections: In FY 2007-08, ADAP permanently redirected its entire \$10.53 million Federal Fund Base award to other OA programs and backfilled with ADAP SF. The shift in funding resulted in a significant drop in the historical Federal Fund expenditures for ADAP from FY 2006-07 to FY 2007-08.

ADAP SF (3080)

The ADAP SF consists of manufacturer rebates collected for drugs purchased under ADAP. This fund is comprised of both mandatory and voluntary supplemental rebates. The use of this fund is established under both state law and federal funding guidance. The ADAP SF was legislatively established in 2004 to support the provision of ADAP services. Section 120956 of the California Health and Safety Code, which established the ADAP SF, states in part:

“... (b) All rebates collected from drug manufacturers on drugs purchased through the ADAP implemented pursuant to this chapter and, notwithstanding 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 ...”

California ADAP receives both mandatory and voluntary supplemental rebates for drugs dispensed to ADAP clients, the former rebate required by state (Health and Safety Code Section 120956) and federal (Medicaid) law and the latter negotiated 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 national ADAP Crisis Task Force (ACTF). The ACTF is a rebate negotiating coalition of some of the largest ADAPs in the country (including California), working on behalf of all state ADAPs. The 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 all ARVs on the ADAP formulary. This is significant, as ARV drugs represent 90 percent of all ADAP drug expenditures. Supplemental rebate agreement terms are generally based on either:

- 1) an additional rebate percentage; and/or
- 2) a price freeze.

Additional Rebate Percentage

The federally-mandated rebate is a percentage of the Average Manufacturer Price (AMP), plus any penalties for substantial price increases. Since the AMP is confidential and not publicized, the resulting rebate amount is also unknown to ADAP. The ACTF negotiations could result in

an additional percentage of the AMP. For example, if the mandated rebate is 15 percent of AMP, and the ACTF negotiates a supplemental rebate with a manufacturer of 7 percent of AMP for a particular drug, then ADAP will receive a total rebate of 22 percent of AMP for that drug.

“Price Freeze” Rebates

The “price freeze” option is another type of rebate offered by the manufacturer to compensate for commercial price increases. Currently, of the 30 available ARV medications on the ADAP formulary, eight (27 percent) are subject to a price freeze rebate. If the manufacturers take a price increase while the price freeze is in effect, the program reimburses retail pharmacies at the higher rates. Initially, these result in higher expenditures for the program that are eventually offset by price freeze rebates received and deposited in the SF.

ADAP Rebate Invoicing

ADAP invoices the manufacturers for drug rebates on a quarterly basis, consistent with both federal drug rebate 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-March, April-June, etc.) in compliance with federal requirements. California ADAP mails drug rebate invoices approximately 60 days after the end of the quarter. For example, the January to March quarter invoice is sent out June 1. 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. Drug manufacturers tend to more closely follow the Medicaid payment timeframe when processing ADAP rebate invoices, though some do take the full 90 days. Approximately 85 percent of ADAP rebates due are received between 30 and 60 days and the remaining 15 percent are received between 60 and 90 days after the mailing of the rebate invoices.

Due to the above invoicing requirements and rebate payment timeframes, ADAP generally receives drug rebates three to six months after program expenditures but this process can take as long as eight months. Consequently, rebate due on expenditures in the second half of a given FY may not be received until the subsequent FY.

Funding from SF (3080) for LHJs, Medicare Part D, and Tropism Assay

Annually, additional SF budget authority is requested as follows:

- \$1 million to the LHJs to help offset the costs of ADAP enrollment and eligibility screening for clients at enrollment sites located throughout the State. Allocation is based on the number of ADAP clients enrolled during the prior calendar year. Funds may only be used for cost associated with the administration of ADAP.
- \$1 million for the Medicare Part D Premium Payment Program. This program assists eligible clients in paying their Part D monthly premiums allowing them to receive the Part D benefit.
- \$132,623 to cover the costs of Tropism Assay, a laboratory-based blood test used to determine whether a client will benefit from the use of Maraviroc, one of the ARV medications on the ADAP formulary.

APPENDIX C: POLICY ISSUES WITH POTENTIAL FUTURE FISCAL IMPACT

ADAP continues to monitor policy issues that have the potential to impact the fiscal condition of ADAP. These issues can occur within the state and federal arenas as well as 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:

Potential for Positive Fiscal Impact (Decreased Costs)

1. Adjusted Blue Book Average Wholesale Price (AWP)

A class action lawsuit brought against a drug wholesaler and a drug price publisher asserted that they fraudulently increased the published AWP of over 400 drugs by 5 percent from late 2001 to 2005. Included in the terms of the settlement, effective September 26, 2009, is a requirement that the defendants adjust the reporting of Blue Book AWP for those prescription drugs identified in the complaint by reducing the mark-up factor used in the calculation. Discussions are currently underway with ADAP's PBM regarding the appropriate rate to reimburse ADAP pharmacies, with the goals of ensuring fiscal responsibility in the use of these resources, maintaining the integrity of the pharmacy network and preserving access for clients to receive their pharmacy services. It is not possible to accurately estimate the fiscal impact at this time. We will continue to monitor the outcomes of the PBM discussions and the potential impact of this issue.

2. Legislation Affecting Medicare Part D True Out Of Pocket Costs (TrOOP)

Current Medicare Part D law prohibits ADAP spending from counting towards a Medicare Beneficiary's TrOOP. Consequently, an ADAP client who enters the "donut hole" (coverage gap) will remain there for the rest of the plan year. ADAP spending on drugs will not count towards the \$3,610 (year 2010) out-of-pocket threshold that moves an individual into catastrophic coverage (client pays 5 percent co-insurance). As a result, ADAP pays 100 percent of their drug costs when covering clients in the donut hole. National HIV advocacy groups continue to advocate that the Centers for Medicare and Medicaid Services (CMS) allow ADAP payments to count towards TrOOP.

On October 1, 2009, an amendment to allow ADAP spending to count towards TrOOP costs, enabling ADAP clients to move from the "donut hole" into catastrophic coverage, was added to the Senate Finance Committee's health care bill, "America's Health Future Act of 2009." A similar provision also currently exists in the House Ways and Means Committee's bill, "America's Affordable Health Choices Act (HR 3200)." Both provisions passed committee with unanimous consent. Negotiations to reconcile the House and Senate bills are expected to begin in early January 2010 with the final vote occurring in late January 2010. Community advocates continue to urge Senate leadership to maintain the "ADAP as TrOOP" provision in the final, merged health care bill. If the provision remains in the final bill and is signed by President Barack Obama, ADAP spending could begin to count towards TrOOP as early as 2010.

We have estimated that in calendar year 2008 we would have saved approximately \$8.22 million in expenditures if ADAP payments were recognized as counting toward TrOOP. Thus such reform would be an important change but would make a relatively small impact on the overall ADAP budget in California. Medicare Part D clients represent an important but relatively small proportion of our clients (approximately 22 percent).

3. Health Reform and The Early Treatment of HIV Act (ETHA)

If enacted, ETHA would provide the state with the option to extend Medi-Cal coverage to low-income people with an HIV diagnosis who have not yet become technically “disabled” by AIDS. Currently under Medicaid, a person must have an AIDS diagnosis before he/she can receive access to appropriate HIV care and treatment services. Such services are essential to slowing or preventing the progression of HIV infection to full blown AIDS. The enactment of this proposal would also relieve part of the financial burden on related programs that assist and serve these individuals, including state ADAPs. An expansion of Medicaid coverage under ETHA or health reform legislation would provide considerable cost offset to ADAP by shifting many ADAP clients to Medi-Cal for their drug coverage.

Stand-alone ETHA legislative proposals were introduced in 2009 by both the House and the Senate. The proposals have now passed their respective houses and will need to be reconciled. The ETHA provisions will sunset in 2013 when individuals become eligible for coverage through expanded health reform provisions. After 2013, individuals with income between 100-133 percent federal poverty level will remain eligible for Medicaid and those with incomes above 133 percent will have the option to purchase insurance coverage through an insurance exchange.

Potential for Negative Fiscal Impact (Increased Expenditures)

1. Increasing Medicare Part D Costs

ADAP experiences ongoing fluctuations in Part D related costs each calendar year. Cost fluctuations are driven by: annual changes, ADAP client plan selection and Part D plan formulary structure and tiers.

Annual Changes

Effective January 1, 2010, changes in Medicare Part D prescription drug benefits will directly affect ADAP costs for services to our clients with this benefit. Factors impacting ADAP costs for clients with Medicare Part D include increased prescription deductibles, out-of-pocket expenses and the coverage gap or “donut hole” (see Table 10, page 18). For the 2010 calendar year, costs for Standard Benefit clients are expected to increase by 4.66 percent. These are typical increases that have occurred since the inception of the Medicare Part D program, and will thus be accounted for in the regression estimates for expenditures. Medicare Part D prescription benefits will also change for calendar year 2011 (effective January 1). The anticipated increase in costs for year 2011 is unknown.

CMS contracts with Medicare Part D drug plans on an annual basis. Benefits available under Part D plans vary from calendar year to calendar year. Annual changes include formulary adjustments, changes to client out-of-pocket costs, and plans entering and exiting the market. CMS attempts to contain some beneficiary out-of-pocket costs by establishing an annual “maximum out-of-pocket” benefit threshold schedule. CMS typically releases information on out-of-pocket thresholds in February and contracted drug plan details in October of the preceding plan year.

TABLE 10: CALIFORNIA STAND ALONE PRESCRIPTION DRUG PLAN (PDP) COMPARISON 2009 & 2010		
	2009	2010
Total Number of PDPs	51 plans	45 plans
Monthly Premium Range	\$18.30-\$129.30	\$17.60-\$105.50
Annual Deductible:		
\$0.00	29 plans	18 plans
\$50-\$195	5 plans	11 plans
Allowable Maximum	\$295 - 17 plans	\$310- 16 plans
Enhanced Coverage (types of coverage offered to clients in the donut hole):		
All Generics	3 plans	1 plan
Many Generics	7 plans	8 Plans (1 plan also offers few brand)
Some Generics	2 plans	0 plans
No Coverage	39 plans	36 plans

*In practice, most plans charge a system of tiered cost-sharing versus the coinsurance amount listed above.

**Table 10 does not include Medicare Advantage Prescription Drug Plans or Special Needs Plans.

ADAP Client Plan Selection

Plan selection plays an important role in the over-all cost of a Part D client to ADAP. With the exception of beneficiaries enrolled in Full-Low Income Subsidy (LIS), individuals can only change plans once per year. CMS rules give each plan the flexibility to charge beneficiaries various out-of-pocket costs as long as the plan stays within the maximum annual threshold. While HRSA allows ADAPs to control Part D costs by limiting which drug plans ADAP clients can enroll in, the California Department of Health Services decided in 2005 to not limit ADAP clients' Part D plan options. As a result, ADAP pays the out-of-pocket costs associated with any of the 100 plus Part D plans operating in California.

The Part D open enrollment period is November 15 through December 31 of each year. Plan coverage begins January 1 of the following year. There appear to be two main factors that influence an ADAP client's Part D plan selection:

- Clients remain in the same Part D plan from year-to-year due to a lack of understanding of the open enrollment system; or
- Clients select Part D plans that charge lower amounts for drugs that are not on the ADAP formulary (drugs costs that are not subsidized by ADAP).

Because ADAP does not limit client plan options, tracking costs associated with this issue will continue to be a challenge as costs will always fluctuate based on the client's individual plan selection.

Part D Plan Formulary Structure and Tiers

Part D plans are permitted to establish drug formularies and are allowed to utilize drugs tiers. Use of drug tiers gives the plan flexibility to charge varying amounts per drug. Generic drugs are typically placed on "Tier 1" and brand or preferred drugs are placed on "Tier 2 or 3". Plans are permitted to place certain "unique or high cost" drugs on "specialty tiers". A recent study conducted for the Medicare Payment Advisory Commission (March 2009) indicates that four classes of drugs (antineoplastics, immunologics, antivirals, and antibacterials) commonly used to treat HIV/AIDS and related conditions account for two-third of the drugs that plans place on higher-cost specialty tiers. The higher cost of drugs on specialty tiers is passed on to ADAP when ADAP pays the client's Part D out-of-pocket costs.

Formulary and tier structure information is typically available when CMS releases plan information in October. Plans are required to develop an "Annual Notice of Change" informing beneficiaries of any major formulary changes.

HIV advocates have formally requested that CMS prohibit the use of specialty tiers as they feel that these tiers unfairly discriminate against people with HIV/AIDS. If CMS does not adopt this recommendation, advocates are requesting that CMS adopt the following: allow exceptions to the tier process, continue to monitor tier activity and conduct a study to compare Medicaid and Veterans Administration drug spending to Part D tiers. Elimination of specialty tiers will reduce ADAP Part D costs. CMS is currently reviewing the issue. Disability advocates are also attempting to include Medicare drug tiering/cost protection provisions in federal health reform legislation.

2. Changes in Treatment Guidelines to Recommend Earlier Treatment

The federal Guidelines for the Use of Antiretroviral Agents in HIV-1-infected Adults and Adolescents were updated on December 1, 2009. The guidelines were previously updated in November 2008. The most significant changes between the 2008 guidelines and the newly update version are recommendations for:

- earlier initiation of antiretroviral therapy; and
- specifically defined antiretroviral therapy regimens for treatment naïve patients.

In both cases, these changes may result in increased utilization of high-cost ARV therapies, though the actual impact is unknown. Physician adoption of the new revised guidelines and the resulting ARV prescribing patterns have yet to be established, given the very recent release of the guidelines. Modeling of the potential impact on ADAP has not been done by any known entity. OA has requested that such modeling be conducted at the federal level by HRSA or the CDC. In the interim, internal exploration of ADAP data has been initiated but OA does not yet have estimates regarding the potential impact of the new guidelines on program expenditures.

3. Elimination of Medi-Cal Optional Benefits

ADAP clients who may be affected by the elimination of the Medi-Cal optional benefits are those who have both Medi-Cal with a SOC and Medicare Part D. Medicare beneficiaries who meet their state Medicaid SOC qualify for federal Part D subsidized benefits, generally moving them from being a standard beneficiary (higher prescription co-pays/co-insurance, with a coverage gap or "donut hole") to a full subsidy beneficiary level (no coverage gap, lower prescription co-pays). Whenever this occurs, ADAP costs for these clients are also reduced accordingly. The

earlier in the calendar year these clients meet their Medi-Cal SOC, the sooner the potential fiscal benefit to ADAP.

Elimination of the Medi-Cal benefits in question (dental, vision, chiropractic, acupuncture, podiatry, incontinence supplies, certain psychology services) reduces the services categories available under Medi-Cal by which these clients might incur their SOC. As long as they remain at the standard beneficiary level, ADAP must pay higher prescription co-pays and 100 percent of the cost of their drugs for the remainder of the calendar year (approximately eight to ten months) once they reach the coverage gap or "donut hole." Elimination of these benefits could affect ADAP clients who have both Medi-Cal with a SOC and Medicare Part D. However, given the relatively small number of ADAP clients with Medi-Cal, we do not anticipate a significant increase in ADAP expenditures. As with all fiscal issues, we will monitor this closely.

4. Potential Changes in Partial Pay Rebate Collections

Currently, ADAP is able to collect full rebate on partial payment transactions for clients with other payers (e.g., private insurance). In FY 2007-08 (most recent available data), rebates on partial payments represented nearly 41 percent of total rebate revenue. This is very cost effective for California's ADAP. Early in 2008, this policy was challenged by a drug manufacturer. This manufacturer subsequently publicly stated in writing that it would not pursue this issue further at this time. Although the manufacturer has stated that it plans to honor the current policy at this time, there remains the potential that the policy may be challenged again in the future. This issue has been of considerable concern to ADAPs nationally. California's ADAP will continue to monitor this issue.

The current federal policy which allows full rebate on partial pay claims is unchanged at this time. The current federal administration has given no indication that they are interested in changing the existing policy, which supports the cost effective provision of prescription drugs under ADAP, Medicaid, and other covered entities.

Potential Fiscal Impact: To Be Determined

1. Potential New PBM Contract Provisions

The current contract for PBM services terminates on June 30, 2010. The reimbursement structure is based on a flat \$6 fee per transaction. The previous PBM contract reimbursement structure was based on a percentage of the average wholesale drug price, therefore when drug prices increased, drug reimbursement costs increased accordingly. ADAP is developing a Request for Proposal (RFP) for the contract period beginning July 1, 2010 and is researching alternative reimbursement structures. Any change in reimbursement to the PBM may have an impact on costs to ADAP. Potential costs or savings cannot be projected until the RFP process is complete and a winning bidder is awarded the contract.

2. 340B Drug Pricing Program

Under current law, drug manufacturers who wish to have their drugs covered by Medicaid must enter into a pricing agreement with the federal Health and Human Services Agency. Eligible 340B entities, including all state Medicaid and ADAPs, have the option of receiving the federal drug pricing discount either through direct purchase of drugs at the discounted Medicaid price or through mandatory drug rebate, which offsets the cost of these drugs purchased at retail prices.

In both instances, the final cost to the programs is approximately the same. ADAP uses the federal mandatory rebate option.

Questions have arisen as to whether the 340B Drug Pricing Program would continue to operate under the auspices of federal health reform. Two congressional committees have reviewed and approved H.R. 444 and S. 1239 which would continue the current program. Both versions propose to raise the minimum mandatory rebate percentage amount from the current 15.1 percent of AMP to 23.1 percent of AMP. If these federal health reform proposals are approved and merged into a measure signed into law by the Administration, ADAP drug expenditures in budget year 2010-2011 could begin generating increased rebate revenue.

However, it is unclear what affect this increased mandatory rebate payment obligation will have on the existing ADAP voluntary supplemental rebate agreements with 14 drug manufacturers. The ACTF, which negotiates the supplemental rebate agreements on behalf of all state ADAPs, indicates at least one ARV drug manufacturer has stated their intent to honor the negotiated voluntary supplemental rebate in addition to the proposed increased mandatory 340B rebate. The intent of the other 13 drug manufacturers is unknown but the ACTF will continue to assess individual manufacturer responses to the proposed legislation.

The actual impact on ADAP rebate revenue is unknown at this time. There is both a potential for increased revenue through the proposed increase to the mandatory rebate and decreased rebate revenue if drug manufacturers were to reduce or eliminate the negotiated supplemental rebates.

APPENDIX D: ACRONYM DEFINITIONS

HIV - *Human Immunodeficiency Virus*. If left untreated, HIV infection damages a person's immune system and can progress to AIDS. Early detection of HIV infection allows for more options for treatment and preventive health care.

AIDS - *Acquired Immunodeficiency Syndrome*. AIDS is caused by HIV. A person who tests positive for HIV can be diagnosed with AIDS when a laboratory test shows that his or her immune system is severely weakened by the virus or when he or she develops at least one of approximately 25 different opportunistic infections. Most HIV-positive people are infected with the virus years before it damages their immune system to make them susceptible to AIDS-related diseases.

ADAP - *AIDS Drug Assistance Program*. ADAP, which functions within the California Department of Public Health, OA, was established in 1987 to help ensure that HIV-positive uninsured and under-insured individuals have access to HIV/AIDS-related pharmaceutical (drug) therapies. The goal of ADAP is to make available, in an effective and timely manner to people living with HIV, drug treatments that can reliably be expected to increase the duration and quality of life. Currently, there are 181 drugs available through ADAP and there are over 4,000 pharmacies statewide where clients can have access to these drugs. Without the drugs available through ADAP, thousands of HIV-positive Californians would face rapidly deteriorating health.

ARVs - *Antiretroviral drugs*. ARVs can slow the progression of HIV to AIDS by decreasing the amount of virus in a person's body. Effective ARV therapy also renders people less infectious than they would otherwise be.

APPENDIX E: MEDICARE PART D DEFINITIONS

Medicare Part D has had a significant impact on ADAP. We provide the following background information to help explain the assumptions in the budget models.

The implementation of the Medicare Part D drug benefit began on January 1, 2006. The income level and assets of beneficiaries determine the level of prescription assistance they will receive.

Categories of coverage

- 1) **Standard Benefit** – This is the maximum allowable out-of-pocket costs permitted under Part D. These beneficiaries must pay the first \$310 of their drug costs out of pocket. After the \$310 deductible, Medicare will pay 75 percent of the cost of each covered prescription and the beneficiary will pay 25 percent, up to \$2,830 in total costs. (Note: For medications on the ADAP formulary, ADAP covers the \$310 deductible and 25 percent co-pay.)
- 2) **“Donut Hole”** - Once a standard beneficiary reaches \$2,830 in drug costs (the combination of what Medicare and the beneficiary have paid) he or she is at the coverage gap or donut hole. Once the standard beneficiary reaches the donut hole, Medicare will stop covering his or her drug costs until the beneficiary spends another \$3,610 on medication. Once the beneficiary has paid this amount in drug costs he or she is eligible for catastrophic coverage. Catastrophic coverage drug costs will vary but will never be more than 5 percent of the drug costs. (Note: for medications on the ADAP formulary, ADAP covers 100 percent of drug costs in the “Donut Hole”.)
- 3) **“TrOOP”**- Acronym for “true-out-of-pocket,” referring to drug costs paid by the beneficiary. A beneficiary’s TrOOP spending determines how they advance through the Part D coverage levels. Medicare law prohibits drug costs paid by ADAP from counting towards a beneficiary’s TrOOP. This rule typically leads to ADAP clients remaining “stuck” in the Part D coverage gap or “Donut Hole” for a majority of the Part D year.
- 4) **Low Income Subsidy (LIS)** – Beneficiaries with incomes below 150 percent of the FPL and with limited assets may be eligible for the low income subsidy (or “extra help” as Medicare calls it). LIS eligibility ensures that beneficiaries have the lowest out-of-pocket costs for medications.
 - a) **Full Subsidy** – Income under 135 percent of FPL level. These beneficiaries do not have to pay a deductible, but pay \$2.50 for generic drugs, \$6.30 for brand drugs, and do not have to contend with the “Donut Hole” (coverage gap). After \$6,440 of out-of-pocket costs, they have no out-of-pocket drug costs for the remainder of the plan year. (Note: for medications on the ADAP formulary, ADAP covers these co-pays.)
 - b) **Partial Subsidy** – Income between 135 percent and 150 percent of FPL. These beneficiaries must pay a \$62 deductible, 15 percent of drug costs after the deductible, and do not have to contend with the “Donut Hole” (coverage gap). After \$6,440 of out of pocket expenses, co-pays are reduced to \$2.50 for generics and \$6.30 for brand drugs. (Note: for medications on the ADAP formulary, ADAP covers the deductible, co-insurance, and co-pays.)

c) Dual Eligible (covered by both Medicare and Medi-Cal)

- i. Full Duals are clients who are eligible for Medi-Cal with no SOC. Medicare subsidizes the cost of a Full Dual's drugs. They pay limited co-pays of \$2.50 to \$6.40 per drug. No out-of-pocket payments are required once total drug costs reach \$6,440. (Note: for medications on the ADAP formulary, ADAP covers these co-pays.)
- ii. Partial Duals are clients who are eligible for Medi-Cal with a SOC. A Partial Dual who has not met his/her Medi-Cal SOC will not automatically qualify for Full LIS. Part D out of pocket costs for Partial Duals will vary depending on the individual's income. A Partial Dual can become a "Full Dual" once they incur their monthly SOC. If a Dual incurs their SOC, they qualify for "Full Dual" subsidy the following month and retain this subsidy for the remainder of the plan year. (Note: for medications on the ADAP formulary, ADAP covers these costs.)

Note: All dollar figures indicated above are for calendar year 2010.

APPENDIX F: NEW DRUGS AND TREATMENT GUIDELINES

New Drug Updates

The number of medications in the pipeline to treat HIV is relatively small.

Maraviroc

In November of 2009, the U.S. Food and Drug Administration approved the expansion of treatment indications for maraviroc in combination with other ARV agents to include treatment-naïve patients. It was earlier approved for use only in adults whose viral loads remain detectable despite existing ARV treatment or who have multiple-drug resistant virus. The net cost of maraviroc to the program falls within the net cost of the other two leading non-nucleoside reverse transcriptase inhibitors (non-NRTI) drugs, efavirenz and atazanavir, which this drug would replace. Thus, OA does not anticipate a significant fiscal impact.

Vicriviroc

Vicriviroc is the second drug in the CCR5 inhibitors class of ARV drugs. It may be filed with the FDA within the first half of 2010, with a subsequent (potential) approval in the following few months. Vicriviroc offers a potential advantage when combined with an existing ARV agent, as it would be taken just once a day (instead of twice a day). However, it may have some disadvantages, like requiring pharmacologic boosting with another ARV. It is anticipated that community pressure around pricing may influence vicriviroc being priced no higher than the other drug (maraviroc) in the CCR5 inhibitor class (fiscal impact described above)

Treatment Guidelines Updates

The federal guidelines for the Use of Antiretroviral Agents in HIV-1-infected Adults and Adolescents were updated on December 1, 2009. The guidelines were previously updated in November 2008. The most significant changes between the 2008 guidelines and the newly update version are recommendations for:

- earlier initiation of ARV therapy; and
- specifically defined ARV therapy regimens for treatment naïve patients.

Selected Key Updates from the Guidelines

Initiation of ARV Therapy

In the updated version of the guidelines, the Panel recommends earlier initiation of ARV therapy with the following specific recommendations:

- ARV therapy should be initiated in all patients with a history of an AIDS-defining illness or with CD4 count < 350 cells/mm³ (AI).
- ARV therapy should also be initiated, regardless of CD4 count, in patients with the following conditions: pregnancy (AI), HIV-associated nephropathy (AII), and hepatitis B virus (HBV) coinfection when treatment of HBV is indicated (AIII).
- ARV therapy is recommended for patients with CD4 counts between 350 and 500 cells/mm³. The Panel was divided on the strength of this recommendation: 55% of Panel members for

strong recommendation (A) and 45% for moderate recommendation (B) (A/B-II).

- For patients with CD4 counts >500 cells/mm³, 50% of Panel members favor starting ARV therapy (B); the other 50% of members view treatment as optional (C) in this setting (B/C-III).

What to Start in Antiretroviral-Naïve Patients

- Increasing clinical trial data in the past few years have allowed for better distinction between the virologic efficacy and safety of different combination regimens. Instead of providing recommendations for individual antiretroviral components to use to make up a combination, the Panel now defines what regimens are recommended in treatment-naïve patients.
- Regimens are classified as “Preferred,” “Alternative,” “Acceptable,” “Regimens that may be acceptable but more definitive data are needed,” and “Regimens to be used with caution.”
- The following changes were made in the recommendations:

Raltegravir + tenofovir/emtricitabine has been added as a “Preferred” regimen based on the results of a Phase III randomized controlled trial (AI).

Four regimens are now listed as “Preferred” regimens for treatment-naïve patients. They are: 1) efavirenz/tenofovir/emtricitabine; 2) ritonavir-boosted atazanavir + tenofovir/emtricitabine; 3) ritonavir-boosted darunavir + tenofovir/emtricitabine; and 4) raltegravir + tenofovir/emtricitabine.

Lopinavir/ritonavir-based regimens are now listed as “Alternative” (BI) instead of “Preferred” regimens, except in pregnant women, where twice-daily lopinavir/ritonavir + zidovudine/lamivudine remains a “Preferred” regimen (AI).

APPENDIX G: 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 some time in the future. California estimates that there were between 148,649 and 179,881 living with HIV/AIDS at the end of 2009, see Table 11, below. This estimate includes people who are HIV positive but are not yet diagnosed (approximately 21 percent) by applying a national estimate of those unaware of their infection status that was developed by the Centers for Disease Control and Prevention (CDC) Morbidity and Mortality Weekly Report, (MMWR, October 3, 2008). Living HIV/AIDS cases are estimated to be 47 percent white, 19 percent African American, 30 percent Latino, 3 percent Asian/Pacific Islander, and 0.5 percent American Indian/Alaskan Native. Most (65 percent) of California's living HIV/AIDS cases are attributed to male-to-male transmission, 9 percent is attributed to injection drug use, 9 percent to heterosexual transmission, and 8 percent to men who have sex with men (MSM) who also practice injection drug use.

The number of living HIV/AIDS cases in the state is expected to grow by approximately 2 percent (with a range of 2,700 – 6,700) 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).

Year	Persons reported with HIV (not AIDS) and presumed living		Persons reported with AIDS and presumed living		Estimated persons living with HIV or AIDS*	
	Low bound	High bound	Low bound	High bound	Low bound	High bound
2006	41,308	57,579	61,490	61,490	140,549	159,691
2007	41,531	58,554	63,390	64,720	143,249	166,421
2008	42,211	61,529	65,290	67,950	145,949	173,151
2009	42,891	64,504	67,190	71,180	148,649	179,881
2010	43,571	67,479	69,090	74,410	151,349	186,611

*Includes persons unreported and/or persons unaware of their HIV infection.

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. Most people get tested infrequently, so incidence estimates largely rely on modeling. California estimates 5,000 – 7,000 new HIV infections annually. This estimate was developed through:

- A series of “Consensus Conferences” convened in California in 2000 that developed population estimates of HIV incidence; and
- Downward adjustment based upon observed reported HIV cases in the code-based HIV surveillance system.

Recent advances in laboratory tools have made estimation of HIV incidence possible using blood samples from people found to be HIV antibody positive. In 2004, CDC began a national

effort to measure incidence using this tool. These results were reported in the August, 2008 issue of MMWR. California's data were not included as they are not yet complete enough to provide accurate estimates. Therefore, California has not yet updated its incidence estimates. The 95 percent confidence interval for the national estimate (48,200 to 64,500 new infections) is consistent with the 5,000 to 7,000 range OA estimated for California in 2005; suggesting new HIV infections have been relatively steady in recent years.

California has implemented HIV Incidence Surveillance using the CDC-developed STARHS (Serologic Testing Algorithm for Recent HIV Seroconversion) methodology. Data from this system will be used to revise California incidence estimates in the coming years. Confidence intervals for 2007 data from this program in San Francisco (552 to 1,033) and Los Angeles (2,390 to 3,886) are generally consistent with the 5,000 to 7,000 range.

APPENDIX H: SENSITIVITY ANALYSIS**FY 2009-10**

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, we started with the estimated total drug costs for FY 2009-10 using the upper bound of the 95 percent confidence interval (CI) from the Linear Regression Model and subtracting \$500,000 for the administration reduction in PBM contract costs (\$417.76 million).

For these factors, clients and expenditures per client, we 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 12 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.

\$ / Client Scenarios	Number of Client Scenarios						
	Hi (-) CI	Med (-) CI	Lo (-) CI	Zero Change in Clients	Lo (+) CI	Med (+) CI	Hi (+) CI
Hi (-): Best	\$393,406,492	\$397,404,087	\$401,401,683	\$405,399,278	\$409,396,874	\$413,394,469	\$417,392,065
Med (-)	\$397,404,087	\$401,442,895	\$405,481,703	\$409,520,511	\$413,559,319	\$417,598,127	\$421,636,935
Lo (-)	\$401,401,683	\$405,481,703	\$409,561,723	\$413,641,743	\$417,721,764	\$421,801,784	\$425,881,804
Zero Change in \$ / Client	\$405,399,278	\$409,520,511	\$413,641,743	\$417,762,976	\$421,884,209	\$426,005,441	\$430,126,674
Lo (+)	\$409,396,874	\$413,559,319	\$417,721,764	\$421,884,209	\$426,046,653	\$430,209,098	\$434,371,543
Med (+)	\$413,394,469	\$417,598,127	\$421,801,784	\$426,005,441	\$430,209,098	\$434,412,756	\$438,616,413
Hi (+): Worst	\$417,392,065	\$421,636,935	\$425,881,804	\$430,126,674	\$434,371,543	\$438,616,413	\$442,861,282

The center cell, highlighted in light blue, shows the revised estimated expenditures for FY 2009-10, using the 95 percent CI from the Linear Regression Model. 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 \$393,406,492 (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 \$442,861,282 (bottom right cell, red). The table provides a range of values to assist in projecting the total expenditures for FY 2009-10.

FY 2010-11

Below is the sensitivity analysis for FY 2010-11, using the same factors and logic as above. The "baseline" or center cell, highlighted in light blue, reflects adjustments to the linear regression expenditure projection including the elimination of services in jails (see Table 1b, Local Assistance Expenditure Estimate row).

TABLE 13: SENSITIVITY ANALYSIS FOR FISCAL YEAR 2010-11 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
Hi (-): Best	\$433,185,266	\$437,585,510	\$441,985,755	\$446,385,999	\$450,786,244	\$455,186,488	\$459,586,733
Med (-)	\$437,585,510	\$442,031,118	\$446,476,726	\$450,922,334	\$455,367,942	\$459,813,550	\$464,259,158
Lo (-)	\$441,985,755	\$446,476,726	\$450,967,697	\$455,458,668	\$459,949,640	\$464,440,611	\$468,931,582
Zero Change in \$ / Client	\$446,385,999	\$450,922,334	\$455,458,668	\$459,995,003	\$464,531,338	\$469,067,672	\$473,604,007
Lo (+)	\$450,786,244	\$455,367,942	\$459,949,640	\$464,531,338	\$469,113,036	\$473,694,733	\$478,276,431
Med (+)	\$455,186,488	\$459,813,550	\$464,440,611	\$469,067,672	\$473,694,733	\$478,321,795	\$482,948,856
Hi (+): Worst	\$459,586,733	\$464,259,158	\$468,931,582	\$473,604,007	\$478,276,431	\$482,948,856	\$487,621,281

APPENDIX I: HISTORY OF PROJECTION METHODS

ADAP's expenditure projection methods have evolved over the years in response to changes in actual expenditure patterns and the relative strengths and limitations of specific estimation methods with respect to specific expenditure patterns.

To project budget estimates for FYs 1998-99 through 2006-07, ADAP used a Linear Regression Model originally recommended by the California Department of Finance (DOF). The major underlying assumption for a Linear Regression Model is that the data closely fit a straight line and the trend increases (or decreases) at a consistent rate or slope over time.

Beginning with the FY 2004-05 projections, the starting point for the regression model was adjusted from July 1997 to July 1998 to provide a better fitting model.

For the FYs 2005-06 and 2006-07 projections, ADAP again adjusted the model to reflect the higher expenditures observed in the previous two FYs. This was accomplished by adding a 5.0 percent adjustment factor to the regression model.

In FY 2005-06, ADAP expenditures decreased for the first time due to the enrollment of ADAP clients into Medicare Part D starting in January 2006 and increased enforcement of client eligibility requirements with respect to utilization of alternative payer sources. As a result, the pattern was no longer a straight line and the Linear Regression Model was not reliable.

- During this time, ADAP was working with HRSA, the National Alliance of State and Territorial AIDS Directors and Focal Point Consulting Group to develop a budget forecasting tool to assist all ADAPs in fiscal projections. The final HRSA tool provided three options (regression, moving average, and percent change).

California ADAP examined these three options and adopted the Percent Change Model; it was applied for the first time to revise the FY 2006-07 projections and estimate the FY 2007-08 expenditures during the fall 2006 budget process.

This model was presented for the development of the FY 2008-09 budget at May Revision and included five factors that contributed to increasing expenditures and by how much (i.e., percent change and corresponding increase in expenditures). The factors of interest were Medicare Part D expenditures, new drug expenditures, drug price increases, increase client expenditures and increase transaction fees for unapproved prescription requests. A key limitation in the Percent Change Model is that HRSA did not offer guidance on how to estimate the percent change to each factor (i.e., the underlying assumptions, thereby making this method more subjective than a Linear Regression Model).

Since FY 2007-08, ADAP has continued to use the Linear Regression Model as its official projection method.