

**AIDS DRUG ASSISTANCE PROGRAM
(ADAP)
November 2010
Estimate Package**

2011-12 GOVERNOR'S BUDGET



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

**CALIFORNIA
DEPARTMENT OF PUBLIC HEALTH**

Table of Contents

<u>SECTION</u>	<u>PAGE</u>
1. FISCAL COMPARISON TABLES	
<u>Expenditures</u>	
Table 1a: Comparison of FY 2010-11 <i>November Estimate</i> to FY 2010-11 Budget Act.....	1
Table 1b: Comparison of FY 2011-12 <i>November Estimate</i> to FY 2010-11 Budget Act	1
Table 1c: Comparison of FY 2011-12 <i>November Estimate</i> to FY 2010-11 <i>November Estimate</i>	1
<u>Resources</u>	
Table 2a: Comparison of FY 2010-11 <i>November Estimate</i> to FY 2010-11 Budget Act	2
Table 2b: Comparison of FY 2011-12 <i>November Estimate</i> to FY 2010-11 Budget Act.....	2
Table 2c: Comparison of FY 2011-12 <i>November Estimate</i> to FY 2010-11 <i>November Estimate</i>	2
2. MAJOR ASSUMPTIONS.....	3
3. FUND CONDITION STATEMENT	13
4. HISTORICAL PROGRAM DATA AND TRENDS	15
APPENDIX A: EXPENDITURE AND REVENUE ESTIMATE METHODS	18
Updated Expenditure Estimate for FY 2010-11	18
New Expenditure Estimate for FY 2011-12	18
Linear Regression Model – Expenditure Estimates	18
Program Expenditure Estimate for FY 2011-12.....	21
ADAP Rebate Revenue.....	22
APPENDIX B: FUND SOURCES.....	24
General Fund.....	25
Federal Fund	25
Reimbursement	26
ADAP Special Fund (3080)	26
APPENDIX C: POLICY ISSUES WITH POTENTIAL FUTURE FISCAL IMPACT	29
APPENDIX D: CURRENT HIV/AIDS EPIDEMIOLOGY IN CALIFORNIA	33
APPENDIX E: SENSITIVITY ANALYSIS	35
APPENDIX F: ADDITIONAL INFORMATION: RENEGOTIATED SUPPLEMENTAL REBATE AGREEMENTS AND HEALTH CARE REFORM LEGISLATION	37

1. FISCAL COMPARISON TABLES

Table 1a: Expenditure Comparison: FY 2010-11 November Estimate to FY 2010-11 Budget Act (000's)															
	2010-11 November Estimate					2010-11 Appropriation ¹					Difference				
	Total	Reimbursement	Federal	State	ADAP Special Fund	Total	Reimbursement	Federal	State	ADAP Special Fund	Total	Reimbursement	Federal	State	ADAP Special Fund
Local Assistance Funding	\$478,535	\$76,277	\$102,715	\$71,440	\$228,103	\$426,413	\$0	\$100,032	\$125,608	\$200,773	\$52,122	\$76,277	\$2,683	(\$54,168)	\$27,330
Drug Expenditure Estimate	476,402	76,277	102,715	71,440	225,970	424,280		100,032	125,608	198,640	52,122	76,277	2,683	(54,168)	27,330
Prescription Costs	462,015	73,973	99,613	69,283	219,146	414,286		96,931	121,714	195,641	47,729	73,973	2,682	(52,432)	23,505
Basic Prescription Costs	465,434	73,973	99,613	69,283	222,565	417,478		96,931	121,714	198,833	47,956	73,973	2,682	(52,432)	23,733
RFP: Change in Reimbursement Rate															
True-Out-Of-Pocket Costs (HCR)	(3,420)				(3,420)	(3,192)				(3,192)	(228)				(228)
PBM Operational Costs	14,387	2,304	3,102	2,157	6,824	9,994		3,101	3,894	2,999	4,393	2,304	1	(1,736)	3,825
Basic PBM Costs	14,887	2,304	3,102	2,657	6,824	13,843		3,101	4,394	6,348	1,044	2,304	1	(1,736)	476
Administrative Reduction ²	(500)			(500)		(500)			(500)						
ADAP PBM RFP Transaction Fees						(3,349)				(3,349)	3,349				3,349
LHJ Administration	1,000				1,000	1,000				1,000					
Medicare Part D	1,000				1,000	1,000				1,000					
Tropism Assay	133				133	133				133					
Support/Administration Funding	\$2,485	\$0	\$1,178	\$411	\$896	\$2,657	\$0	\$1,178	\$411	\$1,068	(\$172)	\$0	\$0	\$0	(\$172)

Table 1b: Expenditure Comparison: FY 2011-12 November Estimate to FY 2010-11 Budget Act (000's)															
	2011-12 Governor's Budget					2010-11 Appropriation ¹					Difference				
	Total	Reimbursement	Federal	State	ADAP Special Fund	Total	Reimbursement	Federal	State	ADAP Special Fund	Total	Reimbursement	Federal	State	ADAP Special Fund
Local Assistance Funding	\$518,496	\$0	\$97,632	\$163,857	\$257,007	\$426,413	\$0	\$100,032	\$125,608	\$200,773	\$92,083	\$0	(\$2,400)	\$38,249	\$56,234
Drug Expenditure Estimate	516,363		97,632	163,857	254,874	424,280		100,032	125,608	198,640	92,083		(2,400)	38,249	56,234
Prescription Costs	504,151		94,683	158,401	251,067	414,286		96,931	121,714	195,641	89,865		(2,248)	36,687	55,426
Basic Prescription Costs	529,801		94,683	175,209	259,909	417,478		96,931	121,714	198,833	112,323		(2,248)	53,495	61,076
RFP: Change in Reimbursement Rate	(1,927)				(1,927)						(1,927)				(1,927)
True-Out-Of-Pocket Costs (HCR)	(6,915)				(6,915)	(3,192)				(3,192)	(3,723)				(3,723)
Client Cost Sharing ³	(16,808)			(16,808)							(16,808)			(16,808)	
PBM Operational Costs	12,212	2,948	5,456	3,807	7,697	9,994		3,101	3,894	2,999	2,218		(153)	1,562	808
Basic PBM Costs	16,102	2,948	5,456	7,697		13,843		3,101	4,394	6,348	2,258		(153)	1,062	1,349
Administrative Reduction ²						(500)			(500)		500			500	
ADAP PBM RFP Transaction Fees	(3,890)				(3,890)	(3,349)				(3,349)	(541)				(541)
LHJ Administration	1,000				1,000	1,000				1,000					
Medicare Part D	1,000				1,000	1,000				1,000					
Tropism Assay	133				133	133				133					
Support/Administration Funding	\$2,586	\$0	\$1,178	\$411	\$997	\$2,657	\$0	\$1,178	\$411	\$1,068	(\$71)	\$0	\$0	\$0	(\$71)

Table 1c: Expenditure Comparison: FY 2011-12 November Estimate to FY 2010-11 November Estimate (000's)															
	2011-12 Governor's Budget					2010-11 November Estimate					Difference				
	Total	Reimbursement	Federal	State	ADAP Special Fund	Total	Reimbursement	Federal	State	ADAP Special Fund	Total	Reimbursement	Federal	State	ADAP Special Fund
Local Assistance Funding	\$518,496	\$0	\$97,632	\$163,857	\$257,007	\$478,535	\$76,277	\$102,715	\$71,440	\$228,103	\$39,961	(\$76,277)	(\$5,083)	\$92,417	\$28,904
Drug Expenditure Estimate	516,363		97,632	163,857	254,874	476,402	76,277	102,715	71,440	225,970	39,961	(76,277)	(5,083)	92,417	28,904
Prescription Costs	504,151		94,683	158,401	251,067	462,015	73,973	99,613	69,283	219,146	42,137	(73,973)	(4,929)	89,118	31,921
Basic Prescription Costs	529,801		94,683	175,209	259,909	465,434	73,973	99,613	69,283	222,565	64,367	(73,973)	(4,929)	105,926	37,343
RFP: Change in Reimbursement Rate	(1,927)				(1,927)						(1,927)				(1,927)
True-Out-Of-Pocket Costs (HCR)	(6,915)				(6,915)	(3,420)				(3,420)	(3,495)				(3,495)
Client Cost Sharing ³	(16,808)			(16,808)							(16,808)			(16,808)	
PBM Operational Costs	12,212	2,948	5,456	3,807	7,697	14,387	2,304	3,102	2,157	6,824	(2,175)	(2,304)	(154)	3,299	(3,017)
Basic PBM Costs	16,102	2,948	5,456	7,697		14,887	2,304	3,102	2,657	6,824	1,214	(2,304)	(154)	2,799	873
Administrative Reduction ²						(500)			(500)		500			500	
ADAP PBM RFP Transaction Fees	(3,890)				(3,890)						(3,890)				(3,890)
LHJ Administration	1,000				1,000	1,000				1,000					
Medicare Part D	1,000				1,000	1,000				1,000					
Tropism Assay	133				133	133				133					
Support/Administration Funding	\$2,586	\$0	\$1,178	\$411	\$997	\$2,485	\$0	\$1,178	\$411	\$896	\$101	\$0	\$0	\$0	\$101

¹ For purposes of display, the post-linear regression adjustments for AWP Rollback/WAC and Elimination of Services to County Jails are incorporated into Basic Prescription Costs (Linear Regression) for FY 2010-11 Appropriation.

² For purposes of November Estimate, the Administrative Reduction is now included in the line: ADAP PBM RFP Transaction Fees for 2011-12 Governor's Budget.

³ General Fund savings in FY 2011/12 in association with expanded cost-sharing policy to offset the General Fund reduction.

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

	2010-11 November Estimate					2010-11 Appropriation					Difference				
	Total	Reimbursement	Federal	State	ADAP Special Fund	Total	Reimbursement	Federal	State	ADAP Special Fund	Total	Reimbursement	Federal	State	ADAP Special Fund
Available Resources	\$478,120	\$76,277	\$103,893	\$71,851	\$226,099	\$419,707	\$0	\$101,210	\$126,019	\$192,478	\$58,413	\$76,277	\$2,683	(\$54,168)	\$33,621
Basic Rebate Revenues ¹	212,792				212,792	192,078				192,078	20,713				20,713
Income from Surplus Money Investments	300				300	400				400	(100)				(100)
Federal Funds	98,810		98,810			98,810		98,810							
General Funds	71,851			71,851		126,019			126,019		(54,168)			(54,168)	
Renegotiated Sup. Rebate/Price Freeze Agreements	352				352						352				352
Renegotiated Sup. Rebate/Price Freeze Agreements	12,656				12,656						12,656				12,656
One-Time Increase in Federal Fund (#1)	2,660		2,660								2,660		2,660		
One-Time Increase in Federal Fund (#2)	2,423		2,423			2,400		2,400			23		23		
One-Time Increase from Safety Net Care Pool	76,277	76,277									76,277	76,277			

TABLE 2b: Resource Comparison: FY 2011-12 November Estimate to FY 2010-11 Budget Act (000's)

	2011-12 Governor's Budget					2010-11 Appropriation					Difference				
	Total	Reimbursement	Federal	State	ADAP Special Fund	Total	Reimbursement	Federal	State	ADAP Special Fund	Total	Reimbursement	Federal	State	ADAP Special Fund
Available Resources	\$522,399	\$0	\$98,810	\$164,268	\$259,321	\$419,707	\$0	\$101,210	\$126,019	\$192,478	\$102,692	\$0	(\$2,400)	\$38,249	\$66,843
Basic Rebate Revenues ¹	232,202				232,202	192,078				192,078	40,124				40,124
Income from Surplus Money Investments	300				300	400				400	(100)				(100)
Federal Funds	98,810		98,810			98,810		98,810							
General Funds	164,268			164,268		126,019			126,019		38,249			38,249	
Renegotiated Sup. Rebate/Price Freeze Agreements	26,819				26,819						26,819				26,819
One-Time Increase in Federal Fund (#1)															
One-Time Increase in Federal Fund (#2)						2,400		2,400			(2,400)		(2,400)		

TABLE 2c: Resource Comparison: FY 2011-12 November Estimate to FY 2010-11 November Estimate (000's)

	2011-12 Governor's Budget					2010-11 November Estimate					Difference				
	Total	Reimbursement	Federal	State	ADAP Special Fund	Total	Reimbursement	Federal	State	ADAP Special Fund	Total	Reimbursement	Federal	State	ADAP Special Fund
Available Resources	\$522,399	\$0	\$98,810	\$164,268	\$259,321	\$478,120	\$76,277	\$103,893	\$71,851	\$226,099	\$44,279	(\$76,277)	(\$5,083)	\$92,417	\$33,222
Basic Rebate Revenues ¹	232,202				232,202	212,792				212,792	19,410				19,410
Income from Surplus Money Investments	300				300	300				300					
Federal Funds	98,810		98,810			98,810		98,810							
General Funds	164,268			164,268		71,851			71,851		92,417			92,417	
Renegotiated Sup. Rebate/Price Freeze Agreements						352				352	(352)				(352)
Renegotiated Sup. Rebate/Price Freeze Agreements	26,819				26,819	12,656				12,656	14,164				14,164
One-Time Increase in Federal Fund (#1)						2,660		2,660			(2,660)		(2,660)		
One-Time Increase in Federal Fund (#2)						2,423		2,423			(2,423)		(2,423)		
One-Time Increase from Safety Net Care Pool						76,277	76,277				(76,277)	(76,277)			

¹ For purposes of display, the adjustment for Elimination of Services to County Jails is incorporated into Basic Rebate Revenues for the FY 2010-11 Appropriation.

2. MAJOR ASSUMPTIONS

New Major Assumptions

1. Change in Methodology (#1): Data Points for Linear Regression Model – As anticipated, the prior linear regression model underestimated actual fiscal year (FY) 2009-10 expenditures. The revised data set for the *November Estimate FY 2011-12* includes 36 data points (August 2007 – July 2010) for actual expenditures, consistent with the number of data points used by Medi-Cal for their expenditure estimate. The methodology used in the *May Revision FY 2010-11* estimate package included data from January 2006 – February 2010. Historically, there has been a spike in expenditures in March, thus including an estimate for March will decrease the likelihood of underestimating the current year budget. March 2011 will be estimated by taking the available March 2011 data, and generating a per-day expenditure average which will be multiplied by the number of days in March.
2. Change in Methodology (#2): Remove Jail Expenditures from all Prior Years Data Included in Linear Regression Model - Elimination of ADAP jail services began on July 1, 2010. Prior estimates to project the impact of eliminating the jails used actual jail expenditures from FY 2008-09 and applied that proportion to the FY 2010-11 expenditure estimate. This revised method eliminates the need to adjust the linear regression result by removing actual jail expenditures from prior data points. This allows the linear regression method to estimate expenditures as if jails had never been served.
3. One-Time Increase in Federal Funds (#1): 2010 Ryan White Part B Supplemental Award (#2X08HA19011-02-00) - The California Department of Public Health (CDPH) received a 2010 supplemental augmentation of \$2.660 million to its federal Ryan White (RW) Part B grant award, which CDPH will use for ADAP. CDPH requested \$3.7 million out of a total of \$17 million available nationally. The *November Estimate FY 2011-12* assumes the increase in federal funds will be spent in the current year.
4. One-Time Increase in Federal Funds (#2): 2010 ADAP Shortfall Relief Award (#1X09HA20246-01-00) - CDPH received a RW supplemental augmentation specifically for ADAP of \$2.423 million. CDPH requested \$3.4 million of the \$25 million available nationally to avoid potential cost-containment measures, including the creation of a client waiting list, reduction in income eligibility and reduction in the drug formulary and/or institution of client cost-sharing during state FY 2010-11. The *November Estimate FY 2011-12* assumes the increase in federal funds will be spent in the current year.
5. One-Time Reimbursement: One-time federal funding through the Safety Net Care Pool – On February 1, 2010, the Centers for Medicare and Medicaid Services approved the Department of Health Care Services (DHCS) 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 the Safety Net Care Pool. DHCS used

certified public expenditures (CPE) from various programs, including ADAP, to claim federal funds. CDPH will receive \$76.277 million of these funds from DHCS as a reimbursement. The *November Estimate FY 2011-12* assumes the reimbursement will be spent in the current year.

6. Client Cost-Sharing Policy – The Budget would increase client share of cost in ADAP to the maximum percentages allowable under federal law for specified ADAP clients, but would limit ADAP clients with private insurance or Medicare Part D to a lower cost-sharing percentage. The increased client share of cost will offset the General Fund reduction.
7. Renegotiated Supplemental Rebate and/or Price Freeze Agreements - The Patient Protection and Affordable Care Act (PPACA), signed into law in March 2010, includes a provision requiring drug manufacturers to increase mandatory 340B rebates from 15 percent of Average Manufacturers' Price (AMP) to 23 percent of AMP for brand name drugs and from 11 percent of AMP to 13 percent of AMP for generics as of January 1, 2010. The mandatory 340B rebate increase for brand name drugs is of particular significance because ninety percent of all ADAP rebates are for antiretroviral (ARV) expenditures, all of which are brand name drugs.

Beginning in May 2010 and continuing over the next few months, the national ADAP Crisis Task Force (ACTF) met with representatives of the eight manufacturers of ARV drugs to negotiate new voluntary supplemental rebate agreements. This was to address the national ADAP fiscal crisis which has resulted from increasing caseload and medication costs in the face of only minimally increased federal resources. This crisis has led to unprecedented numbers of clients on ADAP waiting lists, income eligibility restrictions, formulary reductions, etc. nationally.

During the negotiations with the drug manufacturers, the ACTF took the position that the required eight percent increase in mandatory 340B rebates established a new minimum drug rebate level but that, given the ongoing national ADAP fiscal crisis, manufacturers should provide additional voluntary supplemental rebates/discounts above the new mandatory eight percent increase.

Agreements, with an effective date of July 1, 2010, were reached with seven of the eight manufacturers. Genentech/Roche extended their current agreement to June 2011, due to a major company merger and internal restructuring. It is fully anticipated that the ACTF will meet individually with the three manufacturers whose agreements expire during FY 2010-11 to renegotiate the terms of those agreements (Table 3, next page).

TABLE 3: STATUS OF RENEGOTIATED SUPPLEMENTAL REBATE AND/OR PRICE FREEZE AGREEMENTS				
Company	Covered Drugs	Expiration Date	Impact FY 2010-11	Impact FY 2011-12
Abbott Laboratories	Kaletra (lopinavir/ritonavir) Norvir (ritonavir)	1/1/2011	x	TBD
Boehringer-Ingelheim	Aptivus (tipranavir) Viramune (nevirapine)	6/30/2012	x	x
Gilead Sciences	Viread (tenofovir disoproxil fumarate) Emtriva (emtricitabine) Truvada (tenofovir/emtricitabine) Atripla (emtricitabine/tenofovir/efavirez)	12/31/2013	x	x
Merck	Crixivan (indinavir) Isentress (raltegravir)	12/31/2013	x	x
Tibotec Therapeutics	Prezista (darunavir TMC-114) Intelence (etravirine)	12/31/2012	x	x
ViiV Healthcare	Combivir (zidovudine/lamivudine) Epzicom (abacavir/lamivudine) Lexiva (fosamprenavir) Trizivir (abacavir/lamivudine/zidovudine) Selzentry (maraviroc)	12/31/2010	x	TBD
Bristol Meyers-Squibb	Reyataz (atazanavir) Videx (didanosine) Sustiva (efavirenz) Zerit (stavudine)	12/31/2013	x	x
Genentech/Roche	Fuzeon (enfuvirtide) Invirase (saquinavir mesylate) Valcyte (valganciclovir) Pegasys (pegylated interferon)	Previous Agreement Extended to 6/30/2011	TBD	TBD

Previous voluntary, supplemental agreements with manufacturers have produced an estimated cumulative national ADAP savings of \$1 billion from 2003 to 2009. In 2009, California's drug expenditures represented approximately 25 percent of the national total (2010 National Alliance of State and Territorial AIDS Directors [NASTAD] National ADAP Monitoring Project Annual Report).

Estimating the additional program revenue likely to result from the combination of the increase in mandatory 340B rebates and the renegotiated supplemental agreements is complicated. ADAP will not simply realize an across-the-board increase in brand drug rebate of approximately eight percent (the former 15 percent of AMP vs. the new 23 percent of AMP). The negotiations resulted in varying net reductions in drug costs after rebates:

- Some manufacturers offered rebates above the mandatory 340B rebates increase dictated by PPACA.
- Some manufacturers offered nothing beyond the previous supplemental rebate rates because their prior agreement was already equal to or better than the increased mandatory 340B rebate rate.

- Some manufacturers offered a combination of the above, with some of their drugs providing rebates above the new mandatory 340B rebate rate levels and other drugs with rebates only at the mandatory 340B rebate levels.

To calculate the effects of both the PPACA-mandated increase in the mandatory 340B rebate beginning January 2010 and the change in the ACTF-negotiated voluntary supplemental rebate beginning July 2010, ADAP used a rebate calculation methodology developed by NASTAD's ACTF consultant. The "NASTAD Adjusted Rebates Estimate (NARE)" methodology consists of the steps described below. The accuracy of the NARE methodology will be carefully assessed and validated when actual rebates are received. ADAP will track the actual increase in collected rebate amounts from January through June 2010 closely. The combined factors of increased mandatory 340B rebate and voluntary supplemental rebate will first apply to rebates billed for third quarter (July-September) 2010 and will not be fully known until ADAP receives the associated drug rebates for that period. Rebates for that quarter will likely be received by February 2011.

Estimate for FY 2010-2011 (See Appendix F, page 37 for additional detail):

1. Estimate for January 1, 2010 – June 30, 2010: For each drug, the change in *net* rebate was calculated by comparing the new mandatory 340B rebate rate with the sum of the pre-PPACA mandatory 340B rebate rate plus the pre-July 2010 voluntary supplemental rebate rate agreements in effect during the January-June 2010 time period. This comparison takes into account all the elements of the supplemental rebate agreements, except for the impact of price freezes (Appendix B, page 24). For most products, the sum of the previously negotiated voluntary supplemental rebate rate plus the old pre-PPACA mandatory 340B rebate was already greater than the new mandatory 340B rebate rate. For these products, the new mandatory 340B rebate resulted in no net increase in rebate dollars, because drug companies simply reduced their voluntary supplemental rebate rate by the amount that the mandatory 340B rebate was increased. For a few products, the sum of the previously negotiated voluntary supplemental rebate rate plus the old pre-PPACA mandatory 340B rebate was smaller than the new mandatory 340B rebate rate. For these products, the new mandatory 340B rebate resulted in a net increase in rebate collected. Across all drugs by every manufacturer, the resulting increase in net rebate collected was minimal. The net increased rebate rates were applied to January through June 2010 actual expenditure data, resulting in an estimated increase of \$352,081 in additional rebate dollars, corresponding to an increase in the overall rebate return rate of less than 0.2 percentage points, to 46.38 percent (from 46.22 percent). The application of the NARE methodology assumes that the rebates already collected for January through March 2010 do not reflect the increased mandatory 340B rebate rate. This assumption was made because the PPACA was not signed until March 23, 2010 and federal guidelines regarding implementation of this legislation had not been issued at the time that rebates were invoiced by ADAP and paid by the manufacturers. If it is determined that ADAP has not received some or the entire additional rebate amount owed, then ADAP plans to initiate retroactive billing for these differences.

2. Estimate for July 1, 2010 – December 31, 2010: The new voluntary supplemental rates starting July 2010 were compared to the rates in effect from January through June 2010 (the new mandatory 340B rebate rate plus any remaining voluntary supplemental rates higher than the new mandatory 340B rebate rates) and the net increase was calculated. All changes resulting in higher rebate rates were then applied to FY 2009-10 ADAP actual expenditures to estimate the potential impact on the overall rebate collection rate if the new mandatory 340B rebate and voluntary supplemental rebate rates had been implemented that fiscal year. It is estimated that ADAP would have increased its rebate return rate by approximately five percentage points, resulting in an overall rebate rate of 51.56 percent (from 46.22 percent). Based on the estimated expenditures for July through December 2010 and applying the adjusted overall rebate rate of 51.56 percent, ADAP projects an additional \$12,655,623 million in rebate will be collected.
3. Total Estimate for FY 2010-11: We added the two separate adjustments described above (\$352,081 + \$12,655,623), resulting in an overall increase in rebate revenue of \$13,007,704 million for FY 2010-11. Because of the approximate six-month delay in receiving rebate checks, FY 2010-11 rebate estimates are generated from actual and estimated expenditures from January 2010 – December 2010. The FY 2010-11 revenues benefit from the new mandatory 340B rebate rates in effect from January through June 2010 and again from the higher rates starting July 2010 as a result of the higher voluntary supplemental rates negotiated by the ACTF.

Estimate for FY 2011-12:

Using the methods described in #2 above, we estimate that an additional \$26,819,317 million will be collected in rebates resulting from the combined voluntary supplemental rebate and mandatory 340B rebate increases.

8. RFP: Reduction in Reimbursement Rate for ADAP Pharmacy Benefit Management (PBM) Contract starting July 1, 2011 - The ADAP brand name drug reimbursement rate in the ADAP PBM Contract Request for Proposal (RFP) is reduced from the current rate of Average Wholesale Price (AWP) -14.0 percent to Wholesale Acquisition Cost (WAC) +2.60 percent, which is equivalent to AWP -14.5 percent. In order to convert from AWP to WAC, the ratio between the two pricing standards was identified. As reported by First DataBank, drug manufacturer pricing for WAC pricing is 16.6 percent less than the AWP price for the same drug. Applying this ratio to the AWP -14.5 percent resulted in the new ADAP PBM RFP drug reimbursement rate of WAC +2.60 percent.

Estimate for FY 2011-12:

1. To estimate net expenditures by payer source, which represents the AWP -14 percent drug reimbursement rate from ADAP to the PBM, we first calculated net expenditures, without jail expenditures, for brand drugs dispensed in FY 2009-2010 by payer source [ADAP only (89.5 percent of net expenditures) and all

other payer sources (Medi-Cal, Medicare, private insurance 10.5 percent of net expenditures)]. We did this by subtracting dispense fees and approved transaction fees from total expenditures. Per ADAP's current PBM contract, the difference in reimbursement rate that the PBM negotiates with their pharmacy contractors compared to ADAP's contracted rate with the PBM is evenly split between ADAP and the PBM. Therefore, we then we calculated OA's portion of the split savings for Brand drugs dispensed (excluding jails) in FY 2009-2010 and added that to the first step.

2. The ADAP-only group will benefit from the full reduction in the PBM reimbursement rate as ADAP is the only payer for these clients. The "all other payer sources" group is only partially affected by the PBM reimbursement rate reduction because ADAP only pays client out-of-pocket expenses for these drugs. For this group there is a differential impact depending on the expense type (i.e., co-insurance [which would be affected by the reduction] and co-payments [which would not be affected by the reduction]). Assuming full impact of the AWP reduction for the "all other payer sources" group would result in an overestimate of expenditure savings. We are unable to determine the impact of this Major Assumption on this group, because we do not have information on insurance plans (co-insurance vs. co-payment) to determine if they will be affected by the AWP reduction. Thus, we calculated the estimated expenditure adjustment for both the ADAP-only group and the total of all payer sources, multiplied both by 0.5%, subtracted from both the estimated split savings, and then for both divided the difference by the total FY 2009-10 expenditures to calculate the percent of total FY 2009-2010 expenditures that this represented.
3. For both the ADAP-only group and the all-payer group, we then applied each percentage to the estimated total FY 2011-12 expenditures to calculate a range in potential estimated savings due to the reduction in reimbursement rate for the ADAP PBM contract to AWP – 14.5 percent. We then averaged the two estimates to come up with a single estimate in potential estimated savings (\$1,926,810) due to the reduction in reimbursement rate for the ADAP PBM contract to AWP – 14.5 percent.

Revised Major Assumptions

1. ADAP Pharmacy Benefit Management RFP: Transaction Fees/Change in Date – This Assumption was included in the *May Revision 2010-11*. An RFP to implement a new PBM contract was to be effective July 1, 2010. The PBM RFP was withdrawn when it became clear that there was not sufficient time to allow for a transition to a possible new PBM provider. A new ADAP PBM RFP has been released for services to begin in FY 2011-12. Services for FY 2010-11 are being provided through a one-year contract that includes the provisions of the previous five year contract.

The RFP includes two administrative changes to the PBM contract, effective July 1, 2011: 1) Each non-approved transaction fee will be a \$3.00 maximum instead of the current \$6.00 maximum; and 2) Non-approved transaction fees will be limited to five re-submittals instead of the current unlimited number of re-submittals.

To estimate the expenditure impact from reducing the maximum non-approved transaction fee from \$6.00 to \$3.00 in the new RFP:

1. The percentage of approved (55.5 percent) and non-approved (44.5 percent) transaction fees in FY 2009-10, with jail expenditures removed, was calculated.
2. The total transaction fees estimate was developed as an observed proportion from FY 2009-10, applied to the November Estimate FY 2011-12 linear regression expenditure estimate.
3. The non-approved transaction fee percentage (44.5 percent) was then applied to the unadjusted FY 2011-12 total transaction fees estimate to approximate the hypothetical total non-approved transaction fees before introduction of the reduced \$3.00 fee.
4. This amount was divided by 50 percent ($\$3.00/\6.00) to arrive at the initial adjusted estimate of \$3,667,108.

To estimate the RFP savings achieved by limiting non-approved transactions to a maximum of five submittals per prescription, the FY 2009-10 fees associated with all non-approved transactions submitted six or more times was summed and divided by the total fees for all non-approved transactions to obtain the proportion. This FY 2009-10 percentage of non-approved transaction fees associated with prescriptions submitted more than five times was divided in half (to capture the change from \$6.00 to \$3.00) then applied to the estimated non-approved transaction fees for FY 2011-12 (based on the FY 2009-10 non-approval percent of 44.5 percent). The additional savings achieved by limiting non-approved transactions to a maximum of five submittals per prescription is estimated at \$222,683, with the total savings from these two RFP changes estimated at \$3,889,791.

2. Interest Earned – The *May Revision 2010-11* estimated interest income at \$400,000 for FY 2010-11. Actual interest earned for FY 2009-10 was approximately \$315,000. Since interest rates have continued to decline 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 2010-11 and 2011-12 to \$300,000 annually.
3. Legislation Affecting Medicare Part D True Out Of Pocket Costs (TrOOP) – Prior to the PPACA, Medicare Part D law prohibited ADAP spending from counting towards a Medicare Beneficiary's TrOOP. Consequently, prior to January 1, 2011, an ADAP client who entered the "donut hole" (coverage gap) would remain there for the rest of the plan year. As a result, ADAP has paid 100 percent of the client's drug costs once the client reaches the donut hole. ADAP spending on drugs has not counted towards the \$3,610 (year 2010) out-of-pocket threshold that would move an individual into catastrophic coverage, at which point the client would only be required to pay a five percent co-insurance per prescription for the remainder of the calendar year. PPACA includes provisions to change and ultimately eliminate the Medicare "donut hole" over time. Beginning January 1, 2011, Medicare recipients enrolled in ADAP will benefit from the provision that any expenditure related to ADAP, either their own or any incurred on their behalf, will count towards that client's TrOOP. Also, beginning January 1, 2011, drug manufacturers will pay 50 percent of client donut hole expenditures, which results in additional savings to ADAP.

To estimate the savings from ADAP expenditures counting towards TrOOP and drug manufacturers paying 50 percent of TrOOP starting January 1, 2011, we estimated the expenditure reduction associated with this group (donut hole clients) between January and June 2010 and applied that percentage to the last six months of FY 2010-11, when these legislative and policy changes will take effect. To estimate the hypothetical expenditure reduction from 2010 (jail expenditures removed), we employed the following steps:

Estimate for FY 2010-2011:

1. We identified the actual number of Medicare Part D clients “stuck” in the donut hole from January through June 2010 (635 clients). ADAP payments for the 372 clients with expenditures exceeding the donut hole threshold were totaled; these represent savings associated with ADAP clients who would have moved into catastrophic coverage had the PPACA provision been in effect during this time period.
2. These savings were adjusted to incorporate the five percent co-insurance expenses that are incurred by ADAP while clients are in the catastrophic coverage.
3. For all clients in the donut hole, additional savings to ADAP resulting from the PPACA mandate that drug manufacturers pay 50 percent of prescription costs while clients are in the donut hole were estimated. This requirement will reduce ADAP’s donut hole payments by 50 percent.
4. These three factors were summed to obtain the percentage of total FY 2009-10 expenditures represented by this client pool.
5. This percentage was then applied to FY 2010-11, resulting in an estimated six-month savings due to TrOOP of \$3,419,633.

Estimate for FY 2011-12:

1. To estimate the savings from ADAP expenditures counting towards TrOOP and drug manufacturers paying 50 percent of TrOOP in FY 2011-12 for the time period January - June 2012, we followed the same procedures as above except that we multiplied the percentage of total FY 2009-10 expenditures represented by this client pool by the total expenditure estimate for January - June 2012. This resulted in an estimated six-month savings due to TrOOP of \$3,886,534.
2. To estimate the savings from ADAP expenditures counting towards TrOOP and drug manufacturers paying 50 percent of TrOOP in FY 2011-12 for July - December 2011, we identified the actual number of Medicare Part D clients (total of 715):
 - a. who would have already reached the donut hole threshold during the time period January–June 2009 (393 clients),

- b. who had no donut hole prescriptions during the time period January–June 2009 (55 clients), and
- c. who had some donut hole expenditures but would not have already reached the donut hole threshold during the time period January–June 2009 (267 clients).

For the first group who had already reached the threshold, all ADAP expenditures from July - December 2011 were totaled; these represent savings associated with ADAP clients who would have moved into catastrophic coverage had the PPACA provision been in effect during this time period.

For the second group who had no donut hole prescriptions in the first half of the year (55 clients), we determined how many would reach the threshold in the second half of the year (13 clients) and totaled only ADAP payments exceeding the donut hole threshold, again representing savings associated with ADAP clients who would have moved into catastrophic coverage had the PPACA provision been in effect during this time period.

For the third group who had some donut hole expenditures but not yet reached the threshold by the end of the first half of the year (267 clients), we totaled only ADAP payments exceeding the donut hole threshold, again representing savings associated with ADAP clients (102 clients) who would have moved into catastrophic coverage had the PPACA provision been in effect during this time period.

3. The savings from these three groups of Medicare Part D clients were totaled and adjusted to incorporate the five percent co-insurance expenses that are incurred by ADAP while clients are in the catastrophic coverage. Again, for all clients in the donut hole, additional savings to ADAP resulting from the PPACA mandate that drug manufacturers pay 50 percent of prescription costs while clients are in the donut hole were estimated. These factors were then summed to obtain the percentage of total FY 2009-2010 expenditures represented by this client pool. We then multiplied the percentage of total FY 2009-10 expenditures represented by this client pool by the total expenditure estimate for July - December 2011. This resulted in an estimated six-month savings due to TrOOP of \$3,028,316.
4. The final estimated TrOOP savings for FY 2011-12 was calculated by adding the savings from both halves of the fiscal year, for a total estimated savings of \$6,914,850.

There will not be a revenue impact from TrOOP for either FY 2010-11 or FY 2011-12 as ADAP will be purchasing the same quantity of drugs. Rebate is based upon quantity rather than expenditure per dose, so the rebate revenue will remain the same.

Discontinued Major Assumptions

1. AWP Rollback Projected Savings vs. the Drug Price Increases - Due to unanticipated increases in drug prices prior to and following the institution of the "AWP Rollback," we have not seen and do not anticipate any savings and thus are not longer including an adjustment to the linear regression to account for estimated ongoing savings.
2. Medi-Cal: Newly Qualified Aliens (NQA) - This proposal was rejected by the legislature and is unlikely to be enacted due to provisions in PPACA.
3. Medi-Cal: Permanently Residing Under Color of Law Immigrants and Amnesty Aliens (PRUCOL) - This proposal was rejected by the legislature and is unlikely to be enacted due to provisions in PPACA.
4. Discontinued ADAP Services in County Jails – This change has been incorporated into our standard linear regression methods.

3. FUND CONDITION STATEMENT

The Fund Condition Statement (FCS), (see Table 4, next page) shows the status of the ADAP Special Fund (SF) for FYs 2009-10, 2010-11 and 2011-12 and all the factors that impact the fund including revenues, expenditures, revenue collection rate, interest earned and major assumptions.

For FY 2010-11, revenue estimates are based on actual rebates collected for the period January to March 2010, actual expenditures for April to June 2010 and estimated expenditures for July to December 2010. A 46 percent rebate collection rate was applied to the actual and estimated expenditures for the respective time periods to arrive at estimated revenue of \$159,761,157. Adding actual revenues of \$53,030,370, for January to March, results in estimated revenues of \$212,791,527. These revenues were adjusted to reflect the impact of the New Major Assumption #7 yielding total revenue in the amount of \$225,799,231. It is estimated that there will be an additional \$300,000 of revenue from interest.

For FY 2011-12, revenue estimates are based on estimated expenditures for the periods January through June and July through December 2011. A 46 percent rebate collection rate was applied to arrive at the revenue projection of \$232,201,878. This amount was adjusted to account for the fiscal impact of the New Major Assumption #7 resulting in total revenues of \$259,021,195. It is estimated that there will be an additional amount of \$300,000 of revenue from interest.

Based upon the linear regression and new major assumptions, the revised FY 2010-11 General Fund appropriation is \$71,440,000, a \$54,168,000 decrease from Budget Act. The General Fund appropriation for FY 2011-12 is \$163,857,000, an increase of \$38,249,000 from FY 2010-11 Budget Act and \$92,417,000 from the revised FY 2010-11 appropriation.

NOVEMBER ESTIMATE FUND CONDITION STATEMENT

Table 4: FUND CONDITION STATEMENT (in thousands)				
Special Fund 3080 AIDS Drug Assistance Program Rebate Fund		FY 2009-10 Actuals	FY 2010-11 estimate	FY 2011-12 estimate
1	BEGINNING BALANCE	91,183	11,309	8,352
2	Prior Year Adjustment	-85	0	0
3	Adjusted Beginning Balance	91,098	11,309	8,352
4	REVENUES, TRANSFERS AND OTHER ADJUSTMENTS			
5	Revenues			
6	150300 Income From Surplus Money Investments	315	300	300
7	161400 Miscellaneous Revenue	171,085	225,799	259,021
8	Total Revenues, Transfers, and Other Adjustments	171,400	226,099	259,321
9	Total Resources	262,498	237,408	267,673
10	EXPENDITURES AND EXPENDITURE ADJUSTMENTS			
11	Expenditures			
12	8880 FI\$Cal		1	1
13	0840 State Controllers Office	23	56	33
14	4260 Department of Health Care Service (State Ops)	15		
15	4265 Department of Public Health			
16	State Operations	905	896	997
17	Local Assistance	250,246	228,103	257,007
18				
19				
20	Total Expenditures and Expenditure Adjustments	251,189	229,056	258,038
21	FUND BALANCE	11,309	8,352	9,635

Row 6: Actuals for FY 2009-10, Estimated for FYs 2010-11 and 2011-12 (Revised Major Assump. #2)

315,308	300,000	300,000
---------	---------	---------

Miscellaneous Revenue

Actual Rebates for Jan - Mar 2010	53,030,370	
Actual expenditures for April - June 2010	109,105,789	
Estimated expenditures for July - Dec 2010	238,201,074	
Total Actual and Estimated Expenditures FY 2010-11	347,306,863	
Estimated expenditures for Jan - June 2011		238,201,074
Estimated expenditures for July - Dec 2011		266,585,618
Total Estimated Expenditures FY 2011-12		504,786,692
Estimated revenue at 46% rebate collection rate on \$347,306,863	159,761,157	
Total Revenue FY 2010-11	212,791,527	
Estimated revenue at 46% rebate collection rate on \$504,786,692		232,201,878
Revenue Impact: Renegotiated Sup. Rebate/Price Freeze Agreements for Jan-Jun 2010 (New Major Assump. #7)	352,081	
Revenue Impact: Renegotiated Sup. Rebate/Price Freeze Agreements (for FY 2010-11: Jul - Dec 2010, for FY 2011-12: Jan - Dec 2011 (New Major Assump. #7)	12,655,623	26,819,317
Row 7: Projection of Total Revenue after adjustments	225,799,231	259,021,195

Expenditure Projections: FYs 2010-11 and 2011-12, Linear Regression (New Major Assump. #1 & #2)

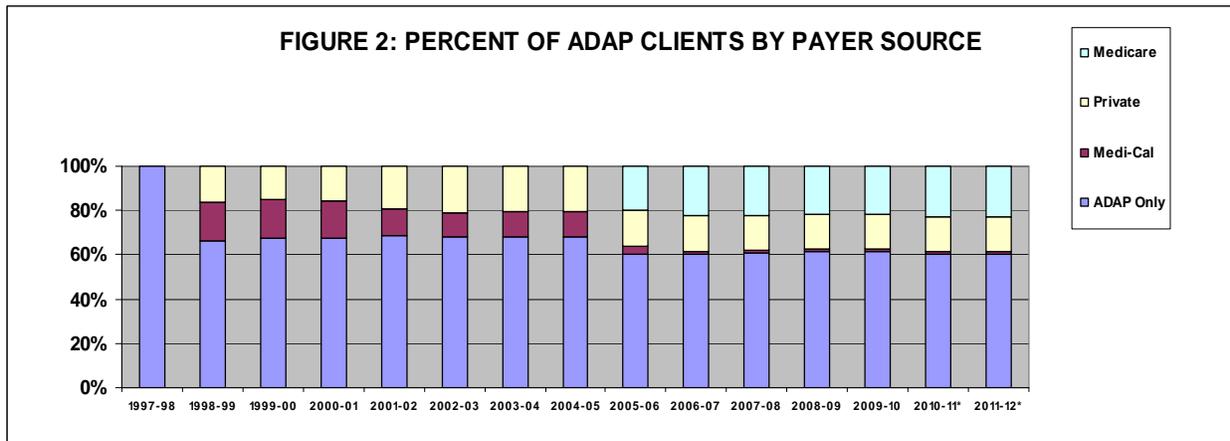
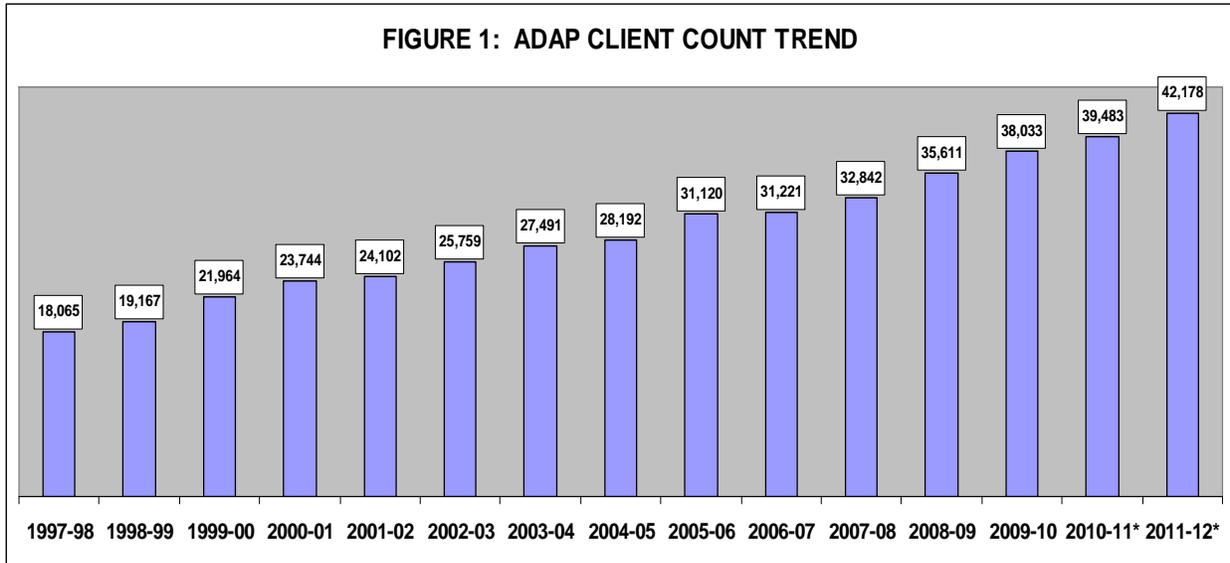
Administrative Reduction to PBM Contract (GF Reduction)	-500,000	
Subtotal: Local Assistance Expenditure Estimate	479,821,780	545,902,686
Expenditure Impact: RFP: ADAP PBM Transaction Fee Savings (Revised Major Assump. #1)	0	-3,889,791
Expenditure Impact: Leg. Affecting Medicare Pt. D TrOOP (HCR) (Revised Major Assump. #3)	-3,419,633	-6,914,850
Expenditure Impact: RFP: Change in Reimburse. Rate for PBM Contract (New Major Assump. #8)		-1,926,810
Subtotal: Expenditure Projection after Adjustments	476,402,147	533,171,235
Less Client Cost Sharing (New Major Assump. #6)		-16,808,000
Revised Subtotal:	476,402,147	516,363,235
*Less: Federal Fund Appropriation (Earmark)	-97,631,979	-97,631,979
Less: One-Time Federal Fund Increase RW Pt. B Supplemental Award (New Major Assump. #3)	-2,659,865	
Less: One-Time Federal Fund Increase RW Pt. B ADAP Shortfall Relief Award (New Major Assump. #4)	-2,423,137	
Less: One-Time Reimbursement funding through the Safety Net Care Pool (New Major Assump. #5)	-76,277,000	
Less: General Fund Appropriation - per Budget Act	-125,608,000	-125,608,000
Less: General Fund savings (New Major Assump. #6)		16,808,000
General Fund Need to avoid a negative fund balance	-13,757,000	-45,422,000
Additional General Fund Need to achieve a prudent reserve	-8,352,000	-9,635,000
General Fund savings due to one-time Reimbursement (New Major Assump. #5)	76,277,000	
Subtotal General Fund revised appropriation	-71,440,000	-163,857,000
Special Fund 3080 Need to meet Expenditure Projection	225,970,166	254,874,256
Local Assistance Local Health Jurisdiction (LHJ)	1,000,000	1,000,000
Local Assistance Medicare Part D	1,000,000	1,000,000
Tropism Assay	132,623	132,623
Row 17: Total Special Fund 3080 Need	228,102,789	257,006,879

*Includes the Ryan White 2010 grant award effective April 1, 2010

4. HISTORICAL PROGRAM DATA AND TRENDS

(*Data for FY 2010-11 and FY 2011-12 are estimated, all other data are actuals)

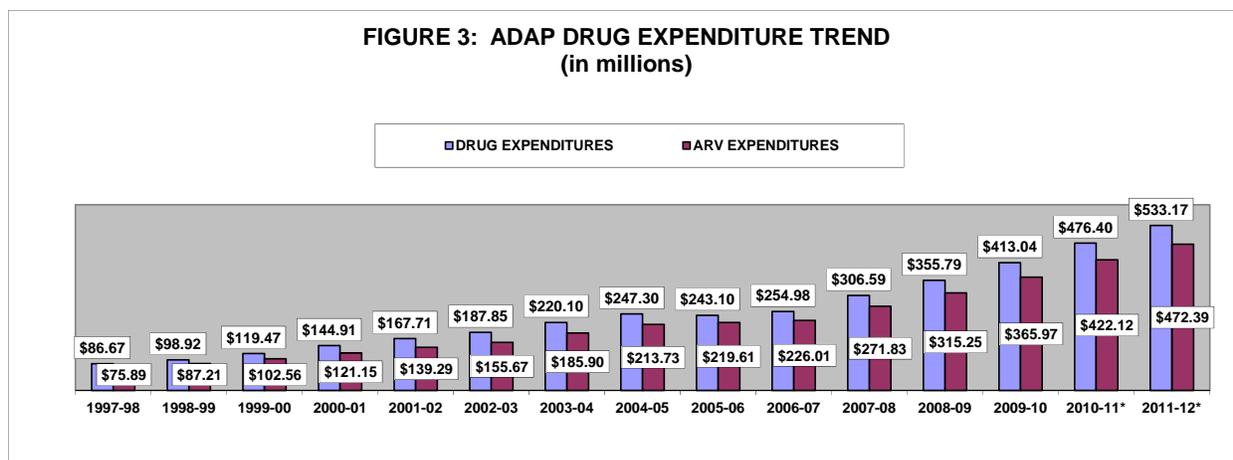
For all figures and tables in Section 4, the data prior to FY 2010-11 is the observed historical data, and thus includes jail transactions. To develop client and prescription estimates for FY 2010-11 and FY 2011-12, we used a model similar to the 36-month regression model for expenditure estimates removing the jail expenditures, where the 36 monthly data points were the number of clients and prescriptions with jail clients and prescriptions removed.



Note: The actual percentage of ADAP clients (minus jail clients) by payer source/coverage group in FY 2009-10 was applied to the estimated client counts in FY 2010-11 and FY 2011-12 to estimate the percentage of clients by payer source.

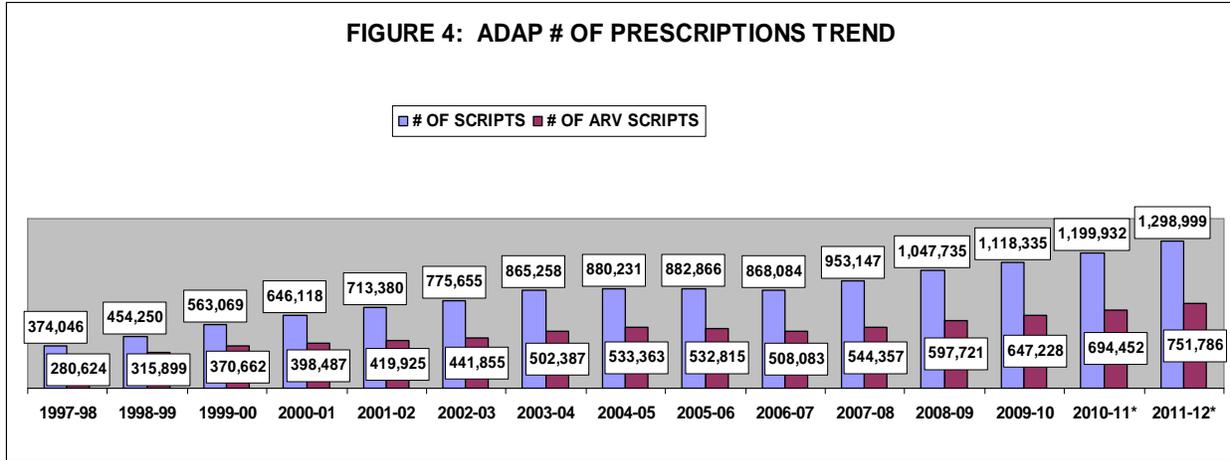
TABLE 5: ESTIMATED ADAP CLIENTS BY COVERAGE GROUP				
	FY 2010-11*		FY 2011-12*	
COVERAGE GROUP	CLIENTS	PERCENT	CLIENTS	PERCENT
ADAP	23,765	60.19%	25,387	60.19%
Medi-Cal	486	1.23%	519	1.23%
Private Insurance	6,300	15.96%	6,730	15.96%
Medicare	8,932	22.62%	9,542	22.62%
TOTAL	39,483	100.00%	42,178	100.00%

Note: The actual percentage of ADAP clients (minus jail clients) by payer source/coverage group in FY 2009-10 was applied to the estimated clients counts in FY 2010-11 and FY 2011-12 to estimate the percentage of clients by payer source.

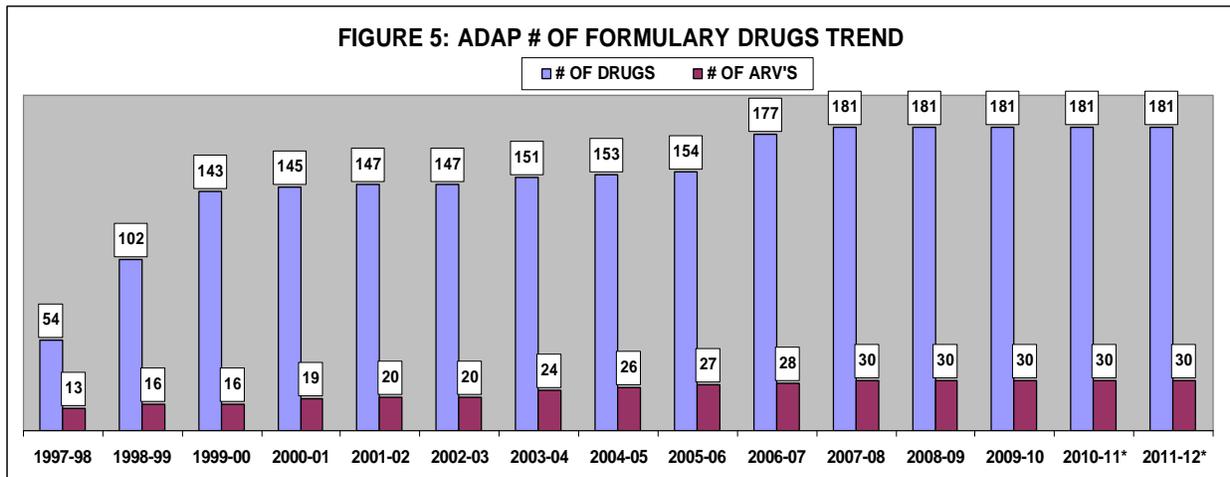


Note: Non-drug expenditures including Tropism Assay (laboratory test required to demonstrate clinical indication for one of the antiretroviral (ARV) agents covered by ADAP; \$132,623 in FY 2008-09 and \$93,359 in FY 2009-10), and annual administrative support of \$1 million for Local Health Jurisdictions (LHJ) and Medicare Part D premium payments of \$1 million are not displayed here.

Note: For ARV expenditures, we used the percentage of ARV expenditures without jail prescriptions in FY 2009-10 and applied it to the estimated drug expenditures in FY 2010-11 and FY 2011-12 to estimate the percentage of ARV expenditures.



Note: For the number ARV prescriptions, we used the percentage of ARV prescriptions without jail prescriptions in FY 2009-10 and applied it to the estimated drug prescriptions in FY 2010-11 and FY 2011-12 to estimate the number of ARV prescriptions.



APPENDIX A: EXPENDITURE AND REVENUE ESTIMATE METHODS

Updated Expenditure Estimate for FY 2010-11

TABLE 6: LINEAR REGRESSION MODEL FOR NOVEMBER ESTIMATE FOR FY 2010 -11 COMPARED TO BUDGET ACT FY 2010 -11			
Revised Estimate	Estimate from Budget Act FY 2010 -11	Change from Previous Estimate (\$)	Change from Previous Estimate (%)
\$480,321,780	\$462,883,048	\$17,438,732	3.77%

New Expenditure Estimate for FY 2011-12

TABLE 7: LINEAR REGRESSION MODEL FOR NOVEMBER ESTIMATE FOR FY 2011-12 COMPARED TO BUDGET ACT FY 2010-11			
November Estimate FY 2011-12	Estimate from Budget Act FY 2010 -11	Change from Previous Estimate (\$)	Change from Previous Estimate (%)
\$545,902,686	\$462,883,048	\$83,019,638	17.94%

Linear Regression Model – Expenditure Estimates

The linear regression methodology is the same as the method used in the previous year, with three caveats. 1) We use updated data points. 2) As explained in new Major Assumption #1 the data set includes 36 data points to reflect actual expenditures for the period August 2007 to July 2010 (the *May Revision 2010-11* used 50 data points from January 2006 through February 2009). This approach is consistent with the number of data points used by Medi-Cal. 3) All prior years' data sets have had jail expenditure data removed. This change will eliminate the need to adjust the linear regression prior to each projection (see New Major Assumption #2).

Figure 6 (next page) shows ADAP historic expenditures by month. The (thick straight red) 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 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, 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 (CI) around the point estimate for our regression estimates. This is the same strategy used during the previous estimate development.

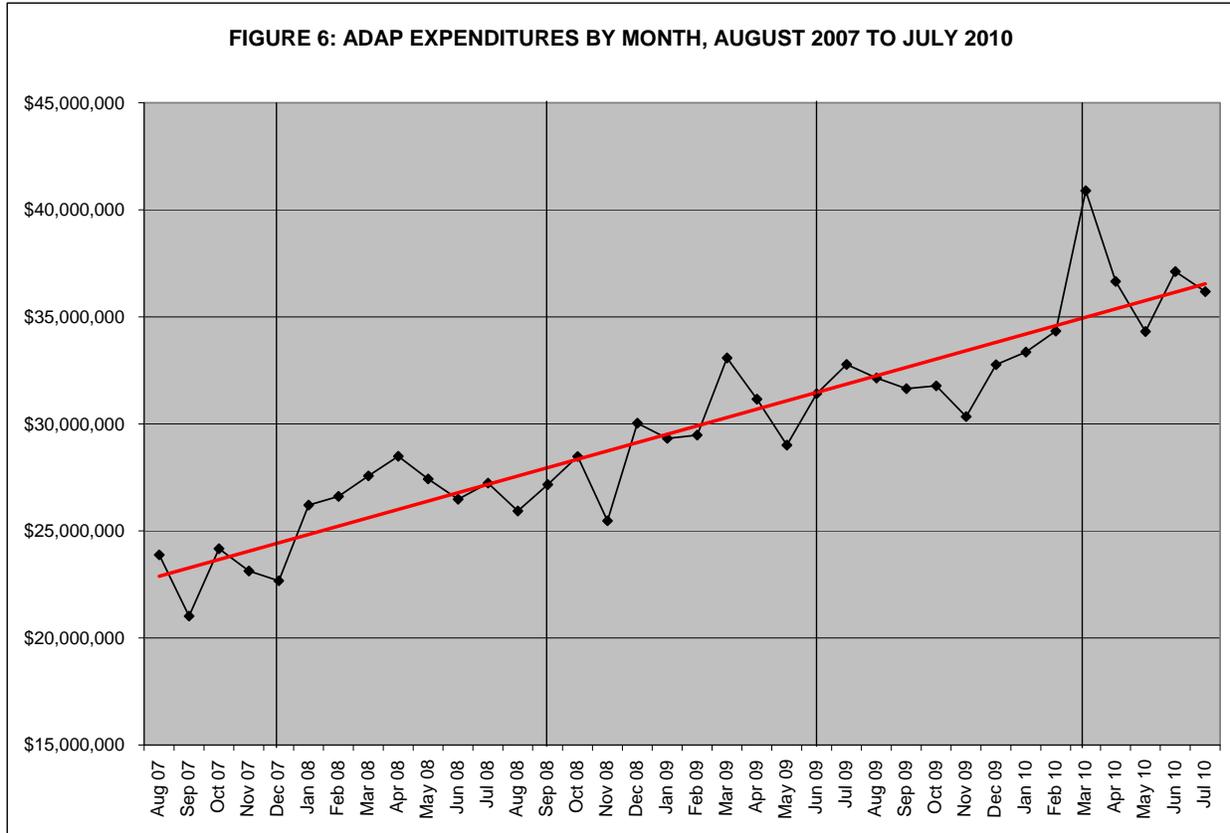


Table 8 below shows historic drug expenditures by FY, annual change and percent change.

TABLE 8: ADAP HISTORIC AND PROJECTED DRUG EXPENDITURES			
(*Data for FY 2010-11 and FY 2011-12 are projected, all other data are actuals)			
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%
2009-10	\$413,035,251	\$57,248,851	16.09%
2010-11*	\$476,402,147	\$63,366,896	15.34%
2011-12*	\$533,171,235	\$56,769,088	11.92%
Total Average	FY 97-98 to 11-12	\$31,892,636	14.02%

Note: Non-drug expenditures including Tropism Assay (\$132,623 in FY 2008-09 and \$93,359 in FY 2009-10), and annual administrative support of \$1 million for 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.

Note: 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.

Program Expenditure Estimate for FY 2011-12

In addition to the drug expenditure estimates noted in Table 9 below, 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

TABLE 9: HISTORIC ADAP REBATE REVENUE COLLECTION PERCENTS BY QUARTER			
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	\$36,272,892	44.04%
2008/09-Q2	\$85,997,429	\$38,043,925	44.24%
2008/09-Q3	\$93,564,283	\$46,249,558	49.43%
2008/09-Q4	\$93,858,017	\$40,766,475	43.43%
2009/10-Q1	\$98,508,463	\$44,591,512	45.27%
2009/10-Q2	\$95,842,924	\$43,566,678	45.46%
2009/10-Q3	\$109,578,075	\$53,030,370	48.40%

Note: As noted in Section 2, the Major Assumption # 7 discussion on estimating rebate for January through June 2010 (page 4), OA does not yet have the information to determine if the rebate collected for 2009/10-Q3 (January through March 2010) reflects the increased mandatory 340B rebate rate.

ADAP Rebate Revenue Estimate Method

To forecast future revenue, the rebate revenue estimate method applies the expected revenue collection rate (46 percent) to estimated or actual expenditures (whichever is more current). Estimated revenue for a given FY is based on drug expenditures during the last two quarters of the previous FY and the first two quarters of the current FY. This six month delay is necessary to take into account the time required for billing the drug manufacturers and receipt of the rebate. Revenue projections are adjusted to reflect assumptions and other adjustments that can increase or decrease revenues. Revenue estimates for FY 2010-11 were developed using actual expenditures for April through June 2010 and estimated expenditures for July through December 2010 (see Table 10, next page). The projected rebate collection rate of 46 percent was then applied to the total actual and estimated expenditures and the resulting estimated revenue was then adjusted due to the fiscal impact of New Major Assumption #7.

Revenue for FY 2011-12 was based on estimated expenditures for January through June 2011 and July through December 2011, applying the 46 percent rebate collection rate and adjusted for New Major Assumption #7.

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

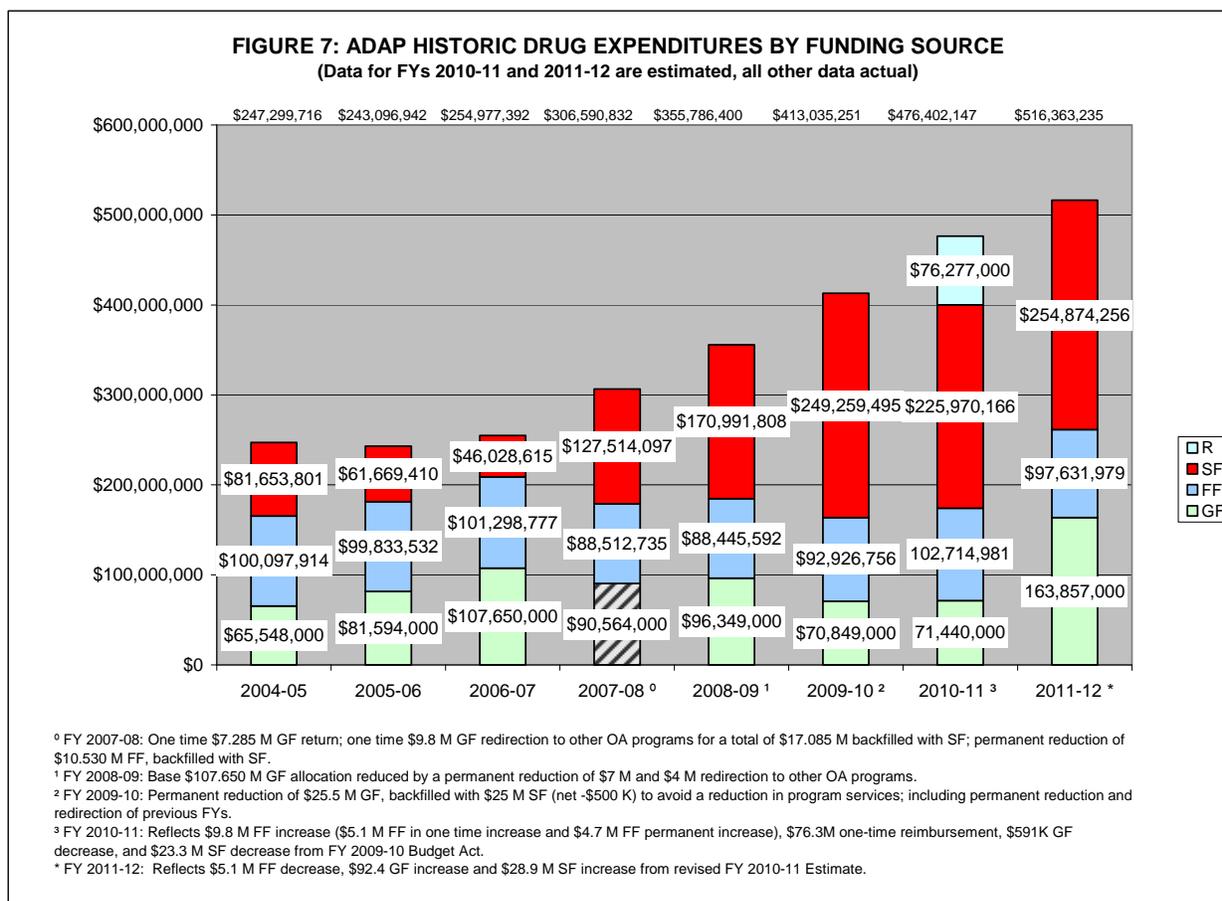
TABLE 10: COMPARISON OF REVENUE* BETWEEN NOVEMBER ESTIMATE FY 2011-12 AND BUDGET ACT 2010-11						
UPDATED ESTIMATE FOR FY 2010-11						
Expenditure Period	Available Data	November Estimate	Available Data	Appropriation	Change (\$)	Change (%)
Jan - Mar 2010	Actual Rebates	\$53,030,370	Estimated Expenditures @ 46%	\$47,383,177	\$5,647,193	11.92%
Apr - Jun 2010	Actual Expenditures @ 46%	\$50,188,663	Estimated Expenditures @ 46%	\$47,383,177	\$2,805,486	5.92%
Jul - Dec 2010	Estimated Expenditures @ 46%	\$109,572,494	Estimated Expenditures @ 46%	\$99,226,018	\$10,346,476	10.43%
Subtotal Revenue		\$212,791,527		\$193,992,372	\$18,799,155	9.69%
FY 2010-11	Renegotiated Supplemental Rebate/Price Freeze Agreements for Jan - Jun 2010 (New Major Assumption #7)	\$352,081		\$0	\$352,081	-
FY 2010-11	Renegotiated Supplemental Rebate/Price Freeze Agreements for FY 2010-11: Jul-Dec 2010 (New Major Assumption #7)	\$12,655,623		\$0	\$12,655,623	-
FY 2010-11	Reduction: Elimination of Services to Jails*			-\$1,914,266	\$1,914,266	-100.00%
Subtotal Revenue		\$225,799,231		\$192,078,106	\$33,721,125	
Interest		\$300,000		\$400,000	-\$100,000	-25.00%
Total Revenue (see Table 4, Fund Condition Statement)		\$226,099,231		\$192,478,106	\$33,621,125	17.47%
* For the November Estimate 2011-12 revenue savings from eliminating services to jails is included in the linear regression projection and not a separate number as in the previous May Revision						
ESTIMATE FOR FY 2011-12						
Expenditure Period	Available Data	November Estimate	Available Data (Expenditure Period)	FY 2010-11 (November Estimate)	Change (\$)	Change (%)
Jan - Jun 2011	Estimated Expenditures @ 46%	\$109,572,494	Actual Rebate (Jan - Mar 2010) Actual Expenditures @ 46% (Jan-Jun 2010)	\$103,219,033	\$6,353,461	6.16%
Jul - Dec 2011	Estimated Expenditures @ 46%	\$122,629,384	Estimated Expenditures @ 46% (Jul - Dec 2010)	\$109,572,494	\$13,056,890	11.92%
Subtotal Revenue		\$232,201,878		\$212,791,527	\$19,410,351	9.12%
			Renegotiated Supplemental Rebate/Price Freeze Agreements for Jan - Jun 2010 (New Major Assumption #7)	\$352,081	-\$352,081	-
FY 2011-12	Renegotiated Supplemental Rebate/Price Freeze Agreements for FY 2010-11: Jul - Dec 2010, for FY 2011-12: Jan - Dec 2011 (New Major Assumption #7)	\$26,819,317		\$12,655,623	\$14,163,694	111.92%
Subtotal Revenue		\$259,021,195		\$225,799,231	\$33,221,964	
Interest		\$300,000		\$300,000	\$0	0.00%
Total Revenue (see Table 4, Fund Condition Statement)		\$259,321,195		\$226,099,231	\$33,221,964	14.69%
*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

Payments of ADAP expenditures in FY 2010-11 are made from four fund sources:

1. State General Fund (GF) appropriations.
2. Federal funding (FF) from the Health Resources and Services Administration (HRSA) through the RW program. In addition, for FY 2010-11, the Office of AIDS (OA) received two one-time fund awards: RW Part B Supplemental Award of \$2,659,865, and ADAP Shortfall Relief Award of \$2,423,137.
3. Reimbursement (R) from DHCS is a one-time funding source for FY 2010-11, as a result of additional federal resources available through the Safety Net Care Pool.
4. ADAP SF consists of both mandatory and voluntary rebates from manufacturers with products on the ADAP formulary and interest payments from ADAP SF.

Figure 7 (below) shows the amount and proportions of the four funding sources for FY 2010-11 and the additional funding need for FY 2011-12. The revised FY 2010-11 General Fund appropriation is \$71,440,000, a \$54,168,000 decrease from Budget Act. The General Fund appropriation for FY 2011-12 is \$163,857,000, an increase of \$38,249,000 from FY 2010-11 Budget Act and \$92,417,000 from the revised FY 2010-11 appropriation.



General Fund

ADAP's GF allocation is used for the purchase of prescription drugs for eligible clients. It is the only source of funding used by ADAP to meet the Medi-Cal Share of Cost (SOC) for eligible clients and prescription expenditures for Medicare Part D clients. This fund source also pays 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.

The revised FY 2010-11 General Fund appropriation is \$71,440,000, a \$54,168,000 decrease from Budget Act. The General Fund appropriation for FY 2011-12 is \$163,857,000, an increase of \$38,249,000 from FY 2010-11 Budget Act and \$92,417,000 from the revised FY 2010-11 appropriation.

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.

For FY 2010-11, ADAP received an increase in Earmarked Federal funding of \$4,705,223 for a total of \$97,631,979 as well as two one-time fund awards: RW Part B Supplemental Award of \$2,659,865, and ADAP Shortfall Relief Award of \$2,423,137. The total increase in federal funds for FY 2010-11 is \$9,788,225, which includes both a presumably permanent increase as well as the two one-time supplements.

Match

HRSA requires grantees to have HIV-related non-HRSA expenditures of at least one half of the HRSA grant award. Since California's 2010 HRSA grant award is \$134,604,892, the match requirement for FY 2010-11 funding is \$66,834,681.

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 2009-10 expenditures at the time of the Year 2011 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 GF expenditures specific to HIV-related activities such as care, treatment, prevention, and surveillance. Expenditures from the SF may be used towards the MOE requirement.

Reimbursement

On February 1, 2010, the Centers for Medicare and Medicaid Services approved the DHCS 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 the Safety Net Care Pool. DHCS used certified public expenditures (CPE) from various programs, including ADAP, to claim federal funds. CDPH will receive \$76.277 million of these funds from DHCS as a reimbursement. The *November Estimate FY 2011-12* assumes the reimbursement will be spent in the current year.

ADAP SF (3080)

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 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 approximately 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 mandatory 340B rebate is a percentage of the AMP, plus any penalties for price increases that exceed the rate for the Consumer Price Index (CPI). Since the AMP is confidential and not publicized, the resulting rebate amount is also unknown to ADAP. ACTF negotiations usually result in an additional voluntary, supplemental percentage of the AMP. For example, the current mandatory 340B rebate for brand drugs is 23 percent of AMP. If the ACTF has negotiated a supplemental rebate of two percent of AMP, then ADAP receives a total rebate of 25 percent of AMP.

"Price Freeze" Rebates

The "price freeze" option is another type of voluntary rebate offered by the manufacturer to compensate for commercial price increases. Currently, of the 31 available ARV medications on the ADAP formulary, ten (32 percent) are subject to a price freeze rebate. These ten drugs represented 52 percent of ADAP drug expenditures in FY 09-10. If the manufacturers impose a price increase that exceeds the CPI (inflation rate) while the price freeze is in effect, the program reimburses retail pharmacies at the higher rates. Though this initially results in higher expenditures for the program, these price freeze agreements eventually offset the cost by increased 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 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-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. Historically, the majority of drug manufacturers have paid rebates more closely to the Medicaid payment timeframe, usually within 30 to 60 days. However, receipt of rebate payments due for the first two quarters of calendar year 2010 indicate the

manufacturers are now 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 generally receives drug rebates six to nine months after program expenditures. 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

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.

New Drugs that May be Available in the Next 3 Years

Possible approval in 2011

Rilpivirine

Rilpivirine is an investigational NNRTI in development for use with other ARV agents in treatment-naïve patients. This drug has shown activity against NNRTI-resistant HIV. Rilpivirine recently completed a Phase III clinical trial and the manufacturer submitted a NDA to the FDA on July 26, 2010. ADAP will monitor the scheduling of the review by the Antiviral Drugs Advisory Committee and potential FDA approval. If approved, ADAP will monitor pricing and supplemental rebate negotiations closely.

Truvada/Rilpivirine combination

Manufacturers are continuing development of a once-daily single-pill co-formulation of nucleoside/nucleotide reverse transcriptase inhibitors tenofovir and emtricitabine the two drugs in the Truvada combination pill -- plus rilpivirine . If approved by the FDA, the proposed Truvada/rilpivirine would become another option for a complete antiretroviral therapy available in a single pill. We are hopeful that pricing and supplemental rebate negotiations would result in price-neutrality with Atripla. If approved, ADAP will monitor pricing and supplemental rebate negotiations closely.

Possible approval in late 2012 or early 2013

Combination elvitegravir, cobicistat, emtricitabine and tenofovir (Quad)

As of September, 2010, a Phase II, 48 week study of an investigational fixed-dose, single-tablet "Quad" (four drug) regimen of elvitegravir, cobicistat, emtricitabine and tenofovir was completed. The first Phase III study of the "Quad" versus Atripla was recently fully enrolled, and the second study of the "Quad" versus a protease-based regimen is now fully enrolled. The results of these two studies are expected to be released in 2011. ADAP will monitor for filing of the New Drug Application (NDA), Antiviral Drugs Advisory Committee scheduling, and potential Food and Drug Administration (FDA) approval. It typically takes approximately six months from filing to approval for ARVs. If approved, ADAP will monitor pricing and supplemental rebate negotiations closely.

Elvitegravir

Elvitegravir is an investigational integrase inhibitor therapy that is 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 reduced dosing requirement. In addition, patients may switch from once a day protease inhibitors (PI) and non-nucleoside reverse transcriptase inhibitors (NNRTI) once a daily integrase inhibitor is available. Assuming successful negotiations with the manufacturer by the ACTF, it is anticipated the net cost of elvitegravir (after rebates) will be comparable to raltegravir, which is comparable to once daily PIs and NNRTIs. This drug is also being studied as part of the previously discussed "Quad" formulation's trials which are in Phase III. If approved, ADAP will monitor pricing and supplemental rebate negotiations closely.

Cobicistat

Cobicistat is being developed both as a pharmacokinetic (PK) booster for integrase inhibitor elvitegravir and as a booster for protease inhibitors. The Phase II study compared efficacy and safety of cobicistat (150 mg) with that of existing booster ritonavir (100 mg daily). Participants are currently being sought for a Phase III clinical trial to further study cobicistat as a protease inhibitor booster. This drug is also being studied as part of the previously discussed "Quad" formulation's trials which are in Phase III. If approved, ADAP will monitor pricing and supplemental rebate negotiations closely.

Possible approval in 2013

GSK1349572

Integrase inhibitor with activity against raltegravir-resistant HIV.

TROFILE DNA assay

The tropism assay manufactured by Monogram BioSciences, Trofile ES, is currently FDA approved for use by physicians when determining the prescribing of maraviroc and is reimbursable through ADAP. Earlier this year Monogram BioSciences received approval for the *Trofile DNA* assay by the FDA. This assay is designed for use in patients with an undetectable HIV RNA level (viral load) who may want to use maraviroc due to side effects or other reasons. Both tests use the same current procedural terminology (CPT) code and bill for the same amount, \$1,575.75 plus a processing fee.

Since the Trofile DNA test would be used in a different patient population, this presents the possibility of minimally increased utilization of the tests and thus a small additional cost to ADAP. In-house monitoring of maraviroc usage in 2010 shows no increased utilization of the drug since the approval for use in treatment-naïve patients. ADAP is currently polling its Medical Advisory Committee (MAC) regarding their recommendations about the potential utility of this test in the clinical management of

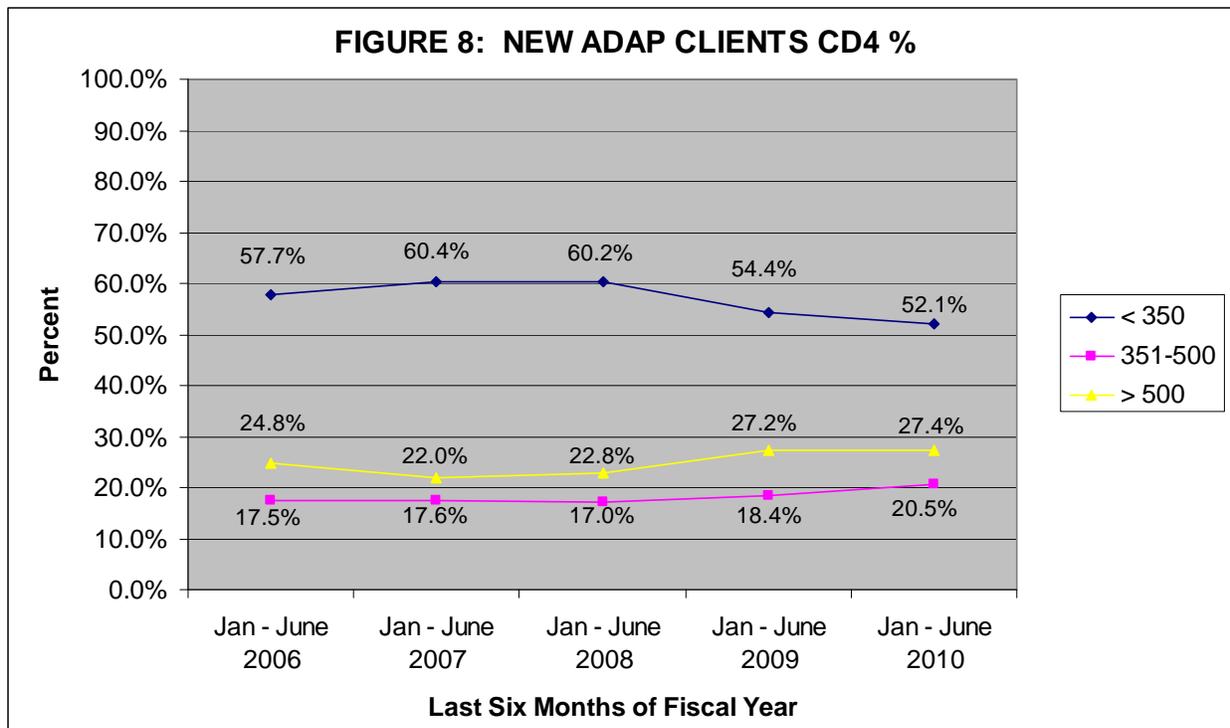
patients with HIV infection. Should it be added to ADAP, its use will be monitored closely. It is not expected to be used frequently.

Changes in Treatment Guidelines to Recommend Earlier Initiation of Antiretroviral Therapy (ARV).

The December 2009 change in the HIV treatment guidelines to recommend early initiation of ARV does not correspond to an increase in the number of clients in January – June 2010 compared to January – June 2009 (Table 11 below and figure 8 next page). Note that the data in the table and figure below are for only the last six months of each fiscal year). There may be a small trend for new clients enrolled with CD4 counts between 351 and 500 and a small reduction in the number of clients with CD4 counts less than 350. A small increase in the January – June 2009 timeframe compared to the two prior years supports the hypothesis that many physicians started implementing these practices before the guidelines were updated. Therefore, we believe that any small changes in our clients due to this guideline change should be captured in the regression data points. We will continue to monitor these trends and propose an adjustment if indicated by the data.

TABLE 11: ADAP NEW CLIENTS* CD4			
January - June	CD4 Range	# of Clients	% of Clients
2006	< 350	1,128	57.7%
	351-500	341	17.5%
	> 500	485	24.8%
	Total	1,954	100.0%
2007	< 350	933	60.4%
	351-500	271	17.6%
	> 500	340	22.0%
	Total	1,544	100.0%
2008	< 350	955	60.2%
	351-500	270	17.0%
	> 500	362	22.8%
	Total	1,587	100.0%
2009	< 350	996	54.4%
	351-500	338	18.4%
	> 500	498	27.2%
	Total	1,832	100.0%
2010	< 350	963	52.1%
	351-500	379	20.5%
	> 500	506	27.4%
	Total	1,848	100.0%

*New Clients are defined as ADAP enrollment date between January - June.



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 some time in the future. California estimates that there will be between 153,394 and 180,119 living with HIV/AIDS at the end of 2010, as seen in Table 12 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, 3.5 percent Asian/Pacific Islander, and 0.4 percent American Indian/Alaskan Native. Most (65 percent) of California's living HIV/AIDS cases are attributed to male-to-male transmission, nine percent is attributed to injection drug use, nine percent to heterosexual transmission, and eight 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 two percent (with a range of 2,800 – 5,700) 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
2008	43,230	56,223	66,577	67,665	147,853	168,689
2009	43,322	57,038	68,967	70,506	150,574	174,454
2010	43,427	57,840	71,410	73,294	153,394	180,119
2011	43,541	58,633	73,879	76,055	156,270	185,727
2012	43,660	59,421	76,366	78,798	159,185	191,296

*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 of the 'consensus conference' estimate based upon observed reported HIV cases in the code-based HIV surveillance system;

numbers observed to date in the names-based HIV surveillance system are consistent with this adjustment.

Recent advances have made estimation of HIV incidence possible using remnant blood samples from people found to be HIV antibody positive. In 2004, CDC began a national effort to measure incidence using state-of-the-art technology. Results of this effort were reported in the August, 2008 issue of Journal of the American Medical Association and MMWR. California's data were not included as they are not yet complete enough to provide accurate estimates. The 95 percent confidence interval for the national estimate (48,200 to 64,500 new infections) is, however, 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 Serologic Testing Algorithm for Recent HIV Seroconversion (STARHS) methodology. Data from this system will be used to revise California incidence estimates in the coming years. The confidence interval for 2008 data from this program in San Francisco (462 to 783) is generally consistent with the 5,000 to 7,000 range that OA estimates for the entire state.

APPENDIX E: SENSITIVITY ANALYSIS**FY 2010-11**

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 expenditures for FY 2010-11 using the upper bound of the 95 percent CI from the linear regression model and subtracted savings for the administration reduction in PBM contract costs and Medicare Part D TrOOP savings.

For these factors, clients and expenditures per client, we created scenarios ranging from negative three percent to positive three percent, in one percent intervals. Those scenarios labeled as “Hi” represent three percent, “Med” represent two percent, and “Lo” represents a one percent change. The left column in Table 13 below lists the seven (including no change) scenarios for changes in \$ / client, starting with the best case scenario {three percent decrease in \$ / client, Hi(-)} and finishing with the worst case scenario {three 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	\$448,437,470	\$453,027,273	\$457,617,076	\$462,206,880	\$466,796,683	\$471,386,486	\$475,976,289
Med (-)	\$453,027,273	\$457,664,394	\$462,301,515	\$466,938,635	\$471,575,756	\$476,212,877	\$480,849,997
Lo (-)	\$457,617,076	\$462,301,515	\$466,985,953	\$471,670,391	\$476,354,829	\$481,039,268	\$485,723,706
Zero Change in \$ / Client	\$462,206,880	\$466,938,635	\$471,670,391	\$476,402,147	\$481,133,903	\$485,865,659	\$490,597,414
Lo (+)	\$466,796,683	\$471,575,756	\$476,354,829	\$481,133,903	\$485,912,976	\$490,692,050	\$495,471,123
Med (+)	\$471,386,486	\$476,212,877	\$481,039,268	\$485,865,659	\$490,692,050	\$495,518,440	\$500,344,831
Hi (+): Worst	\$475,976,289	\$480,849,997	\$485,723,706	\$490,597,414	\$495,471,123	\$500,344,831	\$505,218,540

The center cell, highlighted in light blue, shows the revised estimated expenditures for FY 2010-11, using the 95 percent CI from the linear regression model (less the administration reduction in PBM contract costs and Medicare Part D TrOOP savings). The best case scenario, which is a three percent decrease in \$ / client coupled with a three percent decrease in the number of clients, results in an estimate of \$448,437,470 (top left cell, light green). The worst case scenario, a three percent increase in \$ / client coupled with a three percent increase in number of clients, results in an estimate of \$505,218,540 (bottom right cell, red). The table provides a range of values to assist in projecting the total expenditures for FY 2010-11.

FY 2011-12

Below is the sensitivity analysis for FY 2011-12, using the same logic as above. In this Sensitivity Analysis, ADAP adjusted for several assumptions that impacted ADAP's FY 2011-12 total expenditures, non-approved transaction fees, and total client count. Similar to the FY 2010-11 Sensitivity Analysis, we started with the estimated total drug expenditures for FY 2011-12 using the upper bound of the 95 percent CI from the linear regression model. Then we subtracted savings for the PBM transaction fee savings, Medicare Part D TrOOP savings, and the RFP change in reimbursement rate for PBM contract. The "baseline" or center cell, highlighted in light blue below, reflects all adjustments to the linear regression expenditure projection. The table provides a range of values to assist in projecting the total expenditures for FY 2011-12.

TABLE 14: SENSITIVITY ANALYSIS FOR FISCAL YEAR 2011-12 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	\$501,877,541	\$507,013,731	\$512,149,921	\$517,286,111	\$522,422,301	\$527,558,491	\$532,694,681
Med (-)	\$507,013,731	\$512,202,872	\$517,392,012	\$522,581,152	\$527,770,293	\$532,959,433	\$538,148,574
Lo (-)	\$512,149,921	\$517,392,012	\$522,634,103	\$527,876,194	\$533,118,285	\$538,360,375	\$543,602,466
Zero Change in \$ / Client	\$517,286,111	\$522,581,152	\$527,876,194	\$533,171,235	\$538,466,276	\$543,761,318	\$549,056,359
Lo (+)	\$522,422,301	\$527,770,293	\$533,118,285	\$538,466,276	\$543,814,268	\$549,162,260	\$554,510,251
Med (+)	\$527,558,491	\$532,959,433	\$538,360,375	\$543,761,318	\$549,162,260	\$554,563,202	\$559,964,144
Hi (+): Worst	\$532,694,681	\$538,148,574	\$543,602,466	\$549,056,359	\$554,510,251	\$559,964,144	\$565,418,036

APPENDIX F: ADDITIONAL INFORMATION RENEGOTIATED SUPPLEMENTAL REBATE AGREEMENTS AND HEALTH CARE REFORM LEGISLATION

OA has clarified the relationship between the increased mandatory 340B rebate beginning January 2010 and the voluntary supplemental rebates already in existence between January and June 30, 2010 with NASTAD's ACTF technical assistance consultant. The ACTF approach is to negotiate a sub-340B price as allowed by the enabling 340B program legislation. The negotiated ADAP voluntary, supplemental Direct Purchase price is below 340B pricing and may be frozen for the term of the agreement. For Rebate Model ADAPs like CA, a rebate is calculated as the difference between Average Manufacturer's Price (AMP) and the ADAP Direct Purchase price.

Between January and June 30, 2010, manufacturers continued to honor the ADAP prices that were in place due to prior written agreements, but using the same "total" rebate calculation. This is possible because the rebates are based on the Direct Purchase price, not directly on a percent of AMP. In most cases, the "extra" 8 percent of AMP discount/rebate due to PPACA did not result in the 340B prices being lower than the ADAP price. Therefore the rebate remained the same; the only difference was that the portion attributable to the mandatory 340B program increased, while the portion attributable to the ACTF decreased. The simplified example below illustrates this effect:

Pre-PPACA

AMP =	\$100.00
340B price =	\$ 84.90 (15.1% minimum)
ADAP price =	\$ 75.00
ADAP Rebate =	\$25.00 (\$15.10 from 340B, \$9.90 from ACTF)

Post-PPACA

AMP =	\$100.00
340B price=	\$ 76.90 (23.1% minimum)
ADAP price =	\$75.00
ADAP Rebate =	\$25.00 (\$23.10 from 340B, \$1.90 from ACTF)

In May, the ACTF renegotiated pricing with manufacturers, with the goal of restoring the original value of the ACTF portion. Thus the example changed to the below, after new written agreements were put into place for July 1 implementation.

Post-PPACA & post ACTF renegotiations

AMP =	\$100.00
340B price=	\$ 76.90 (23.1% minimum)
ADAP price =	\$67.00
ADAP Rebate =	\$33.00 (\$23.10 from 340B, \$9.90 from ACTF)

In summary, for most products, the sum of the previously negotiated voluntary supplemental rebate rate plus the old pre-PPACA mandatory 340B rebate was already greater than the new mandatory 340B rebate rate. For these products, the new mandatory 340B rebate resulted in no net increase in rebate dollars, because drug

companies simply reduced their voluntary supplemental rebate rate by the amount that the mandatory 340B rebate was increased. For a few products, the sum of the previously negotiated voluntary supplemental rebate rate plus the old pre-PPACA mandatory 340B rebate was smaller than the new mandatory 340B rebate rate. For these products, the new mandatory 340B rebate resulted in a net increase in rebate collected. Across all drugs by every manufacturer, the resulting increase in *net* rebate collected was minimal. Starting in July 2010, the new ACTF-negotiated voluntary supplemental rebates came into effect. These, combined with the new PPACA mandatory 340B rebate in effect since January 2010, led to substantially greater ADAP drug savings.