

NOVEMBER ESTIMATE

**AIDS DRUG ASSISTANCE PROGRAM
(ADAP)**

2009-10 GOVERNOR'S BUDGET



**CALIFORNIA
DEPARTMENT OF PUBLIC HEALTH**

Table of Contents

<u>SECTION</u>	<u>PAGE</u>
COMPARISON TABLE	
EXECUTIVE SUMMARY	1
A: SUMMARY TABLE	2
B: BACKGROUND	3
C: HISTORICAL CASELOAD FACTORS	6
D: ESTIMATE METHOD DETAILS	8
<u>FY 2008-09</u>	
May Revision Background	8
Updated Percent Change Estimate	11
Linear Regression Estimate	13
<u>FY 2009-10</u>	
Percent Change Estimate	14
Linear Regression Estimate	15
E: FUND SOURCES OVERVIEW	16
General Fund	16
Federal Fund	17
ADAP Rebate Fund	18
F: ADAP REBATE FUND REVENUE AND EXPENDITURE PROJECTIONS	20
G: POLICY ISSUES WITH POTENTIAL IMPLICATIONS FOR ADAP	25
H: APPENDICES	28
1. Definitions	28
2. New Drug Updates	30
3. Treatment Guidelines Updates	31
4. HIV/AIDS Case Update	32

TABLE A - Cost Comparison of 2008-09 Enacted Budget to 2008-09 November Estimate

	2008-09 ENACTED BUDGET				ADJUSTMENTS/DIFFERENCES				2008-09 NOVEMBER ESTIMATE			
	Total	Federal	State	Rebate	Total	Federal	State	Rebate	Total	Federal	State	Rebate
Local Assistance	\$ 332,329,838	\$ 88,765,592	\$ 96,349,000	\$ 147,215,246	\$ 29,795,136	\$ (320,000)	\$ -	\$ 30,115,136	\$ 362,124,974	\$ 88,445,592	\$ 96,349,000	\$ 177,330,382
Prescription costs	\$ 319,183,147	\$ 81,297,309	\$ 94,119,662	\$ 143,766,176	\$ 29,447,084	\$ (320,000)	\$ -	\$ 29,767,084	\$ 348,630,231	\$ 80,977,309	\$ 94,119,662	\$ 173,533,260
PBM operational costs	\$ 11,146,691	\$ 7,468,283	\$ 2,229,338	\$ 1,449,070	\$ 348,052	\$ -	\$ -	\$ 348,052	\$ 11,494,743	\$ 7,468,283	\$ 2,229,338	\$ 1,797,122
Subtotal Estimate	\$ 330,329,838	\$ 88,765,592	\$ 96,349,000	\$ 145,215,246	\$ 29,795,136	\$ (320,000)	\$ -	\$ 30,115,136	\$ 360,124,974	\$ 88,445,592	\$ 96,349,000	\$ 175,330,382
LHJ Administration	\$ 1,000,000	\$ -	\$ -	\$ 1,000,000	\$ -	\$ -	\$ -	\$ -	\$ 1,000,000	\$ -	\$ -	\$ 1,000,000
Medicare Part D Premiums	\$ 1,000,000	\$ -	\$ -	\$ 1,000,000	\$ -	\$ -	\$ -	\$ -	\$ 1,000,000	\$ -	\$ -	\$ 1,000,000
Support/administration costs	\$ 2,481,447	\$ 1,177,695	\$ 217,752	\$ 1,086,000	\$ 2,000	\$ -	\$ -	\$ 2,000	\$ 2,483,447	\$ 1,177,695	\$ 217,752	\$ 1,088,000

TABLE B - Cost Comparison of 2008-09 Enacted Budget to 2009-10 November Estimate

	2008-09 ENACTED BUDGET				ADJUSTMENTS/DIFFERENCES				2009-10 NOVEMBER ESTIMATE			
	Total	Federal	State	Rebate	Total	Federal	State	Rebate	Total	Federal	State	Rebate
Local Assistance	\$ 332,329,838	\$ 88,765,592	\$ 96,349,000	\$ 147,215,246	\$ 85,768,005	\$ (320,000)	\$ -	\$ 86,088,005	\$ 418,097,843	\$ 88,445,592	\$ 96,349,000	\$ 233,303,251
Prescription costs	\$ 319,183,147	\$ 81,297,309	\$ 94,119,662	\$ 143,766,176	\$ 84,303,488	\$ (320,000)	\$ -	\$ 84,623,488	\$ 403,486,635	\$ 80,977,309	\$ 94,119,662	\$ 228,389,664
PBM operational costs	\$ 11,146,691	\$ 7,468,283	\$ 2,229,338	\$ 1,449,070	\$ 1,464,517	\$ -	\$ -	\$ 1,464,517	\$ 12,611,208	\$ 7,468,283	\$ 2,229,338	\$ 2,913,587
Subtotal Estimate	\$ 330,329,838	\$ 88,765,592	\$ 96,349,000	\$ 145,215,246	\$ 85,768,005	\$ (320,000)	\$ -	\$ 86,088,005	\$ 416,097,843	\$ 88,445,592	\$ 96,349,000	\$ 231,303,251
LHJ Administration	\$ 1,000,000	\$ -	\$ -	\$ 1,000,000	\$ -	\$ -	\$ -	\$ -	\$ 1,000,000	\$ -	\$ -	\$ 1,000,000
Medicare Part D Premiums	\$ 1,000,000	\$ -	\$ -	\$ 1,000,000	\$ -	\$ -	\$ -	\$ -	\$ 1,000,000	\$ -	\$ -	\$ 1,000,000
Support/administration costs	\$ 2,481,447	\$ 1,177,695	\$ 217,752	\$ 1,086,000	\$ 78,000	\$ -	\$ -	\$ 78,000	\$ 2,559,447	\$ 1,177,695	\$ 217,752	\$ 1,164,000

For the 2008/09 Enacted Budget, prescription cost estimates were derived by subtracting the PBM operational cost estimated in the "Percent Change Model." For the November estimates, linear regression was used to derive both prescription cost and PMB operational cost estimates as described in detail in Section D.

TABLE C - Revenue Comparison of 2008-09 Enacted Budget to 2008-09 November Estimate

	2008-09 ENACTED BUDGET				ADJUSTMENTS/DIFFERENCES				2008-09 NOVEMBER ESTIMATE			
	Total	Federal	State	Rebate	Total	Federal	State	Rebate	Total	Federal	State	Rebate
Total ADAP Revenues	\$ 311,608,039	\$ 89,623,287	\$ 96,566,752	\$ 125,418,000	\$ 46,233,000	\$ -	\$ -	\$ 46,233,000	\$ 357,841,039	\$ 89,623,287	\$ 96,566,752	\$ 171,651,000

TABLE D - Revenue Comparison of 2008-09 Enacted Budget to 2009-10 November Estimate

	2008-09 ENACTED BUDGET				ADJUSTMENTS/DIFFERENCES				2009-10 NOVEMBER ESTIMATE			
	Total	Federal	State	Rebate	Total	Federal	State	Rebate	Total	Federal	State	Rebate
Total ADAP Revenues	\$ 311,608,039	\$ 89,623,287	\$ 96,566,752	\$ 125,418,000	\$ 59,790,000	\$ -	\$ -	\$ 59,790,000	\$ 371,398,039	\$ 89,623,287	\$ 96,566,752	\$ 185,208,000

Deposits to ADAP Rebate Fund consist of drug manufacturer rebates, as described in detail in Section E.

Executive Summary

I. ADAP EXPENDITURE ESTIMATES

AIDS Drug Assistance Program (ADAP)
2009-10 November Estimate Summary
(Dollars in Thousands)

Fund Source	2008-09 Budget Act	Revised FY 2008-09 Estimate	Change from 2008-09 Budget Act	FY 2009-10 Estimate	Change from 2008-09 Budget Act
General Fund	\$ 96,349	\$ 96,349	\$ -	\$ 96,349	\$ -
Federal Fund	\$ 88,766	\$ 88,446	\$ -320	\$ 88,446	\$ -320
ADAP Rebate Fund	\$ 147,215	\$ 177,330	\$ 30,115	\$ 233,303	\$ 86,088
Total Program	\$ 332,330	\$ 362,125	\$ 29,795	\$ 418,098	\$ 85,768
Clients Served*	34,168	34,184	16	35,584	1,416

* A number of factors are used to develop the ADAP costs estimate for budget building purposes. These are costs related to Medicare Part D, new antiretroviral drugs, drug price increases, physicians switching clients to more expensive antiretroviral drug combinations, increased client costs and increased prescription transaction fees. These costs apply to new and continuing clients.

II. ADAP REBATE FUND REVENUE ESTIMATES

The Fund Condition Statement prepared for May Revision reflected estimated revenues of \$125.418 million to the ADAP Rebate Fund. As ADAP expenditures increase, manufacturer rebates and credits to ADAP due to ADAP-specific price freezes also increase. Thus, ADAP Rebate Fund revenue is currently estimated to be \$165.463 million for FY 2008-09 and \$178.531 million for FY 2009-10.

III. ADAP REBATE FUND CONDITION STATEMENT ESTIMATES

The Fund Condition Statement prepared for May Revision showed a balance of \$54.263 million at the end of FY 2008-09. Using the revised expenditure and revenue estimate described above, the ADAP Rebate Fund Condition Statement for the FY 2008-09 Governor's Budget shows an estimated balance of \$73.438 million at the end of FY 2008-09, and \$24.014 million at the end of FY 2009-10.

IV. POLICY ISSUES WITH POTENTIAL IMPLICATIONS FOR ADAP

The following Federal policy issues may impact ADAP: annual adjustments to the Medicare Part D program, including increases to the Part D plan premiums and other out-of-pocket costs to clients; ADAP counting toward True Out-of-Pocket (TrOOP) costs enabling clients to move from the "donut hole" into catastrophic coverage; and the ability of ADAP to collect full rebate on partial pay third-party payer transactions. In addition, many pharmaceutical manufacturers are adding co-pay programs that may reduce ADAP's co-payments, thus reducing the ability to collect rebate on those transactions.

SECTION A: SUMMARY TABLE

TABLE 1: SUMMARY ESTIMATES FROM BOTH ESTIMATION METHODS (includes all fund sources)			
FY 2008-09 May Revision (prior to \$7m BBR) Percent Change Model			
\$330,329,838			
FY 2008-09 Estimate	Pg	FY 2009-10 Estimate	Pg
Updated Percent Change Model			
\$327,794,687	11	\$350,757,254	14
Linear Regression Model			
\$360,124,974	13	\$416,097,843	15

Estimated expenditure increase between proposed Linear Regression Model and May Revision Estimate for FY 2008-09 and 2009-10 are \$29,795,136 and \$85,768,005, respectively.

\$2 million additional budget authority: The estimates in Table 1 do not include an additional \$2 million requested annually by the California Department of Public Health (CDPH), Center for Infectious Diseases, Office of AIDS, AIDS Drug Assistance Program (ADAP) for:

- \$1 million provided to the Local Health Jurisdictions (LHJs) to help offset the costs of ADAP enrollment and eligibility screening for clients at each enrollment site 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.

SECTION B: BACKGROUND

ADAP's expenditure projections 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 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 FY 2005-06 and 2006-07 projections, ADAP again adjusted the model to reflect the higher expenditures observed in the previous two fiscal years. 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 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 Health Resources and Services Administration (HRSA), the National Alliance of State and Territorial AIDS Directors (NASTAD) 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 using the following methodology:

Four steps in the Percent Change Model estimate process

1. The starting point is the previous year's expenditures.
2. Factors are identified that will increase (or decrease) the annual expenditures.
3. Percent costs (or savings) are estimated for each factor.
4. To obtain the current year budget estimate, the costs (or savings) for each factor are added to the previous year's expenditures.

With respect to the specific factors (#2 above) to include, HRSA's original percent change model has two variations: simple forecasting (number of clients, cost per client, drug costs, administration and dispensing, and insurance costs) and advanced forecasting (overall percent change and one-time changes to overall drug costs, dispensing and admin, ADAP flexibility costs, and insurance costs). California ADAP included the following five factors in its modification of the HRSA percent change model:

Five “Factors” used in the California ADAP Percent Change Model

1. Medicare Part D costs
2. New drug costs
3. Drug price increases (this factor also includes clients who switch to more expensive drugs)
4. Increase client costs
5. Non-approved transaction fees

Key limitation in HRSA’s Percent Change Model Guidance

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.

The specifics of how ADAP adapted this model are described in **Section D, 1. Historical: FY 2008-09 Budget, Methods for May Revision.**

In late FY 2007-08, **ADAP expenditures again increased.** This change in the actual expenditure pattern back to a straight line made it possible to consider using a **linear regression model** again (see Figure 1 red portion of the line and Table 2).

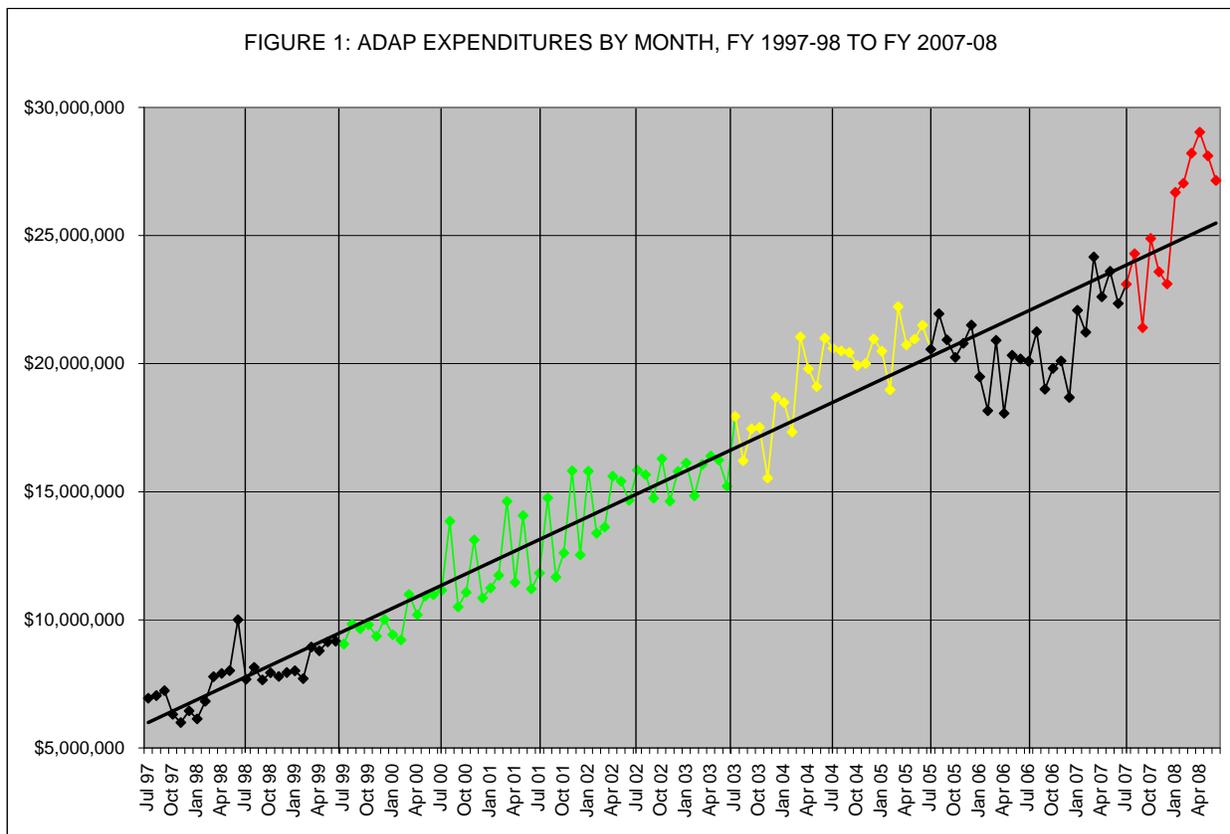
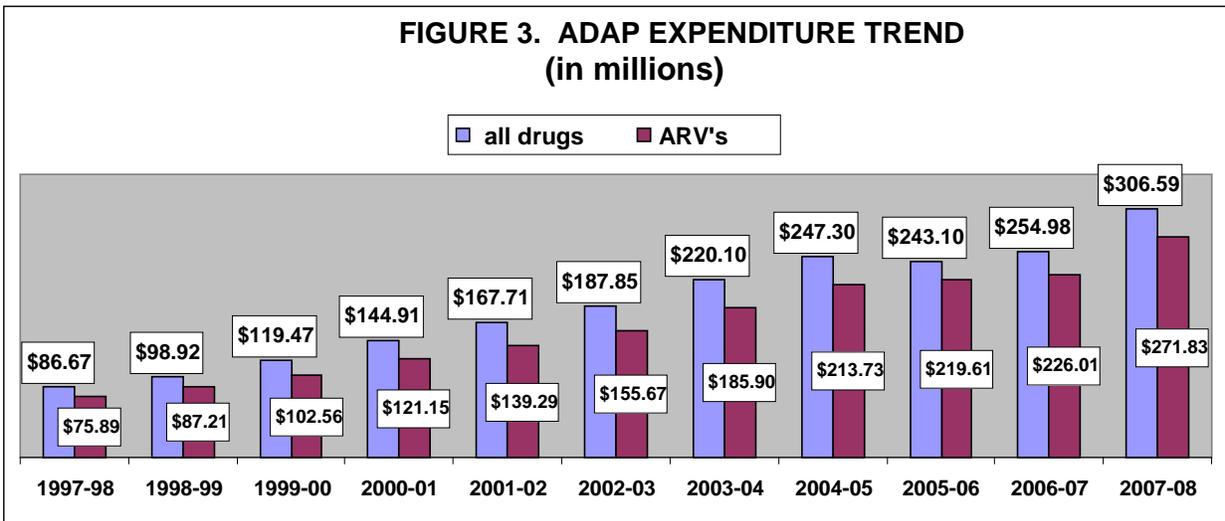
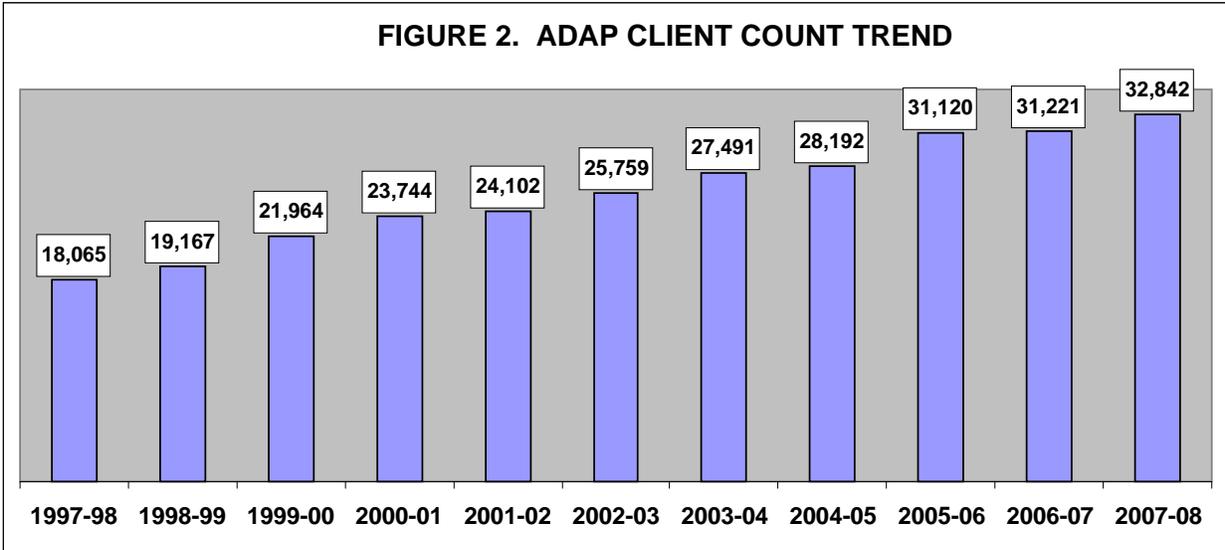


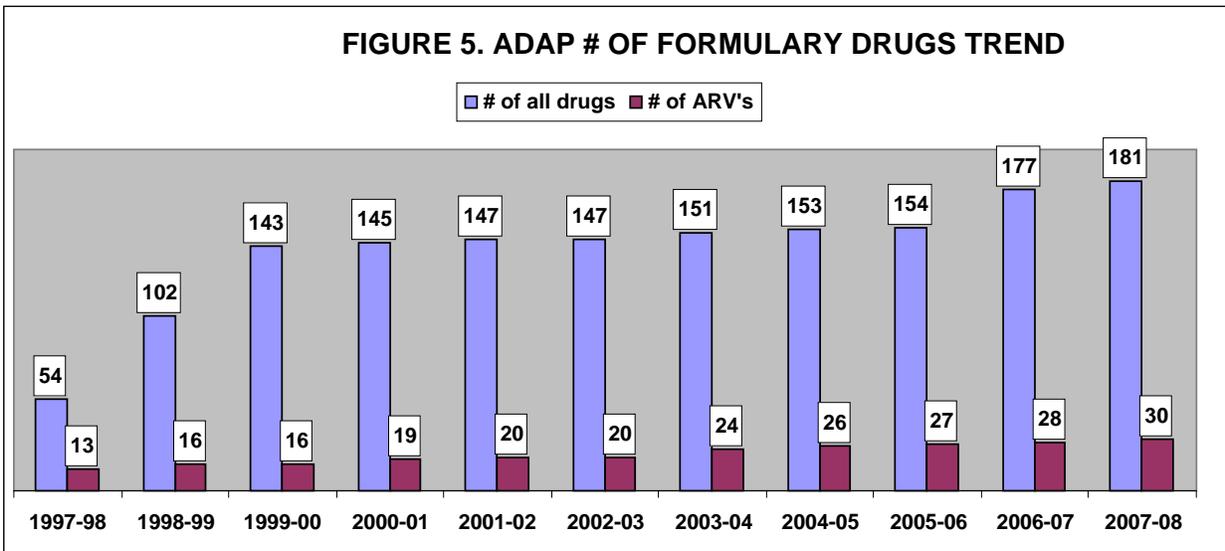
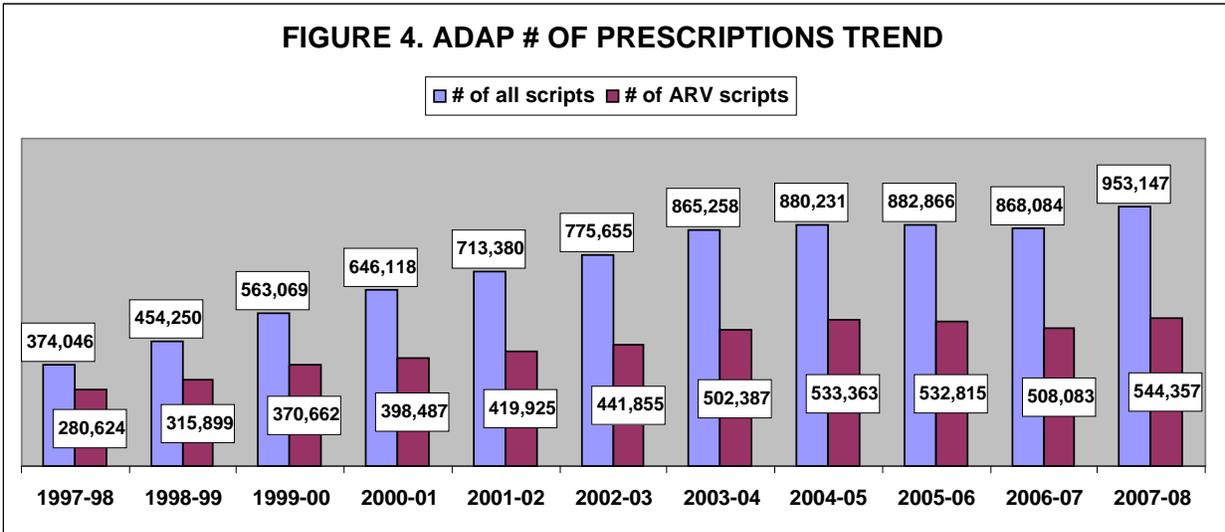
TABLE 2: ADAP HISTORIC EXPENDITURES			
Fiscal Year	Expenditures	Annual Change in Absolute Expenditures	Pct Annual Change
1997-98	\$86,674,336	N/A	N/A
1998-99	\$98,924,742	\$12,250,406	14.13%
1999-00	\$119,465,151	\$20,540,409	20.76%
2000-01	\$144,913,504	\$25,448,353	21.30%
2001-02	\$167,709,426	\$22,795,922	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%
Average of All years	98-99 TO 07-08	\$21,991,650	13.69%
Average of "Normal Growth" Years	99-00 TO 02-03	\$22,232,349	17.45%
Average of "High Growth" Years	03-04 TO 04-05	\$29,722,789	14.76%
Average of "Mega-High Growth" Years	07-08	\$51,613,440	20.24%

As a result of 1) changes in actual expenditure patterns that again reflect a straight line that can be reliably subject to linear regression methods and 2) relative limitations of the percent change model compared to linear regression models, for the updated FY 2008-09 expenditure estimate and the FY 2009-10 expenditure estimate presented in this estimate package, we have considered both **linear regression** and **percent change** models.

SECTION C: HISTORICAL CASELOAD FACTORS

Antiretroviral (ARV) therapy was very different before 1997, when the Protease Inhibitor and Non-Nucleoside Analogue drug classes were not yet available. At that time, only single and dual nucleoside therapy was used and ADAP was thus a much less complex program. The program was centralized in 1997; prior to that ADAP was administered at the LHJ level and data on prescriptions and clients are not reliably available.





**SECTION D: ESTIMATE METHOD DETAILS
 FY 2008-09 UPDATE**

I. Historical: FY 2008-09 Budget, Detailed Methods for May Revision

TABLE 3: PERCENT CHANGE MODEL (Prepared April 17, 2008)		
#	Factors	FY 2008-09 Estimate
0	FY 2007-08 expenditure estimate	\$308,876,934
1	Medicare Part D costs	\$3,307,711
2	New drug costs: ARVs	\$3,900,000
3	Drug price increase costs	\$7,716,240
4	Increase client costs	\$6,177,539
5	Increase non-approved fees	\$351,414
6	Subtotal	\$330,329,838
7	Budget Balancing Reduction (BBR)	-\$7,000,000
8	Total	\$323,329,838

Staff began expenditure estimates using the previous year’s expenditure estimate. The revised figure of \$308,876,934 was the starting point for the revised FY 2008-09 expenditure estimate.

FY 2007-08 Expenditure Estimate **\$308,876,934**

1. Medicare Part D **\$3,307,711**

Estimated Medicare Part D increases were developed using the following methodology:

We started with FY 2006-07, Part D actual expenditures of \$12,721,966. Then we estimated a 30 percent increase for FY 2007-08 (\$3,816,590) for a total need of \$16,538,556. This figure became the starting point for FY 2008-09, when Part D costs were estimated to increase 20 percent (due to anticipated increased stability in Medicare Part D), or \$3,307,711.

The 30 percent estimate for FY 2007-08 was based on the following three factors: an increase in premiums, additional clients enrolling in Part D, and clients transitioning within Part D subcategories. Please see descriptions regarding these various categories in the Appendix.

TABLE 4: ESTIMATED MEDICARE PART D COSTS, FY 2008-09	
Time	Total
FY 2006-07 Actual Expenditures	\$12,721,966
+ 30% of 06-07	\$3,816,590
FY 2007-08 Estimate	\$16,538,556
20% FY 2007-08 Estimate	\$3,307,711
FY 2008-09 Estimate of increase need compared to 07-08	\$3,307,711

Notes on Medicare Part D

Current Part D costs for FY 2007-08 are at \$16,164,029, which is close to the FY 2007-08 estimate of \$16,538,556.

Part D costs are monitored on a monthly basis to ensure our estimates are reliable. However, Part D costs in FY 2008-09 will likely exceed previous years because more clients are in the standard benefit category in the first three months of calendar year 2008 than in the past year due to the increase in client caseload. Other factors contributing to this issue include clients who no longer qualify for low income subsidy and thus become standard benefit clients subject to the “donut hole,” when all eligible costs are absorbed by ADAP. In addition, ADAP payments have sometimes been inadvertently counted towards true out of pocket costs (TrOOP) by the Medicare Part D Prescription Drug Plans in the past; this results in clients moving out of the donut hole, into catastrophic coverage, and no longer relying entirely on ADAP. CDPH/OA predicts this will occur significantly less often over time, as insurers are better at recognizing this issue. As a result of both of these factors, more clients will remain in the more expensive donut hole as opposed to transitioning to a lower cost catastrophic coverage category. Part D related costs should stabilize over time, allowing for more accurate estimates in the future.

2. New Drug Costs

Two new antiretrovirals anticipated for approval in FY 2008-09:

Rilpivirine **\$2,000,000**

NNRTI calculated to replace Efavirenz or Nevirapine but at increased cost. Approval anticipated March 2009. Indication is for treatment naïve clients. Currently, approximately 9,900 clients are on NNRTI therapy. Assumed total of 1,000 clients would access this medication. Assumed this medication would replace one of the currently available NNRTIs as a choice for initial therapy or switch early in therapy. Assumed cost would be approximately \$100 per month more than currently available NNRTIs. Assumed ramped up usage by 200 clients per month from approval to total of 1,000 clients.

Elvitegravir **\$1,900,000**

Integrase Inhibitor calculated as a new cost and considered add-on therapy. Approval expected in mid-fiscal year (approximately January 2009). Initial indication is for treatment of experienced clients. Assumed 10 percent of clients fail therapy yearly (approximately 1800 clients). Assumed half of those failing therapy may be candidates for integrase therapy (900). Assumed half of those would go on the new integrase inhibitor instead of the currently available product (450). Did not assume clients on current integrase inhibitor that are failing therapy would switch to new product – resistance patterns of integrase inhibitors are still relatively new. Assumed a cost to the program of \$1,000 per month. Assumed ramped up usage by 100 clients per month from approval to total of 450 clients.

3. Drug Price Increase Costs **\$7,716,240**

The model assumes an estimated three percent increase in overall expenditures based on observed price increases over the past two fiscal years. Estimated FY 2007-08 expenditures are \$257,208,001. Three percent of this is \$7,716,240. This adjustment is added to the revised FY 2007-08 budget amount.

Historically, ARV drug prices increased 5 percent on two-thirds of ARVs between FY 2002-03 and FY 2005-06 until more recent years when larger increases were noted. In the last two years, three-quarters of the ARVs on the formulary experienced a 6 percent price increase.

The impact on ADAP costs will depend upon when the actual price increase occurs; utilization rate of the medications; different reimbursement rates depending on PBM contracts with provider pharmacies; and type of insurance coverage.

4. Increased Client Costs **\$6,177,539**

The program does not use a direct calculation of estimated increase in caseload multiplied by average cost per client to determine increased client costs. Rather, the increase in client costs is estimated by applying a 2 percent increase to the previous fiscal year's estimated drug expenditures. This is the same logic used in the HRSA model. Increased client costs are estimated to be \$6,177,539.

5. Transaction Fees **\$351,414**

ADAP has two categories of transaction fees: approved and non-approved. Approved transaction fees are an administrative fee provided to the Pharmacy Benefits Manager (PBM) of \$6.00 per prescription approved for dispensing. Non-approved transaction fees are charges to ADAP for prescriptions processed but not approved by the PBM. In FY 2007-08, both approved and non-approved transaction fees increased over the last year, although the proportion remains relatively constant. Approved transaction fees have been accounted for by including it in the drug price increase category. For the first time, we are accounting for increased non-approved transaction fees in our budget modeling. We estimate the increase in non-approved transaction fees to cost the program \$351,414 in FY 2008-09. This is based on the increase in non-approved transaction fees from FY 2006-07 (actual fees were \$4,266,282) to FY 2007-08 (estimated at \$4,617,696, which is based on actual fees from July to March [\$3,308,562] and averaging January to March [\$436,378] for the remaining three months {\$1,309,134}).

Subtotal	\$330,329,838
Minus the May Revision BBR	<u>(\$7,000,000)</u>
Total	\$323,329,838

II. Methods for FY 2008-09 Revised Expenditure Estimate

Introduction and Overview

We have considered two approaches to estimating total ADAP expenditures for the updated FY 2008-09 expenditure estimate:

- An updated **percent change** model
- A **linear regression** model

The model outputs are summarized in Table 1 and explained in detail in this section (D).

Considerations regarding Linear Regression and Percent Change Models

Figure 1 shows ADAP historic expenditures by month. The data points are color coordinated to match the three absolute expenditure growth periods shown in Table 2. 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 (black line goes straight through the green data points).
- During low growth periods, a linear regression model would overestimate expenditures (black regression line goes under the black data points).
 - Thus, for this low growth period in the past, we elected to use the percent change model.
- During high growth periods, a linear regression model using the point estimate would underestimate expenditures (black line goes under the yellow data points).
 - Thus, given the recent high growth expenditure period and the desire to not underestimate the need for ADAP to utilize the ADAP Rebate Fund to address increasing expenditures, we elected to use the upper bound of the 95 percent confidence interval around the point estimate for our regression estimates.

Alternate Method Consideration 1: Updated Percent Change Model

The Percent Change Model utilized for FY 2008-09's May Revision was modified as follows:

- FY 2007-08 estimated expenditures were replaced with FY 2007-08 actual expenditures as the baseline (line 0 in Table 5).
- Assumptions and thus percent changes applied to the factors listed in lines 1, 3, 4 and 5 in Table 5 were the same as those used in the May Revision estimate, but were applied to actual FY 2007-08 expenditures for each of these factors.
- New drug costs were updated to reflect the current new drug pipeline. The program had anticipated the approval of two new antiretrovirals during FY 2008-09. Since May Revision, the development of one of the antiretrovirals (Elvitegravir) has not proceeded as expected. The medication is still in development and will eventually make it to market; however, it is now anticipated to be approved during FY 2009-10.

**TABLE 5: PERCENT CHANGE MODEL
(with FY 2007-08 actual expenditures)**

#	Factors	FY 2008-09 Estimate
0	FY 2007-08 actual expenditures	\$306,590,832
1	Medicare Part D costs	\$3,887,104
2	New drug costs: ARVs	\$2,000,000
3	Drug price increase costs	\$8,809,934
4	Increase client costs	\$6,131,817
5	Increase non-approved fees	\$375,000
6	Total	\$327,794,687

Implications

Given the subjective assumptions underlying the Percent Change method and lack of guidance from HRSA about these assumptions, this is an adequate but less than ideal approach when a linear regression model can be used.

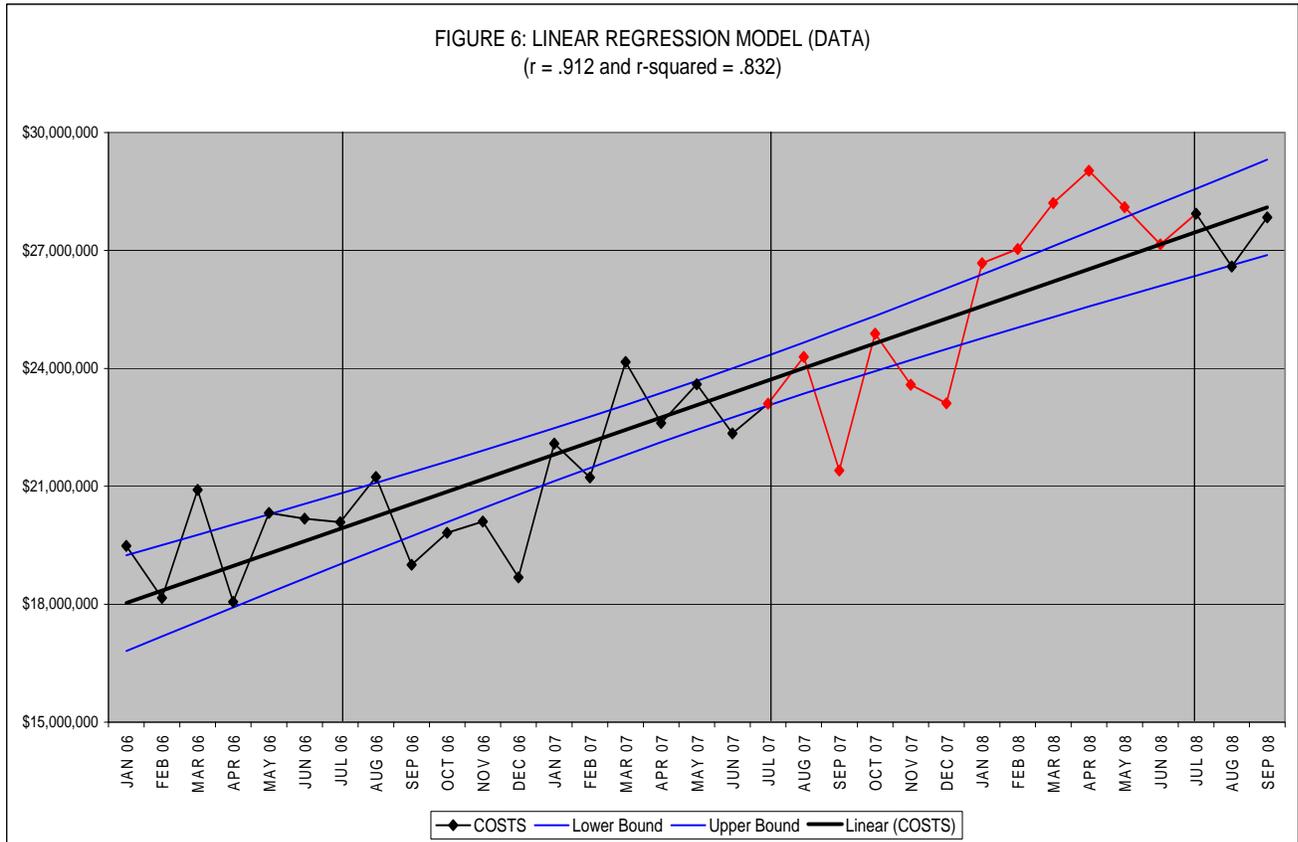
Given our current ability to effectively utilize linear projection methods applied to actual expenditures which once again fit a straight line, it is not prudent to rely solely on the percent change method to develop budget projections at this time.

In the future, if actual expenditures again change dramatically and linear regression is no longer reliable, further refinements can be made to the assumptions in the Percent Change model to more accurately reflect expenditure estimate.

Alternate Method Consideration 2: Linear Regression Estimate

The close of FY 2007-08 gave ADAP another year's worth of data points to reexamine linear regression models. Table 6 and Figure 6 show the 95 percent confidence interval associated with this estimate. The estimated increase shown in Table 6 reflects the difference between the May Revise projection and the updated estimate for FY 2008-09 using the upper bound of the 95 percent confidence interval.

TABLE 6: LINEAR REGRESSION MODEL, FY 2008-09		
Point Estimate	Upper Bound of 95% CI	Estimated Increase Compared to May Revise
\$349,374,203	\$360,124,974	\$29,795,136



FY 2009-10

Alternate Method Consideration 1: Updated Percent Change Model

For the FY 2009-10 Percent Change Model:

1. The starting point is FY 2008-09's estimate of \$327,794,687 from updated Percent Change Model, Table 5.
2. Similar to FY 2008-09, Medicare Part D costs are assumed to increase another 20 percent (\$4,664,524), which reflects continued growth in this factor.
3. New drug costs include Elvitegravir (\$1,900,000), which was originally expected to be FDA-approved in FY 2008-09.
4. Drug price increases, including clients switching to more expensive drugs, are assumed to continue to increase 3 percent (\$9,342,149). Although there may be higher price increases up front, especially with price freezes that result in credits to the ADAP Rebate Fund, fewer clients are anticipated to switch from less expensive ARVs to the more expensive Atripla, Truvada, or Reyataz.
5. As in FY 2008-09, another 2 percent increase (\$6,555,894) due to increase client costs is assumed.
6. Non-approved transactions will increase slightly from the previous year to a total of \$500,000.

**TABLE 7: PERCENT CHANGE MODEL
 (using the same assumptions used for
 the FY 2008-09 expenditure estimate)**

#	Factors	FY 2009-10 estimate
0	FY 2008-09 estimate	\$327,794,687
1	Medicare Part D costs	\$4,664,524
2	New drug costs: ARVs	\$1,900,000
3	Drug price increase costs	\$9,342,149
4	Increase client costs	\$6,555,894
5	Increase non-approved fees	\$500,000
6	Total	\$350,757,254

Implications

Same as the Percent Change Model for FY 2008-09; it is not prudent to rely solely on the percent change method to develop budget projections at this time given the reasonable linear regression alternative.

Alternate Method Consideration 2: Linear Regression Estimate

The estimate for FY 2009-10 using the upper bound of the 95 percent confidence interval, is \$416.1 million. The estimated increase shown in column 4 reflects the difference between the May Revise projection and the updated estimate for FY 2009-10 using the upper bound of the 95 percent confidence interval.

TABLE 8: LINEAR REGRESSION MODEL, FY 2009-10		
Point Estimate	Upper Bound 95% CI	Estimated Increase Compared to May Revise
\$395,640,174	\$416,097,843	\$85,768,005

Implications

Given our current ability to effectively utilize linear projection methods applied to actual expenditures which one again fit a straight line, this is the preferred method at this time.

Given the recent high growth expenditure period and the desire to not underestimate the need for ADAP to utilize the ADAP Rebate Fund to address increasing expenditures, we elected to use the upper bound of the 95 percent confidence interval around the point estimate for our final budget projections.

SECTION E: FUND SOURCES

To comply with federal and state mandates, ADAP funds must be used as the payer of last resort to provide pharmaceutical therapies to eligible HIV positive clients who are either uninsured or under-insured.

The program receives:

- state funding from the General Fund
- federal funding from the Health Resources and Services Administration (HRSA) through the Ryan White HIV/AIDS Treatment Modernization Act of 2006, Part B, ADAP Earmark grant
- both voluntary and mandatory rebates from manufacturers with products on the ADAP formulary, as well as credits related to ADAP-specific price freezes, for deposit into the ADAP Rebate Fund.

The following information highlights each of the sources that funds ADAP. Please note that the historical expenditures noted below are only for the prescription costs that are part of the estimate calculations and do not include expenditures for local health jurisdiction administration or Medicare Part D premium payments nor encumbrances that did not materialize into actual expenditures.

General Fund

ADAP’s General Fund 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 for eligible clients, prescription expenditures for Medicare Part D clients, and a portion of the transaction fees invoiced by ADAP’s pharmacy benefits management (PBM) contractor.

General Fund expenditures have fluctuated over the last several years as a result of the rising drug costs, new drugs, evolving use of antiretroviral combination drug therapy, and increasing number of clients.

Unique savings and redirections in FY 2007-08: Due to ADAP’s eligibility screening enhancements and effective rebate collection system, in FY 2007-08, program returned \$7.285 million on a one-time basis to the State’s General Fund; redirected \$9.8 million in General Fund to other OA programs, and increased ADAP Rebate Fund authority by \$17.085 million to back fill these redirections. The shift in funding explains the significant drop in the General Fund expenditures from FY 2006-07 to FY 2007-08.

TABLE 9: GENERAL FUND HISTORICAL EXPENDITURES	
Fiscal Year	Actual Expenditures
FY 2004-05	\$65,548,000
FY 2005-06	\$81,594,000
FY 2006-07	\$107,650,000
FY 2007-08	\$90,564,000

Federal Fund

ADAP receives its Part B Earmark grant award from HRSA, which can only be used for ADAP-related services. This award is predicated upon the State of California meeting the Maintenance of Effort (MOE) requirement for maintaining expenditures for HIV-related activities. This is to ensure that federal funds are used to supplement existing state expenditures, and not used to supplant budget allocations at the state level. Non-compliance with this requirement would result in withholding the entire Part B federal grant award to California.

Unique savings and redirections in FY 2007-08: In FY 2007-08, ADAP redirected its entire \$10.53 million Federal Fund Base award to other OA programs and back filled with ADAP rebate funds. The shift in funding explains the significant drop in the historical Federal Fund expenditures from FY 2006-07 to FY 2007-08.

TABLE 10: FEDERAL FUND HISTORICAL EXPENDITURES	
Fiscal Year	Actual Expenditures
FY 2004-05	\$100,097,914
FY 2005-06	\$99,833,532
FY 2006-07	\$101,298,777
FY 2007-08	\$88,512,735

ADAP Rebate Fund

The ADAP Rebate Fund consists of rebates collected for drugs purchased under ADAP, as well as credits to account for the difference between what ADAP pays and price freeze amounts. This fund is comprised of both mandated base and voluntary supplemental rebates. The use of these funds is established under both state law and federal funding guidance. The ADAP Rebate Fund was legislatively established in 2004 to support the provision of ADAP services. Section 120956 of the Health and Safety Code, which established the ADAP Rebate Fund, states in part:

“...(b) All rebates collected from drug manufacturers on drugs purchased through the AIDS Drug Assistance Program (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 ...”

Despite California’s economic challenges, ADAP has been fortunate to receive increases in its General Fund amounts in past years. Due to the program efficiencies as explained above, program returned \$7.285 million to the General Fund in FY 2007-08 and utilized more of the ADAP Rebate Fund to continue to meet expenditure demands.

**TABLE 11: ADAP REBATE FUND
HISTORICAL EXPENDITURES**

Fiscal Year	Actual Expenditures
FY 2004-05	\$81,653,801
FY 2005-06	\$61,669,410
FY 2006-07	\$46,028,615
FY 2007-08	\$127,514,097

ADAP Drug Rebates

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 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 88 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, the mandated base rebate may be 15 percent of AMP, and the ACTF negotiates a supplemental rebate of 7 percent of AMP, then ADAP will receive a total rebate of 22 percent of AMP.

Price Freeze “Credits”

The “price freeze” option is an additional rebate offered by the manufacturer to compensate for their commercial price increases. Currently, of the 29 available ARV medications on the ADAP formulary, eight (28 percent) are subject to a price freeze until December 31, 2010. When 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 credits deposited in the Special Fund.

ADAP Rebate Invoicing

ADAP invoices the manufacturers for drug rebate 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 usually received between 30 and 60 days after the mailing of the rebate invoices.

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

SECTION F: ADAP REBATE FUND REVENUE AND EXPENDITURE PROJECTIONS

Background

ADAP Rebate Fund revenues include rebates and credits due to price freezes. Rebates include both mandatory and supplemental (voluntary) rebate. Supplemental rebate 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 rebate agreement at any time with only a 30-day written notice. Therefore, continued receipt of supplemental rebates cannot be guaranteed. Price freeze agreements are also temporary and subject to revision.

The number of antiretroviral (ARV) medications subject to a price freeze fluctuates over time.

- In 2005 there were five medications subject to a price freeze
- Two medications were subject to a price freeze between 2005 and 2008
- Currently, of the 29 available ARV medications, eight (28 percent) are subject to a price freeze until December 31, 2010.

ADAP tracks drug expenditures and the total revenue (rebate and credit) received by quarter.

FY-QTR	Total Expenditures	Received in Rebate \$	Total Revenue Collection Rate
2005/06-Q1	\$63,433,758	\$21,910,438	34.54%
2005/06-Q2	\$62,536,173	\$20,562,751	32.88%
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	\$24,787,899	41.08%
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	\$35,405,290	49.46%
2007/08-Q3	\$81,926,045	\$43,780,223	53.44%

2. Fund Condition Statement (FCS) Estimates

Based on the historical increase in Special Fund revenue relative to ADAP expenditures, ADAP revised its estimated revenue rate from 39 percent (used for May Revise) to 46 percent, reflecting the average revenue rate since the inception of Medicare Part D.

May Revision Background

For the May Revision estimate, ADAP assumed a 39 percent revenue collection rate on total expenditures for FY 2007-08 and FY 2008-09.

In March 2008 via the revenue projection (10R) budget building process, ADAP increased the projected revenue amount for FY 07-08 by \$24,602,172 to \$118,046,429 due to the addition of three new antiretroviral drugs (ARV) to the ADAP formulary, which would generate an increase in rebate revenues.

TABLE 13: 10R (as of 03/28/08)				
05-06 Actual	06-07 Actual	07-08 Estimated	07-08 Revised Estimate	08-09 Projected
\$82,470,530	\$95,384,924	\$93,444,257	\$118,046,429	\$125,417,477

The FCS was updated using the revised estimate figure from the 10R process. The presumption was made that the 10R process included projections for income from surplus money investments, resulting in net revenue of \$114,475,429. This presumption was incorrect and will be corrected in future FCSs. Also, it was noted that the investments were projected to be stable which may not reflect market conditions. OA is conducting an analysis to determine a method to more accurately project investment income for future FCSs.

TABLE 14: MAY REVISION FUND CONDITION STATEMENT

3080 AIDS Drug Assistance Program Rebate Fund	2006-07	2007-08	2008-09
BEGINNING BALANCE	38,642	80,523	65,997
Prior Year Adjustment	132	0	0
Adjusted Beginning Balance	38,774	80,523	65,997
REVENUES, TRANSFERS AND OTHER ADJUSTMENTS			
Revenues			
150300 Income From Surplus Money Investments	3,571	3,571	3,571
161400 Miscellaneous Revenue	95,385	114,475	121,847
Total Revenues, Transfers, and Other Adjustments	98,956	118,046	125,418
Total Resources	137,730	198,569	191,415
EXPENDITURES AND EXPENDITURE ADJUSTMENTS			
Expenditures			
0840 State Controller (State Operations)	1	1	1
4260 Department of Health Services			
State Operations	1,073	147	150
Local Assistance	55,945	0	0
4265 Department of Public Health			
State Operations		1,084	1,086
Local Assistance		131,340	135,915
Pro Rata	188	0	0
Total Expenditures and Expenditure Adjustments	57,207	132,572	137,152
FUND BALANCE	80,523	65,997	54,263

TABLE 15: FUND CONDITION STATEMENT* (in thousands)				
	3080 AIDS Drug Assistance Program Rebate Fund	FY 2007-08 actual	FY 2008-09 estimate	FY 2009-10 estimate
1	BEGINNING BALANCE	80,523	80,356	73,438
2	Prior Year Adjustment			0
3	Adjusted Beginning Balance			
4	REVENUES, TRANSFERS AND OTHER ADJUSTMENTS			
5	Revenues			
6	150300 Income From Surplus Money Investments	5,054	6,188	6,677
7	161400 Miscellaneous Revenue	129,824	165,463	178,531
8	Total Revenues, Transfers, and Other Adjustments	134,878	171,651	185,208
9	Total Resources	215,401	252,007	258,646
10	EXPENDITURES AND EXPENDITURE ADJUSTMENTS			
11	Expenditures			
12	0840 State Controllers Office (State Operations)	1	1	-
13	4260 Department of Health Care Services (State Operations)	-	150	165
14	4265 Department of Public Health			
15	State Operations	1,415	1,088	1,164
16	Local Assistance	133,629	177,330	233,303
17				
18				
19	Total Expenditures and Expenditure Adjustments	135,045	178,569	234,632
20	FUND BALANCE – Reserve for economic uncertainties	80,356	73,438	24,014

Row 6: Estimated interest is calculated at 3.74% of Revenue in Row 7

Row 7: Revenue estimate

<i>Actual rebate collected for Jan - Mar 2008 expenditures</i>	43,848,430	
Actual expenditures April - June 2008	84,316,871	
Estimated expenditures July - Dec 2008	180,062,487	
Estimated expenditures Jan - June 2009		180,062,487
Estimated expenditures July - Dec 2009		208,048,922
		388,111,409
Estimated Calendar Year	264,379,358**	388,111,409
46% revenue collection rate	121,614,505	178,531,248

**FY 08/09 estimate expenditures for three quarters of Calendar Year since First Quarter actual rebate collected is known

Row 16: Expenditure estimate

Upper bound expenditure estimate	360,124,974	416,097,843
less General Fund appropriation	- 96,349,000	- 96,349,000
less Federal Fund appropriation	- 88,445,592	- 88,445,592
ADAP Rebate Fund need to meet expenditure estimate	175,330,382	231,303,251
Local Assistance LHJ	+ 1,000,000	+ 1,000,000
Local Assistance Medicare Part D	+ 1,000,000	+ 1,000,000
	177,330,382	233,303,251

The Fund Condition Statement was developed assuming a revenue collection rate of 46 percent based on an average of rebate collections from January 2006 to March 2008. The expenditures were determined based on our recommended linear regression methodology using the upper bound of the 95 percent confidence interval. The ADAP Rebate Fund is a critical component of the ADAP budget since these funds are used to meet the identified expenditure need for ADAP assuming flat General and Federal fund allocations. As noted above, the balance in the ADAP Rebate Fund at the end of FY 2008-09 is estimated to be \$73.438 million, decreasing to \$24.014 million at the end of FY 2009-10.

Although the ADAP Rebate Fund revenues increase as expenditures rise, it only increases by a fraction of expenditures, thus the balance in the fund will continue to decrease as long as there is increased demand on the program without reductions in costs due to external factors like the introduction of Medicare Part D in 2006.

SECTION G: POLICY ISSUES WITH POTENTIAL IMPLICATIONS FOR ADAP

ADAP anticipates that the following policy issues may have potential implications on the ADAP budget:

Medicare Part D

Background

The Centers for Medicare and Medicaid Services (CMS) contracts with Medicare Part D drug plans on an annual basis and benefits available under Part D plans will vary from year to year, including 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.

Summary and Timing

Part D related ADAP costs will continue to fluctuate annually (CY). CMS has indicated that costs could increase or decrease depending on the level of competition in a state or region. To date, California Part D plan costs have only increased.

Implications

ADAP will experience ongoing fluctuations in Part D related costs from year to year. Cost fluctuations will be driven by the following factors:

- Annual adjustments to Medicare's Part D maximum out-of-pocket costs thresholds (see table below).
- Annual adjustments to regional plan premiums. *CMS released the 2009 California Part D Plan (PDP) details on September 25, 2008. California PDP premium costs will increase by approximately 30 percent.*
- ADAP client plan selections (clients enrolling in high cost vs. low cost plans).
- ADAP client Part D Low Income Subsidy (LIS) eligibility.
- Plan prescription co-pay requirements

TABLE 16: CALIFORNIA STAND ALONE PRESCRIPTION DRUG PLAN (PDP) COMPARISON 2008 & 2009		
	2008	2009
Total Number of PDPs	56 plans	51 plans
Monthly Premium Range	\$14.30-\$102.70	\$18.30-\$129.30
Annual Deductible:		
\$0.00	33 plans	29 plans
\$50-\$250	4 plans	5 plans
Allowable Maximum	\$275 – 10 plans	\$295 - 17 plans
Enhanced Coverage (types of coverage offered to clients in the donut hole):		
All Generics	7 plans	3 plans
Many Generics	6 plans	7 plans
Some Generics	2 plans	2 plans
No Coverage	41 plans	39 plans

ADAP Counting Towards TrOOP:**Background**

While Medicare Part D law prohibits ADAP spending from counting towards a Medicare Beneficiary's true out-of-pocket costs (TrOOP), CMS does permit state pharmaceutical assistance programs (SPAPs) to count towards TrOOP. Various HIV advocacy groups continue to challenge CMS to facilitate ADAP payments counting towards TrOOP.

Summary and Timing

The HIV Medicare/Medicaid Workgroup is planning to submit an "administrative fix" proposal in their "First 100-Days" document. Timing of a potential fix to this issue is currently unknown.

Implications

If ADAP payments counted towards TrOOP, this would be a considerable cost offset to the program, allowing clients to move out of the "donut hole" and into catastrophic coverage. This would reduce the State's costs significantly.

Partial Pay Rebate

Background

Currently, ADAP is able to collect full rebate on partial payment transactions for clients with other payers, e.g., private insurance. This is very cost effective for California's ADAP, however early in 2008 this policy was challenged by one of the drug manufacturers. We have no guarantee how long this practice will be allowed to continue.

Summary and Timing

Although this manufacturer has stated that it plans to honor the current policy at this time, there is the potential that the policy may be challenged again in the future. This issue has been of considerable concern to ADAPs nationally. ADAP will continue to monitor this issue.

Implications

A change in policy would have a considerable fiscal effect on the stability of California's ADAP. Since rebate funds are a significant part of ADAP's budget, any change in the ability to collect full rebate on these cost-effective transactions would have severe consequences on the ability to sustain the current level of service to ADAP clients. In FY 2006-07, rebates on partial payments represented nearly 40 percent of total rebate revenue.

Pharmaceutical Manufacturer Prescription Copayment Programs

Background

Several pharmaceutical manufacturers have recently announced their intention to provide assistance with insurance prescription copayments. Four of the ARV manufacturers with products on the ADAP formulary are in different phases of implementation of their assistance programs for clients using specified HIV drugs. Each of the programs has varying benefit limits and requirements for participation.

Summary and Timing

Of the four ARV manufacturers, one is currently in the planning phase for program implementation, one is in the pilot phase with selected locations and participating clinics, a third is expected to rollout their assistance program in mid-November 2008, and the fourth manufacturer is now soliciting applications from clients with high co-payment obligations.

Implications

For each prescription copayment that a pharmaceutical manufacturer pays on behalf of an ADAP client, ADAP will no longer be able to collect rebate on those transactions. The potential fiscal implication to the ADAP Rebate Fund would be significant because these transactions are extremely cost effective since each manufacturer pays both mandated and supplemental rebates on these ARV drugs.

SECTION H: APPENDICES

1. 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, Office of AIDS (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 3,000 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 on average.

Medicare Part D Prescription Drug Benefit Related Definitions

This program 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** – Beneficiaries with incomes over 150 percent of federal poverty level are not eligible for low income subsidies. Medicare will pay a portion of these beneficiaries' drug costs. These beneficiaries must pay the first \$275 of their drug costs *out of pocket*. After the \$275 deductible, Medicare will pay 75 percent of the cost of each covered prescription and the beneficiary will pay 25 percent, up to \$2,510 in total costs. **The costs paid out of pocket by beneficiaries are called TrOOP.** (Note, for medications on the ADAP formulary, ADAP covers this 25 percent co-pay.)

- 1) **“Donut Hole”**. Once a standard beneficiary reaches \$2,510 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 \$3,216.25 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 are never more than \$2.25 for generic drugs and \$5.60 for brand products. (Note, for medications on the ADAP formulary, ADAP covers all costs in the Donut Hole.)
- 2) **Low Income Subsidy (LIS)** – Beneficiaries with incomes below 150 percent of the federal poverty level 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 federal poverty level. These beneficiaries do not have to pay a deductible, but pay \$2.25 for generic drugs and \$5.60 for brand drugs, and do not have to contend with the donut hole (coverage gap). After \$5,726.25 of out of pocket costs, they no longer pay co-pays. (Note, for medications on the ADAP formulary, ADAP covers these co-pays.)
 - b) Partial Subsidy – Income between 135 percent and 149 percent of federal poverty level. These beneficiaries must pay a \$56.00 deductible, 15 percent of drug costs after the deductible, and do not have to contend with the donut hole (coverage gap). After \$5,726.25 of out of pocket expenses, co-pays are reduced to \$2.25 for generics and \$5.60 for brand drugs. (Note, for medications on the ADAP formulary, ADAP covers these co-pays.)
- 3) **Dual Eligible** (covered by *both* Medicare and Medi-Cal)
 - a) Full Duals are clients who are eligible for Medi-Cal with **no** Share of Cost (SOC). Full Duals pay limited co-pays of \$2.25 to \$5.60 per drug. No copayments are required once total drug costs reach \$5,726.25. (Note, for medications on the ADAP formulary, ADAP covers these co-pays.)
 - b) Partial Duals are clients who are eligible for Medi-Cal *with* a SOC. A Partial Dual who has not met their 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. (Note, for medications on the ADAP formulary, ADAP covers these co-pays.)

2. New Drug Updates

TABLE 17: ANTIRETROVIRALS IN THE PIPELINE (as of 9/11/2008)					
Agent	Class	Manufacturer	Phase	Anticipated Approval (NATAP)	Anticipated Approval (TAG)
Rilpivirine (TMC278)	NNRTI	Tibotec	III	2008 or 2009	2008-09
Vicriviroc	CCR5 antagonist	Schering	III	2008	2008-09
Elvitegravir	Integrase inhibitor	Gilead	II/III	2008	2008-09?
Bevirimat	Maturation inhibitor	Panacos	II	2008	Stalled
TNX – 355	CD4 blocker	Genentech	II	2008-09	Stalled
Apicitabine	NRTI	Avexa	II/III		>2010
Amdoxovir	NRTI	RFS Pharma	II		>2010
INCB 009471	CCR5 antagonist	Incyte	II		Discontinued
AMD – 070	CXCR4 antagonist	AnorMED	II		Suspended
Racivir	NRTI	Pharmasset	II		
UK -453,061	NNRTI	Pfizer	II		

This information is from various sources including Treatment Action Group (TAG) 2008 pipeline report, National AIDS Treatment Advocacy Project (NATAP) 2007 report, Pharmaceutical Research and Manufacturers of America (PhRMA) 2007 report.

Originally the program projected two medications to be approved in FY 2008-09. However, since the original projections were made, the development of one of the medications (Elvitegravir) has slowed. It is now anticipated this medication will not be approved until FY 2009-10.

Vicriviroc is also nearing FDA approval. The program has analyzed the impact this medication may have on the budget and determined it to have minimal impact. Vicriviroc is in the same classification of medications as another medication (maraviroc) that was added to the formulary late in Calendar Year 2007. Maraviroc's usage has been much less than originally predicted and if Vicriviroc is approved by the FDA, the usage is expected to be minimal.

The number of medications in the pipeline to treat HIV is relatively small. While in the past two years there have been four new drugs, including two new classes, the future approvals do not look as promising.

3. Treatment Guidelines Updates

The Guidelines for the Use of Antiretroviral Agents in HIV-1-Infected Adults and Adolescents were recently updated (January 29, 2008). These guidelines are developed by the U.S. Department of Health and Human Services (DHHS) Panel on Antiretroviral Guidelines for Adults and Adolescents, a working group of the Office of AIDS Research Advisory Council. There have been two updates to the Guidelines in a short period of time as the previous revision was dated December 1, 2007.

The changes included in the December 1, 2007, update include:

1. HLA B5701 test for hypersensitivity to Abacavir
2. Viral tropism test for utility of a CCR5 antagonist
3. Initiation of therapy. Recommended for all patients with a history of an AIDS defining illness and for those with a CD4 less than 350. Prior, medication was offered to those with a CD4 between 200 and 350, all pregnant women, patients with HIV associated nephropathy, and a co-infection with hepatitis B

The changes included in the January 29, 2008, update include:

1. Revised recommendations for several "preferred" and "alternative" antiretroviral components for treatment-naïve patients.

The change in recommendations of when to initiate therapy could impact the program. However, these recommendations have been out for more than six months and the old guidelines recommended that clinicians consider therapy for patients with CD4 counts between 200 and 350.

A recent study seems to suggest starting HIV treatment in clients with a CD4 count below 500 versus the currently recommended 350. However, the investigators indicated the interpretation of the data is based on observational data that mimics what would be seen in a clinical trial. The investigators also note a randomized clinical trial will be necessary to confirm the findings from the study to support any changes to the currently established treatment guidelines. If future revisions change the recommended CD4 count for ARV initiation, the demand for ADAP could increase significantly.

4. HIV/AIDS Case Update

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 are between 134,971 and 173,083 living with HIV/AIDS in 2008.* This estimate includes people who are HIV+ but are not yet diagnosed (approximately 21 percent) by applying a national estimate of those unaware that was developed by the CDC (MMWR, October 3, 2008). Living HIV/AIDS cases are estimated to be 48 percent white, 19 percent African American, 29 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 intravenous drug use, 9 percent to heterosexual transmission, and 8 percent to MSM who also practice intravenous drug use.

The number of HIV/AIDS cases in the State is expected to grow by just over 1 percent (4,000 – 7,000) 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).

TABLE 18: ESTIMATED PERSONS LIVING WITH HIV IN CALIFORNIA, 2006-2010

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	40,445	61,445	61,490	61,490	129,402	159,336
2007	40,942	63,706	63,390	64,720	132,187	166,210
2008	41,438	65,967	65,290	67,950	134,971	173,083
2009	41,935	68,228	67,190	71,180	137,755	179,956
2010	42,431	70,489	69,090	74,410	140,540	186,830

*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.
- 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, the CDC began a national effort to measure incidence using this tool. These results were reported in the August, 2008, issue of the 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.

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. Based on recent revised estimates available from San Francisco, these data are not expected to change incidence estimates markedly.