

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

2009-10 MAY REVISION



**CALIFORNIA
DEPARTMENT OF PUBLIC HEALTH**

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TABLE 1a - Cost Comparison of May Revision to November Estimate FY 2008-09 (000's)

	NOVEMBER ESTIMATE FY 2008-09				CHANGE				MAY REVISION - FY 2008-09			
	Federal	State	ADAP Special Fund		Total	Federal	State	ADAP Special Fund	Total	Federal	State	ADAP Special Fund
Local Assistance	\$362,125	\$88,446	\$96,349	\$177,330	-\$5,824			-\$5,824	\$356,302	\$88,446	\$96,349	\$171,507
Baseline Prescription Costs	348,630	80,977	94,120	173,533	-5,897			-5,897	342,734	80,977	94,120	167,637
Baseline PBM Operational Costs	11,495	7,468	2,229	1,797	73			73	11,568	7,468	2,229	1,870
Baseline Subtotal	360,125	88,446	96,349	175,330	-5,824			-5,824	354,302	88,446	96,349	169,507
Medi-Cal Premise PC 163 (PRUCOL) Formulary Revisions Implement Monthly Premiums Estimate Subtotal	360,125	88,446	96,349	175,330	-5,824			-5,824	354,302	88,446	96,349	169,507
LHJ Administration	1,000			1,000					1,000			1,000
Medicare Part D Premiums	1,000			1,000					1,000			1,000
Support/administration costs	\$2,483	\$1,178	\$218	\$1,088	\$	\$	\$	\$	\$2,483	\$1,178	\$218	\$1,088

TABLE 1b - Cost Comparison of May Revision to November Estimate FY 2009-10 (000's)

	NOVEMBER ESTIMATE FY 2009-10				CHANGE				MAY REVISION - FY 2009-10			
	Total	Federal	State	ADAP Special Fund	Total	Federal*	State	ADAP Special Fund	Total	Federal	State	ADAP Special Fund
Local Assistance	\$418,098	\$88,446	\$96,349	\$233,303	-\$11,945	\$4,481	-\$12,300	-\$4,126	\$406,153	\$92,927	\$84,049	\$229,177
Baseline Prescription Costs	403,487	80,977	94,120	228,390	-3,592	4,481	-12,300	-8,074	399,894	85,458	94,120	220,316
Baseline PBM Operational Costs	12,611	7,468	2,229	2,914	28			28	12,639	7,468	2,229	2,941
Baseline Subtotal	416,098	88,446	96,349	231,303	-3,565	4,481	-12,300	-8,046	412,533	92,927	96,349	223,257
Medi-Cal Premise PC 163 (PRUCOL) Formulary Revisions Implement Monthly Premiums Estimate Subtotal	416,098	88,446	96,349	231,303	-11,945	4,481	-12,300	-4,126	404,153	92,927	84,049	227,177
LHJ Administration	1,000			1,000					1,000			1,000
Medicare Part D Premiums	1,000			1,000					1,000			1,000
Support/administration costs	\$2,559	\$1,178	\$218	\$1,164	\$	\$	\$	\$	\$2,559	\$1,178	\$218	\$1,164

*Includes the Ryan White Part B HIV Care Grant Program Grant Award Effective April 1, 2009

TABLE 1c - Revenue Comparison of May Revision to November Estimate FY 2008-09 (000's)

	NOVEMBER ESTIMATE - FY 2008-09				CHANGE				MAY REVISION - FY 2008-09			
	Total	Federal	State	ADAP Special Fund	Total	Federal	State	ADAP Special Fund	Total	Federal	State	ADAP Special Fund
Total ADAP Revenues (w/Support)	\$357,841	\$89,623	\$96,567	\$165,463	-\$8,794	\$	\$	-\$2,606	\$349,047	\$89,623	\$96,567	\$162,857
Baseline Revenue	351,653	89,623	96,567	165,463	-5,006			-5,006	346,647	89,623	96,567	160,457
Medi-Cal Premise PC 163 (PRUCOL) Formulary Revisions Implement Monthly Premiums Income from Surplus Money Investments	6,188			6,188	-3,788			-3,788	2,400			2,400

TABLE 1d - Revenue Comparison of May Revision to November Estimate FY 2009-10 (000's)

	NOVEMBER ESTIMATE - FY 2009-10				CHANGE				MAY REVISION - FY 2009-10			
	Total	Federal	State	ADAP Special Fund	Total	Federal	State	ADAP Special Fund	Total	Federal	State	ADAP Special Fund
Total ADAP Revenues (w/Support)	\$371,398	\$89,623	\$96,567	\$185,208	-\$9,240	\$4,481	-\$12,300	-\$1,421	\$362,158	\$94,104	\$84,267	\$183,787
Baseline Revenue	364,721	89,623	96,567	178,531	-5,936	4,481	-12,300	1,883	358,785	94,104	84,267	180,414
Medi-Cal Premise PC 163 (PRUCOL) Formulary Revisions Implement Monthly Premiums Income from Surplus Money Investments	6,677			6,677	-3,788			-3,788	3,373			3,373

Executive Summary

I. INTRODUCTION

The *May Revision* version of the ADAP Estimate Package follows the same lay-out and order of the *November Estimate Package*, except where specifically noted. This *May Revision* proposes to decrease the General Fund support of ADAP by \$12.3 million by 1) reducing the formulary to achieve a \$10 million savings and 2) introducing premium payments with anticipated revenue of \$2.3 million.

II. ADAP EXPENDITURE ESTIMATES (Updated for *May Revision*)

Fund Source	FY 2008-09			FY 2009-10**		
	November Estimate	May Revision	Change	November Estimate	May Revision	Change
General Fund	\$96,349	\$96,349	\$0	\$96,349	\$84,049	-\$12,300
Federal Fund	\$88,446	\$88,446	\$0	\$88,446	\$92,927	\$4,481
Special Fund	\$177,330	\$171,507	-\$5,823	\$233,303	\$229,177	-\$4,126
Total Program	\$362,125	\$356,302	-\$5,823	\$418,098	\$406,153	-\$11,945
Clients Served	34,168	34,287	119	35,584	35,791***	207

* A number of factors are used to develop the ADAP cost estimate for budget building purposes. These are costs related 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.

**Includes the Ryan White Part B HIV Care Grant Program 2009 Grant Award effective April 1, 2009.

***Implementing a premium payment obligation may deter some individuals from staying in, enrolling or re-enrolling in ADAP. Such consequences will have an impact on expenditures and rebate revenue; we do not know what this impact will be at this time.

The *November Estimate* included estimated expenditures of \$362.125 million for FY 2008-09 and \$418.098 million for FY 2009-10.

As in the *November Estimate*, the updated *May Revision* uses the Linear Regression methodology to project expenditures. The data set was updated to include current data. Thus, the *May Revision* utilizes data points from January 2006 to February 2009 while the *November Estimate* used data points only through September 2008.

The *May Revision* expenditure projection for FY 2008-09 is \$356.302 million (a decrease of \$5.823 million compared to the *November Estimate*) and for FY 2009-10, \$406.153 million (Tables 1a and 2; a decrease of \$11.945 million compared to the *November Estimate*).

III. ADAP SPECIAL FUND REVENUE ESTIMATES (Updated for *May Revision*)

The *November Estimate* included estimated revenues of \$171.651 million in the ADAP Special Fund for FY 2008-09 and \$185.208 million for FY 2009-10 using a 46 percent rebate collection rate (see Table 12, page 26).

As in the *November Estimate*, the updated *May Revision* uses the 46 percent rebate collection rate to project revenue. However, updated expenditure data as well as actual revenue data is available for the *May Revision*. The *May Revision* revenue projection for FY 2008-09 is \$162.857 million (a decrease of \$8.794 million compared to the *November Estimate*) and for FY 2009-10 is \$183.787 million (a decrease of \$1.421 million compared to the *November Estimate*). The decrease in the revenue estimate for FY 2008-09 is due in large part to the availability of updated expenditure data for the period July 2008 through December 2008 (see Table 12, page 26). For the *November Estimate*, expenditures for the period July 2008 through December 2008 were based on one-half of the estimated expenditures for drugs for that fiscal year. For the *May Revision*, actual expenditures for that six-month period came in at less than half of the annual estimate, resulting in a \$5.381 million reduction in projected revenue. In addition, revenues for FY 2008-09 were significantly impacted by a \$3.788 million reduction in estimated interest earned for that fiscal year. Also, there will be a \$10 million reduction in expenditures resulting from formulary modification and an increase of \$2.3 million in revenue due to implementation of premium payments in FY 2009-10. This contributed to an overall reduction in FY 2009-10 revenues of \$1.421 million. The revenue reduction was also the result of a decreased estimate of \$3.677 million in interest earned for that fiscal year (see Table 12, page 26 for more details). For purposes of projecting revenue, half of the \$10 million will be available, as we only take into account the first two quarters of FY 2009-10 (46% of \$5 million). It is coincidental that the \$2.3 million loss in revenue is the same as the \$2.3 million revenue achieved by implementing monthly premiums (see Table 1d, page 1).

It is important to note that historical drug expenditure data are now showing that drug expenditures are consistently lower in the first half of the fiscal year as compared to the second half of the fiscal year. Current revenue projection methodology however, does not directly take this phenomenon into account and this may impact revenue projections.

IV. ADAP SPECIAL FUND CONDITION STATEMENT (Updated for *May Revision*)

The Fund Condition Statement prepared for the *November Estimate* showed a balance of \$73.438 million at the end of FY 2008-09 and \$24.014 million at the end of FY 2009-10.

The *May Revision* ADAP Special Fund Condition Statement (see Table 13, page 29) shows an estimated balance of \$94.508 million at the end of FY 2008-09 (an increase of \$21.070 million compared to the *November Estimate*). This increase is due mainly to a prior year adjustment of \$24.041 million (see page 27). For FY 2009-10 the estimated fund balance is \$47.766 million, an increase of \$23.752 million compared to the *November Estimate*. This increase is mainly due to the carryover from FY 2008-09 and ADAP's recommendation to collect premiums from ADAP clients with incomes >200 percent of the Federal Poverty Level (FPL). It is also impacted by a reduction in estimated interest earned for FY 2009-10.

V. POLICY ISSUES WITH POTENTIAL IMPLICATIONS FOR ADAP (Updated for *May Revision*)

Update on Federal policy issues that may impact ADAP:

- Medicare
 - No new policy changes to the Medicare Part D program at this time.

- There will be annual adjustments to the Medicare Part D program on January 1, 2010, including potential increases to the Part D plan premiums and other out-of-pocket costs to clients.
- Federal advocacy continues to support ADAP payments to count toward True Out-of-Pocket (TrOOP) costs enabling ADAP clients to move from the “donut hole” into catastrophic coverage. However, there is no new Federal legislative or regulatory activity addressing this issue at this time.
- No new information regarding potential manufacturer challenges to the ability of ADAP to collect full rebate on partial pay third-party payer transactions.
- New: the Early Treatment of HIV Act (ETHA) is again being discussed in Congress. This legislation would allow state Medicaid programs to enroll all income-eligible individuals with HIV infection, regardless of disability status, and would shift some current ADAP clients to Medi-Cal if it is passed by Congress and adopted in California.

Update on state policy issues that may impact ADAP:

- No changes in Medi-Cal eligibility or services in the enacted budget that impact ADAP.
- New Major Assumption Policy Change 163 (PC-163) (Medi-Cal *November Estimate*): Newly Qualified Aliens (NQAs) and Permanently Residing Under Color of Law (PRUCOL) immigrants: will take effect on October 1, 2009 and result in an estimated increase of \$1.620 million in ADAP expenditures for FY 2009-10 and \$2.160 million on an annual basis thereafter.

Prior policy issues that are not a current concern:

- The pharmaceutical manufacturer co-pay programs exclude ADAP clients and thus do not negatively impact ADAPs ability to collect rebate on partial pay transactions.

SECTION A: EXPENDITURE SUMMARY TABLE (Updated for *May Revision*)

Note: Table 3 has been modified from the *November Estimate* as follows:

- As in the *November Estimate*, the Linear Regression Model continues to be the primary estimate method; thus it is presented first.
- The Linear Regression Model continues to use a starting point of January 2006; it also includes actual expenditure data through February 2009 (five additional data points compared to the *November Estimate*).
- The Percent Change Model uses actual data from April 2008 to February 2009 and updated assumptions.

TABLE 3: SUMMARY OF ESTIMATES FROM BOTH ESTIMATE METHODOLOGIES (includes all fund sources)			
FY 2008-09		FY 2009-10	
November Estimate			
\$360,124,974		\$416,097,843	
May Revision			
Updated Linear Regression Model			
\$354,301,860	Page 18	\$412,533,061	Page 19
Updated Percent Change Model			
\$359,255,759	Page 18	\$415,824,637	Page 19

The estimates in Table 3 do not include:

- A reduction in expenditures of \$10 million resulting from reductions to the formulary.
- An estimated \$1.620 million in additional expenditures for FY 2009-10 as a result of Medi-Cal’s New Major Assumption Policy Change 163 (PC-163): Newly Qualified Aliens (NQAs) and Permanently Residing Under Color of Law (PRUCOL) immigrants.
- \$2 million of additional budget authority requested annually by the California Department of Public Health (CDPH), Center for Infectious Diseases, Office of AIDS, and 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

From November Estimate

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

To project budget estimates for FYs 1998-99 through 2006-07, ADAP used a **Linear Regression Model** originally recommended by the 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), 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 administration, 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. Increased client costs
5. Increase transaction fees for unapproved prescription requests

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, Estimate 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 (Figure 1, red portion of the line and Table 4, page 9).

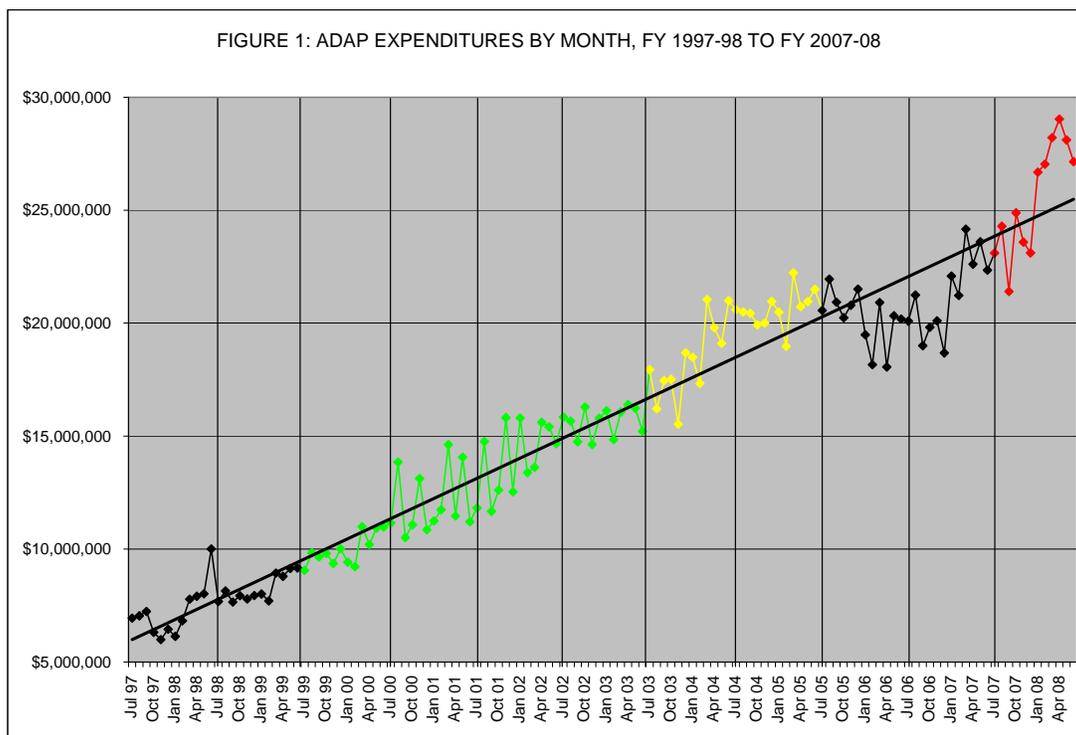


TABLE 4: ADAP HISTORIC EXPENDITURES			
Fiscal Year	Expenditures	Annual Change in Absolute Expenditures	Pct Annual Change
1997-98	\$86,674,336	N/A	N/A
1998-99	\$98,924,742	\$12,250,406	14.13%
1999-00	\$119,465,151	\$20,540,409	20.76%
2000-01	\$144,913,504	\$25,448,353	21.30%
2001-02	\$167,709,426	\$22,795,922	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%

Table 4 and Figure 1 have been color coordinated to allow the user to easily compare the three absolute expenditure growth periods. The green, yellow and red numbers in Table 4 refer to the green, yellow and red dots in Figure 1. The thick straight black (regression) line represents the best fitting straight line for estimating the expenditures.

Table 4 shows the ADAP historic expenditures by fiscal year and the annual change and percent change. The lower portion of the table shows the different growth periods ADAP has experienced. Normal growth periods were from FY 1999-00 to FY 2002-03 with an annual change of \$22.32 million (17.45 percent). High growth periods were from FY 2003-04 to FY 2004-05 with an annual change of \$29.72 million (14.76 percent). Last fiscal year, FY 2007-08, was the only mega-high growth year with a \$51.61 million increase (20.24 percent).

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 the *November Estimate*, we considered both **Linear Regression** and **Percent Change** Models.

New for May Revision

- For the *November Estimate*, ADAP adjusted the starting point from July 1998 used in previous models to January 2006 to more accurately reflect recent expenditure trends. The final estimate was based on the upper bound of the 95 percent confidence interval.
- As in the *November Estimate*, the Linear Regression Model continues to be the primary estimate method.
- The Linear Regression model uses a starting point of January 2006 with actual expenditure data through February 2009 (an additional five data points compared to the

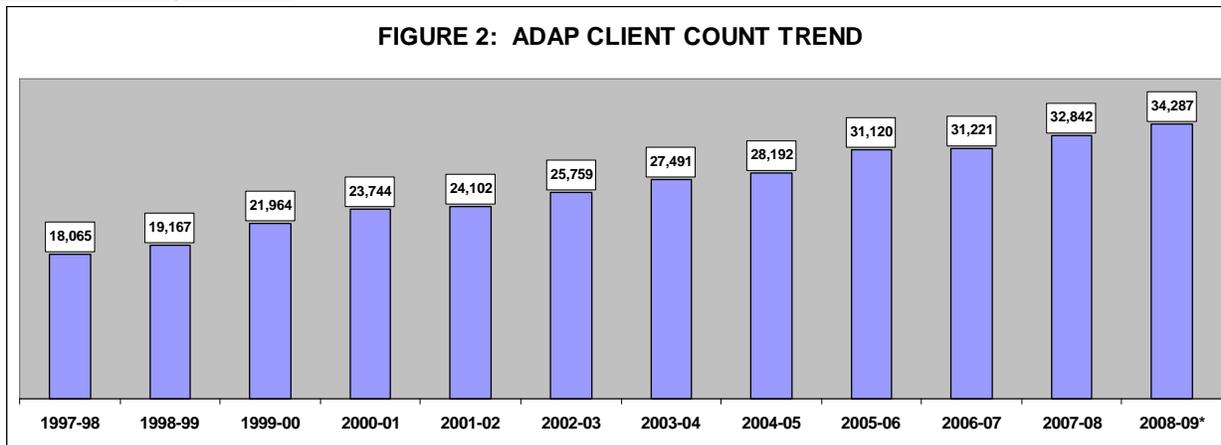
November Estimate). The final estimate was based on the upper bound of the 95 percent confidence interval.

- The Percent Change Model uses actual data from April 2008 through February 2009 and updated assumptions.

SECTION C: HISTORICAL CASELOAD FACTORS

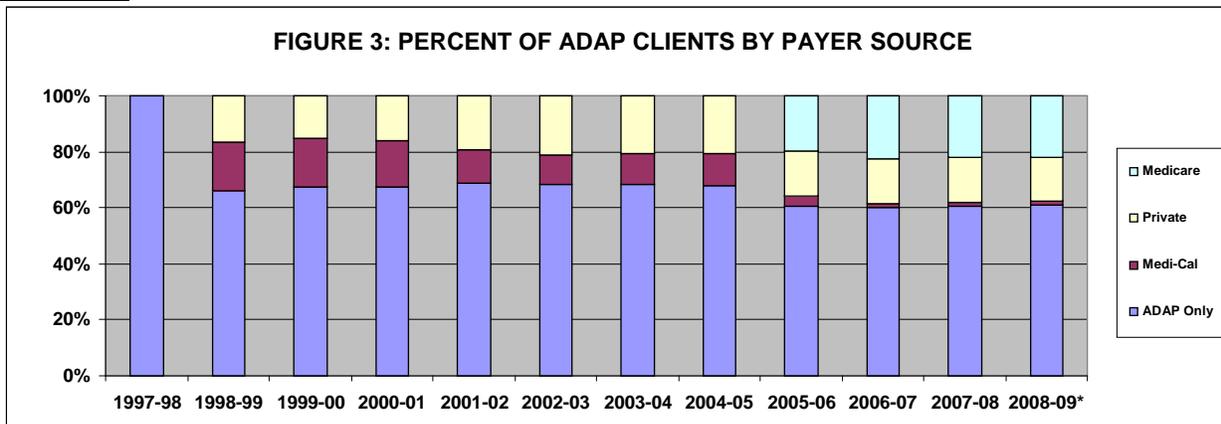
Antiretroviral (ARV) therapy was very different before 1997, when the Protease Inhibitor and Non-Nucleoside Analogue drug classes were not yet available. At that time, only single and dual nucleoside therapy was used and ADAP was thus a much less complex program. The program was centralized in 1997;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

Updated for May Revision



* Actuals except for estimated FY 2008-09 clients.

New Figure



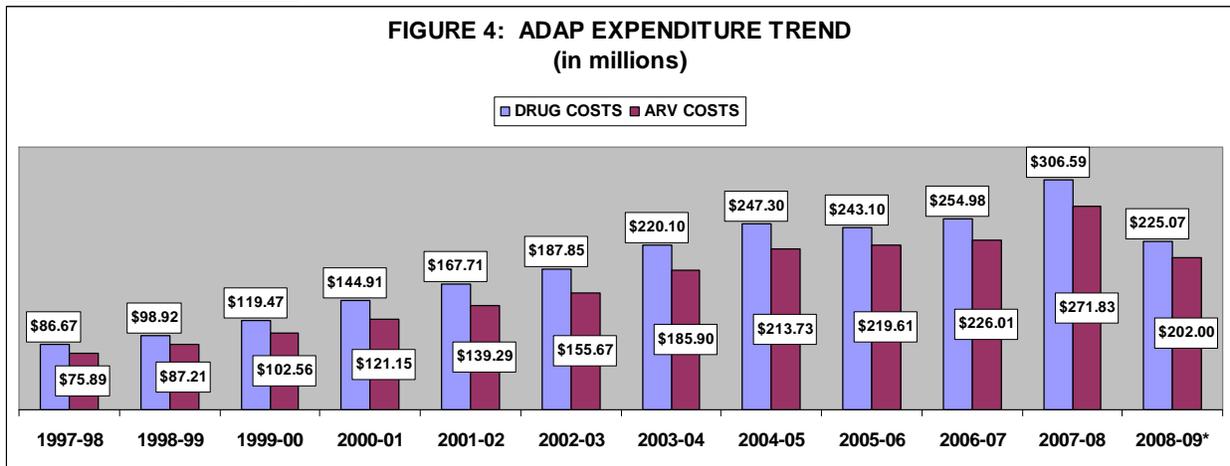
*FY 2008-09 clients and expenditures represent actuals through February 2009 and thus do not include the full fiscal year.

New Table

**TABLE 5: ESTIMATED ADAP CLIENTS BY COVERAGE GROUP
FY 2008-09**

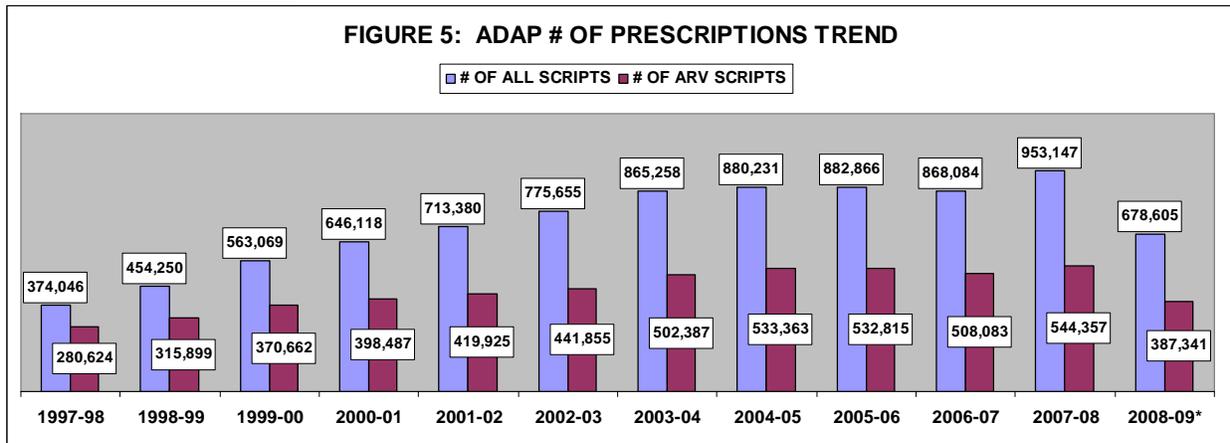
Coverage Group	Clients	Percent
ADAP	21,014	61.29%
Medi-Cal	408	1.19%
Private Insurance	5,367	15.65%
Medicare	7,498	21.87%
TOTAL	34,287	100.00%

Updated for May Revision



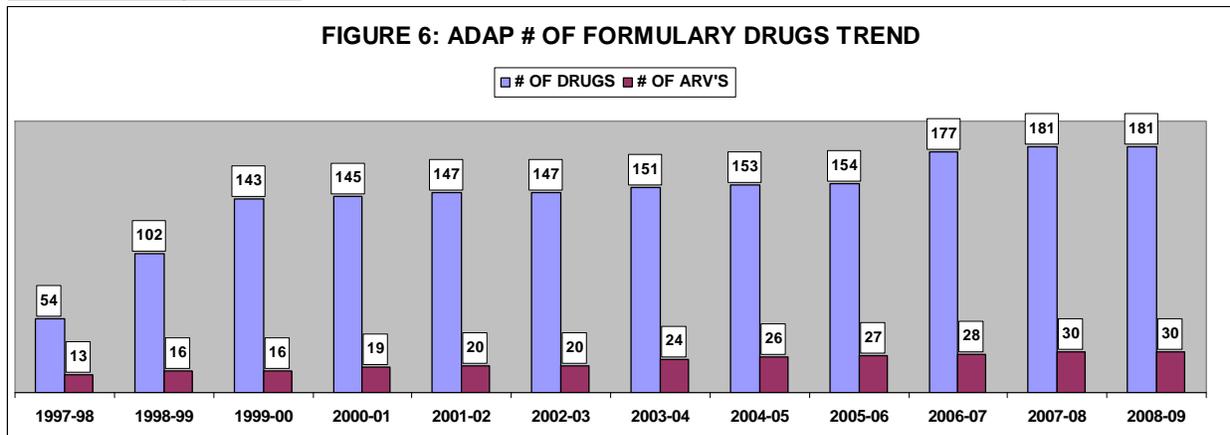
*FY 2008-09 clients and expenditures represent actuals through February 2009 and thus do not include the full fiscal year.

Updated for May Revision



*FY 2008-09 clients and expenditures represent actuals through February 2009 and thus do not include the full fiscal year.

Updated for May Revision



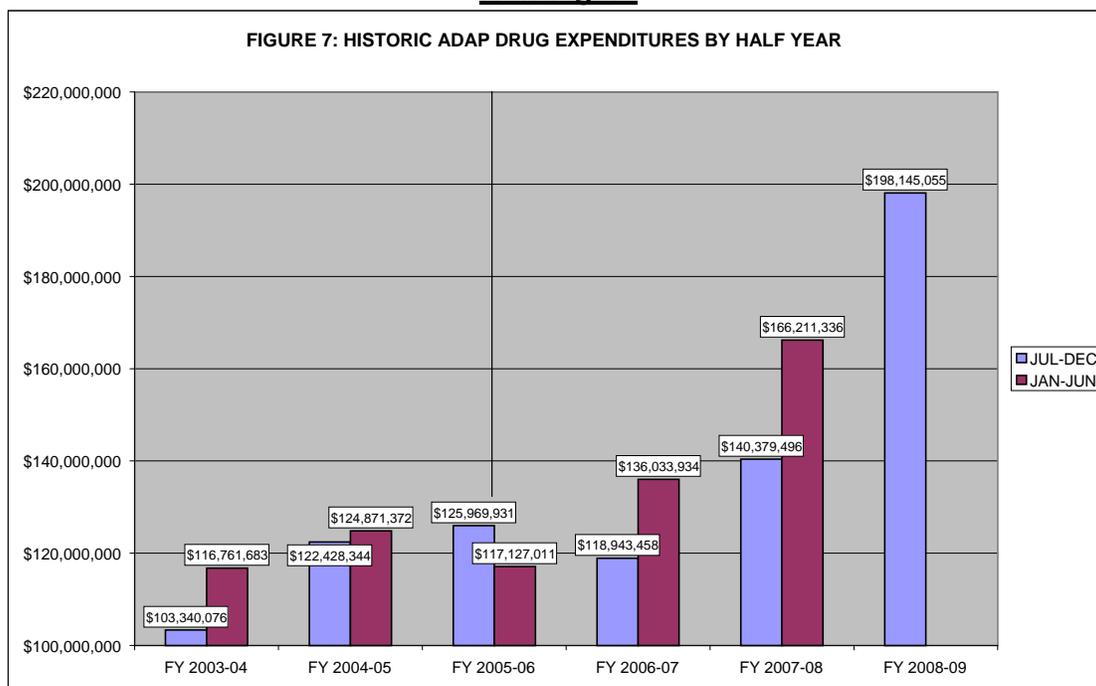
SECTION D: ESTIMATE METHODS FOR *MAY REVISION* FY 2008-09 and FY 2009-10

INTRODUCTION AND OVERVIEW

For the *May Revision*, the projection models that were presented in the *November Estimate* were updated as follows:

- The Linear Regression Model was based on the same methodology as in the *November Estimate* and used updated data points to include actual expenditures from January 2006 through February 2009 (as opposed to January 2006 through September 2008 in the *November Estimate*).
- The Percent Change Model was updated to include actual data from April 2008 through February 2009 as well as updated assumptions. The *November Estimate* used actual data only up to March 2008.
- The timing of the May Revision does not allow the inclusion of actual expenditures in the second half of the fiscal year in which ADAP has historically experienced accelerated growth (Figure 7). This limitation of the regression model could result in an underestimate of expenditures.

New Figure



CONSIDERATIONS REGARDING THE PROJECTION MODELS

Linear Regression Model (From November Estimate)

Figure 1, page 8 shows ADAP historic expenditures by month. The data points are color coordinated to match the three absolute expenditure growth periods shown in Table 4, page 9. 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 over 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 not to underestimate the need for ADAP to utilize the ADAP Special 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.

Updated for May Revision

The Linear Regression Model was based on the same projection methodology as used for the *November Estimate*. However, the model was updated with additional data points to maximize its predictive accuracy.

Five more data points (actual monthly expenditures from October 2008 through February 2009) were added to the data set for a total of 38 data points. In the 2008 *November Estimate*, the Linear Regression Model included actual expenditures only through September 2008. For comparison, Medi-Cal utilizes a 36-month historical trend analysis for their estimate.

Percent Change Model

Updated for May Revision

The *November Estimate* used Percent Change Model assumptions that were developed for the *May Revision* released in May 2008. The assumptions were based on the expected change from FY 2006-07 actuals to FY 2007-08 estimates. Once FY 2007-08 actuals were available the changes were greater than expected. For the current *May Revision*, the changes to the assumptions take into consideration the increased change from FY 2006-07 to FY 2007-08 as well as the projected change from FY 2007-08 to FY 2008-09. Table 6, page 15 displays the assumptions used for each cost factor for the *November Estimate* and the current *May Revision*. Tables 8 and 10, pages 19 and 20 show expenditure projections by factor for FYs 2008-09 and 2009-10, respectively, for both the *November Estimate* and *May Revision*.

TABLE 6: ASSUMPTIONS FOR PERCENT CHANGE MODELS, FY 2008-09			
#	Factors	November Estimate	May Revision
0	FY 2007-08 (total expenditures)	\$306,590,832	\$306,590,832
1	Medicare Part D costs	20% of Part D Costs	30% of Part D Costs
2	New drug costs: ARVs	\$2 million	\$0
3	Drug price increase costs	3% of total expenditures	11% of total expenditures
4	Increase client costs	2% of total expenditures	4% of total expenditures
5	Increase transaction fees for unapproved prescription requests	0.12% of total expenditures	0.27% of total expenditures

0. Starting Point

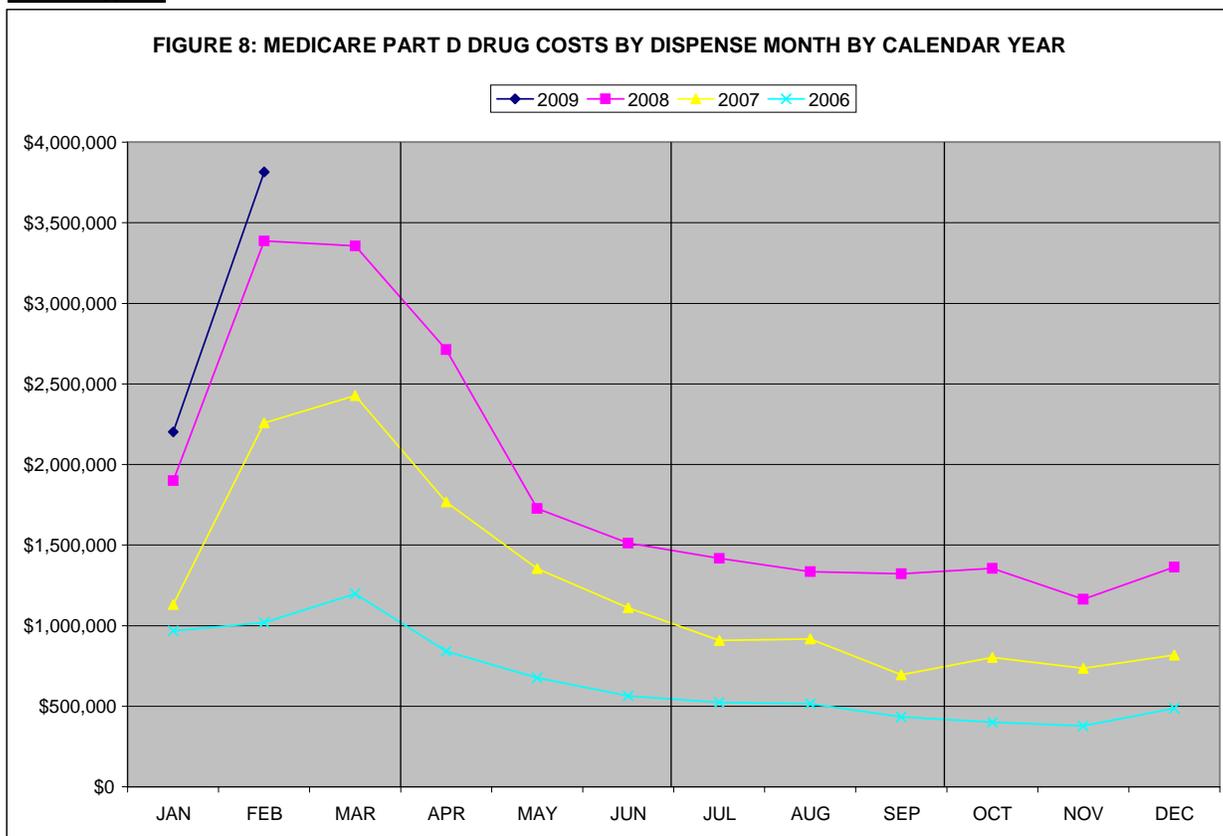
No change: FY 2007-08 actual expenditures of \$306.591 million were the starting point for both *November Estimate* and *May Revision*.

1. Medicare Part D Costs (Figure 8, page 16)

- The *November Estimate* forecasted a 20 percent increase in Part D costs (\$3,887,104) from FY 2007-08 actuals to FY 2008-09 estimated.
- This 20 percent increase for FY 2008-09 was based upon an earlier projection that used a 30 percent increase from FY 2006-07 actuals to develop a FY 2007-08 estimates.
- However, actual increases in expenditures for the period FY 2006-07 through FY 2007-08 were 53 percent (FY 2006-07 \$12,721,966 to FY 2007-08 \$19,477,179).
- For the *May Revision*, it is unlikely that a 50 percent plus trend will continue in FY 2008-09. Because of historical and current expenditure data the increase will likely be no lower than 20 percent, as such, we are using a 30 percent increase.
- This 30 percent increase (\$5,843,154) was applied to FY 2007-08 actuals of \$19,447,179.

Factors influencing Medicare Part D costs include increase in premiums, deductibles, and out-of-pocket expenses (depending upon specific Part D plan coverage), additional clients enrolling in Part D, and clients transitioning within Part D subcategories. Please see descriptions regarding these various categories in the Appendices, page 37.

New Figure



2. New Drug Costs: ARVs

The *November Estimate* included \$2 million for one new antiretroviral (Rilpivirine) in FY 2008-09 and \$1.90 million for another antiretroviral (Elvitegravir) in FY 2009-10. There are *no new drug costs* included in the *May Revision* for FY 2008-09 since no drugs are anticipated to be FDA-approved before 2010 (see New Drug Updates, page 39).

3. Drug Price Increase Costs

- The *November Estimate* assumed a three percent increase in overall expenditures from the FY 2007-08 estimated expenditures to FY 2008-09 based on observed drug price increases in the prior two fiscal years.
- The three percent increase also considered the historic average drug price increase for a normal growth year.
- However, the actual increase between FY 2006-07 and FY 2007-08 was ten percent.
- For the *May Revision* an increase of 11 percent is estimated because of an observed increase in expenditures for ARVs through February 2009 which is consistent with a mega-high growth year.
- The impact on ADAP costs will depend upon when the actual price increase occurs; utilization rate of the medications; different reimbursement rates depending upon contracts with provider pharmacies; and, type of insurance coverage.

4. Increase in Client Costs

- The *November Estimate* forecasted that client costs would be two percent (\$6,131,817) of actual FY 2007-08 drug expenditures (\$306,590,832).
- This two percent increase was based upon historic average increase in client costs for a normal growth year.
- However, the actual increase between FY 2006-07 and FY 2007-08 was six percent; nevertheless the increases in drug expenditures related to the number of clients are not expected to continue at the six percent level.
- For the *May Revision* the increase in client costs is estimated to be four percent (\$12,263,633) of FY 2007-08 actual drug expenditures (\$306,590,832) which will be in line with a mega-high growth year.
- The Program does not use a direct calculation of estimated increase caseload multiplied by average cost per client to determine increase client costs. Rather, the increase in client costs is estimated by applying a percent increase to the previous fiscal years estimated drug expenditures. This is the same logic as used by the HRSA model.
- As with drug price increase costs, increase in client costs are checked against historic increases in expenditures for the particular factor and applying the appropriate percent increase.

5. Increase in Transaction Fees for Unapproved Prescription Requests

- ADAP has two categories of transaction fees: fees paid for the processing of approved prescription requests and fees paid for processing unapproved prescription requests (such as prescriptions originally submitted to ADAP but the PBM redirected the prescription to another payer).
- Approved transaction fees are an administrative fee provided to the Pharmacy Benefits Manager (PBM) of \$6.00 per prescription. Transaction fees for unapproved prescription requests are charges to ADAP for prescriptions processed but not approved by the PBM.
- The *November Estimate* for transaction fees for unapproved prescription requests was 0.12 percent of FY 2007-08 actual drug expenditures.
- Based upon recent data trends, the *May Revision* increased the estimate to 0.27 percent of FY 2007-08 actual drug expenditures.
- In FY 2007-08, both transaction fees increased over the last year, although the proportion between the two remains relatively constant.
- Approved transaction fees have been accounted for by including them in the cost factor for drug price increases.

For the FY 2009-10 percent change projections, the same assumptions for FY 2008-09 are applied, with the following two modifications:

- New drug costs: two new drugs are anticipated to possibly be FDA-approved and placed on the ADAP formulary during this period. These two new drugs are estimated to increase program costs by \$1.300 million.
- Drug price increase costs: these are estimated to increase program costs by nine percent, which is a reduction from the FY 2008-09 assumptions of 11 percent. The smaller increase in costs is based upon the settlement of a federal lawsuit (see page 35). The lawsuit was based on fraudulent increases of five percent to the average wholesale price (AWP) of over 400 branded drugs and publishing the false prices by a drug pricing publisher and drug wholesaler. This action caused members of

various consumer classes including the government to pay too much for those drugs. The terms of the settlement requires the defendants to reduce the mark-up factor utilized in connection with the calculation of the AWP.

From November Estimate

Summary and Implications

As in the *November Estimate*, the Linear Regression Model continues to be the primary estimate method; thus it is presented first.

Given the subjective assumptions underlying the Percent Change Model and lack of guidance from HRSA about developing 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.

New for May Revision

As noted under Section V. Updated Policy Issues with Potential Implications for ADAP, New Major Assumption PC-163 NQAs/PRUCOL (page 4): will increase costs in FY 2009-10 by \$1.620 million.

REVISED PROJECTIONS FOR FY 2008-09

2008 November Estimate = \$360,124,974

Linear Regression Model (Updated)

TABLE 7: LINEAR REGRESSION MODEL FOR MAY REVISION, FY 2008-09 (ACTUAL DATA JANUARY 2006 THROUGH FEBRUARY 2009)		
Point Estimate	Upper Bound of 95% CI	Change From November Estimate
\$350,294,665	\$354,301,860	-\$5,823,114

Percent Change Model (Updated)

TABLE 8: PERCENT CHANGE MODEL FOR MAY REVISION, FY 2008-09 (ACTUAL DATA APRIL 2008 THROUGH FEBRUARY 2009)				
#	Factors	November Estimate	May Revision	Change
0	FY 2007- 08	\$306,590,832	\$306,590,832	\$0
1	Medicare Part D costs	\$3,887,104	\$5,843,154	\$1,956,050
2	New drug costs: ARVs	\$2,000,000	\$0	-\$2,000,000
3	Drug price increase costs	\$8,809,934	\$33,724,992	\$24,915,057
4	Increase client costs	\$6,131,817	\$12,263,633	\$6,131,817
5	Increase transaction fees for unapproved prescription requests	\$375,000	\$833,148	\$458,148
6	TOTAL	\$327,794,687	\$359,255,759	\$31,461,072

REVISED PROJECTIONS FOR FY 2009-10

2008 November Estimate = \$416,097,843

Linear Regression Model (Updated)

TABLE 9: LINEAR REGRESSION MODEL FOR MAY REVISION, FY 2009-10 (ACTUALS THROUGH FEBRUARY 2009)		
Point Estimate	Upper Bound of 95% CI	Change From November Estimate
\$396,800,420	\$412,533,061	-\$3,564,782

New at May Revision

This estimate will modify the ADAP formulary to achieve a \$10 million savings to the General Fund by reducing expenditures for FY 2009-10. This formulary modification will require consultation with the ADAP Medical Advisory Committee.

This estimate will implement premium payment requirements for ADAP clients who earn >200% of the FPL. This program modification will result in an increase in program revenue of approximately \$2.3 million in FY 2009-10.

Implementing a premium payment obligation may deter some individuals from staying in, enrolling or re-enrolling in ADAP. Such consequences will have an impact on expenditures and rebate revenue; we do not know what this impact will be at this time.

Percent Change Model (Updated)

The assumptions for each factor are similar to those for FY 2008-09 except for new drug costs and drug price increase costs.

TABLE 10: PERCENT CHANGE MODELS, FY 2009-10				
#	Factors	November Estimate	May Revision	Change
0	FY 2008-09 EST	\$359,255,759	\$359,255,759	\$31,461,072
1	Medicare Part D costs	\$4,664,524	\$7,596,100	\$2,931,575
2	New drug costs: ARVs	\$1,900,000	\$1,300,000	-\$600,000
3	Drug price increase costs	\$9,342,149	\$32,333,018	\$22,990,870
4	Increase client costs	\$6,555,894	\$14,370,230	\$7,814,337
5	Increase transaction fees for unapproved prescription requests	\$500,000	\$969,530	\$469,530
6	TOTAL	\$350,757,254	\$415,824,637	\$65,067,384

SECTION E: FUND SOURCES

From November Estimate

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 Special Fund.

The following information highlights each of the sources that funds ADAP. Please note that the expenditures discussed 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 Special Fund authority by \$17.085 million to back fill these redirections. The shift in funding resulted in a significant drop in the General Fund expenditures from FY 2006-07 to FY 2007-08.

New at May Revision

There will be a \$12.3 million reduction in General Funds, which will be offset by modifying the formulary to achieve \$10 million in savings and implementing a premium payment obligation for clients, with a projected \$2.3 million increase in revenue.

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 Special Funds. The shift in funding resulted in a significant drop in the historical Federal Fund expenditures from FY 2006-07 to FY 2007-08.

New at May Revision

Federal Funds for FY 2009-10 include an additional \$4.481 million available through the Ryan White Part B HIV Care Grant Program 2009 grant award effective April 1, 2009.

From November Estimate

ADAP Special (Rebate) Fund

The ADAP Special 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 Special 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 Special 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 Special Fund to continue to meet expenditure demands.

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 SPECIAL FUND REVENUE AND EXPENDITURE PROJECTIONS

Background (Updated for *May Revision*)

ADAP Special 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. 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 (Table 11).

For the November Estimate, the assumed revenue collection rate was 46%.

FY-QTR	Total Expenditures	Received in Rebate \$	Total Revenue Collection Rate
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	\$24,788,637	41.09%
2006/07-Q2	\$58,609,374	\$24,489,209	41.78%
2006/07-Q3	\$67,474,884	\$32,724,197	48.50%
2006/07-Q4	\$68,559,050	\$31,061,704	45.31%
2007/08-Q1	\$68,797,779	\$32,923,274	47.86%
2007/08-Q2	\$71,581,717	\$34,668,809	48.43%
2007/08-Q3	\$81,926,045	\$43,901,210	53.59%
2007/08-Q4	\$84,285,291	\$39,108,430	46.40%

Decrease in Rebate Revenue for FY 2008-09 (New for *May Revision*)

Table 12, page 26 displays a comparison of revenue estimates (rebate collection) between the *November Estimate* and *May Revision* for FYs 2008-09 and 2009-10. For FY 2008-09, the projected revenue for *May Revision* is \$8.794 million less than that for the *November Estimate*. The main reason for the decline of the estimate was the availability of updated expenditure data for the period July 2008 through December 2008. Current revenue projection methodology applies the estimated revenue collection rate (46 percent) to estimated or actual expenditures (whichever is more current) to forecast future revenue. Revenues for a given fiscal year are based on drug expenditures for the last two quarters of the previous fiscal year and first two quarters of that fiscal year to take into account the time required for billing and collection. For example, for the *November Estimate*, revenue projections for FY 2008-09 used actual rebates collected from expenditures from January 2008 through March 2008, actual expenditures for the period April 2008 through June 2008 and estimated drug expenditures for the period July 2008

through December 2008 (half of the estimated expenditures for FY 2008-09). However, for the *May Revision*, available data included updated actual rebates collected from expenditures for the period January 2008 through March 2008, actual rebates collected from expenditures for April 2008 through June 2008, and actual expenditures for July 2008 through December 2008. Because actual expenditures for July 2008 through December 2008 (*May Revision*) were less than projected for this time period during the *November Estimate*, projected revenues were also less. Table 12 shows that most of the \$8.794 million decrease in revenue for FY 2008-09 was due to this reason. (Historical data now show that drug expenditures are lower in the first half of the fiscal year compared to the second half of the same fiscal year.) In addition, revenue estimates for the *May Revision* were negatively impacted because updated estimates for interest earned on revenue during FY 2008-09 were \$3.788 million less than estimated in the *November Estimate*.

For FY 2009-10, projected revenues for the *May Revision* are \$1.421 million lower than those in the *November Estimate*. This decline is due to a reduction of \$10 million in expenditures for FY 2009-10, a revised estimate of interest earned during this fiscal year and an increase in Special Fund due to the introduction of a premium payment obligation for ADAP Clients (see Table 12 below). While estimates for both *November Estimate* and *May Revision* are based on estimated expenditures for the period January 2009 through December 2009, the *May Revision* uses more recent drug expenditure data as compared to the *November Estimate*. It should be noted that FY 2009-10 revenue projections may also experience a pattern similar to those of FY 2008-09 as mentioned above due to the current revenue projection methodology.

New for May Revision

ADAP will implement premium payment requirements for clients who earn >200% of the FPL. This will result in an increase in revenue deposited in the Special Fund of approximately \$2.3 million in FY 2009-10. It is possible that implementing premium payment obligations may deter some individuals from staying in, enrolling or re-enrolling in ADAP, with resulting impact on expenditure and rebate revenue.

TABLE 12: COMPARISON OF REVENUE (REBATES)* BETWEEN NOVEMBER 2008 AND MAY REVISION AT 46 % OF EXPENDITURES					
For FY 2008-09					
Expenditure Period	Available Data	November Estimate	Available Data	May Revision	Change
Jan-Mar 08	Actual Rebates	\$43,848,430	Actual Rebates	\$43,901,210	\$52,780
Apr-June 08	Actual Expenditures @ 46%	\$38,785,761	Actual Rebates	\$39,108,430	\$322,669
Jul-Dec 08	Estimated Expenditures @ 46% **	\$82,828,744	Actual Expenditures @ 46%	\$77,447,486	-\$5,381,258
Subtotal Revenue		\$165,462,935		\$160,457,126	-\$5,005,809
Interest		\$6,188,314		\$2,400,000	-\$3,788,314
Total Revenue (see Table 13, Fund Condition Statement)		\$171,651,249		\$162,857,126	-\$8,794,123

For FY 2009-10					
Expenditure Period	Available Data	November Estimate	Available Data	May Revision	Change
Jan - Jun 09	Estimated Expenditures @ 46%	\$82,828,744	Estimated Expenditures @ 46%	\$85,531,370	\$2,702,626
Jul-Dec 09	Estimated Expenditures @ 46% **	\$95,702,504	Estimated Expenditures @ 46%**	\$92,955,203	-\$2,747,301
Subtotal Revenue		\$178,531,248		\$178,486,573	-\$44,675
Interest		\$6,677,069		\$3,000,000	-\$3,677,069
Premium Payments				\$2,300,000	\$2,300,000
Total Revenue (see Table 13, Fund Condition Statement)		\$185,208,317		\$183,786,573	-\$1,421,744

*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 fiscal year (when expenditures are lowest) and the second half (when expenditures are highest, see Figure 7).

**Note: Revenue for the *November Estimate* for FY 2008-09 and FY 2009-10 and the *May Revision Estimate* for FY 2009-10 were based on half of the projected expenditures for that year.

Fund Condition Statement (FCS) for the Special Fund

From November Estimate

Based on the historical increase in the ADAP Special Fund revenue relative to expenditures, ADAP revised its estimated revenue rate from 39 percent to 46 percent on April 1, 2008 to reflect the average revenue rate since the inception of Medicare Part D.

Updated for May Revision

The Fund Condition Statement (Table 13, page 29) was developed assuming a revenue collection rate of 46 percent of the average of rebate collections from expenditures from January 2006 through June 2008 (see Table 11, page 25). The expenditures were determined based on the Linear Regression methodology using actual expenditure data from January 2006 to February 2009. This expenditure figure was then reduced by \$10 million due to savings resulting from formulary modifications. The balance in the ADAP Special Fund at the end of FY 2008-09 is estimated to be \$94.508 million (increase of \$21.070 million from the *November Estimate*) and \$47.766 million (increase of \$23.752 million from the *November Estimate*) at the end of FY 2009-10. This balance includes reduced rebate revenue resulting from the formulary-associated expenditure reductions and increased deposits from premium collections which are anticipated to start half way through the fiscal year.

Fund balances for the *November Estimate* were \$73.438 million and \$24.014 million, respectively.

Although the ADAP Special Fund revenues increase as expenditures rise, they only increase 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 such as the introduction of Medicare Part D in 2006.

Prior Year Adjustments (New for May Revision)

The prior year adjustment of \$24.041 million (Table 13, page 29) for FY 2008-09 includes the following:

Revenue Adjustments

1. Deposit in FY 2007-08 (\$7,309,066.40) was credited to FY 2006-07 in error and was not included in any Financial Statements since FY 2006-07 Financial Statements were already completed.
2. Two ADAP deposits for FY 2007-08 (\$1,258,678.66) were credited twice to FY 2007-08. When correcting the error, the debit was mistakenly made to FY 2006 instead of FY 2007. Therefore, the FY 2007-08 Financial Statements counted the deposits twice.
3. A dishonored check (\$5,262,517.07) from a drug manufacturer was inadvertently deducted twice from the Schedule 10R.

Net adjustments to revenue: + \$11,312,904.81 (\$11.313 million)

Expenditure Adjustments

1. FY 2007-08 closed with an encumbrance (\$5,732,056.90) that was unspent. This amount was included in the FY 2007-08 Financial Statements as an expenditure and has since been disencumbered.

2. FY 2006-07 closed with an encumbrance (\$7,384,344.93) that was unspent. This amount was included in the FY 2006-07 Financial Statements as an expenditure and has since been disencumbered.
3. FY 2007-08 expenditures (\$387,935.22) have been posted in FY 2008-09 for FY 2007-08 after the completion of the FY 2007-08 Financial Statements. These expenditures need to be reflected in FY 2007-08.

Net adjustments to expenditures: -\$12,728,466.61 (\$12.728 million)

MAY REVISION FUND CONDITION STATEMENT

TABLE 13: FUND CONDITION STATEMENT

		FY 2007-08	FY 2008-09	FY 2009-10*
Special Fund 3080 AIDS Drug Assistance Program Rebate Fund		actual	estimate	estimate
1	BEGINNING BALANCE	80,523	80,356	94,508
2	Prior Year Adjustment		24,041	0
3	Adjusted Beginning Balance	80,523	104,397	94,508
4	REVENUES, TRANSFERS AND OTHER ADJUSTMENTS			
5	Revenues			
6	150300 Income From Surplus Money Investments	5,054	2,400	3,000
7	161400 Miscellaneous Revenue	129,824	160,457	180,787
8	Total Revenues, Transfers, and Other Adjustments	134,878	162,857	183,787
9	Total Resources	215,401	267,254	278,295
10	EXPENDITURES AND EXPENDITURE ADJUSTMENTS			
11	Expenditures			
12	0840 State Controllers Office	1	1	23
13	4260 Department of Health Care Service (State Ops)		150	165
14	4265 Department of Public Health			
15	State Operations	1,415	1,088	1,164
16	Local Assistance	133,629	171,507	229,177
17				
18				
19	Total Expenditures and Expenditure Adjustments	135,045	172,746	230,529
20	FUND BALANCE	80,356	94,508	47,766

Row 2: Prior Year Adjustment - see page 27 for explanation

Row 6: Estimates based on actual interest earned through three quarters of SFY 2008-

2,400,000	3,000,000
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Row 7: Miscellaneous Revenue

<i>Actual rebate collected for Jan - Mar 2008 expenditures</i>	43,901,210	
<i>Actual rebates collected for April - June 2008 expenditures</i>	39,108,430	
<i>Subtotal actual rebates collected</i>	83,009,640	
<i>Actual expenditures for July - Dec 2008</i>	168,364,100	
Estimated expenditures for Jan - June 2009		185,937,760
Estimated expenditures for July - Dec 2009		202,076,530
Estimated Calendar Year		388,014,290
Estimated revenue at 46% rebate collection rate on 168,364,100	77,447,486	
Total projected revenue (83,009,640 + 77,447,486)	160,457,126	
Estimated revenue at 46% rebate collection rate on 388,014,290		178,486,573
Revenue due to Premium Payments		2,300,000
Miscellaneous Revenue		180,786,573

Local Assistance Expenditure estimate

Row 16: Linear Regression Expenditure Projection	354,301,860	412,533,061
Add: PRUCOL Medi-Cal Premise PC 163		1,620,000
Subtotal		414,153,061
Reduction to Expenditures		-10,000,000
Total Local Assistance Expenditure estimate	354,301,860	404,153,061
less: General Fund appropriation	- 96,349,000	- 84,049,000
*less: Federal Fund appropriation	- 88,445,592	- 92,926,756
Special Fund 3080 need to meet expenditure estimate	169,507,268	227,177,305
Local Assistance LHJ	+ 1,000,000	1,000,000
Local Assistance Medicare Part D	+ 1,000,000	1,000,000
Row 16: Total Special Fund Need	171,507,268	229,177,305

*Includes the Ryan White Part B HIV Care Grant Program 2009 grant award effective April 1, 2009

SECTION G: POLICY ISSUES WITH POTENTIAL IMPLICATIONS FOR ADAP (Updated for *May Revision*)

Policy Update Summary (New for *May Revision*)

Update on Federal policy issues that may impact ADAP:

- No new information regarding potential manufacturer challenges to the ability of ADAP to collect full rebate on partial pay third-party payer transactions.
- New: the Early Treatment of HIV Act (ETHA) is again being discussed in Congress. This legislation would allow state Medicaid programs to enroll all income-eligible individuals with HIV infection, regardless of disability status, and would shift some current ADAP clients to Medi-Cal if it is passed by Congress and adopted in California.

Update on state policy issues that may impact ADAP:

- No changes in Medi-Cal eligibility or services in the enacted budget that impact ADAP.
- New Major Assumption Policy Change 163 (PC-163) (Medi-Cal *November Estimate*) about Newly Qualified Aliens (NQAs) and Permanently residing Under Color of Law (PRUCOL) immigrants. This is a major assumption from DHCS which proposes to eliminate or “rollback” full-scope Medi-Cal for NQAs who have been in the country for less than five years and for PRUCOL immigrants who are not defined as eligible qualified aliens under federal law. It is estimated that PRUCOL will increase costs in FY 2009-10 by \$1.620 million.

Prior policy issues that are not a current concern:

- The pharmaceutical manufacturer co-pay programs exclude ADAP clients and thus do not negatively impact ADAPs ability to collect rebate on partial pay transactions.

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

Medicare Part D (Updated for *May Revision*)

- There are no new policy changes to the Medicare Part D program at this time.
- Federal advocacy continues to support ADAP payments to count toward True Out-of-Pocket (TrOOP) costs enabling ADAP clients to move from the “donut hole” into catastrophic coverage. However, there is no new Federal legislative or regulatory activity addressing this issue at this time.

Background

The Centers for Medicare and Medicaid Services (CMS) contracts with Medicare Part D drug plans on an annual basis. Benefits available under Part D plans will vary from calendar year to calendar year. Annual changes include formulary adjustments, changes to client out-of-pocket costs, and plans entering and exiting the market. CMS attempts to contain some beneficiary out-of-pocket costs by establishing an annual “maximum out-of-pocket” benefit threshold schedule.

Summary and Timing

Part D related ADAP costs will continue to fluctuate annually (calendar year). CMS typically releases information regarding out-of-pocket thresholds and plan contracts in October of the preceding plan year. This limits ADAP's ability to project costs based on actual plan information.

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 27 percent (30 percent in the *November Estimate*).
- ADAP client plan selections (clients enrolling in high cost vs. low cost plans).
- ADAP client Part D Low Income Subsidy (LIS) eligibility.
- Plan formulary structures including placement of ARVs on higher cost tiers.
- Plans incorrectly counting ADAP payments towards TrOOP.

(Updated for *May Revision*)

TABLE 14: 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

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

**Table 14 does not include Medicare Advantage Prescription Drug Plans or Special Needs Plans.

ADAP Client Plan Selection (Updated for May Revision)

Background

Plan selection plays an important role in the over-all cost of a Part D client to ADAP. Under CMS rules, individuals are permitted to change plans annually. CMS rules give each plan the flexibility to charge beneficiaries various out-of-pocket costs as long as they stay within the maximum annual threshold (Table 14, page 31). In 2006, DHS made the decision to not limit ADAP client Part D plan options. As a result, ADAP pays the out-of-pocket costs associated with any of the 100+ Part D plans in California.

Summary and Timing

The Part D open enrollment period is November 15 through December 31 of each year. Plan coverage begins January 1st of the following year. ADAP can expect cost fluctuations associated with plan selection in January of each year. These fluctuations will continue on a monthly basis.

Implications

There appear to be two main factors that contribute to an ADAP client's Part D plan selection:

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

New at May Revision

Because ADAP does not limit client plan options, tracking costs associated with this issue will continue to be a challenge.

Part D Plan Formulary Structure and Tiers (New for May Revision)

Background

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

Summary and Timing

Formulary and tier structure information is typically available when CMS releases plan information in October (benefits take effect in January of the following year). Plans are required

to develop an “Annual Notice of Change” informing beneficiaries of any major formulary changes.

Implications

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

ADAP Counting Towards TrOOP (Updated for May Revision)

Background

An individual’s true-out-of-pocket drug spending determines when they advance through the varying levels of Part D coverage. Medicare Part D law prohibits ADAP spending from counting towards a Medicare Beneficiary’s true out-of-pocket costs (TrOOP). This rule typically means that an ADAP client who enters the “donut hole” will remain in the donut hole for a majority of the plan year. This is due to the fact that ADAP spending on drugs will not count towards the \$3,453.75 out-of-pocket threshold that moves an individual into catastrophic coverage (client pays 5% co-insurance). Beneficiaries (ADAP) pay 100% of their drug costs when they are in the donut hole. Various HIV advocacy groups continue to challenge CMS to facilitate ADAP payments counting towards TrOOP.

Although ADAP payments are not supposed to count towards TrOOP, some Part D plans are incorrectly applying ADAP payments towards the beneficiary’s TrOOP. This activity was widespread when Part D was implemented in 2006 and has decreased as the Part D program has matured. ADAP anticipates that this activity will continue to decrease as more plans begin to identify ADAP payments in their pharmacy transactions.

New for May Revision

National advocacy groups are continuing to attempt to have the ADAP/TrOOP law changed.

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 result in a significant reduction in ADAP costs.

Partial Pay Rebate (Updated for May Revision)

The new federal administration has given no indication that they are interested in changing the existing policy, which supports the cost effective provision of prescription drugs under ADAP, Medicaid and other covered entities.

Background

Currently, ADAP is able to collect full rebate on partial payment transactions for clients with other payers, e.g., private insurance.

In FY 2007-08, rebates on partial payments represented nearly 41 percent of total rebate revenue.

From November Estimate

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 remains the potential that the policy may be challenged again in the future. This issue has been of considerable concern to ADAPs nationally. California's ADAP will continue to monitor this issue.

Implications (New for May Revision)

The current federal policy which allows full rebate on partial pay claims is unchanged at this time.

The Early Treatment of HIV Act (ETHA) (New for May Revision)

Background

ETHA proposes to amend Title XIX of the Social Security Act giving states the option of extending their Medicaid coverage to all income eligible people living with HIV, regardless of their disability status. States taking advantage of this option would be provided with an enhanced federal Medicaid match.

Summary and Timing

This legislation was reintroduced in the House (H.R. 1616) on March 19, 2009 and currently has 43 co-sponsors. There appears to be significant support for this bill in Congress; California's ADAP will continue to closely monitor its progress.

Implications

- If this bill is passed by Congress and enacted in California, it would result in cost savings to ADAP when newly eligible clients transition to Medi-Cal.

State policy issues that may impact ADAP

There are no changes in Medi-Cal eligibility or services in the enacted budget that impact ADAP.

Medi-Cal Policy Change 163: New Qualified Aliens (NQAs) and Permanently Residing Under Color of Law (PRUCOL) immigrants and Amnesty Aliens (New for May Revision)**Background**

DHCS Medi-Cal Policy Change 163 proposes to eliminate (rollback) full-scope Medi-Cal for NQAs who have been in the country for less than five years and for PRUCOL immigrants who are not defined as eligible qualified aliens under federal law.

Summary and Timing

According to data provided by DHCS, ADAP may have an additional 90 clients accessing the program effective October 1, 2009. It is assumed that these clients will be 100 percent ADAP without the benefit of any other payer and will access ADAP for 12 months. The cost of providing services to these clients is estimated at \$2,000 per month. This monthly total is based on the FY 2007-08 average cost per client of \$22,430 for a 100 percent ADAP only client who accessed the program for 12 months. This number was rounded up to \$24,000 and divided by 12 for an average of \$2,000 per month. The estimated cost include Pharmacy Benefits Manager costs for transaction fees for approved prescription requests but does not include transaction fees for unapproved prescription request.

Implications

For FY 2009-10, it is estimated that the cost of providing services to these clients will be \$1.620 million (90 clients x 9 months x \$2,000/months/client).

New at May Revision**Pharmaceutical Manufacturer Prescription Copayment Programs (Updated for May Revision)**

We have learned that the pharmaceutical manufacturer co-pay programs do not apply to ADAP clients and thus has no impact on ADAP.

Adjustments to the Blue Book AWP Resulting from Recent Litigation (New for May Revision)**Background**

A class action lawsuit brought against a drug wholesaler and a drug price publisher asserted that they fraudulently increased the published "average wholesale price" (AWP) of over 400 drugs by five percent from late 2001 to 2005. In March of 2009 the United State District Court for the District of Massachusetts entered a final order and judgment amending the settlement of the case against New England Carpenter's Health Benefits Fund versus First Data Bank and McKesson Corp. Included in the terms of the settlement is a requirement that the defendants adjust the reporting of Blue Book AWP for those prescription drugs identified in the complaint by reducing the mark-up factor utilized in connection with the calculation of the Blue Book AWP. The fraudulent prices caused members of various consumer classes, including the government, whose payments for prescription drugs are tied to the published AWP, to overpay for those drugs.

Summary and Timing

Adjustments to the Blue Book AWP will take effect in about 180 days from the date of the final judgment (entered on March 30, 2009).

Implications

The fraudulent publishing of the drug prices put unnecessary upward pressure on the cost of drugs including some of those used for the treatment of HIV-related diseases. This settlement will have the effect of lowering to a limited extent the increase in the cost of drug pricing.

SECTION H: APPENDICES

1. Definitions (From November Estimate)

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

ARVs - Antiretroviral drugs. ARVs can slow the progression of HIV to AIDS by decreasing the amount of virus in a person's body. Effective ARV therapy also renders people less infectious on average.

Medicare Part D Prescription Drug Benefit Related Definitions (Updated for May Revision)

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 – This is the maximum allowable out-of-pocket costs permitted under Part D. These beneficiaries must pay the first \$295 of their drug costs *out of pocket*. After the \$295 deductible, Medicare will pay 75 percent of the cost of each covered prescription and the beneficiary will pay 25 percent, up to \$2,700 in total costs. (Note, for medications on the ADAP formulary, ADAP covers the \$295 deductible and 25 percent co-pay.)

2) “Donut Hole” - Once a standard beneficiary reaches \$2,700 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 \$3,453.75 on medication. Once the beneficiary has paid this amount in drug costs he or she is eligible for catastrophic coverage. Catastrophic coverage drug costs will vary but will never be more than 5 percent of the drug costs. (Note, for medications on the ADAP formulary, ADAP covers 100 percent of drug costs in the Donut Hole.)

New for May Revision

3) “TrOOP”- Acronym for “true-out-of-pocket”, referring to drug costs paid by the beneficiary. A beneficiary’s TrOOP spending determines how they advance through the Part D coverage levels. Medicare law prohibits drug costs paid by ADAP to count towards a beneficiary’s TrOOP. This rule typically leads to ADAP clients remaining “stuck” in the Part D coverage gap or “Donut Hole” for a majority of the Part D year.

(Updated for May Revision)

4) 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 \$2.40 for generic drugs, \$6.00 for brand drugs, and do not have to contend with the donut hole (coverage gap). After \$6,153.75 of out-of-pocket costs, they have no out-of-pocket drug costs for the remainder of the plan year. (Note, for medications on the ADAP formulary, ADAP covers these co-pays.)
- b) Partial Subsidy – Income between 135 percent and 150 percent of federal poverty level. These beneficiaries must pay a \$60.00 deductible, 15 percent of drug costs after the deductible, and do not have to contend with the donut hole (coverage gap). After \$6,153.75 of out of pocket expenses, co-pays are reduced to \$2.40 for generics and \$6.00 for brand drugs. (Note, for medications on the ADAP formulary, ADAP covers the deductible, co-insurance and co-pays.)
- c) **Dual Eligible** (covered by *both* Medicare and Medi-Cal)

a) Full Duals are clients who are eligible for Medi-Cal with **no** Share of Cost (SOC). Medicare subsidizes the cost of a Full Dual’s drugs. They pay limited co-pays of \$2.40 to \$6.00 per drug. No out-of-pocket payments are required once total drug costs reach \$6,153.75. (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. A Partial Dual can become a “Full Dual” once they incur their monthly Share-of-Cost. If a Dual **incurs** their SOC, they qualify for “Full Dual” subsidy the following month and retain this subsidy for the remainder of the plan year. (Note, for medications on the ADAP formulary, ADAP covers these costs.)

Note: all dollar figures indicated above are for Calendar Year 2009.

2. New Drug Updates (New for May Revision)

The Office of AIDS Division Chief is being considered for appointment to the FDA Antiviral Advisory Committee. In recent discussions with FDA, the committee does not anticipate meeting prior to 2010, suggesting that they do not expect any new drug applications to be approved prior to that time.

No updates have been published to the reference reports (Treatment Action Group 2008 pipeline report, National AIDS Treatment Advocacy Project 2007 report) used in the *November Estimates Package* and reflected in the table provided in the *November Estimate*. We have removed that table as it is no longer up-to-date.

In order to obtain more current information on the anticipated drug approval dates, the Pacific AIDS Education Training Center (PAETC) provided the following information on the three ARVs that are most advanced in the approval process:

- Rilpivirine (NNRTI) – approval anticipated in mid 2010
- Vicriviroc (CCR5 antagonist) – approval anticipated no sooner than July 1, 2010
- Elvitegravir (Integrase inhibitor) – approval anticipated in April – June 2010

From November Estimate

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 (Updated for May Revision)

The Guidelines for the Use of Antiretroviral Agents in HIV-1-Infected Adults and Adolescents were updated on November 3, 2008. The updates were minor and are not anticipated to change prescribing practices in any significant ways. We continue to closely monitor discussions regarding these guidelines and updates that might recommend earlier initiation of treatment.

From November Estimate

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 (Updated for May Revision)

HIV Prevalence

Prevalence reflects the number of people who are currently infected with HIV and thus who could qualify for ADAP currently or some time in the future. *California estimates that there were between 145,949 and 173,151 living with HIV/AIDS at the end of 2008 (Table 15, page 41).* 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 47 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 living HIV/AIDS cases in the State is expected to grow by approximately 2 percent (2,700 – 6,700) each year for the next two years and it is expected that this increasing trend will continue for the foreseeable future. This increase is attributed to stable incidence

rates and longer survival of those infected (primarily due to the effectiveness and availability of treatment).

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

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

HIV Incidence

Incidence is a measure of new infections over a specified period of time (typically a year) and thus provides an indication of the future need for ADAP support. Most people get tested infrequently, so incidence estimates largely rely on modeling. California estimates 5,000 – 7,000 new HIV infections annually. This estimate was developed through:

- A series of “Consensus Conferences” convened in California in 2000 that developed population estimates of HIV incidence.
- 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.

5. Sensitivity Analysis (New for May Revision)**FY 2008-09**

We also conducted a sensitivity analysis exploring the impact on total expenditures by increasing and decreasing the number of clients and the cost per client. For this sensitivity analysis, we started with the estimated total drug costs for FY 2008-09 using the upper bound of the 95 percent confidence interval from the Linear Regression Model (\$354.30 million).

For these factors, clients and cost 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 16 lists the seven (including no change) scenarios for changes in cost/client, starting with the best case scenario {three percent decrease in cost/client, Hi(-)} and finishing with the worst case scenario {three percent increase in cost/client, Hi(+)}. The seven scenarios for changes in client counts are listed across the table.

Cost / Client Scenarios	Number of Client Scenarios						
	HI (-) CL	MED (-) CL	LO (-) CL	Zero Change in Clients	LO (+) CL	MED (+) CL	HI (+) CL
Hi (-): Best	\$333,664,480	\$337,051,664	\$340,438,848	\$343,826,032	\$347,213,217	\$350,600,401	\$353,987,585
Med (-)	\$337,051,664	\$340,473,768	\$343,895,871	\$347,317,975	\$350,740,079	\$354,162,182	\$357,584,286
Lo (-)	\$340,438,848	\$343,895,871	\$347,352,894	\$350,809,917	\$354,266,941	\$357,723,964	\$361,180,987
Zero Change in Cost / Client	\$343,826,032	\$347,317,975	\$350,809,917	\$354,301,860	\$357,793,803	\$361,285,745	\$364,777,688
Lo (+)	\$347,213,217	\$350,740,079	\$354,266,941	\$357,793,803	\$361,320,664	\$364,847,526	\$368,374,388
Med (+)	\$350,600,401	\$354,162,182	\$357,723,964	\$361,285,745	\$364,847,526	\$368,409,308	\$371,971,089
Hi (+): Worst	\$353,987,585	\$357,584,286	\$361,180,987	\$364,777,688	\$368,374,388	\$371,971,089	\$375,567,790

The center cell, highlighted in light turquoise, shows the estimated expenditures for FY 2008-09, using the 95 percent confidence interval from the Linear Regression Model (starting January 2006). The best case scenario, which is a three percent decrease in cost/client coupled with a three percent decrease in the number of clients, results in an estimate of \$333,664,480 (top left cell, light green). The worst case scenario, a three percent increase in cost/client coupled with a three percent increase in number of clients, results in an estimate of \$375,567,790 (bottom right cell, red). The table provides a range of values to assist in projecting the total expenditures for FY 2008-09 .

Below is the sensitivity analysis for FY 2009-10, using the same factors and logic as above.

TABLE 17: SENSITIVITY ANALYSIS FOR FISCAL YEAR 2009-10 ESTIMATE USING LINEAR REGRESSION MODEL							
Cost / Client Scenarios	Number of Client Scenarios						
	HI (-) CL	MED (-) CL	LO (-) CL	Zero Change in Clients	LO (+) CL	MED (+) CL	HI (+) CL
Hi (-): Best	\$388,475,840	\$392,424,318	\$396,372,796	\$400,321,274	\$404,269,752	\$408,218,230	\$412,166,707
Med (-)	\$392,424,318	\$396,413,502	\$400,402,686	\$404,391,870	\$408,381,053	\$412,370,237	\$416,359,421
Lo (-)	\$396,372,796	\$400,402,686	\$404,432,575	\$408,462,465	\$412,492,355	\$416,522,245	\$420,552,135
Zero Change in Cost / Client	\$400,321,274	\$404,391,870	\$408,462,465	\$412,533,061	\$416,603,657	\$420,674,252	\$424,744,848
Lo (+)	\$404,269,752	\$408,381,053	\$412,492,355	\$416,603,657	\$420,714,958	\$424,826,260	\$428,937,562
Med (+)	\$408,218,230	\$412,370,237	\$416,522,245	\$420,674,252	\$424,826,260	\$428,978,268	\$433,130,275
Hi (+): Worst	\$412,166,707	\$416,359,421	\$420,552,135	\$424,744,848	\$428,937,562	\$433,130,275	\$437,322,989