

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

**2010-11 MAY REVISION**



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

**CALIFORNIA  
DEPARTMENT OF PUBLIC HEALTH**

# Table of Contents

<u>SECTION</u>	<u>PAGE</u>
<b>1. FISCAL COMPARISON TABLES</b>	
<u>Expenditures</u>	
Table 1a: Comparison of FY 2009-10 <i>May Revision</i> to FY 2009-10 Budget Act.....	1
Table 1b: Comparison of FY 2009-10 <i>May Revision</i> to FY 2009-10 <i>November Estimate</i> .....	1
Table 1c: Comparison of FY 2010-11 <i>May Revision</i> to FY 2009-10 <i>May Revision</i> .....	2
Table 1d: Comparison of FY 2010-11 <i>May Revision</i> to FY 2010-11 Governor’s Budget .....	2
<u>Resources</u>	
Table 2a: Comparison of FY 2009-10 <i>May Revision</i> FY 2009-10 Budget Act .....	3
Table 2b: Comparison of FY 2009-10 <i>May Revision</i> to FY 2009-10 <i>November Estimate</i> .....	3
Table 2c: Comparison of FY 2010-11 <i>May Revision</i> to FY 2009-10 <i>May Revision</i> .....	3
Table 2d: Comparison of FY 2010-11 <i>May Revision</i> to FY 2010-11 Governor’s Budget .....	3
<b>2. MAJOR ASSUMPTIONS .....</b>	<b>4</b>
<b>3. FUND CONDITION STATEMENT .....</b>	<b>9</b>
<b>4. HISTORICAL PROGRAM DATA AND TRENDS .....</b>	<b>11</b>
<b>APPENDIX A: EXPENDITURE AND REVENUE ESTIMATE METHODS .....</b>	<b>13</b>
Updated Expenditure Estimate for FY 2009-10 .....	13
New Expenditure Estimate for FY 2010-11.....	13
Linear Regression Model – Expenditure Estimates .....	13
Program Expenditure Estimate for FY 2010-11 .....	15
ADAP Rebate Revenue .....	15
<b>APPENDIX B: FUND SOURCES .....</b>	<b>18</b>
General Fund .....	19
Federal Fund.....	19
ADAP Special Fund (3080).....	20
<b>APPENDIX C: POLICY ISSUES WITH POTENTIAL FUTURE FISCAL IMPACT .....</b>	<b>23</b>
Potential for Positive Fiscal Impact (Decreased Costs).....	23
Potential for Negative Fiscal Impact (Increased Expenditures).....	24
<b>APPENDIX D: ACRONYM DEFINITIONS .....</b>	<b>28</b>
<b>APPENDIX E: MEDICARE PART D DEFINITIONS.....</b>	<b>29</b>
<b>APPENDIX F: NEW DRUGS AND TREATMENT GUIDELINES.....</b>	<b>31</b>
<b>APPENDIX G: CURRENT HIV/AIDS EPIDEMIOLOGY IN CALIFORNIA .....</b>	<b>33</b>
<b>APPENDIX H: SENSITIVITY ANALYSIS.....</b>	<b>35</b>
<b>APPENDIX I: HISTORY OF PROJECTION METHODS .....</b>	<b>37</b>

# 1. FISCAL COMPARISON TABLES

**TABLE 1a: Expenditure Comparison: FY 2009-10 May Revision to FY 2009-10 Budget Act**

	2009-10 May Revision				2009 Budget Act				Difference			
	Total	Federal	State	Rebate Fund	Total	Federal	State	Rebate Fund	Total	Federal	State	Rebate Fund
<b>Local Assistance Funding</b>	<b>\$402,498</b>	<b>\$92,927</b>	<b>\$70,849</b>	<b>\$238,722</b>	<b>\$414,033</b>	<b>\$92,927</b>	<b>\$70,849</b>	<b>\$250,257</b>	<b>(\$11,535)</b>	<b>\$0</b>	<b>\$0</b>	<b>(\$11,535)</b>
Drug Expenditure Estimate	400,365	92,927	70,849	236,589	412,033	92,927	70,849	248,257	(11,668)	0	0	(11,668)
Prescription Costs	387,954	90,046	68,653	229,255	399,894	85,458	69,698	244,738	(11,940)	4,588	(1,045)	(15,483)
Basic Prescription Costs	392,588	90,046	68,653	233,889	399,894	85,458	69,698	244,738	(7,306)	4,588	(1,045)	(10,849)
AWP Rollback/WAC	(4,634)	0	0	(4,634)	0	0	0	0	(4,634)	0	0	(4,634)
Eliminate Services to County Jails	0	0	0	0	0	0	0	0	0	0	0	0
NQA	0	0	0	0	0	0	0	0	0	0	0	0
PRUCOL	0	0	0	0	0	0	0	0	0	0	0	0
Medi-Cal Optional Benefits	0	0	0	0	0	0	0	0	0	0	0	0
True-Out-Of-Pocket Costs (HCR)	0	0	0	0	0	0	0	0	0	0	0	0
PBM Operational Costs	12,411	2,881	2,196	7,334	12,139	7,468	1,151	3,520	272	(4,588)	1,045	3,815
Basic PBM Costs	12,911	2,881	2,696	7,334	12,639	7,468	1,651	3,520	272	(4,588)	1,045	3,815
Administrative Reduction	(500)	0	(500)	0	(500)	0	(500)	0	0	0	0	0
RFP Non-approved Trans Fee Savings	0	0	0	0	0	0	0	0	0	0	0	0
AWP Rollback/WAC	0	0	0	0	0	0	0	0	0	0	0	0
Eliminate Services to County Jails	0	0	0	0	0	0	0	0	0	0	0	0
NQA	0	0	0	0	0	0	0	0	0	0	0	0
PRUCOL	0	0	0	0	0	0	0	0	0	0	0	0
Medi-Cal Optional Benefits	0	0	0	0	0	0	0	0	0	0	0	0
True-Out-Of-Pocket Costs (HCR)	0	0	0	0	0	0	0	0	0	0	0	0
LHJ Administration	1,000	0	0	1,000	1,000	0	0	1,000	0	0	0	0
Medicare Part D	1,000	0	0	1,000	1,000	0	0	1,000	0	0	0	0
Tropism Assay*	133	0	0	133	0	0	0	0	133	0	0	133
<b>Support/Administration Funding</b>	<b>2,648</b>	<b>1,178</b>	<b>411</b>	<b>1,059</b>	<b>2,559</b>	<b>1,178</b>	<b>218</b>	<b>1,164</b>	<b>88</b>	<b>0</b>	<b>193</b>	<b>(105)</b>

**TABLE 1b: Expenditure Comparison: FY 2009-10 May Revision to FY 2009-10 November Estimate**

	2009-10 May Revision				2009-10 in 2010-11 Governor's Budget (November Estimate)				Difference			
	Total	Federal	State	Rebate Fund	Total	Federal	State	Rebate Fund	Total	Federal	State	Rebate Fund
<b>Local Assistance Funding</b>	<b>\$402,498</b>	<b>\$92,927</b>	<b>\$70,849</b>	<b>\$238,722</b>	<b>\$419,896</b>	<b>\$92,927</b>	<b>\$70,849</b>	<b>\$256,120</b>	<b>(\$17,398)</b>	<b>\$0</b>	<b>\$0</b>	<b>(\$17,398)</b>
Drug Expenditure Estimate	400,365	92,927	70,849	236,589	417,763	92,927	70,849	253,987	(17,398)	0	0	(17,398)
Prescription Costs	387,954	90,046	68,653	229,255	405,297	90,046	69,137	246,114	(17,343)	0	(485)	(16,858)
Basic Prescription Costs	392,588	90,046	68,653	233,889	405,297	90,046	69,137	246,114	(12,709)	0	(485)	(12,224)
AWP Rollback/WAC	(4,634)	0	0	(4,634)	0	0	0	0	(4,634)	0	0	(4,634)
Eliminate Services to County Jails	0	0	0	0	0	0	0	0	0	0	0	0
NQA	0	0	0	0	0	0	0	0	0	0	0	0
PRUCOL	0	0	0	0	0	0	0	0	0	0	0	0
Medi-Cal Optional Benefits	0	0	0	0	0	0	0	0	0	0	0	0
True-Out-Of-Pocket Costs (HCR)	0	0	0	0	0	0	0	0	0	0	0	0
PBM Operational Costs	12,411	2,881	2,196	7,334	12,466	2,881	1,712	7,874	(55)	0	485	(539)
Basic PBM Costs	12,911	2,881	2,696	7,334	12,966	2,881	2,212	7,874	(55)	0	485	(539)
Administrative Reduction	(500)	0	(500)	0	(500)	0	(500)	0	0	0	0	0
RFP Non-approved Trans Fee Savings	0	0	0	0	0	0	0	0	0	0	0	0
AWP Rollback/WAC	0	0	0	0	0	0	0	0	0	0	0	0
Eliminate Services to County Jails	0	0	0	0	0	0	0	0	0	0	0	0
NQA	0	0	0	0	0	0	0	0	0	0	0	0
PRUCOL	0	0	0	0	0	0	0	0	0	0	0	0
Medi-Cal Optional Benefits	0	0	0	0	0	0	0	0	0	0	0	0
True-Out-Of-Pocket Costs (HCR)	0	0	0	0	0	0	0	0	0	0	0	0
LHJ Administration	1,000	0	0	1,000	1,000	0	0	1,000	0	0	0	0
Medicare Part D	1,000	0	0	1,000	1,000	0	0	1,000	0	0	0	0
Tropism Assay*	133	0	0	133	133	0	0	133	0	0	0	0
<b>Support/Administration Funding</b>	<b>2,648</b>	<b>1,178</b>	<b>411</b>	<b>1,059</b>	<b>2,648</b>	<b>1,178</b>	<b>411</b>	<b>1,059</b>	<b>0</b>	<b>0</b>	<b>0</b>	<b>0</b>

\*Tropism Assay is a laboratory test required to demonstrate clinical indication for one of the antiretroviral agents covered by ADAP. These costs were not displayed separately prior to the November Estimate 2010-11.

	2010-11 May Revision				2009-10 May Revision				Difference			
	Total	Federal <sup>2</sup>	State	Rebate Fund	Total	Federal	State	Rebate Fund	Total	Federal	State	Rebate Fund
<b>Local Assistance Funding</b>	<b>\$433,550</b>	<b>\$97,632</b>	<b>\$125,608</b>	<b>\$210,310</b>	<b>\$402,498</b>	<b>\$92,927</b>	<b>\$70,849</b>	<b>\$238,722</b>	<b>\$31,052</b>	<b>\$4,705</b>	<b>\$54,759</b>	<b>(\$28,412)</b>
Drug Expenditure Estimate	431,417	97,632	125,608	208,177	400,365	92,927	70,849	236,589	31,052	4,705	54,759	(28,412)
<b>Prescription Costs</b>	<b>421,200</b>	<b>94,605</b>	<b>121,714</b>	<b>204,880</b>	<b>387,954</b>	<b>90,046</b>	<b>68,653</b>	<b>229,255</b>	<b>33,246</b>	<b>4,559</b>	<b>53,061</b>	<b>(24,375)</b>
Basic Prescription Costs	448,534	94,605	129,711	224,217	392,588	90,046	68,653	233,889	55,946	4,559	61,059	(9,672)
AWP Rollback/WAC	(16,194)	0	0	(16,194)	(4,634)	0	0	(4,634)	(11,560)	0	0	(11,560)
Eliminate Services to County Jails	(9,852)	0	(7,997)	(1,855)	0	0	0	0	(9,852)	0	(7,997)	(1,855)
NQA	272	0	0	272	0	0	0	0	272	0	0	272
PRUCOL	1,632	0	0	1,632	0	0	0	0	1,632	0	0	1,632
True-Out-Of-Pocket Costs (HCR)	(3,192)	0	0	(3,192)	0	0	0	0	(3,192)	0	0	(3,192)
<b>PBM Operational Costs</b>	<b>10,218</b>	<b>3,027</b>	<b>3,894</b>	<b>3,297</b>	<b>12,411</b>	<b>2,881</b>	<b>2,196</b>	<b>7,334</b>	<b>(2,193)</b>	<b>146</b>	<b>1,698</b>	<b>(4,037)</b>
Basic PBM Costs	14,349	3,027	4,650	6,673	12,911	2,881	2,696	7,334	1,438	146	1,953	(661)
Administrative Reduction	(500)	0	(500)	0	(500)	0	(500)	0	0	0	0	0
RFP Non-approved Trans Fee Savings	(3,349)	0	0	(3,349)	0	0	0	0	(3,349)	0	0	(3,349)
AWP Rollback/WAC	0	0	0	0	0	0	0	0	0	0	0	0
Eliminate Services to County Jails	(315)	0	(256)	(59)	0	0	0	0	(315)	0	(256)	(59)
NQA	5	0	0	5	0	0	0	0	5	0	0	5
PRUCOL	28	0	0	28	0	0	0	0	28	0	0	28
Medi-Cal Optional Benefits	0	0	0	0	0	0	0	0	0	0	0	0
True-Out-Of-Pocket Costs (HCR)	0	0	0	0	0	0	0	0	0	0	0	0
LHJ Administration	1,000	0	0	1,000	1,000	0	0	1,000	0	0	0	0
Medicare Part D	1,000	0	0	1,000	1,000	0	0	1,000	0	0	0	0
Tropism Assay <sup>1</sup>	133	0	0	133	133	0	0	133	0	0	0	0
<b>Support/Administration Funding</b>	<b>2,657</b>	<b>1,178</b>	<b>411</b>	<b>1,068</b>	<b>2,648</b>	<b>1,178</b>	<b>411</b>	<b>1,059</b>	<b>9</b>	<b>0</b>	<b>0</b>	<b>9</b>

	2010-11 May Revision				2010-11 Governor's Budget (November Estimate)				Difference			
	Total	Federal <sup>2</sup>	State	Rebate Fund	Total	Federal	State	Rebate Fund	Total	Federal	State	Rebate Fund
<b>Local Assistance Funding</b>	<b>\$433,550</b>	<b>\$97,632</b>	<b>\$125,608</b>	<b>\$210,310</b>	<b>\$462,128</b>	<b>\$92,927</b>	<b>\$158,311</b>	<b>\$210,890</b>	<b>(\$28,578)</b>	<b>\$4,705</b>	<b>(\$32,703)</b>	<b>(\$580)</b>
Drug Expenditure Estimate	431,417	97,632	125,608	208,177	459,995	92,927	158,311	208,757	(28,578)	4,705	(32,703)	(580)
<b>Prescription Costs</b>	<b>421,200</b>	<b>94,605</b>	<b>121,714</b>	<b>204,880</b>	<b>446,061</b>	<b>90,046</b>	<b>153,888</b>	<b>202,127</b>	<b>(24,861)</b>	<b>4,559</b>	<b>(32,174)</b>	<b>2,753</b>
Basic Prescription Costs	448,534	94,605	129,711	224,217	456,950	90,046	163,118	203,786	(8,416)	4,559	(33,407)	20,431
AWP Rollback/WAC	(16,194)	0	0	(16,194)	0	0	0	0	(16,194)	0	0	(16,194)
Eliminate Services to County Jails	(9,852)	0	(7,997)	(1,855)	(10,889)	0	(9,230)	(1,659)	1,037	0	1,233	(196)
NQA	272	0	0	272	0	0	0	0	272	0	0	272
PRUCOL	1,632	0	0	1,632	0	0	0	0	1,632	0	0	1,632
True-Out-Of-Pocket Costs (HCR)	(3,192)	0	0	(3,192)	0	0	0	0	(3,192)	0	0	(3,192)
<b>PBM Operational Costs</b>	<b>10,218</b>	<b>3,027</b>	<b>3,894</b>	<b>3,297</b>	<b>13,934</b>	<b>2,881</b>	<b>4,423</b>	<b>6,630</b>	<b>(3,716)</b>	<b>146</b>	<b>(529)</b>	<b>(3,333)</b>
Basic PBM Costs	14,349	3,027	4,650	6,673	14,782	2,881	5,218	6,683	(433)	146	(568)	(10)
Administrative Reduction	(500)	0	(500)	0	(500)	0	(500)	0	0	0	0	0
RFP Non-approved Trans Fee Savings	(3,349)	0	0	(3,349)	0	0	0	0	(3,349)	0	0	(3,349)
AWP Rollback/WAC	0	0	0	0	0	0	0	0	0	0	0	0
Eliminate Services to County Jails	(315)	0	(256)	(59)	(348)	0	(295)	(53)	33	0	39	(6)
NQA	5	0	0	5	0	0	0	0	5	0	0	5
PRUCOL	28	0	0	28	0	0	0	0	28	0	0	28
True-Out-Of-Pocket Costs (HCR)	0	0	0	0	0	0	0	0	0	0	0	0
LHJ Administration	1,000	0	0	1,000	1,000	0	0	1,000	0	0	0	0
Medicare Part D	1,000	0	0	1,000	1,000	0	0	1,000	0	0	0	0
Tropism Assay <sup>1</sup>	133	0	0	133	133	0	0	133	0	0	0	0
<b>Support/Administration Funding</b>	<b>2,657</b>	<b>1,178</b>	<b>411</b>	<b>1,068</b>	<b>2,657</b>	<b>1,178</b>	<b>411</b>	<b>1,068</b>	<b>0</b>	<b>0</b>	<b>0</b>	<b>0</b>

<sup>1</sup> Tropism Assay is a laboratory test required to demonstrate clinical indication for one of the antiretroviral agents covered by ADAP. These costs were not displayed separately in prior to the November Estimate 2010-11.

<sup>2</sup> Includes the Ryan White 2010 grant award effective April 1, 2010

TABLE 2a: Resource Comparison: FY 2009-10 May revision to FY 2009-10 Budget Act

	2009-10 May Revision				2009 -10 Budget Act				Difference			
	Total	Federal	State	Rebate Fund	Total	Federal	State	Rebate Fund	Total	Federal	State	Rebate Fund
<b>Available Resources</b>	<b>\$340,475</b>	<b>\$94,104</b>	<b>\$71,260</b>	<b>\$175,111</b>	<b>\$348,586</b>	<b>\$94,105</b>	<b>\$71,067</b>	<b>\$183,414</b>	<b>(\$8,111)</b>	<b>\$0</b>	<b>\$193</b>	<b>(\$8,303)</b>
Basic Rebate Revenues	174,711	0	0	174,711	180,414	0	0	180,414	(5,703)	0	0	(5,703)
Income from Surplus Money Investments	400	0	0	400	3,000	0	0	3,000	(2,600)	0	0	(2,600)
Federal Funds	94,104	94,104	0	0	94,105	94,105	0	0	(1)	(1)	0	0
General Fund	71,260	0	71,260	0	71,067	0	71,067	0	193	0	193	0
Eliminate Services to County Jails	0	0	0	0	0	0	0	0	0	0	0	0
NQA	0	0	0	0	0	0	0	0	0	0	0	0
PRUCOL	0	0	0	0	0	0	0	0	0	0	0	0
True-Out-Of-Pocket Costs (HCR)	0	0	0	0	0	0	0	0	0	0	0	0
Increased Rebate Rate (HCR)	0	0	0	0	0	0	0	0	0	0	0	0

TABLE 2b: Resource Comparison: FY 2009-10 May Revision to FY 2009-10 November Estimate

	2009-10 May Revision				2009 -10 in 2010-11 Governor's Budget (November Estimate)				Difference			
	Total	Federal	State	Rebate Fund	Total	Federal	State	Rebate Fund	Total	Federal	State	Rebate Fund
<b>Available Resources</b>	<b>\$340,475</b>	<b>\$94,104</b>	<b>\$71,260</b>	<b>\$175,111</b>	<b>\$349,665</b>	<b>\$94,104</b>	<b>\$71,260</b>	<b>\$184,300</b>	<b>(\$9,189)</b>	<b>\$0</b>	<b>\$0</b>	<b>(\$9,189)</b>
Basic Rebate Revenues	174,711	0	0	174,711	182,300	0	0	182,300	(7,589)	0	0	(7,589)
Income from Surplus Money Investments	400	0	0	400	2,000	0	0	2,000	(1,600)	0	0	(1,600)
Federal Funds	94,104	94,104	0	0	94,105	94,104	0	0	(1)	0	0	0
General Fund	71,260	0	71,260	0	71,260	0	71,260	0	0	0	0	0
Eliminate Services to County Jails	0	0	0	0	0	0	0	0	0	0	0	0
NQA	0	0	0	0	0	0	0	0	0	0	0	0
PRUCOL	0	0	0	0	0	0	0	0	0	0	0	0
True-Out-Of-Pocket Costs (HCR)	0	0	0	0	0	0	0	0	0	0	0	0
Increased Rebate Rate (HCR)	0	0	0	0	0	0	0	0	0	0	0	0

TABLE 2c: Resource Comparison: FY 2010-11 May Revision to FY 2009-10 May Revision

	2010-11 May Revision				2009-10 May Revision				Difference			
	Total	Federal <sup>1</sup>	State	Rebate Fund	Total	Federal	State	Rebate Fund	Total	Federal	State	Rebate Fund
<b>Available Resources</b>	<b>\$417,499</b>	<b>\$98,810</b>	<b>\$126,019</b>	<b>\$192,670</b>	<b>\$340,475</b>	<b>\$94,104</b>	<b>\$71,260</b>	<b>\$175,111</b>	<b>\$77,023</b>	<b>\$4,705</b>	<b>\$54,759</b>	<b>\$17,559</b>
Basic Rebate Revenues	193,992	0	0	193,992	174,711	0	0	174,711	19,282	0	0	19,282
Income from Surplus Money Investments	400	0	0	400	400	0	0	400	0	0	0	0
Federal Funds	98,810	98,810	0	0	94,104	94,104	0	0	4,705	4,705	0	0
General Fund	126,019	0	126,019	0	71,260	0	71,260	0	54,759	0	54,759	0
Eliminate Services to County Jails	(1,914)	0	0	(1,914)	0	0	0	0	(1,914)	0	0	(1,914)
NQA	27	0	0	27	0	0	0	0	27	0	0	27
PRUCOL	164	0	0	164	0	0	0	0	164	0	0	164
Medi-Cal Optional Benefits	0	0	0	0	0	0	0	0	0	0	0	0
True-Out-Of-Pocket Costs (HCR)	0	0	0	0	0	0	0	0	0	0	0	0
Increased Rebate Rate (HCR)	0	0	0	0	0	0	0	0	0	0	0	0

TABLE 2d: Resource Comparison: FY 2010-11 May Revision to FY 2010-11 Governor's Budget

	2010-11 May Revision				2010-11 Governor's Budget (November Estimate)				Difference			
	Total	Federal <sup>1</sup>	State	Rebate Fund	Total	Federal	State	Rebate Fund	Total	Federal	State	Rebate Fund
<b>Available Resources</b>	<b>\$417,499</b>	<b>\$98,810</b>	<b>\$126,019</b>	<b>\$192,670</b>	<b>\$457,583</b>	<b>\$94,104</b>	<b>\$158,722</b>	<b>\$204,756</b>	<b>(\$40,085)</b>	<b>\$4,705</b>	<b>(\$32,703)</b>	<b>(\$12,087)</b>
Basic Rebate Revenues	193,992	0	0	193,992	204,469	0	0	204,469	(10,477)	0	0	(10,477)
Income from Surplus Money Investments	400	0	0	400	2,000	0	0	2,000	(1,600)	0	0	(1,600)
Federal Funds	98,810	98,810	0	0	94,104	94,104	0	0	4,705	4,705	0	0
General Fund	126,019	0	126,019	0	168,247	0	168,247	0	(42,228)	0	(42,228)	0
Eliminate Services to County Jails	(1,914)	0	0	(1,914)	(1,712)	0	0	(1,712)	(202)	0	0	(202)
NQA	27	0	0	27	0	0	0	0	27	0	0	27
PRUCOL	164	0	0	164	0	0	0	0	164	0	0	164
True-Out-Of-Pocket Costs (HCR)	0	0	0	0	0	0	0	0	0	0	0	0
Increased Rebate Rate (HCR)	0	0	0	0	0	0	0	0	0	0	0	0

<sup>1</sup> Includes the Ryan White 2010 grant award effective April 1, 2010

## 2. MAJOR ASSUMPTIONS

### Estimate Methodology for Information Only

Unadjusted expenditure estimates for the FY 2010-11 *May Revision* Estimate were derived from a linear regression model as used in the *November Estimate* for FY 2009-10. The data set for the FY 2010-11 *May Revision Estimate* includes data through February, 2010. The data set for the FY 2010-11 *November 2009 Estimate* included data through July 2009. The unadjusted revenue data set (January 2006 through March 2009 for the *November Estimate* and through June 2009 for the *May Revision* data set) is used to estimate the revenue percent, which is applied to the revised, adjusted expenditure estimate for current and budget years.

Expenditure and revenue adjustments were made to estimate the impact of eight issues, including six new and two modified Major Assumptions, primarily in chronological order based on date of implementation: (1) Average Wholesale Price (AWP) rollback; (2) change in the reimbursement structure for the ADAP Pharmacy Benefits Manager (PBM) Request for Proposals (RFP); (3) Medi-Cal New Qualified Aliens (NQA) policy change; (4) Medi-Cal Permanently Residing Under Color of Law Immigrants and Amnesty Aliens (PRUCOL) policy change; (5) new federal legislation affecting Medicare Part D True Out of Pocket Costs (TrOOP); (6) increase in Federal Funds; (7) discontinuation of ADAP services in county jails (modified Major Assumption); and (8) decrease interest earned on Special Fund (SF) (modified Major Assumption). Because of the overlap between AWP and some of the subsequent major assumptions, a second adjustment was made to avoid double counting the impact of the AWP rollback. All of the final adjustments were added to or subtracted from the initial FY 2010-11 expenditure and revenue estimates to arrive at the final adjusted expenditure and revenue estimates.

### New Major Assumptions

1. Average Wholesale Price (AWP) Rollback - ADAP's pharmacy benefits management (PBM) contract includes a maximum drug reimbursement rate that will be paid by ADAP to pharmacies based on AWP. A class action lawsuit was filed against First DataBank and McKesson Corporation in 2005, asserting that they fraudulently increased the published AWP of over 400 brand drugs by four percent beginning in 2001. Included in the terms of the settlement, effective September 26, 2009, is a requirement that the defendants make a one-time adjustment to the reporting of Blue Book AWP for those prescription drugs identified in the complaint by reducing the mark-up factor used in the calculation. As a result of this legal decision lowering the value of AWP for brand drugs, which was implemented by ADAP effective March 10, 2010, we estimate \$4,633,975 drug cost savings in FY 2009-10 and \$16,193,665 additional savings in FY 2010-11.

In order to develop these estimates, we 1) calculated "hypothetical" savings using the data from the most recent past fiscal year, then 2) calculated the percent of the total expenditures that this hypothetical savings would have represented, and 3) applied that percent to the revised, unadjusted expenditure estimate. This was done for both current and budget years.

We applied these three steps to two groups of ADAP clients (“ADAP-only” and “all other payer sources”). The ADAP only group will benefit from the full rollback as ADAP is the only payer for these clients. The “all other payer sources” group is only partially affected by the AWP rollback due to ADAP payment of out-of-pocket expenses for which there is a differential impact depending on the expense type (i.e, co-insurance [which would be affected by the rollback] and co-payments [which would not be affected by the rollback]). Assuming full impact of the AWP roll-back for this group would result in an overestimate of the expenditure reduction. At this time, we are unable to determine the impact for this group and we made the decision to use the mid-point between the ADAP-only group and the combination of both groups for this estimated expenditure adjustment.

2. ADAP Pharmacy Benefits Manager (PBM) Request for Proposal (RFP) - A new PBM contract will be effective July 1, 2010. The RFP for this contract was released March 26, 2010 and includes two changes that will result in savings to ADAP: 1) a reduced ceiling for non-approved transaction fees (currently \$6.00 per transaction; the new RFP maximum is \$3.00 per transaction and approved transaction fees maximum remains at \$6.00 per transaction.) and 2) a limit to the number of times a non-approved transaction can be submitted (currently no restriction; the new RFP imposes a cap of five times).

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

1. The percentage of approved (55.5 percent) and non-approved (44.5 percent) transaction fees in FY 2008-09 was calculated.
2. The total transaction fees estimate was developed as an observed proportion from FY 2008-09, applied to the *May Revision* linear regression expenditure estimate.
3. The non-approved transaction fee percentage (44.5 percent) was then applied to the unadjusted FY 2010-11 total transaction fees estimate to approximate the hypothetical total non-approved transaction fees before introduction of the reduced \$3.00 fee.
4. This amount was divided by 50 percent ( $\$3.00/\$6.00$ ) to arrive at the initial adjusted estimate of \$3,189,731.

The additional savings achieved by limiting non-approved transactions to a maximum of five submittals per prescription is estimated at \$159,282, with the total savings from the RFP changes estimated at \$3,349,013.

3. Medi-Cal Newly Qualified Aliens (NQA) - The NQA policy change will be effective October 1, 2010 (nine months of FY 2010-11). ADAP expenditure increases are estimated at \$2,120 per month per client (15 clients per month per Department of Health Care Services (DHCS) estimates) for nine months, and then adjusted for the four percent AWP decrease. These new clients will become ADAP only clients, for which ADAP pays 100 percent of their drug costs. The \$2,120 per month per client expense was estimated by calculating the average expenditure per ADAP only client for the past four complete fiscal years (FY 2005-06 through 2008-09), which showed that each year

the average expenditure increased by approximately \$1,000. Therefore, \$2,000 was added to the FY 2008-09 average expenditure per ADAP only client (\$23,438) to estimate the FY 2010-11 average expenditure per ADAP only client (\$25,438) and dividing by 12 to obtain the average monthly expenditure per client (\$2,120).

The ADAP revenue impact is estimated at 29 percent of expenditures for their clients. The *average* rebate collection rate for *all* ADAP clients is 46 percent of expenditures. However, NQA will be ADAP only clients. The 29 percent rate was the 2008-09 rebate collection rate for ADAP only clients. To obtain the NQA impact on FY 2010-11 revenue, the estimated increase in expenditures for the NQA clients was multiplied by 29 percent, and then multiplied again by 33 percent since rebate in FY 2010-11 would only be collected for three months of expenditures due to the six month delay in receiving rebate. Since the AWP decrease does not impact rebate (because there is no change in the number of drug units purchased, which is how rebate is calculated), the estimated new expenditures for NQA clients prior to the AWP adjustment was used (\$286,200).

4. Medi-Cal Permanently Residing Under Color of Law Immigrants and Amnesty Aliens (PRUCOL) - The PRUCOL policy change will be effective October 1, 2010 (nine months of FY 2010-11). ADAP expenditure increases are estimated at \$2,120 per month per client (90 clients per month per DHCS estimates) for nine months and then adjusted for the four percent AWP decrease. These new PRUCOL clients are similar to the new NQA clients in that they will become ADAP only clients. The \$2,120 per month per client estimate was calculated in the same manner as NQA estimate in the above section.

Similar to the NQA clients, the ADAP revenue impact of the PRUCOL clients is estimated at 29 percent of expenditures (the average rebate collection rate for ADAP only clients), multiplied again by 33 percent to incorporate the six month delay in receiving rebate. The estimated new expenditures from PRUCOL without the AWP adjustment was used (\$1,717,200).

5. Legislation Affecting Medicare Part D True Out Of Pocket Costs (TrOOP) – Prior to HCR, Medicare Part D law prohibited ADAP spending from counting towards a Medicare Beneficiary's TrOOP. Consequently, prior to January 1, 2011, an ADAP client who enters the "donut hole" (coverage gap) will remain there for the rest of the plan year. ADAP spending on drugs will not count towards the \$3,610 (year 2010) out-of-pocket threshold that moves an individual into catastrophic coverage (client pays 5 percent co-insurance). As a result, ADAP pays 100 percent of their drug costs when covering clients in the donut hole.

On March 23, 2010, President Obama signed into law the House Health Care Reform Bill, HR 4872, which includes provisions to change and ultimately eliminate over time the Medicare "donut hole". Beginning January 1, 2011, Medicare recipients enrolled in ADAP will benefit from the provision that any expenditure related to ADAP, either one's own or any incurred on their behalf, will count towards that client's TrOOP.

To estimate the savings from ADAP expenditures counting towards TrOOP as of January 1, 2011, we estimated the expenditure reduction associated with this group

(donut hole clients) between January and June, 2009 and applied that percentage to the last six months of FY 2010-2011, when this legislative change will take effect. To estimate the hypothetical expenditure reduction from 2009, we employed the following three steps:

1. We identified the actual number of Medicare Part D clients “stuck” in the donut hole from January through June 2009 (718 clients). ADAP payments for the 410 clients with expenditures exceeding the donut hole threshold were totaled; these represent savings associated with ADAP clients who would have moved into catastrophic coverage had the HCR provision been in effect during this time period.
2. These savings were adjusted to incorporate the five percent co-insurance expenses that are incurred upon transition to catastrophic coverage.
3. Finally, for all clients in the donut hole, additional savings to ADAP resulting from the HCR mandate that drug manufacturers pay 50 percent of prescription costs while clients are in the donut hole, were estimated. This requirement will reduce ADAP’s payments by 50 percent.

Then,

4. These three factors were summed, adjusting for the four percent AWP rollback explained on page 4, to obtain the percentage of total FY 2008-09 expenditures represented by this client pool.
5. This percentage was then applied to FY 2010-11, resulting in an estimated six-month savings due to TrOOP of \$3,192,032.

There will not be a revenue impact for FY 2010-11 due to the six month delay between expenditures for drugs and rebate revenue collections.

6. Increase in Federal Funds - On April 1, 2010, CDPH received a \$4.7 million augmentation to its federal Ryan White Care Act (RWCA) Part B grant award for ADAP. The *May Revision* Estimate assumes the increase in federal funds will be spent in the budget year, offsetting \$4.7 million in General Fund (GF) expenditures.

### **Revised Major Assumptions**

There are no Revised Major Assumptions.

### **Discontinued Major Assumptions**

There are no Discontinued Major Assumptions.

### **Modified Assumption**

1. Discontinue ADAP Services in County Jails - ADAP began serving eligible inmates in county jails in 1994 due to the increasing fiscal impact on local jurisdictions in meeting their mandate to provide medical services to their incarcerated populations. Thirty-six counties and their 44 local jails participated in ADAP in FY 2008-09, serving 1,862

clients. No new jails were added to this program since FY 2003-04 due to fiscal pressures on ADAP. In FY 2010-11, it is projected that 2,093 incarcerated individuals would have been served by ADAP should this reduction not have occurred. The client impact estimate was updated for the *May Revision* by multiplying the FY 2008-09 percent of clients that were jail clients by the projected number of clients in FY 2010-11 based on linear regression. The impact of this change will increase the fiscal burden at the county level. Both the Government Code (Section 29602) and the Penal Code (Sections 4011et seq. and 4015[a]) address the issue of providing medical care to inmates in local jails. These codes specifically provide that local and county correctional facilities are primarily liable for inmate care in the jails.

Change from Prior Estimate: The same methods are used in the *May Revision* estimate as were used in the *November Estimate*. The differences in the *May Revision* expenditure and revenue estimates resulting from the jail coverage policy change result from 1) updating the percent of expenditures attributed to jail clients by utilizing complete FY 2008-09 data (2.31 percent) and multiplying this percent by the revised, unadjusted FY 2010-11 expenditure estimate; 2) updating the percent of rebate attributed to jail clients by utilizing FY 2008-09 data (1.8 percent); 3) the changes in total estimated ADAP expenditures and revenues noted in tables 1a-1d (pages 1-2) and tables 2a-2d (page 3) *May Revision* estimate; and 4) the AWP decrease of four percent in brand prescription drugs. The jail policy change is estimated to reduce expenditures in FY 2010-11 by \$10,167,238. The impact on revenue was calculated by taking the July through December 2010 estimated expenditures and multiplying by 46 percent (the overall ADAP rebate revenue rate) and then multiplying by 1.8 percent to capture the amount of rebate loss resulting from no longer serving jail clients, resulting in a revenue loss of \$1,914,266. The net change in estimated savings from this proposal is -\$1,271,710 compared to the *November Estimate*.

2. Decrease Interest Earned on SF 3080 - The Budget Act of FY 2009-10 estimated interest income at \$3 million for FY 2009-10. Actual interest earned for FY 2008-09 was \$2.1 million. Since interest rates have declined due to the economic downturn, and there will be less money in the fund to accumulate interest, the estimate has been reduced for both FYs 2009-10 and 2010-11 to \$2 million annually.

Change from Prior Estimate: This is a modified assumption for FY 2010-11 that will also impact FY 2009-10 revenues. Estimated interest income for FY 2009-10 and FY 2010-11 has been reduced to \$400,000 to reflect projections based on actual earnings through the first nine months of the current year.

### 3. FUND CONDITION STATEMENT

(Updated for *May Revision*)

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

For FY 2009-10 revenue estimates, the FCS for *May Revision* includes actual rebates collected for January to June 2009 whereas the *November Estimate* had to rely on actual drug expenditures with the application of a 46 percent estimated reimbursement rate. For the period July to December 2009, the *May Revision* applied the 46 percent reimbursement rate to actual expenditures while the *November Estimate* had only estimated expenditures available to calculate estimated rebate (Table 9, page 17).

For FY 2010-11 revenue estimates, the *May Revision* and the *November Estimate* both used estimated expenditures (using a 46 percent collection rate) for the period January to December 2010. However, the *May Revision* expenditure estimates were more current than those used for the *November Estimate* (Table 9, page 17).

The GF augmentation need for the *May Revision* is estimated at \$54.759 million, \$32.703 million less than the estimated need in the *November Estimate*.

## MAY REVISION ESTIMATE FUND CONDITION STATEMENT

<b>TABLE 3: FUND CONDITION STATEMENT</b>				
(in thousands)				
Special Fund 3080 AIDS Drug Assistance Program Rebate Fund		FY 2008-09 actuals	FY 2009-10 estimate	FY 2010-11 estimate
1	BEGINNING BALANCE	80,356	91,183	26,325
2	Prior Year Adjustment	23,938	0	0
3	Adjusted Beginning Balance	104,294	91,183	26,325
4	REVENUES, TRANSFERS AND OTHER ADJUSTMENTS			
5	Revenues			
6	150300 Income From Surplus Money Investments	2,106	400	400
7	161400 Miscellaneous Revenue	157,852	174,711	192,270
8	Total Revenues, Transfers, and Other Adjustments	159,958	175,111	192,670
9	Total Resources	264,252	266,294	218,995
10	EXPENDITURES AND EXPENDITURE ADJUSTMENTS			
11	Expenditures			
12	8880 FISCAL			1
13	0840 State Controllers Office	1	23	57
14	4260 Department of Health Care Service (State Ops)	0	165	159
15	4265 Department of Public Health			
16	State Operations	1,158	1,059	1,068
17	Local Assistance	171,910	238,722	210,310
18				
19	Total Expenditures and Expenditure Adjustments	173,069	239,969	211,595
20	<b>FUND BALANCE</b>	<b>91,183</b>	<b>26,325</b>	<b>7,400</b>

Row 6: Estimates based on trend of interest FY 2009-10.

	400,000	400,000
--	---------	---------

Miscellaneous Revenue

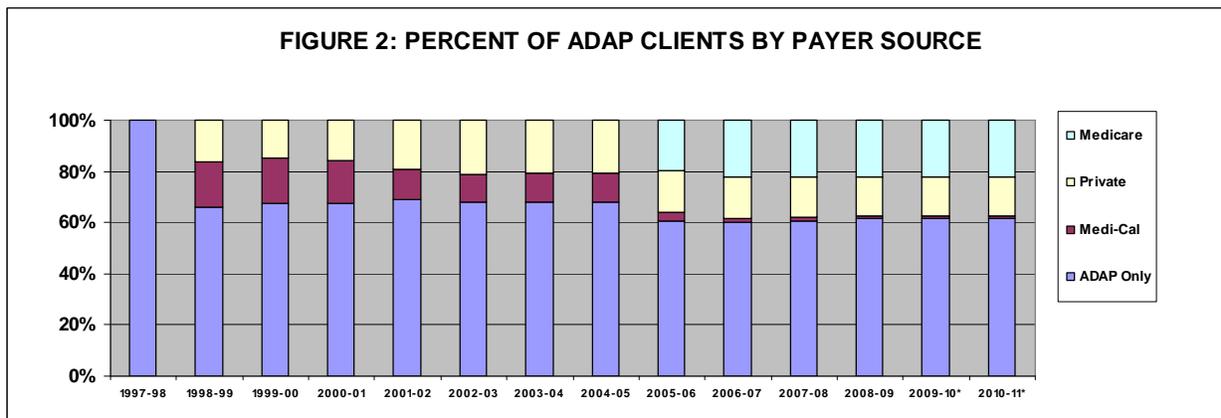
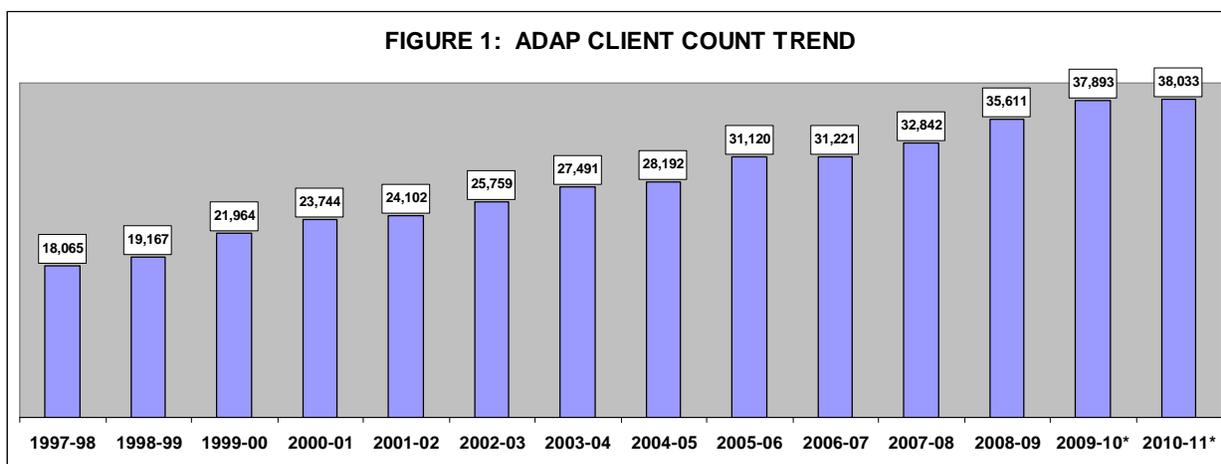
Actual Rebates collected for Jan - March 2009	45,508,900	
Actual Rebates collected for April - June 2009	39,800,097	
Subtotal: Actual rebates collected	85,308,997	
Actual Expenditures for July - December 2009	194,351,387	
Estimated expenditures for Jan - June 2010		206,013,814
Estimated expenditures for July - Dec 2010		215,708,734
Estimated Calendar Year Expenditures		421,722,548
Estimated revenue at 46% rebate collection rate on \$194,351,387	89,401,638	
Total projected revenue (\$85,308,997 + \$89,401,638)	174,710,635	
Estimated revenue at 46% rebate collection rate on \$421,722,548		193,992,372
<b>Revenue Impact: Eliminate Services to Jails</b>		-1,914,266
<b>Revenue Impact: NQA</b>		27,389
<b>Revenue Impact: PRUCOL</b>		164,336
<b>Revenue Impact: True-Out-Of-Pocket (HCR)</b>		0
<b>Revenue Impact: Increased Rebate Rate (HCR)</b>		0
<b>Row 7: Projection of Total Revenue after adjustments</b>	174,710,635	192,269,832
Linear Regression Expenditure Projection	405,499,176	462,883,048
Administrative Reduction to PBM Contract (GF Reduction)	-500,000	-500,000
Administrative Reduction: Non-Approved Transaction Fee Savings (RFP)		-3,349,013
Subtotal: Local Assistance Expenditure Estimate	404,999,176	459,034,035
<b>Expenditure Impact: AWP Rollback/WAC</b>	-4,633,975	-16,193,665
<b>Expenditure Impact: Eliminate Services to Jails</b>		-10,167,238
<b>Expenditure Impact: NQA</b>		276,624
<b>Expenditure Impact: PRUCOL</b>		1,659,743
<b>Expenditure Impact: True-Out-Of-Pocket (HCR)</b>		-3,192,032
Subtotal: Expenditure Projection after Adjustments	400,365,201	431,417,467
*Less: Federal Fund Appropriation (Earmark)	-92,926,756	-97,631,979
Less: General Fund Appropriation	-70,849,000	-70,849,000
SF Balance After Strategies (Need)		-47,359,000
Additional Need (Reserve - 3.5% of SF Expenditures)		-7,400,000
<b>General Fund Augmentation</b>		<b>-54,759,000</b>
Special Fund 3080 need to meet Expenditure Estimate	236,589,445	208,177,488
Local Assistance LHJ	1,000,000	1,000,000
Local Assistance Medicare Part D	1,000,000	1,000,000
Tropism Assay	132,623	132,623
<b>Row 16: Total Special Fund Need</b>	<b>238,722,068</b>	<b>210,310,111</b>

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

### 4. HISTORICAL PROGRAM DATA AND TRENDS

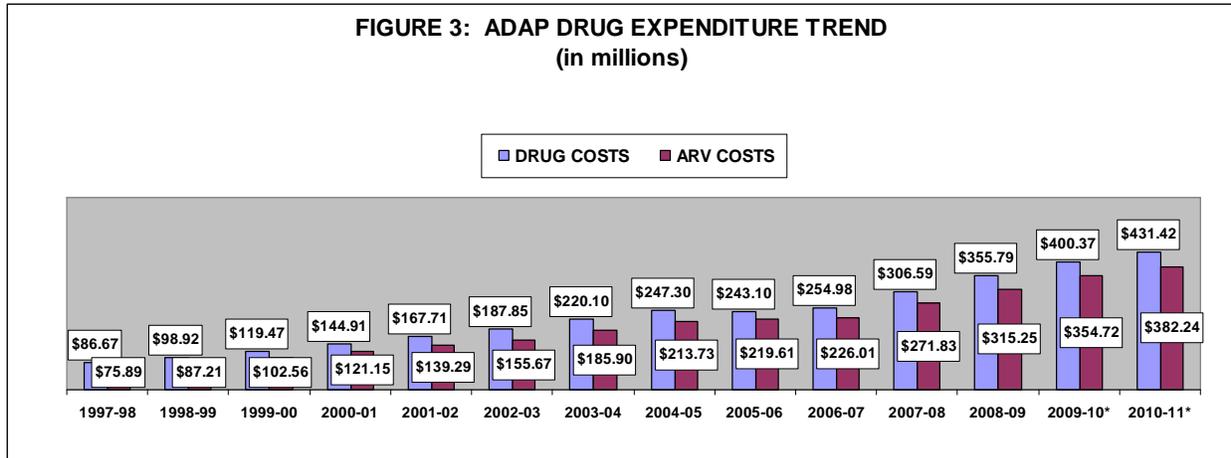
(\*Data for FYs 2009-10 and 2010-11 are estimated, all other data actual)  
(Updated for *May Revision*)

All data represent actuals except FYs 2009-10 and 2010-11 data which are estimates derived from the following methods: 1) for the clients and prescription estimates (Figures 1, 2 and 4), the January 2006 linear regression model with monthly clients and prescriptions as data points, respectively, was used; for the drugs estimate (Figure 3), we applied the percentage of prescriptions/drugs in FY 2008-09 to the FYs 2009-10 and 2010-11 prescription estimate. Note that figures below for FY 2010-11 include the increases for the PRUCOL/NQA Major Assumptions and the decrease for elimination of jails Modified Assumption.

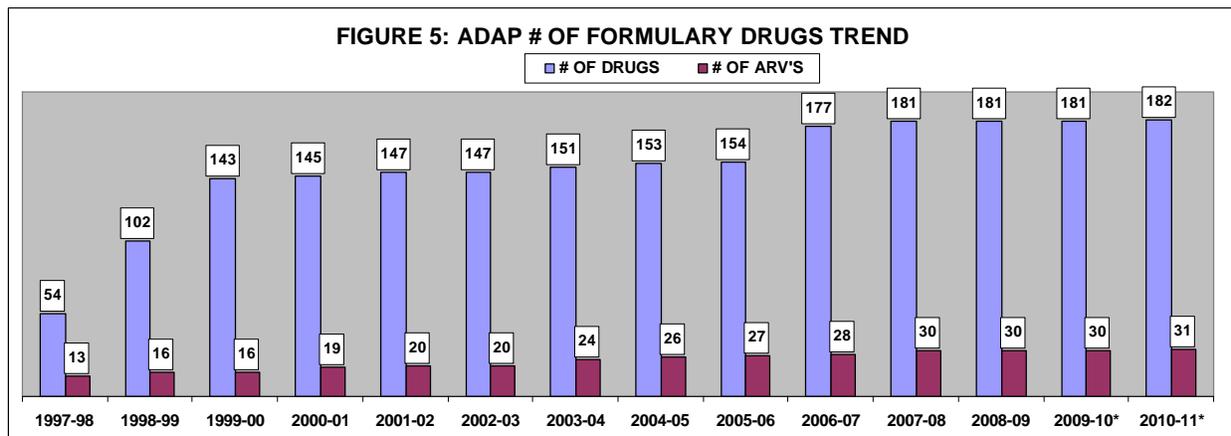
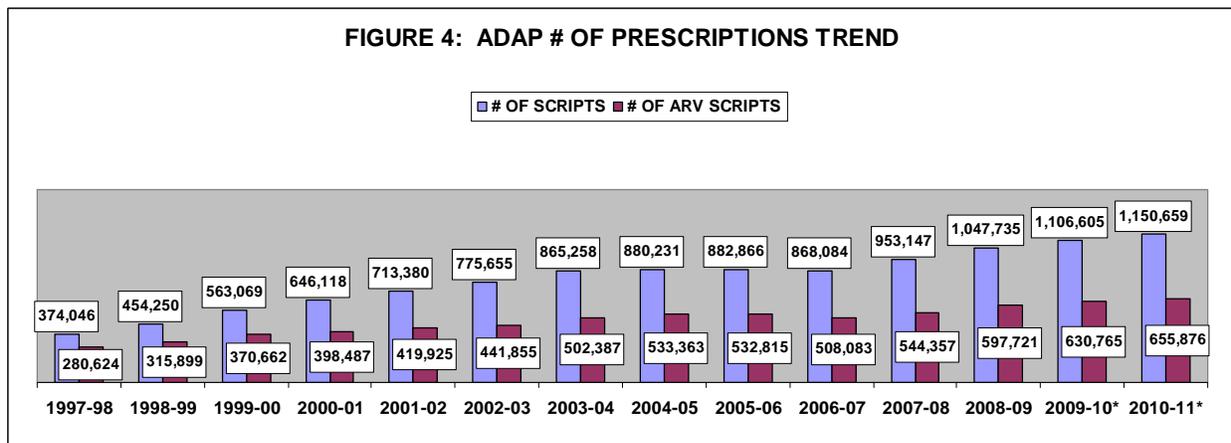


**TABLE 4: ESTIMATED ADAP CLIENTS BY COVERAGE GROUP**

COVERAGE GROUP	FY 2009-10*		FY 2010-11*	
	CLIENTS	PERCENT	CLIENTS	PERCENT
ADAP	23,247	61.35%	23,374	61.46%
Medi-Cal	440	1.16%	440	1.16%
Private Insurance	5,885	15.53%	5,890	15.49%
Medicare	8,321	21.96%	8,329	21.90%
<b>TOTAL</b>	<b>37,893</b>	<b>100.00%</b>	<b>38,033</b>	<b>100.00%</b>



Note: Non-drug expenditures including Tropism Assay (laboratory test required to demonstrate clinical indication for one of the antiretroviral (ARV) agents covered by ADAP; \$132,623 in FY 2008-09 and \$58,563 to date in FY 2009-10), and annual administrative support of \$1 million for Local Health Jurisdictions (LHJs) and Medicare Part D premium payments of \$1 million are *not* displayed here.



## APPENDIX A: EXPENDITURE AND REVENUE ESTIMATE METHODS

### Updated Expenditure Estimate for FY 2009-10

TABLE 5: LINEAR REGRESSION MODEL FOR MAY REVISION COMPARED TO NOVEMBER ESTIMATE, FY 2009-10 (ACTUAL DATA JANUARY 2006 THROUGH FEBRUARY 2010)			
May Revision	November Estimate	Change from Previous Estimate (\$)	Change from Previous Estimate (%)
\$405,499,176	\$418,262,976	(\$12,763,800)	-3.05%

### New Expenditure Estimate for FY 2010-11

TABLE 6: LINEAR REGRESSION MODEL FOR MAY REVISION COMPARED TO NOVEMBER ESTIMATE, FY 2010-11 (ACTUAL DATA JANUARY 2006 THROUGH FEBRUARY 2010)			
May Revision	November Estimate	Change from Previous Estimate (\$)	Change from Previous Estimate (%)
\$462,883,048	\$471,732,143	(\$8,849,095)	-1.88%

#### Linear Regression Model – Expenditure Estimates

The Linear Regression methodology is the same as that used to develop the *November estimate*. Updated data points include actual expenditures from January 2006 through February 2010 (as opposed to January 2006 through July 2009 for the *November Estimate*) to maximize its predictive accuracy. Thus, seven more data points (expenditures from August 2009 through February 2010) were added to the data set for a total of 50 data points. The additional data increased the precision of the estimate and thus decreased the spread of the confidence interval, leading to a larger decrease in the upper bound of the 95 percent confidence interval than in the corresponding point estimate.

Figure 6, page 14 shows ADAP historic expenditures by month. The (thick straight black) regression line represents the best fitting straight line for estimating the expenditures:

- During normal growth periods, a Linear Regression Model should accurately predict expenditures (the black regression line goes straight through the data points).
- During low growth periods, a Linear Regression Model would overestimate expenditures (the black regression line goes over the data points).
- During high growth periods, a Linear Regression Model using the point estimate would underestimate expenditures (the black regression line goes under the data points). Thus, given the recent relatively high growth expenditure period beginning in FY 2007-08, and the desire not to underestimate the need for ADAP to utilize the ADAP SF to address increasing expenditures, we continue to use the upper bound

of the 95 percent confidence interval around the point estimate for our regression estimates. This is the same strategy used for the *November Estimate*.

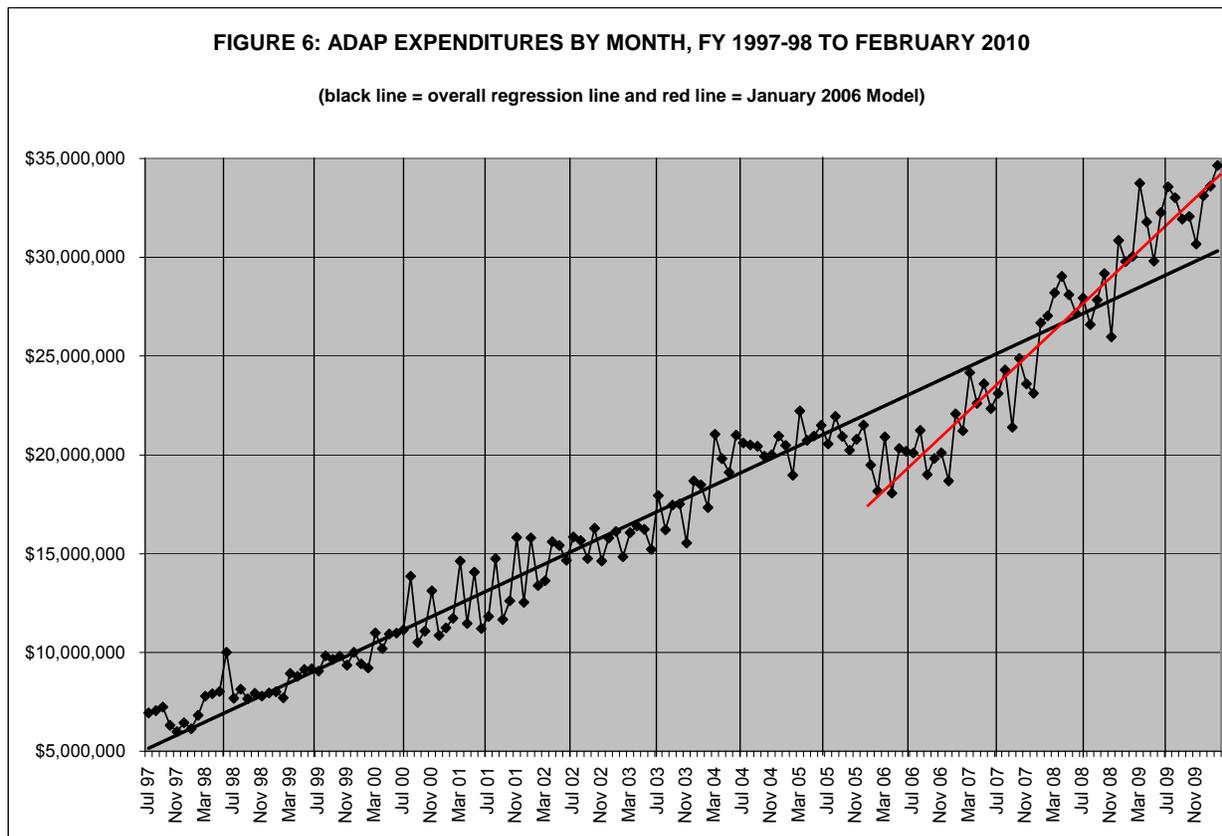


Table 7 shows historic drug expenditures by FY, annual change and percent change.

<b>TABLE 7: ADAP HISTORIC DRUG EXPENDITURES</b>			
Fiscal Year	Expenditures	Annual Change in Expenditures	Pct Annual Change
1997-98	\$86,674,336	N/A	N/A
1998-99	\$98,924,742	\$12,250,405	14.13%
1999-00	\$119,465,151	\$20,540,409	20.76%
2000-01	\$144,913,504	\$25,448,353	21.30%
2001-02	\$167,709,426	\$22,795,922	15.73%
2002-03	\$187,854,138	\$20,144,712	12.01%
2003-04	\$220,101,760	\$32,247,622	17.17%
2004-05	\$247,299,716	\$27,197,956	12.36%
2005-06	\$243,096,942	-\$4,202,774	-1.70%
2006-07	\$254,977,392	\$11,880,450	4.89%
2007-08	\$306,590,832	\$51,613,440	20.24%
2008-09	\$355,786,400	\$49,195,569	16.05%
<b>Total Average</b>	<b>98-99 to 08-09</b>	<b>\$24,464,733</b>	<b>13.90%</b>

Note: Non-drug expenditures including Tropism Assay (\$132,623 in FY 2008-09 and \$58,563 to date in FY 2009-10), and annual administrative support of \$1 million for Local Health Jurisdictions (LHJs) and Medicare Part D premium payments of \$1 million are *not* displayed here. Drug costs *do* include administrative costs at the pharmacy and PBM level.

**Program Expenditure Estimate for FY 2010-11**

In addition to the drug expenditure estimates noted in Table 7, page 14, total estimated program costs include:

1. Tropism Assay \$132,623
2. Administrative support for LHJs \$1 million
3. Medicare Part D premium payments \$1 million

**ADAP Rebate Revenue**  
(Updated for May Revision)

<b>TABLE 8: HISTORIC ADAP REBATE REVENUE COLLECTION PERCENTS BY QUARTER</b>			
<b>FY-QTR</b>	<b>\$ Drugs Purchased</b>	<b>Received in Rebate \$</b>	<b>Received / Purchased</b>
2002/03-Q1	\$46,263,616	\$10,136,693	21.91%
2002/03-Q2	\$46,714,748	\$10,257,857	21.96%
2002/03-Q3	\$47,028,955	\$10,146,224	21.57%
2002/03-Q4	\$47,846,818	\$10,846,426	22.67%
2003/04-Q1	\$51,607,688	\$12,275,494	23.79%
2003/04-Q2	\$51,732,389	\$15,045,513	29.08%
2003/04-Q3	\$56,857,403	\$17,801,378	31.31%
2003/04-Q4	\$59,904,280	\$19,249,713	32.13%
2004/05-Q1	\$61,533,761	\$19,334,264	31.42%
2004/05-Q2	\$60,894,584	\$18,691,012	30.69%
2004/05-Q3	\$61,680,181	\$19,176,357	31.09%
2004/05-Q4	\$63,191,190	\$15,847,186	25.08%
2005/06-Q1	\$63,433,758	\$21,866,164	34.47%
2005/06-Q2	\$62,536,173	\$20,612,704	32.96%
2005/06-Q3	\$58,562,814	\$26,768,577	45.71%
2005/06-Q4	\$58,564,197	\$25,095,840	42.85%
2006/07-Q1	\$60,334,084	\$24,791,394	41.09%
2006/07-Q2	\$58,609,374	\$24,489,071	41.78%
2006/07-Q3	\$67,474,884	\$32,724,197	48.50%
2006/07-Q4	\$68,559,050	\$31,734,710	46.29%
2007/08-Q1	\$68,797,779	\$33,524,051	48.73%
2007/08-Q2	\$71,581,717	\$35,262,749	49.26%
2007/08-Q3	\$81,926,045	\$44,200,318	53.95%
2007/08-Q4	\$84,285,291	\$39,834,969	47.26%
2008/09-Q1	\$82,366,671	\$36,272,892	44.04%
2008/09-Q2	\$85,997,429	\$38,043,895	44.24%
2008/09-Q3	\$93,564,283	\$45,508,900	48.64%
2008/09-Q4	\$93,858,017	\$39,800,097	42.40%

46.05%

## ADAP Rebate Revenue Estimate Method

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

Revenue estimates for the *May Revision* have been calculated using updated data for actual rebates collected, actual expenditures and for estimated expenditures. Specifically, the revenue estimates for FY 2009-10 were based on actual rebates collected for the period January to June 2009 (last half of FY 2008-09) and actual expenditures (with a 46 percent rebate collection rate) for the period July to December 2009 (first half of FY 2009-10). Revenue estimates for FY 2010-11 used estimated expenditures for the period January to December 2010 (as did the *November Estimate*) however the expenditures projection were based on an updated linear regression estimate.

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

The *May Revision* for FY 2010-11 includes additional new or revised policy adjustments (see Table 3, page 10, Fund Condition Statement) that will either increase or decrease revenue estimates developed using the process described above. One of these adjustments (eliminating services to jails) was revised to increase the amount of lost revenues, despite the decrease in the expenditure savings, because the actual proportionate jail rebate collection rate in the updated time period was higher (*November Estimate* 1.58 percent and *May Revision* 1.80 percent). Two other adjustments (NQA and PRUCOL) are new to the *May Revision* and will both result in increases in revenue.

While the elimination of services to county jails reduces expenditures, it also results in an associated reduction in rebate revenue collected. The methodology used to calculate the reduction in rebate revenue is based on the percentage of revenue associated with jail services in FY 2008-09. This percentage is applied to estimated revenue from the first half of FY 2010-11. Revenue from the last half of FY 2009-10 will not be impacted from this adjustment because elimination of jail services will begin in

July 2010. Revenue adjustments for NQA and PRUCOL were developed by applying a percentage against their respective estimated increases in expenditures.

(Updated for May Revision)

TABLE 9: COMPARISON OF REBATE REVENUE* BETWEEN MAY REVISION AND NOVEMBER ESTIMATE FOR FY 2009-10 AND FY 2010-11						
UPDATED ESTIMATE FOR FY 2009-10						
Expenditure Period	Available Data	May Revision	Available Data	November Estimate	Change (\$)	Change (%)
Jan - Mar 2009	Actual Rebates	\$45,508,900	Actual Expenditures @ 46%	\$43,039,570	\$2,469,330	5.74%
Apr - Jun 2009	Actual Rebates	\$39,800,097	Actual Expenditures @ 46%	\$43,174,688	-\$3,374,591	-7.82%
Jul - Dec 2009	Actual Expenditures @ 46%	\$89,401,638	Estimated Expenditures @ 46%	\$96,085,484	-\$6,683,846	-6.96%
Subtotal Revenue		\$174,710,635		\$182,299,742	-\$7,589,107	-4.16%
Interest		\$400,000		\$2,000,000	-\$1,600,000	-80.00%
<b>Total Revenue</b> (see Table 3, Fund Condition Statement)		\$175,110,635		\$184,299,742	-\$9,189,107	-4.99%
UPDATED ESTIMATE FOR FY 2010-11						
Expenditure Period	Available Data	May Revision	Available Data	Governor's Budget	Change (\$)	Change (%)
Jan - Jun 2010	Estimated Expenditures @ 46%	\$94,766,355	Estimated Expenditures @ 46%	\$96,085,484	-\$1,319,129	-1.37%
Jul - Dec 2010	Estimated Expenditures @ 46%	\$99,226,018	Estimated Expenditures @ 46%	\$108,383,393	-\$9,157,375	-8.45%
Subtotal Revenue		\$193,992,373		\$204,468,878	-\$10,476,505	-5.12%
FY 2010-11	Reduction: Elimination of Services to Jails	-\$1,914,266		-\$1,712,458	-\$201,808	11.78%
FY 2010-11	Increase: NQA	\$27,389		\$0	\$27,389	N/A
FY 2010-11	Increase: PRUCOL	\$164,336		\$0	\$164,336	N/A
FY 2010-11	Medi-Cal Optional Benefits (no revenue impact)	\$0		\$0	\$0	N/A
FY 2010-11	Decrease: True-out-of-pocket (HCR) (no revenue impact)	\$0		\$0	\$0	N/A
FY 2010-11	Increase: Rebate rate (HCR) (no revenue impact)	\$0		\$0	\$0	N/A
Interest		\$400,000		\$2,000,000	-\$1,600,000	-80.00%
<b>Total Revenue</b> (see Table 3, Fund Condition Statement)		\$192,669,832		\$204,756,420	-\$12,086,588	-5.90%

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

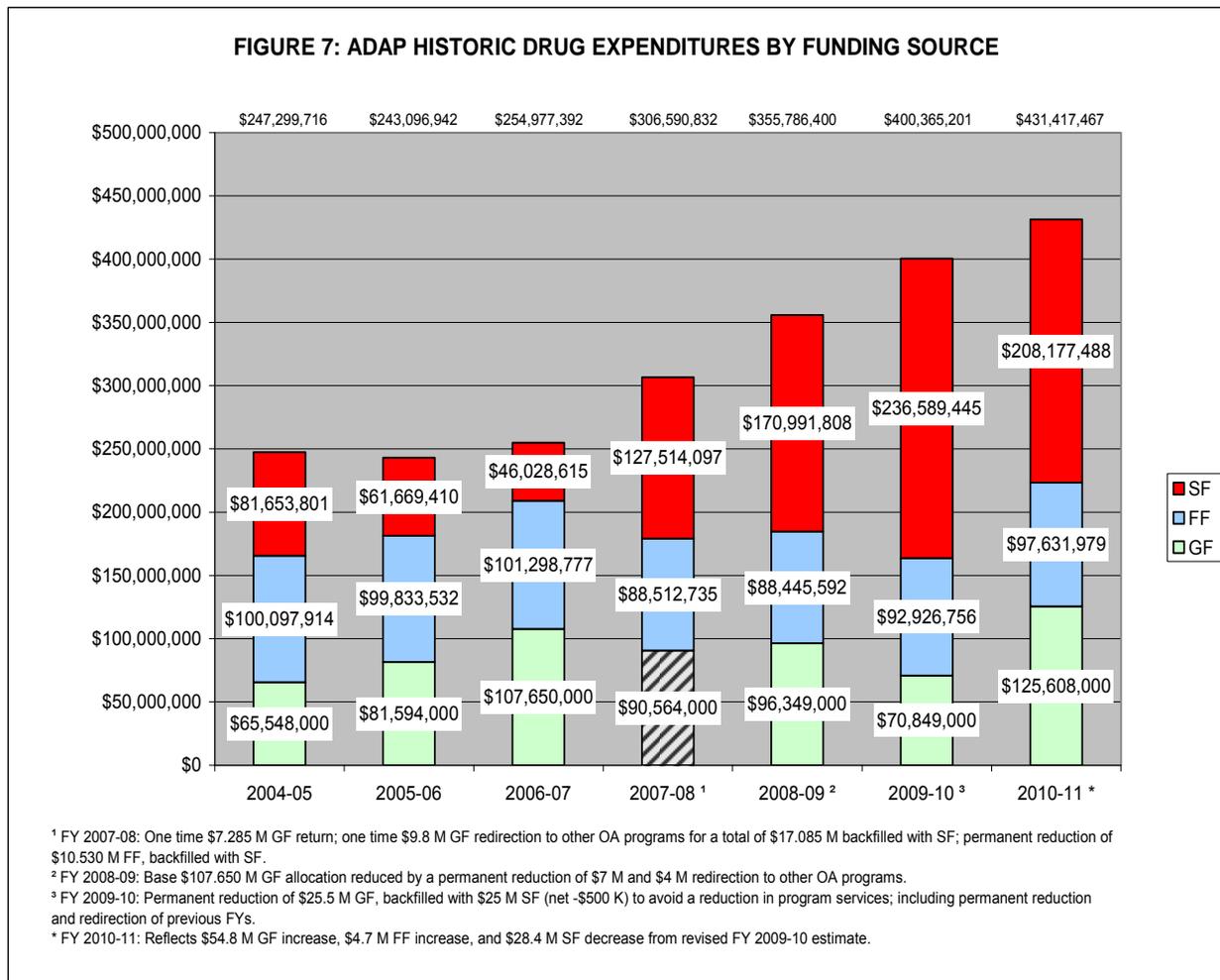
## APPENDIX B: FUND SOURCES

(Updated for *May Revision*)

Payment of ADAP expenditures are made from three fund sources:

1. State GF
2. Federal funding from the Health Resources and Services Administration (HRSA) through the Ryan White HIV/AIDS Treatment Extension Act of 2009 (RW), Part B, ADAP Earmark grant. OA was recently notified of an increase in its ADAP grant award of \$4.7 million for the period April 1, 2010 to March 31, 2011.
3. ADAP SF consists of both mandatory and voluntary rebates from manufacturers with products on the ADAP formulary.

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



## General Fund

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

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

The GF augmentation need for the *May Revision* is estimated at \$54.759 million, \$32.703 million less than the estimated need in the *November Estimate*.

## Federal Fund

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

For FY 2010-11, ADAP received an increase in Federal funding of \$4,705,223 for a total of \$97,631,979.

### **Match**

HRSA requires grantees to have HIV-related non-HRSA expenditures of at least one half of the HRSA grant award. Since California's 2010 HRSA grant award is \$134,604,892, the match requirement for FY 10-11 funding is \$66,834,681. California has met this requirement every year using GF.

### **Maintenance of Effort (MOE)**

HRSA requires grantees to maintain HIV-related expenditures at a level that is not less than the prior fiscal year. California's MOE target, based on FY 2008-09 expenditures at the time of the Year 2010 HRSA grant application, is \$502,476,676. Expenditures included in California's MOE calculations are not limited to OA programs and include HIV-related expenditures for all state agencies able to report GF expenditures specific

to HIV-related activities such as care, treatment, prevention, and surveillance. Expenditures from the SF may be used towards the MOE requirement.

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

### **ADAP SF (3080)**

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

“... (b) All rebates collected from drug manufacturers on drugs purchased through the ADAP implemented pursuant to this chapter and, notwithstanding Section 16305.7 of the Government Code, interest earned on these moneys shall be deposited in the fund exclusively to cover costs related to the purchase of drugs and services provided through ADAP ...”

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

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

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

Supplemental rebate agreements are in place for all ARVs on the ADAP formulary. This is significant, as ARV drugs represent 90 percent of all ADAP drug expenditures. Supplemental rebate agreement terms are generally based on either:

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

### ***Additional Rebate Percentage***

The federally-mandated rebate is a percentage of the Average Manufacturer Price (AMP), plus any penalties for price increases that exceed increases in the Consumer Price Index. Since the AMP is confidential and not publicized, the resulting rebate amount is also unknown to ADAP. The ACTF negotiations could result in an additional percentage of the AMP. For example, if the mandated rebate is 15 percent of AMP, and the ACTF negotiates a supplemental rebate with a manufacturer of seven percent of AMP for a particular drug, then ADAP will receive a total rebate of 22 percent of AMP for that drug.

### ***“Price Freeze” Rebates***

The “price freeze” option is another type of voluntary rebate offered by the manufacturer to compensate for commercial price increases. Currently, of the 31 available ARV medications on the ADAP formulary, eight (27 percent) are subject to a price freeze rebate. If the manufacturers take a price increase while the price freeze is in effect, the program reimburses retail pharmacies at the higher rates. Initially, these result in higher expenditures for the program that are eventually offset by price freeze rebates received and deposited in the SF.

### **ADAP Rebate Invoicing**

ADAP invoices the manufacturers for drug rebates on a quarterly basis, consistent with both federal drug rebate law and drug industry standards. All ADAPs are required to invoice drug manufacturers within 90 days of the end of a given calendar year quarter (e.g., January-March, April-June, etc.) in compliance with federal requirements. California ADAP mails drug rebate invoices approximately 60 days after the end of the quarter. For example, the January to March quarter invoice is sent out June 1. The time between the end of the billing quarter and the mailing of the invoice is necessary to generate and confirm the accuracy of the rebate invoices.

### **Timeframe for Receipt of Rebates**

Federal HRSA guidance on ADAP rebate indicates that drug manufacturers are to pay rebate invoices from ADAP within 90 days of receipt. Federal Medicaid rebate law requires that drug manufacturers pay drug rebates within 30 days of receipt of a rebate invoice. Drug manufacturers tend to more closely follow the Medicaid payment timeframe when processing ADAP rebate invoices, though some do take the full 90 days. Approximately 85 percent of ADAP rebates due are received between 30 and 60 days and the remaining 15 percent are received between 60 and 90 days after the mailing of the rebate invoices.

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

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

Annually, additional SF budget authority is requested as follows:

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

## **APPENDIX C: POLICY ISSUES WITH POTENTIAL FUTURE FISCAL IMPACT**

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

### ***Potential for Positive Fiscal Impact (Decreased Costs)***

#### **1. HCR: Potential Increased 340B Rebate Rate Application to ADAP**

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

The passage in the House of Representatives of the House Health Care Reform bill on March 21, 2010 has created uncertainty about the impact on the 340B rebate program for ADAP. The new law will increase the federally mandated Medicaid rebate amount for brand drugs from the current 15.1 percent of Average Manufacturer Price (AMP) to 23.1 percent of AMP. Generics will see the rebate amount change from the current 11 percent of AMP to 13 percent of AMP. These rebate rate increases will be in effect for any drugs purchased on or after January 1, 2010. The increase in the federally mandated Medicaid rebate rate, if applied to ADAP, would make a significant impact as the 15.1 percent of AMP for brand drugs has been in place since before the inception of ADAP rebates in FY 1997-98. However, the full impact of the 340B expansion, including if it will be applied to ADAP, remains unclear at this time at both the state and federal levels.

On March 29, 2010, the National Alliance of State and Territorial AIDS Directors (NASTAD) met with the safety net hospital association, who runs the 340B Coalition. Both the association's legal counsel and NASTAD are working to gain a better understanding of the new rebate provision. The 340B Coalition is requesting a meeting with the U.S Department of Health and Human Services, Health Resources and Services Administration (HRSA) and the Office of Pharmacy Affairs (OPA) to discuss health reform and its effects on the 340B program. NASTAD hopes this meeting will occur before the end of April but this is not certain. The timeline for obtaining clear answers on how expansion of the 340B rebate program will impact ADAP is unknown, as implementation at the federal level could be settled easily or be subject to legal challenges that could postpone implementation for months. NASTAD is in the process of working with a variety of partners and OPA to seek clarification.

Though much uncertainty exists, there are specific actions that must occur at the federal level in order to implement the increased drug rebate rate, should it be determined that this will apply to ADAP. In order for drug manufacturers to begin payment of the new rebate rates, the federal Centers for Medicare and Medicaid (CMS) must put into place the logistical pieces necessary to implement the new rates, including changing all of the federally established Unit Rebate Amounts (URAs) upon which rebate is paid. A unique URA must be identified for each drug product/form/strength. Drug products are identified and reported using a unique number, the National Drug Code (NDC), which is a universal product identifier for human drugs. CMS must establish new URAs using the increased rebate rates for every NDC dispensed under the Medicaid program. Early estimates for CMS implementation of the new rebate rates for Medicaid is approximately July 1, 2010. Until these rates are in place, drug manufacturers will have no standard by which to pay rebates and, consequently, ADAP will not receive the increased rebate amounts even if it is determined that ADAP will be eligible.

The increase in the federally mandated rebate may have an adverse effect on the voluntary, supplemental rebate negotiated by the ADAP Crisis Task Force (ACTF) on behalf of all ADAPs nationally. New supplemental rebate negotiations with each of the eight antiretroviral drug manufacturers took place on May 5-7, 2010. The ACTF finalized supplemental rebate agreements with only three of the eight manufacturers during the meeting, while negotiations with the remaining five drug manufacturers are ongoing. The ACTF hopes to complete the remaining supplemental rebate agreements by July 1, 2010 but we cannot be certain this will occur.

### ***Potential for Negative Fiscal Impact (Increased Expenditures)***

#### **1. Increasing Medicare Part D Costs**

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

##### Annual Changes

Effective January 1, 2010, changes in Medicare Part D prescription drug benefits directly affect ADAP costs for services to our clients with this benefit. Factors impacting ADAP costs for clients with Medicare Part D include increased prescription deductibles, out-of-pocket expenses and the coverage gap or “donut hole”. For the 2010 calendar year, costs for Standard Benefit clients increased by approximately 4.7 percent. These are typical increases that have occurred since the inception of the Medicare Part D program, and are thus accounted for in the regression estimates for expenditures. Medicare Part D prescription benefits will also change for calendar year 2011.

CMS contracts with Medicare Part D drug plans on an annual basis. Benefits available under Part D plans vary from calendar year to calendar year. Annual changes include formulary adjustments, changes to client out-of-pocket costs, and plans entering and exiting the market. CMS attempts to contain some beneficiary out-of-pocket costs by

establishing an annual “maximum out-of-pocket” benefit threshold schedule. CMS typically releases information on out-of-pocket thresholds each February and contracted drug plan details in October preceding the new plan year.

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

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

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

### ADAP Client Plan Selection

Plan selection plays an important role in the over-all cost of a Part D client to ADAP. With the exception of beneficiaries qualified for Full-Low Income Subsidy (LIS), individuals can only change plans annually during open enrollment. CMS rules give each plan the flexibility to charge beneficiaries various out-of-pocket costs as long as the plan stays within the maximum annual threshold. While HRSA allows ADAPs to control Part D costs by limiting which drug plans ADAP clients can enroll in, the California Department of Health Services decided in 2005 to not limit ADAP clients' Part D plan options. As a result, ADAP pays the out-of-pocket costs associated with any of the 47 Part D plans operating in California.

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

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

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

### Part D Plan Formulary Structure and Tiers

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 study conducted for the Medicare Payment Advisory Commission (March 2009) indicated that four classes of drugs (antineoplastics, immunologics, antivirals, and antibacterials) commonly used to treat HIV/AIDS and related conditions accounted for two-thirds of the drugs that plans place on higher-cost specialty tiers. The higher cost of drugs on specialty tiers is passed on to ADAP when ADAP pays the client's Part D out-of-pocket costs.

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

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

## **2. Changes in Treatment Guidelines to Recommend Earlier Treatment**

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

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

In both cases, these changes may result in increased utilization of high-cost ARV therapies, though the actual impact is unknown. Physician adoption of the new revised guidelines and the resulting ARV prescribing patterns have yet to be established, given the very recent release of the guidelines. Modeling of the potential impact on ADAP has not been done by any known entity. OA has requested that such modeling be conducted at the federal level by HRSA or the CDC. The OA Division Chief moderated a discussion with HRSA and CDC representatives on this issue at recent national

meeting. The discussion focused on developing reliable methods and identifying relevant data sources. We expect that preliminary, general estimates are likely to be available in the coming months.

### **3. Potential Changes in Partial Pay Rebate Collections**

Currently, ADAP is able to collect full rebate on partial payment transactions for clients with other payers (e.g., private insurance). In FY 2008-09 (most recent available data), rebates on partial payments represented nearly 44 percent of total rebate revenue. This is very cost effective for California's ADAP. Early in 2008, this policy was challenged by a drug manufacturer. This manufacturer subsequently publicly stated in writing that it would not pursue this issue further at this time. Although the manufacturer has stated that it plans to honor the current policy at this time, there remains the potential that the policy may be challenged again in the future. This issue has been of considerable concern to ADAPs nationally. California's ADAP will continue to monitor this issue.

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

## APPENDIX D: ACRONYM DEFINITIONS

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

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

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

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

## APPENDIX E: MEDICARE PART D DEFINITIONS

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

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

### Categories of coverage

- 1) Standard Benefit – This is the maximum allowable out-of-pocket costs permitted under Part D. For calendar year 2010 these beneficiaries must pay the first \$310 of their drug costs out of pocket. After the \$310 deductible, Medicare will pay 75 percent of the cost of each covered prescription and the beneficiary will pay 25 percent, up to \$2,830 in total costs. (Note: for medications on the ADAP formulary, ADAP covers the \$310 deductible and 25 percent co-pay).
- 2) “Donut Hole” – At this time, once a standard beneficiary reaches \$2,830 in drug costs (the combination of what Medicare and the beneficiary have paid) he or she is at the coverage gap or “donut hole”. When the standard beneficiary reaches the donut hole, Medicare will stop covering his or her drug costs until the beneficiary spends another \$3,610 on medication. Once the beneficiary has paid this amount in drug costs he or she is eligible for catastrophic coverage. Catastrophic coverage drug costs will vary by each Part D drug plan’s provisions 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”.) As a result of the passage of the Health Care Reform law, a beneficiary’s cost responsibility while in the “donut hole” will be phased down over time from 100 percent in 2010 to 25 percent by 2020. In addition, pharmaceutical companies will be required to provide a 50 percent discount on all brand-name drugs and 25 percent discount on generics to those clients while in this coverage gap.
- 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 currently prohibits drugs costs paid by ADAP from counting towards a beneficiary’s TrOOP. This rule has typically led to ADAP clients remaining “stuck” in the Part D coverage gap or “donut hole” for a majority of the Part D year. The Health Care Reform act includes the provision to allow ADAP expenditures to count towards TrOOP beginning January 2011, thus allowing clients to reach catastrophic coverage level sooner and have lower total drug costs.
- 4) Low Income Subsidy (LIS) – Beneficiaries with incomes below 150 percent of the FPL and with limited assets may be eligible for the low income subsidy (or “extra help” as Medicare calls it). LIS eligibility ensures that beneficiaries have the lowest out-of-pocket costs for medications.

- a) Full Subsidy – Income under 135 percent of FPL level. These beneficiaries do not have to pay a deductible, but pay \$2.50 for generic drugs, \$6.30 for brand drugs, and do not have to contend with the “Donut Hole” (coverage gap). After \$6,440 of out-of-pocket costs, they have no out-of-pocket drug costs for the remainder of the plan year. (Note: for medications on the ADAP formulary, ADAP covers these co-pays.)
- b) Partial Subsidy – Income between 135 percent and 150 percent of FPL. These beneficiaries must pay a \$62 deductible, 15 percent of drug costs after the deductible, and do not have to contend with the “Donut Hole” (coverage gap). After \$6,440 of out of pocket expenses, co-pays are reduced to \$2.50 for generics and \$6.30 for brand drugs. (Note: for medications on the ADAP formulary, ADAP covers the deductible, co-insurance, and co-pays.)
- c) Dual Eligible (covered by both Medicare and Medi-Cal)
  - i. Full Duals are clients who are eligible for Medi-Cal with no SOC. Medicare subsidizes the cost of a Full Dual’s drugs. They pay limited co-pays of \$2.50 to \$6.40 per drug. No out-of-pocket payments are required once total drug costs reach \$6,440. (Note: for medications on the ADAP formulary, ADAP covers these co-pays.)
  - ii. Partial Duals are clients who are eligible for Medi-Cal with a SOC. A Partial Dual who has not met his/her Medi-Cal SOC will not automatically qualify for Full LIS. Part D out of pocket costs for Partial Duals will vary depending on the individual’s income. A Partial Dual can become a “Full Dual” once they incur their monthly SOC. If a Dual incurs their SOC, they qualify for “Full Dual” subsidy the following month and retain this subsidy for the remainder of the plan year. (Note: for medications on the ADAP formulary, ADAP covers these costs.)

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

## APPENDIX F: NEW DRUGS AND TREATMENT GUIDELINES

### New Drug Updates

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

#### Maraviroc

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

#### Vicriviroc

Vicriviroc is the second drug in the CCR5 inhibitors class of ARV drugs and was, until recently, being investigated for use with both treatment-experienced as well as treatment-naïve patients. Due to disappointing results in phase three studies conducted with the treatment-experienced persons, the manufacturer has pulled the application with the FDA for approval with this population. However, phase 2 trials with treatment-naïve patients will continue. Thus the potential impact to the ADAP program will not involve the entire HIV+ population. The timeline for possible approval or trial success is difficult to predict. But it is anticipated that community pressure around pricing may influence vicriviroc being priced no higher than the other drug, maraviroc, in the CCR5 inhibitor class. OA does not anticipate a significant fiscal impact to the program.

### Treatment Guidelines Updates

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

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

#### *Selected Key Updates from the Guidelines*

##### Initiation of ARV Therapy

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

- ARV therapy should be initiated in all patients with a history of an AIDS-defining illness or with CD4 count < 350 cells/mm<sup>3</sup> (AI).
- ARV therapy should also be initiated, regardless of CD4 count, in patients with the following conditions: pregnancy (AI), HIV-associated nephropathy (AII), and hepatitis B virus (HBV) co infection when treatment of HBV is indicated (AIII).
- ARV therapy is recommended for patients with CD4 counts between 350 and 500 cells/mm<sup>3</sup>. The Panel was divided on the strength of this recommendation: 55 percent of Panel members for strong recommendation (A) and 45 percent for moderate recommendation (B) (A/B-II).
- For patients with CD4 counts >500 cells/mm<sup>3</sup>, 50 percent of Panel members favor starting ARV therapy (B); the other 50 percent of members view treatment as optional (C) in this setting (B/C-III).

### What to Start in Antiretroviral-Naïve Patients

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

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

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

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

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

### HIV Prevalence

Prevalence reflects the number of people who are currently infected with HIV and thus who could qualify for ADAP currently or some time in the future. California estimates that there were between 150,574 and 174,454 living with HIV/AIDS at the end of 2009, see Table 11, below. This estimate includes people who are HIV positive but are not yet diagnosed (approximately 21 percent) by applying a national estimate of those unaware of their infection status that was developed by the Centers for Disease Control and Prevention (CDC) Morbidity and Mortality Weekly Report, (MMWR, October 3, 2008). Living HIV/AIDS cases are estimated to be 47 percent white, 19 percent African American, 30 percent Latino, 3 percent Asian/Pacific Islander, and 0.5 percent American Indian/Alaskan Native. Most (65 percent) of California's living HIV/AIDS cases are attributed to male-to-male transmission, 9 percent is attributed to injection drug use, 9 percent to heterosexual transmission, and 8 percent to men who have sex with men (MSM) who also practice injection drug use.

The number of living HIV/AIDS cases in the state is expected to grow by approximately two percent (with a range of 2,800 – 5,700) each year for the next two years and it is expected that this increasing trend will continue for the foreseeable future. This increase is attributed to stable incidence rates and longer survival of those infected (primarily due to the effectiveness and availability of treatment).

Year	Persons reported with HIV (not AIDS) and presumed living		Persons reported with AIDS and presumed living		Estimated persons living with HIV or AIDS*	
	Low bound	High bound	Low bound	High bound	Low bound	High bound
2007	43,163	55,384	64,506	64,506	145,541	162,517
2008	43,230	56,223	66,577	67,665	147,853	168,689
2009	43,322	57,038	68,967	70,506	150,574	174,454
2010	43,427	57,840	71,410	73,294	153,394	180,119
2011	43,541	58,633	73,879	76,055	156,270	185,727

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

### HIV Incidence

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

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

Recent advances in laboratory tools have made estimation of HIV incidence possible using blood samples from people found to be HIV antibody positive. In 2004, CDC began a national effort to measure incidence using this tool. These results were reported in the August, 2008 issue of MMWR. California's data were not included as they are not yet complete enough to provide accurate estimates. Therefore, California has not yet updated its incidence estimates. The 95 percent confidence interval for the national estimate (48,200 to 64,500 new infections) is consistent with the 5,000 to 7,000 range OA estimated for California in 2005 suggesting new HIV infections have been relatively steady in recent years.

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

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

ADAP conducted a sensitivity analysis exploring the impact on total expenditures by increasing and decreasing the number of clients and the expenditures per client (\$ /client). For this sensitivity analysis, we started with the estimated total drug expenditures for FY 2009-10 using the upper bound of the 95 percent confidence interval (CI) from the Linear Regression Model and subtracted savings for the administration reduction in PBM contract costs and AWP rollback.

For these factors, clients and expenditures per client, we created scenarios ranging from negative three percent to positive three percent, in one percent intervals. Those scenarios labeled as “Hi” represent three percent, “Med” represent two percent, and “Lo” represents a one percent change. The left column in Table 12 lists the seven (including no change) scenarios for changes in \$ / client, starting with the best case scenario {three percent decrease in \$ / client, Hi (-)} and finishing with the worst case scenario {three percent increase in \$ / client, Hi(+)}. The seven scenarios for changes in client counts are listed across the table.

<b>\$ / Client Scenarios</b>	<b>Number of Client Scenarios</b>						
	<b>Hi (-) CI</b>	<b>Med (-) CI</b>	<b>Lo (-) CI</b>	<b>Zero Change in Clients</b>	<b>Lo (+) CI</b>	<b>Med (+) CI</b>	<b>Hi (+) CI</b>
<b>Hi (-): Best</b>	\$377,020,766	\$380,852,256	\$384,683,745	\$388,515,234	\$392,346,723	\$396,178,213	\$400,009,702
<b>Med (-)</b>	\$380,852,256	\$384,723,245	\$388,594,234	\$392,465,223	\$396,336,212	\$400,207,201	\$404,078,191
<b>Lo (-)</b>	\$384,683,745	\$388,594,234	\$392,504,723	\$396,415,212	\$400,325,701	\$404,236,190	\$408,146,679
<b>Zero Change in \$ / Client</b>	\$388,515,234	\$392,465,223	\$396,415,212	\$400,365,201	\$404,315,190	\$408,265,179	\$412,215,168
<b>Lo (+)</b>	\$392,346,723	\$396,336,212	\$400,325,701	\$404,315,190	\$408,304,679	\$412,294,168	\$416,283,656
<b>Med (+)</b>	\$396,178,213	\$400,207,201	\$404,236,190	\$408,265,179	\$412,294,168	\$416,323,156	\$420,352,145
<b>Hi (+): Worst</b>	\$400,009,702	\$404,078,191	\$408,146,679	\$412,215,168	\$416,283,656	\$420,352,145	\$424,420,634

The center cell, highlighted in light blue, shows the revised estimated expenditures for FY 2009-10, using the 95 percent CI from the Linear Regression Model. The best case scenario, which is a three percent decrease in \$/client coupled with a three percent decrease in the number of clients, results in an estimate of \$377,020,766 (top left cell, light green). The worst case scenario, a three percent increase in \$/client coupled with a three percent increase in number of clients, results in an estimate of \$424,420,634 (bottom right cell, red). The table provides a range of values to assist in projecting the total expenditures for FY 2009-10.

**FY 2010-11**

Below is the sensitivity analysis for FY 2010-11, using the same logic as above. In this Sensitivity Analysis, ADAP adjusted for several assumptions that impacted ADAP's FY 2010-11 total expenditures, non-approved transaction fees, and total client count. Similar to the FY 2009-10 Sensitivity Analysis, we started with the estimated total drug expenditures for FY 2010-11 using the upper bound of the 95 percent CI from the Linear Regression Model. Then we subtracted savings for the administration reduction in PBM contract costs, AWP rollback, reduction and limit on non-approved transactions, and changes in jail policy coverage. Additional expenditures from serving NQA and PRUCOL clients were included for final total expenditures. For final clients served, corresponding adjustments were made for jail policy coverage and NQA and PRUCOL clients. The "baseline" or center cell, highlighted in light blue below, reflects all adjustments to the linear regression expenditure projection. The table provides a range of values to assist in projecting the total expenditures for FY 2010-11.

<b>\$ / Client Scenarios</b>	<b>Number of Client Scenarios</b>						
	<b>Hi (-) CI</b>	<b>Med (-) CI</b>	<b>Lo (-) CI</b>	<b>Zero Change in Clients</b>	<b>Lo (+) CI</b>	<b>Med (+) CI</b>	<b>Hi (+) CI</b>
<b>Hi (-): Best</b>	\$406,099,794	\$410,255,148	\$414,410,502	\$418,565,856	\$422,721,211	\$426,876,565	\$431,031,919
<b>Med (-)</b>	\$410,255,148	\$414,453,341	\$418,651,534	\$422,849,727	\$427,047,919	\$431,246,112	\$435,444,305
<b>Lo (-)</b>	\$414,410,502	\$418,651,534	\$422,892,565	\$427,133,597	\$431,374,628	\$435,615,660	\$439,856,691
<b>Zero Change in \$ / Client</b>	\$418,565,856	\$422,849,727	\$427,133,597	\$431,417,467	\$435,701,337	\$439,985,207	\$444,269,078
<b>Lo (+)</b>	\$422,721,211	\$427,047,919	\$431,374,628	\$435,701,337	\$440,028,046	\$444,354,755	\$448,681,464
<b>Med (+)</b>	\$426,876,565	\$431,246,112	\$435,615,660	\$439,985,207	\$444,354,755	\$448,724,302	\$453,093,850
<b>Hi (+): Worst</b>	\$431,031,919	\$435,444,305	\$439,856,691	\$444,269,078	\$448,681,464	\$453,093,850	\$457,506,236

## APPENDIX I: HISTORY OF PROJECTION METHODS

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

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

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

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

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

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

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

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

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