

# **Genetic Disease Screening Program (GDSP)**

**FY 2016-17 November Estimate**



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**Department of Public Health**

**TABLE OF CONTENTS**

<b>I.</b>	<b>ESTIMATE</b>	
	a. Program Overview	2
	b. Combined State Operations and Local Assistance Expenditure Overview	2
	c. Local Assistance Expenditure Projections	3
	i. Current Year	3
	ii. Budget Year	3
	iii. Future Fiscal Considerations	3
	iv. Expenditure Estimate Methodology	3
	v. NBS Expenditure Projections	4
	vi. PNS Expenditure Projections	5
	vii. Operational Support Expenditure Projections	5
	d. State Operations Expenditure Projections	6
	e. Revenue Projections	6
	i. Combined NBS/PNS Revenue	6
	ii. Revenue Estimate Methodology	7
	iii. NBS Revenue	7
	iv. PNS Revenue	7
<b>II.</b>	<b>FUND CONDITION STATEMENT</b>	9
<b>III.</b>	<b>General Assumptions</b>	10
	1. New Assumptions/ Premises	10
	2. Existing (Significantly Changed) Assumptions/Premises	11
	3. Unchanged Assumptions/Premises	11
	4. Discontinued Assumptions/Premises	11
<b>IV.</b>	<b>APPENDIX A: Newborn Screening Program Assumptions and Rationale</b>	12
	1. Contract Laboratories	12
	2. Technical And Scientific	14
	3. Case Management and Coordination	15
	4. Diagnostic Services	17
	5. Reference Laboratories	19
<b>V.</b>	<b>APPENDIX B: Prenatal Screening Program Assumptions and Rationale</b>	21
	1. Contract Laboratories	21
	2. Technical And Scientific	23
	3. Prenatal Diagnostic Services	24
	4. Case Management and Coordination	27
<b>VI.</b>	<b>APPENDIX C: Revenue Assumptions</b>	29
	1. NBS Revenue	29
	2. PNS Revenue	29

**GDSP Program Overview**

The California Department of Public Health (CDPH), Genetic Disease Screening Program (GDSP) Estimate provides a revised projection of Fiscal Year (FY) 2015-16 expenditures along with projected costs for FY 2016-17 Local Assistance and State Operations budget for GDSP.

The GDSP Local Assistance budget funds two distinct programs: the Newborn Screening Program (NBS) and the Prenatal Screening Program (PNS). NBS is a mandatory program that screens all infants born in California for genetic diseases. Parents may opt out their newborn from the program by claiming religious exemptions. PNS is an opt-in program for women who desire to participate. The screening-test provides the pregnant woman with a risk profile. Screens that meet or exceed a specified risk threshold are identified and further testing and counseling/coordination services are offered at no additional expense to the participant.

**Combined State Operations and Local Assistance Overview**

The GDSP 2015 Budget Act appropriation is \$118,634,018, of which \$89,712,018 is for Local Assistance and \$28,922,000 is for State Operations. GDSP estimates revised FY 2015-16 expenditures of \$114,484,327 which is a decrease of \$4,149,691 or 3.5% compared to the 2015 Budget Act. The combined State Operations and Local Assistance budget expenditures for FY 2016-17 total \$118,486,783, which is a decrease of \$147,235 or 0.1% compared to the 2015 Budget Act.

Table 1 shows the difference between the 2015 Budget Act appropriation and the revised FY 2015-16 expenditures and proposed FY 2016-17 expenditures for GDSP. The increase in State Operations in FY 2015-16 of \$420,000 or 1.5% is associated with baseline adjustments for salary, benefits and other state staff and facility costs. The decrease in Local Assistance of \$4,569,691 in FY 2015-16 is attributed to changes in caseload for both the NBS and PNS programs as well as the fact that women with positive PNS screening results continue to choose the less invasive and less expensive, Non-Invasive Prenatal Testing (NIPT) option as a covered benefit more often than expected. NIPT is less expensive than amniocentesis and chorionic villus sampling (CVS), the other covered benefits available to women who have positive PNS screening results. Also, in FY 2016-17 GDSP will move \$3.9 million dollars from State Operations to Local Assistance because the testing of Severe Combined Immunodeficiency (SCID) is now possible with an FDA approved test kit allowing the testing to be moved from the central lab-in-a-lab to the regional testing laboratories. The existing funding for these contract laboratories is Local Assistance dollars.

Table 1

GDSP: Current Year and Budget Year Budget Summaries Compared to 2015 Budget Act

Fund 0203 Genetic Disease Testing Fund	FY 2015-16 Budget Act	FY 2015-16			FY 2016-17		
		November Estimate FY 2015-16	Change from Budget Act	Percent Change from Budget Act	November Estimate FY 2016-17	Change from Budget Act	Percent Change from Budget Act
Total	\$ 118,634,018	\$ 114,484,327	\$ (4,149,691)	-3.5%	\$ 118,486,783	\$ (147,235)	-0.1%
State Operations	\$ 28,922,000	\$ 29,342,000	\$ 420,000	1.5%	\$ 26,336,000	\$ (2,586,000)	-8.9%
Local Assistance	\$ 89,712,018	\$ 85,142,327	\$ (4,569,691)	-5.1%	\$ 92,150,783	\$ 2,438,765	2.7%

**GDSP Local Assistance Projections**

**Current Year (FY 2015-16)**

The GDSP 2015 Budget Act appropriation for GDSP’s Local Assistance is \$89,712,018. GDSP anticipates revised FY 2015-16 expenditures of \$85,142,327 which is a decrease of \$4,569,691 or 5.1% compared to the 2015 Budget Act. The difference between the 2015 Budget Act and the revised estimated expenditures is the result of caseload fluctuations in current year in PNS which radiates out to savings in the Case Management and Coordination Services and prenatal diagnostic center areas. In addition, the continuing increased choice of NIPT as a follow-up procedure by women with positive PNS results, also contributes to the decrease.

**Budget Year (FY 2016-17)**

For FY 2016-17, GDSP estimates Local Assistance expenditures will total \$92,150,783, which is an increase of \$2,438,765 or 2.7% compared to the 2015 Budget Act. This projected increase in expenditures is due to increased spending in NBS to test for Adrenoleukodystrophy (ALD) as required by Chapter 565, Statute of 2014 (AB 1559).

Table 2 shows the difference between the 2015 Budget Act appropriation and the revised FY 2015-16 expenditures and proposed FY 2016-17 expenditures for the GDSP Local Assistance.

Table 2

Local Assistance Total: Current Year and Budget Year Budget Summaries Compared to 2015 Budget Act							
Fund 0203 Genetic Disease Testing Fund	FY 2015-16 Budget Act	FY 2015-16			FY 2016-17		
		November Estimate FY 2015-16	Change from Budget Act	Percent Change from Budget Act	November Estimate FY 2016-17	Change from Budget Act	Percent Change from Budget Act
Local Assistance Total	\$ 89,712,018	\$ 85,142,327	\$ (4,569,691)	-5.1%	\$ 92,150,783	\$ 2,438,765	2.7%
NBS	\$ 36,357,366	\$ 36,039,031	\$ (318,335)	-0.9%	\$ 42,769,479	\$ 6,412,113	17.6%
PNS	\$ 39,975,652	\$ 35,724,295	\$ (4,251,357)	-10.6%	\$ 36,002,304	\$ (3,973,348)	-9.9%
Operational Support	\$ 13,379,000	\$ 13,379,000	\$ -	0.0%	\$ 13,379,000	\$ -	0.0%

**Future Fiscal Considerations**

Beyond FY 2015-16 GDSP foresees two developments that may impact the program’s budget and operations:

**Electronic Medical Records (EMR)** - In the coming years GDSP will have to adapt its systems and capacities to allow for the implementation and meaningful use of EMR. As the rest of healthcare moves to electronic storage and access to medical records, GDSP, as a provider of health care services, needs to ensure that we are included in the process. The fiscal impacts of implementing EMR are unknown at this time, as the scope and complexity of the project are still being determined. GDSP will actively pursue any Federal Grant opportunities that may become available to support the adoption of EMR.

**Assembly Bill (AB) 959, Lesbian, Gay, Bisexual, and Transgender Disparities Reduction Act** - This bill requires CDPH programs that collect Race/Ethnicity to also collect Sexual Orientation and Gender Identity information as early as possible, but no later than July 1, 2018. Currently GDSP collects Race/Ethnicity on the NBS and PNS Test Requisition Forms (TRF) and

will have to modify the TRF and make changes to the SIS system to be able to collect this information. This addition will cost up to \$160,000 in one-time costs to make changes to Screening Information System and ongoing costs of up to \$105,000 for printing of the revised TRFs. GDSP expects these changes to go into effect in FY 2017-18.

### Expenditure Methodology / Key Drivers of Cost

The GDSP Local Assistance expenditures are split into three areas: PNS, NBS and Operational Support. Operational Support costs are considered fixed, in that they do not fluctuate greatly with changes in caseload. For both PNS and NBS programs areas, the key drivers of cost are the following:

1. NBS and PNS projected caseloads for the following:
  - a. Total clients served
  - b. Cases that receive Case Management
  - c. Cases that are referred for Diagnostic Services
  - d. Cases that are referred to Reference Laboratories (NBS only)
2. Average Case Cost for the following services:
  - a. Contract Laboratories
  - b. Technology & Scientific Supplies (Tech & Sci)
  - c. Case Management and Coordination Services (CMCS)
  - d. Follow-Up Diagnostic Services (FDS)
  - e. Reference Laboratories (NBS only)

To calculate the total projected Local Assistance costs, CDPH projects NBS and PNS caseloads and multiplies them against their respective projected average cost. Once total NBS and PNS costs are calculated, they are added to the Operational Support costs to calculate the total GDSP Local Assistance cost.

- NBS Total Costs equal the sum of:
  - Total Clients Served x Contract Laboratory Average Cost
  - Total Clients Served x Technology and Scientific Average Cost
  - Case Management Cases x Case Management and Coordination Average Cost
  - Diagnostic Services Cases x Diagnostic Services Average Cost
  - Reference Laboratory Cases x Reference Laboratory Average Cost
- PNS Total Costs equal the sum of:
  - Total Clients served x Contract Laboratory Average Cost
  - Total Clients Served x Technology and Scientific Average Cost
  - Case Management Cases x Case Management and Coordination Average Cost
  - Diagnostic Services Cases x Diagnostic Services Average Cost
- Operational Support Costs are the sum of various services contracts that support GDSP, including IT and courier services.

Below, we summarize the projections for each of the drivers of cost for the NBS and PNS programs. More detailed description of the assumptions and rationale underlying each component of cost is presented in the appendices.

**NBS Expenditure Projections (See Appendices A1-A5)**

For FY 2015-16 GDSP revised NBS Local Assistance expenditures total \$36,039,031, which is a decrease of \$318,335 or 0.9% compared to 2015 Budget Act amount of \$36,357,366.

For FY 2016-17 GDSP estimates that NBS Local Assistance expenditures will total \$42,769,479, which is an increase of \$6,412,113 or 17.6 % compared to 2015 Budget Act amount. Newborn Screening expenditure increases are due to additional costs for ALD screening and follow-up, the transfer of SCID funds from State Operations to Local Assistance, contract increases to CMCS, Tech & Sci, and Reference Labs costs.

Table 3 shows the difference between the 2015 Budget Act (based on May Revision Estimates) appropriation and the revised FY 2015-16 expenditures and proposed FY 2016-17 expenditures for the Newborn Screening program costs by client type.

Table 3

NBS: Current Year and Budget Year Budget Summaries Compared to 2015 Budget Act

Fund 0203 Genetic Disease Testing Fund	FY 2015-16 Budget Act	FY 2015-16			FY 2016-17		
		November Estimate FY 2015-16	Change from Budget Act	Percent Change from Budget Act	November Estimate FY 2016-17	Change from Budget Act	Percent Change from Budget Act
<b>Total</b>	\$ 36,357,366	\$ 36,039,031	\$ (318,335)	-0.9%	\$ 42,769,479	\$ 6,412,113	17.6%
Lab Dollars	\$ 6,832,090	\$ 6,778,501	\$ (53,589)	-0.8%	\$ 8,227,065	\$ 1,394,975	20.4%
Tech Sci	\$ 21,783,476	\$ 21,537,773	\$ (245,703)	-1.1%	\$ 26,742,077	\$ 4,958,601	22.8%
Reference Lab	\$ 1,935,000	\$ 1,871,181	\$ (63,819)	-3.3%	\$ 1,877,854	\$ (57,146)	-3.0%
CMCS	\$ 4,324,800	\$ 4,141,325	\$ (183,475)	-4.2%	\$ 4,168,179	\$ (156,621)	-3.6%
Diagnostic Services	\$ 1,482,000	\$ 1,710,250	\$ 228,250	15.4%	\$ 1,754,305	\$ 272,305	18.4%

**PNS Expenditures Projections (See Appendices B1-B4)**

For FY 2015-16 GDSP revised PNS Local Assistance expenditures total \$35,724,295, which is a decrease of \$4,251,357 or 10.6% compared to 2015 May Revision amount of \$39,975,652.

For FY 2016-17 GDSP estimates that PNS Local Assistance expenditures will total \$36,002,304, which is a decrease of \$3,973,348 or 9.9% compared to 2015 Budget Act amount. The decrease in cost in the current year and budget year are due to a projected decrease in the average cost of Prenatal Diagnostic Center (PDC) services. This decrease in average cost is the result of an increase in the use of Non-Invasive Prenatal Testing (NIPT). NIPT is used as a follow-up service for women that opt in to diagnostic care. NIPT represents cost savings compared to the panel of invasive tests it replaces.

Table 4 shows the difference between the 2015 Budget Act (based on May Revision Estimates) appropriation and the revised FY 2015-16 expenditures and proposed FY 2016-17 expenditures for the Prenatal Screening program costs by client type.

Table 4

PNS: Current Year and Budget Year Budget Summaries Compared to 2015 Budget Act

Fund 0203 Genetic Disease Testing Fund	FY 2015-16 Budget Act	FY 2015-16			FY 2016/17		
		November Estimate FY 2015-16	Change from Budget Act	Percent Change from Budget Act	November Estimate FY 2016-17	Change from Budget Act	Percent Change from Budget Act
<b>Total</b>	\$ 39,975,652	\$ 35,724,295	\$ (4,251,357)	-10.6%	\$ 36,002,304	\$ (3,973,348)	-9.9%
Contract Lab	\$ 5,721,517	\$ 4,875,395	\$ (846,122)	-14.8%	\$ 4,910,324	\$ (811,193)	-14.2%
Tech & Sci	\$ 13,392,952	\$ 12,483,407	\$ (909,545)	-6.8%	\$ 12,572,842	\$ (820,110)	-6.1%
CMCS	\$ 5,670,000	\$ 5,582,036	\$ (87,964)	-1.6%	\$ 5,644,096	\$ (25,904)	-0.5%
PDC	\$ 15,191,183	\$ 12,783,458	\$ (2,407,725)	-15.8%	\$ 12,875,043	\$ (2,316,140)	-15.2%

**Operational Support Projections**

For FY 2015-16 GDSP estimates that Operational Support expenditures will total \$13,379,000, which is no change compared to 2015- Budget Act amount of \$13,379,000. In FY 2016-17 GDSP projects Operational Support expenditures will total \$13,379,000, which is no change compared to the 2015 Budget Act amount of \$13,379,000. Table 5 shows the difference between the 2015 Budget Act (based on May Revision Estimates) appropriation and the revised FY 2015-16 expenditures and proposed FY 2016-17 expenditures for the Program Operational Support costs.

Table 5

Operational Support: Current Year and Budget Year Budget Summaries Compared to 2015 Budget Act

Fund 0203 Genetic Disease Testing Fund	FY 2015-16 Budget Act	FY 2015-16			FY 2016-17		
		November Estimate FY 2015-16	Change from Budget Act	Percent Change from Budget Act	November Estimate FY 2016-17	Change from Budget Act	Percent Change from Budget Act
Operational Support	\$ 13,379,000	\$ 13,379,000	\$ -	0.0%	\$ 13,379,000	\$ -	0.0%

**State Operations**

State Operations expenditures are estimated separately from Local Assistance expenditures. State Operations expenditures fluctuate based on Department of Finance standard adjustments for salaries, benefits, and other state staff and facility costs.

In FY 2015-16, GDSP estimates that State Operations expenditures will total \$29,342,000, which is an increase of \$420,000 or 1.45% compared to 2015 Budget Act amount and is associated with baseline adjustments for salary, benefits and other state staff and facility costs.

In FY 2016-17, GDSP estimates State Operations expenditures will total \$26,336,000, which is a decrease of \$2,586,000 or 8.9% compared to 2015 Budget Act. The decrease is associated with the transfer of \$3,900,000 from State Operations to Local Assistance. The move of \$3.9 million dollars from State Operations to Local Assistance is due to the fact that testing of Severe Combined Immunodeficiency (SCID) is now being done with an FDA approved test kit in the regional testing laboratories as opposed to the central lab-in-a-lab that was used when GDSP began testing for SCID.

Table 6 shows the difference between the 2015 Budget Act appropriation and the revised FY 2015-16 expenditures and proposed FY 2016-17 expenditures for the GDSP State Operations costs.

Table 6

State Operations: Current Year and Budget Year Budget Summaries Compared to 2015 Budget Act							
Fund 0203 Genetic Disease Testing Fund	FY 2015-16 Budget Act	FY 2015-16			FY 2016-17		
		November Estimate FY 2015-16	Change from Budget Act	Percent Change from Budget Act	November Estimate FY 2016-17	Change from Budget Act	Percent Change from Budget Act
State Operations	\$ 28,922,000	\$ 29,342,000	420,000	1.45%	\$ 26,336,000	\$ (2,586,000)	-8.9%

**Revenue Projections**

**Combined NBS and PNS Revenue**

GDSP has revised revenue estimates for FY 2015-16 totaling \$117,906,212, which is a decrease of \$3,458,000 or less than 2.8% compared to 2015 Budget Act amount of \$121,364,212.

For FY 2016-17 GDSP projects revenue will total \$124,109,523, which is an increase of \$2,745,311 or 2.3% compared to the 2015 Budget Act amount of \$121,364,212.

All other assumptions and calculations remain unchanged from the 2015 Budget Act.

**Revenue Methodology**

Effective July 1, 2014 PNS charges a fee of \$207, \$197 of which is deposited into the Genetic Disease Testing Fund (Fund 0203), the remaining \$10 is deposited into the California Birth Defects Monitoring Program Fund (Fund 3114). GDSP collects PNS fees from individual participants, private insurers and Medi-Cal.

For PNS, GDSP is able to collect approximately 98% of all fees owed on behalf of Medi-Cal clients (which is approximately 45% of the total caseload), and approximately 83% of the fees owed by individuals with private insurances.

GDSP uses the following formula to estimate revenue generated from PNS fees:

$$\text{(Fee} \times \text{PNS Participants} \times \text{Medi-Cal Participation Rate} \times \text{Medi-Cal Collection Rate)} + \text{(Fee} \times \text{PNS Participants} \times (1 - \text{Medi-Cal Participation Rate}) \times \text{Private Payer Collection Rate)}$$

NBS participants are charged a fee of \$112.70. Unlike PNS, where GDSP bills patients and collects fees from insurers, GDSP collects NBS revenue from hospitals and providers directly (this is only possible because NBS is a mandated service). As such the billing for NBS services is much more streamlined resulting in a 98% collection rate. GDSP uses the following formula to estimate revenue generated from NBS fees.

$$\text{Fee} \times \text{\# of Projected Newborns screened} \times \text{Collection Rate}$$

**NBS Revenue (See Appendix C-1)**

In FY 2015-16 NBS revenue is expected to total \$54,510,292, which is a decrease of \$169,203 or 0.3% compared to 2015 Budget Act amount of \$54,679,495. This decrease is attributed to a slight decrease in caseload.

In FY 2016-17 GDSP projects NBS revenue will total \$60,259,384, which is an increase of \$5,579,889 or 10.2% compared to 2015 Budget Act amount of \$54,679,495.

GDSP anticipates initiating screening for Adrenoleukodystrophy (ALD) in mid-2016. Additional testing and follow-up costs associated with screening for ALD necessitate a fee increase of \$11.00 per specimen that will begin July 1, 2016. The program participation fee will be \$123.70, which is charged directly to hospitals or other providers. The collection rate remains unchanged. Revenue for NBS for FY 2016-17 will be \$60,259,384, an increase of \$5,579,889 or 10.2%.

**PNS Revenue (See Appendix C2)**

In FY 2015-16 PNS revenue is expected to total \$63,395,920, which is a decrease of \$3,288,797 or 4.9% compared to the 2015 Budget Act amount of \$66,684,717.

In FY 2016-17 GDSP projects PNS revenue will total \$63,850,139, which is a decrease of \$2,834,578 or 4.3% compared to the 2015 Budget Act amount of \$66,684,717.

Table 7 shows the revised current year revenue projections for current year and budget year compared to 2015 Budget Act.

**Table 7**

GDSP Revenue: Current Year and Budget Year Revenue Summaries Compared to 2015 Budget Act							
Fund 0203 Genetic Disease Testing Fund	FY 2015-16 Budget Act	FY 2015-16			FY 2016-17		
		November Estimate FY 2015-16	Change from Budget Act	Percent Change from Budget Act	November Estimate FY 2016-17	Change from Budget Act	Percent Change from Budget Act
<b>Total</b>	\$ 121,364,212	\$ 117,906,212	\$ (3,458,000)	-2.8%	\$ 124,109,523	\$ 2,745,311	2.3%
NBS	\$ 54,679,495	\$ 54,510,292	\$ (169,203)	-0.3%	\$ 60,259,384	\$ 5,579,889	10.2%
PNS	\$ 66,684,717	\$ 63,395,920	\$ (3,288,797)	-4.9%	\$ 63,850,139	\$ (2,834,578)	-4.3%

**Fund Condition Statement**

GENETIC DISEASE TESTING FUND  
FUND CONDITION REPORT  
DOLLARS IN THOUSANDS

	2014-15	2015-16	2016-17
<b>RESOURCES</b>			
BEGINNING BALANCE	\$14,966	\$18,118	\$21,556
Prior Year Adjustment	-6,628	0	-
Adjusted Beginning Balance	8,338	18,118	21,556
<b>REVENUES</b>			
121100 Genetic Disease Testing Fees <sup>1/</sup>	121,001	117,906	124,110
150300 Income from Surplus Investments	11	11	11
161000 Escheat of Unclaimed Checks & Warrants	56	56	56
TOTALS, REVENUES	121,068	117,973	124,177
<b>TOTAL RESOURCES</b>	\$129,406	\$136,091	\$145,733

<b>EXPENDITURES AND EXPENDITURE ADJUSTMENTS</b>			
4265 Department of Public Health (State Operations)	25,781	29,342	26,336
4265 Department of Public Health (Local Assistance)	85,507	85,142	92,151
November Estimate Adjustments (Local Assistance)	-	0	0
0840 State Controller (State Operations)	-	0	-
8880 Financial Information System for California (State Operations)	-	51	36
<b>TOTAL EXPENDITURES AND EXPENDITURE ADJUSTMENTS</b>	<b>111,288</b>	<b>114,535</b>	<b>118,523</b>

<b>FUND BALANCE</b>	18,118 16%	21,556 19%	27,210 23%
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**REVENUE PROJECTIONS**

**2015-16**

2015-16 NBS FEES BASED ON	493,547 TESTS @	\$112.70	AND 98% Provider <sup>1/</sup>	=	\$54,510,292
2015-16 PNS FEES BASED ON	197,207 TESTS @	\$197.00	AND 83% Non Medi-Cal <sup>2/</sup>	=	\$32,245,303
2015-16 PNS FEES BASED ON	161,352 TESTS @	\$197.00	AND 98% Medi-Cal <sup>3/</sup>	=	\$31,150,617
	358,559				\$63,395,920
<b>GDSP Total</b>					<b>\$117,906,212</b>

**2016-17**

2016-17 NBS FEES BASED ON	497,083 TESTS @	\$123.70	AND 98% Provider <sup>1/</sup>	=	\$60,259,384
2016-17 PNS FEES BASED ON	198,620 TESTS @	\$197.00	AND 83% Non Medi-Cal <sup>2/</sup>	=	\$32,476,344
2016-17 PNS FEES BASED ON	162,508 TESTS @	\$197.00	AND 98% Medi-Cal <sup>3/</sup>	=	\$31,373,794
	361,128				\$63,850,139
<b>GDSP Total</b>					<b>\$124,109,523</b>

1/ NBS Fees based on 98% hospital and other provider collection rate  
 2/ PNS Fees based on 83% of private payer / insurance collection rate  
 3/ PNS Fees based on 98% Medi-Cal Collection rate

**General Assumptions****1. New Assumptions/ Premises****Transfer of Funds from State Operations to Local Assistance**

**Background:** When funds were allocated to GDSP for the addition of Severe Combined Immunodeficiency (SCID) testing to the Newborn Screening (NBS) panel following the chaptering of AB 395 in October 2011, all the funds were placed in State Operations. GDSP expected to do all the testing in-house, however, it was determined to be more appropriate to have SCID testing done by our regional screening laboratories and contracted with the regional screening laboratories to screen for SCID. Currently, funding for the regional screening laboratories is budgeted in Local Assistance. Therefore to be consistent with the way our funding is budgeted, GDSP needs to shift funds from State Operations to Local Assistance to pay for testing and test kits.

**Description of Change:** GDSP will need to transfer the funds for SCID testing (approximately \$3.9 million) from State Operations to Local Assistance.

**Discretionary:** No

**Reason for Adjustment/ Change:**

An FDA-approved testing kit for the screening of SCID is being used in the regional screening laboratories and funds need to be available in Local Assistance.

**Fiscal Impact (Range) and Fund Source(s):** This will require a shift of approximately \$3.9 million from State Operations to Local Assistance. The fund source is the Genetic Disease Testing Fund (0203).

**Assembly Bill (AB) 1559 (Chapter 565, Statute of 2014); Newborn Screening Program**

**Background:** AB 1559 (Chapter 565, Statute of 2014) will require the California Department of Public Health (CDPH) GDSP to expand statewide screening of newborns to include screening for adrenoleukodystrophy (ALD) as soon as ALD is adopted by the federal Recommended Uniform Screening Panel (RUSP). The federal Advisory Committee on Heritable Disorders in Newborns and Children (ACHDNC) recommended approval of ALD at the August 2015 meeting. The official recommendation was provided on September 25, 2015. The HHS Secretary will consider the recommendation and can add ALD to the RUSP at any time. HHS Secretary Burwell has approved one new disorder during her brief tenure, after eight months of consideration.

**Description of Change:** GDSP will be required to add ALD to the Newborn Screening panel and begin screening all babies in California for the disease as soon as ALD is added to the RUSP, so planning and preparation need to occur even before the HHS Secretary makes this final recommendation.

**Discretionary:** No

**Reason for Adjustment/ Change:**

Passage of AB 1559 which requires GDSP to add ALD as soon as ALD is adopted by the federal Recommended Uniform Screening Panel (RUSP)

**Fiscal Impact (Range) and Fund Source(s):** Approximately \$4.6 million per year and will require a fee increase of approximately \$11 per patient. Fund source is the Genetic Disease Testing Fund (0203).

**2. Existing (Significantly Changed) Assumptions/Premises**

None

**3. Unchanged Assumptions/Premises**

None

**4. Discontinued Assumptions/Premises**

**Lab Consolidation**

CDPH/GDSP contracts with seven laboratories around the state to provide NBS and PNS services for the babies and pregnant women of California. GDSP completed the consolidation of the seven regional laboratories to five in January 2015.

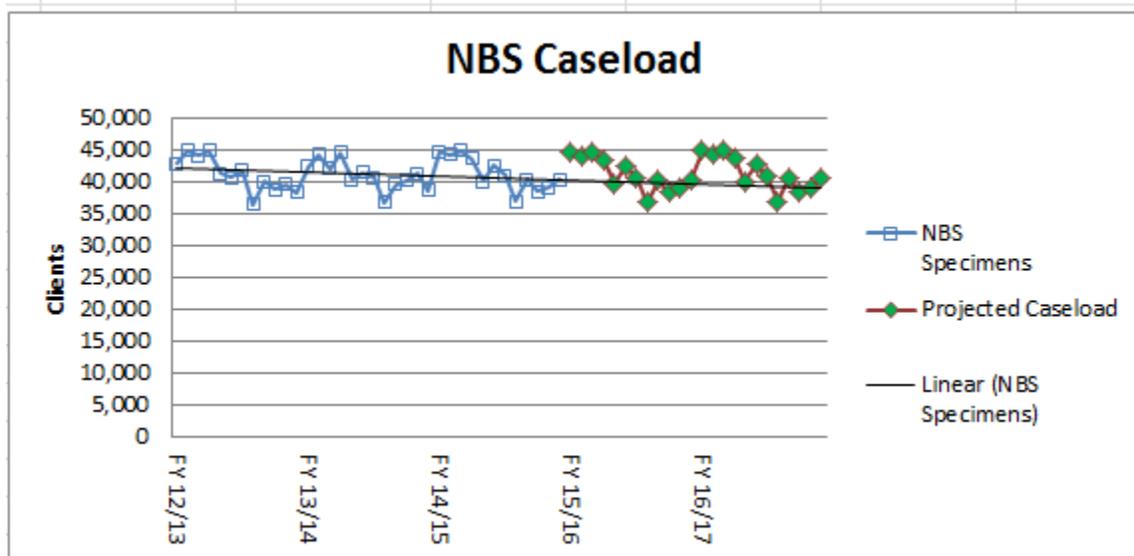
**Appendices**

**Appendix A: NBS Assumptions and Rationale**

**1. Contract Laboratories**

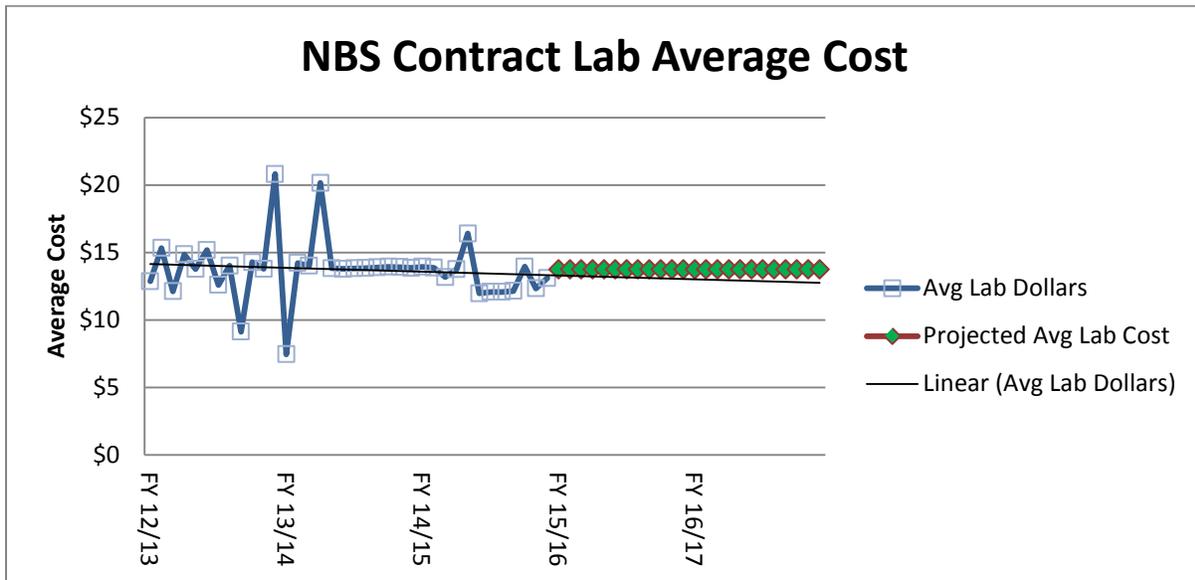
Overview: Laboratory testing of specimens is performed at regional screening laboratories contracted by the state to screen newborns for 75+ specific genetic disorders. Costs include laboratory services for processing genetic screening tests. Screening laboratories ascertain the possible presence of a birth defect or a congenital disorder; a screening test is not diagnostic, additional follow-up is likely to be required for a case that has an initial positive or questionable screening test result. The state contracts with several regional contract laboratories that are paid on a per specimen basis. Costs associated with Contract Laboratories and Technical and Scientific supplies are both driven by the total number of clients NBS serves. The total caseload is determined as a percentage of the Department of Finance (DOF) Demographic Research Unit’s (DRU) projected number of live births. This estimate assumes that 98% of the DOF/DRU projected births will participate in the NBS program.

Total Caseload – GDSP estimates current year caseload will total 493,547, a decrease of 2,877 or 0.58% compared to the FY 2014-15 actual total caseload of 496,424. Caseload in FY 2016-17 is estimated at 497,083, which is an increase of 3,536 or 0.72% compared to the current year estimate. This year increase is due to the DOF/DRU’s projected increase in the number of live births, GDSP assumes that 98% of births will participate in the NBS program each year. The following chart shows the actual NBS cases by month, along with our projected numbers for the remainder of the current year and budget year.

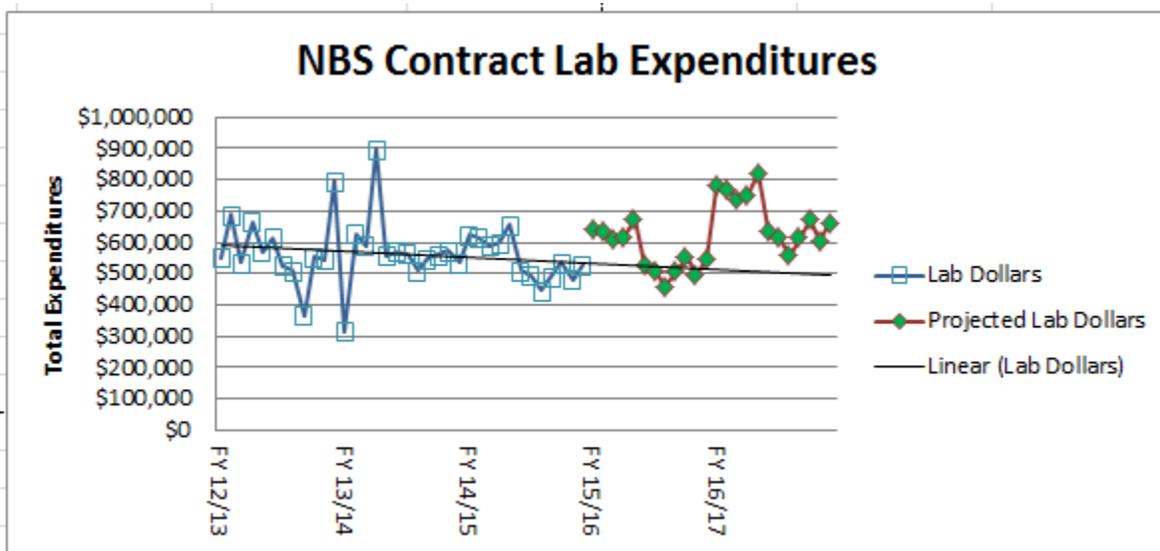


Contract Laboratory Average Cost Projections- GDSP estimates current year average laboratory cost per participant will be \$13.73, which is an increase of \$0.49 or 3.67% compared to the FY 2014-15 actual average laboratory cost per participant of \$13.24. Average laboratory cost per participant in FY 2016-17 is estimated at \$13.73, the increase in average cost in the

current year is the result of transition of SCID testing to the regional laboratories as well as laboratory consolidation, both of which required one-time costs for laboratory equipment.



Contract Laboratory Total Cost Projections - GDSP estimates current year contract laboratory cost to total \$6,778,502, which is an increase of \$203,598 or 3.10% compared to FY 2014-15 actual contract laboratory costs of \$6,574,903. Laboratory costs in FY 2016-17 are estimated to total \$8,227,065, an increase of \$1,448,563 or 21.37% compared to the current year estimate. The increase in cost in the current year is caused by the cost per client increase. The increase in costs in the budget year is the result of transferring \$1,400,000 of SCID dollars from State Operations to Contract Laboratory.

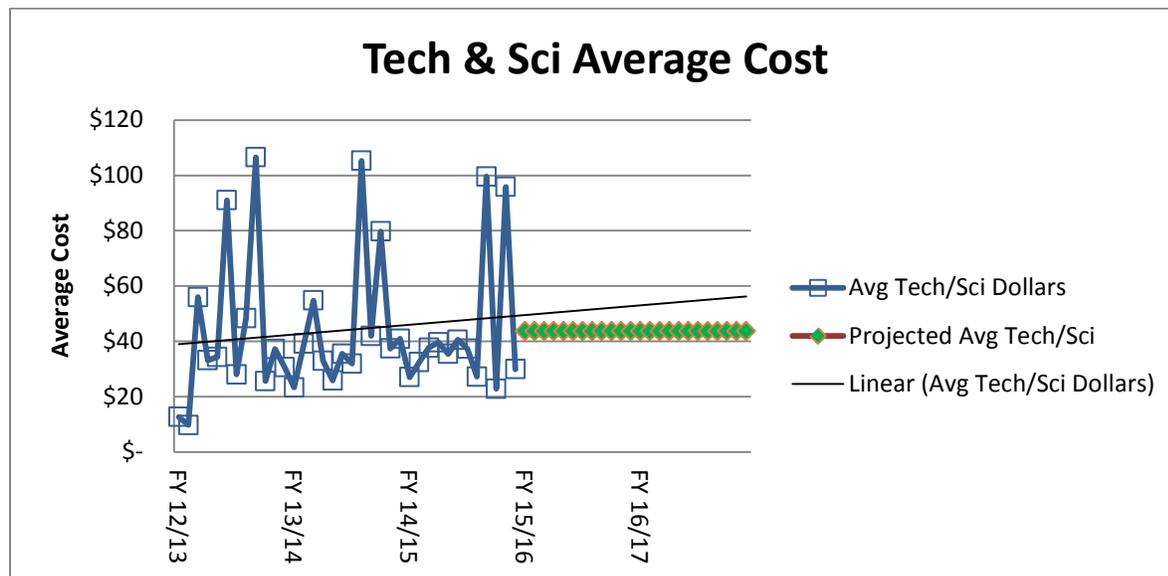


**2. Technical and Scientific**

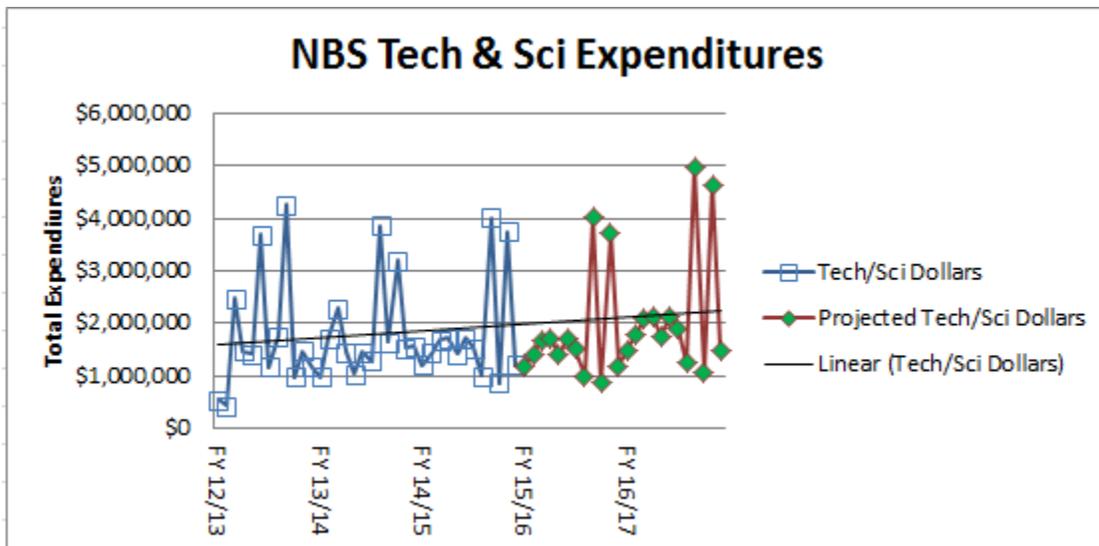
Overview: Costs associated with specimen screening include: reagents kits, supplies, processing, and limited maintenance and support (as it directly relates to the reagents) of laboratory equipment that is with the contract laboratories. In addition, there are minimal fixed costs associated with specimen screening including: laboratory supplies, blood specimen filter paper, blood specimen storage, and costs for special packaging for blood specimen transport, etc. Reagent kits, which are the majority of the Technology & Scientific costs, are purchased in lots based on anticipated caseload volume. Reagents vary in cost depending upon the type of screening performed.

Technical and Scientific Caseload: See Appendix A 1

Technical and Scientific Average Cost- GDSP estimates current year average Technical and Scientific cost per participant will be \$43.64, an increase of \$0.11 or 0.25% compared to FY 2014-15 actual average Technical and Scientific cost per participant of \$43.53. Average laboratory cost per participant in FY 2016-17 is estimated at \$43.64, which is no change compared to the current year estimate. The increase in average cost in the current year is the result of inflationary increases in the cost of reagents.



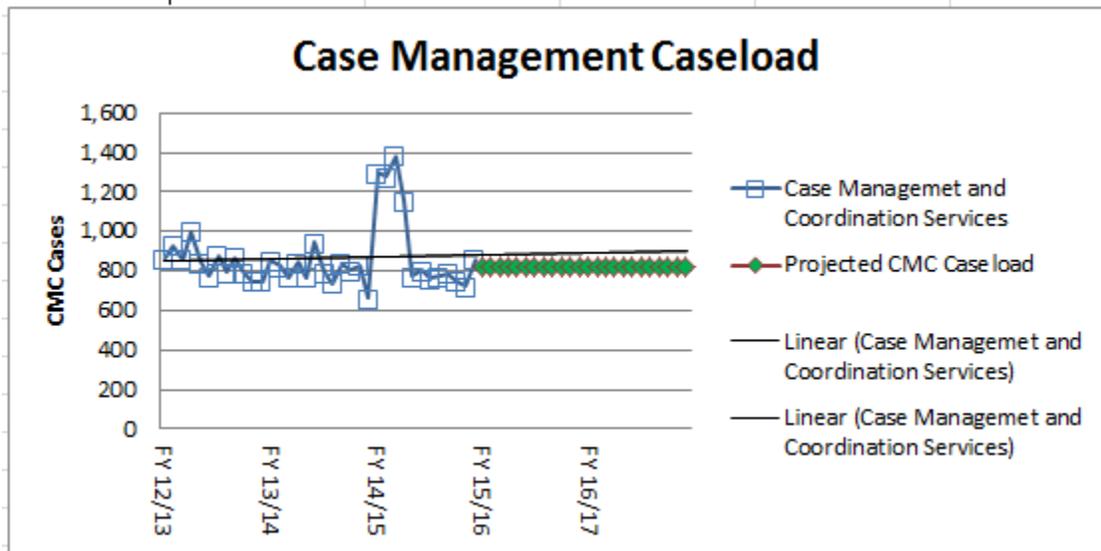
Technical and Scientific Total Cost- GDSP estimates current year Technical and Scientific costs to total \$21,537,773, which is a decrease of \$71,657 or 0.33% compared to FY 2014-15 actual technical and scientific costs of \$21,609,430. Technical and Scientific costs in FY 2016-17 are estimated to total \$26,742,077, which is an increase of \$5,204,304 or 24.16% compared to the current year estimate. The current year decrease in cost is attributable to case load decrease. The anticipated increase in FY 2016-17 is attributable to the transfer \$2,500,000 of SCID dollars from State Operations, additional funds for ALD screening and a 3% across the board increase in the cost of reagent kits.



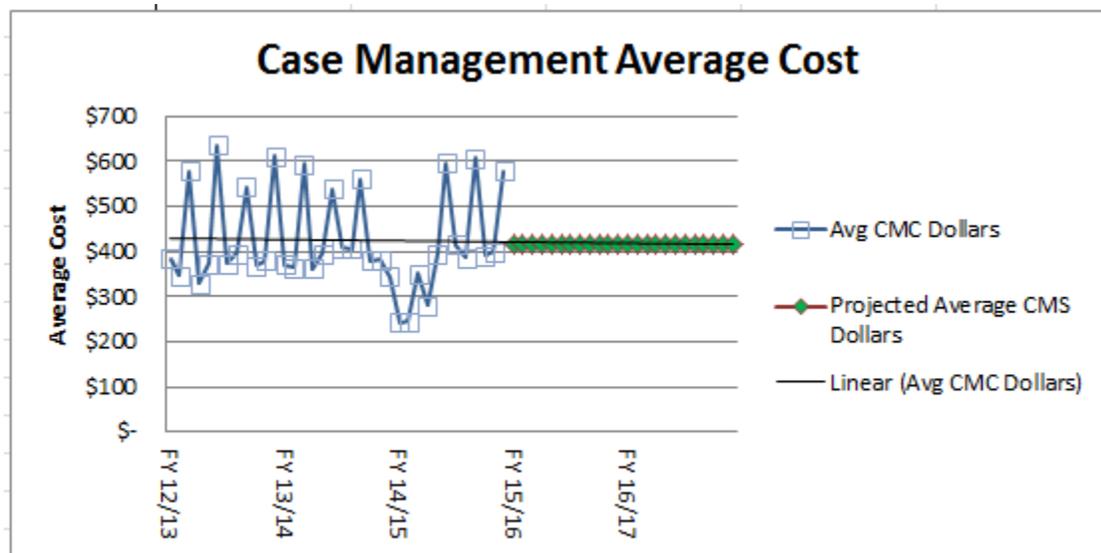
**3. Case Management and Coordination Services:**

Overview- Services are provided to infants who screen initial positive or have questionable screening test results for the 75+ genetic disorders screened. These services include: time-sensitive coordination for specific confirmatory testing, family consultation – including consultation with the infant’s pediatrician, genetic disease counseling, family educational services, and coordinated care referrals to specialized medical institutions. The NBS Area Service Centers (ASC) provide critical coordination and tracking services to ensure appropriate diagnostic measures are completed, and that affected infants are provided with appropriate medical care and receive treatment within a critical timeframe. The ASCs are reimbursed based on caseload and the type of service performed; this funding supports a required core team of clinical professionals. Costs vary by ASC, dependent upon the geographical location as well as the volume of caseload served.

Case Management and Coordination Services (CMCS) Caseload- GDSP estimates current year CMCS caseload will total 9,895, which is a decrease of 1,449 or 12.77% compared to FY 2014-15 actual CMCS caseload of 11,344. CMCS caseload in FY 2016-17 is estimated at 9,954, which is an increase of 16 or 0.16% compared to the current year estimate. The current year case load decrease is attributed to challenges GDSP experienced in FY 2014-15 with presumptive positive rates for one of the newborn screening tests. Case management caseload was higher than expected in FY 2014-15. It has stabilized and is expected to remain at pre FY 2014-15 levels with a slight addition for ALD cases.

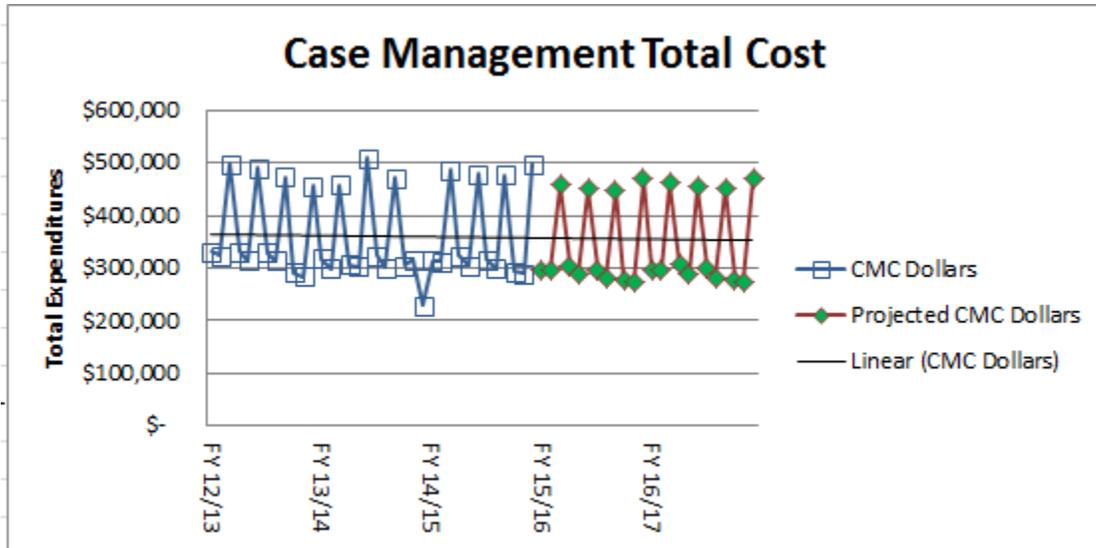


Case Management and Coordination Services (CMCS) Average Cost- GDSP estimates current year average CMCS cost per participant will be \$418.53, which is an increase of \$30.78 or 7.94% compared to FY 2014-15 actual average CMCS cost per participant of \$387.75. The average cost was artificially low in FY 2014-15 because of the increase in the number of positive screens (due to the higher than expected false positive rate with one of the tests). With the reduction of the number of positives, the average cost increases because there are some static charges associated with case management which do change based on caseload. Average CMCS cost per participant in FY 2016-17 is estimated at \$418.53, which is no change compared to the current year estimate. CMCS costs are a combination of fixed costs and incremental (per case) reimbursement.



Case Management and Coordination Services (CMCS) Total Cost- GDSP estimates current year CMCS costs to total \$4,141,325, which is a decrease of \$257,276 or 5.85% compared to FY 2014-15 actual CMCS total costs of \$4,398,601. CMCS costs in FY 2016-17 are estimated

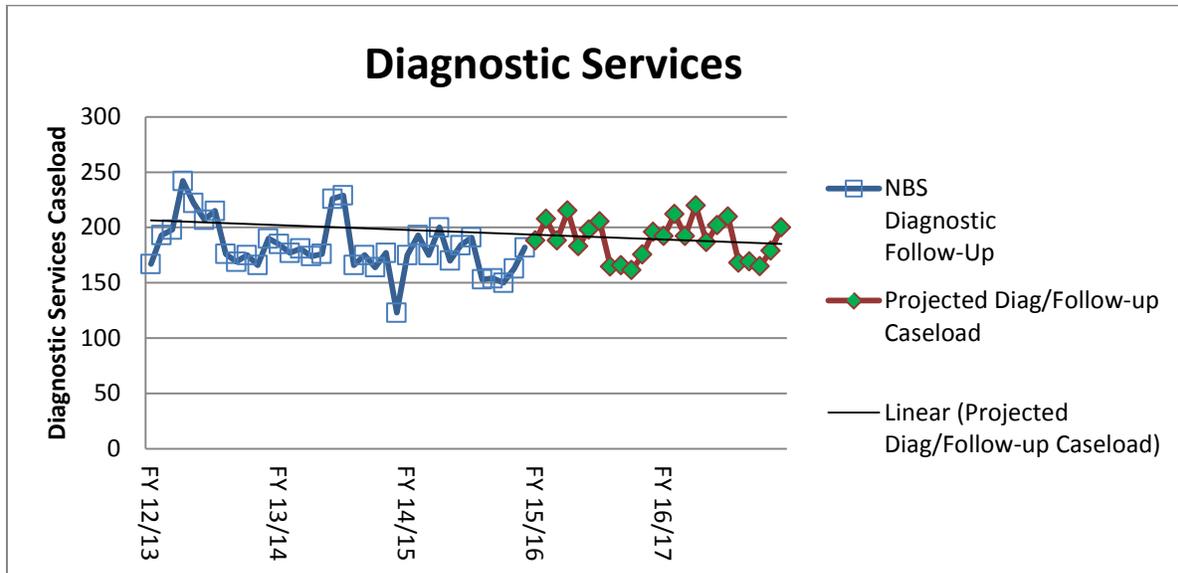
to total \$4,168,179, which is an increase of \$26,854 or 0.65% compared to the current year estimate. The increase is caused by the projected increase in caseload and follow-up of ALD cases in FY 2016-17.



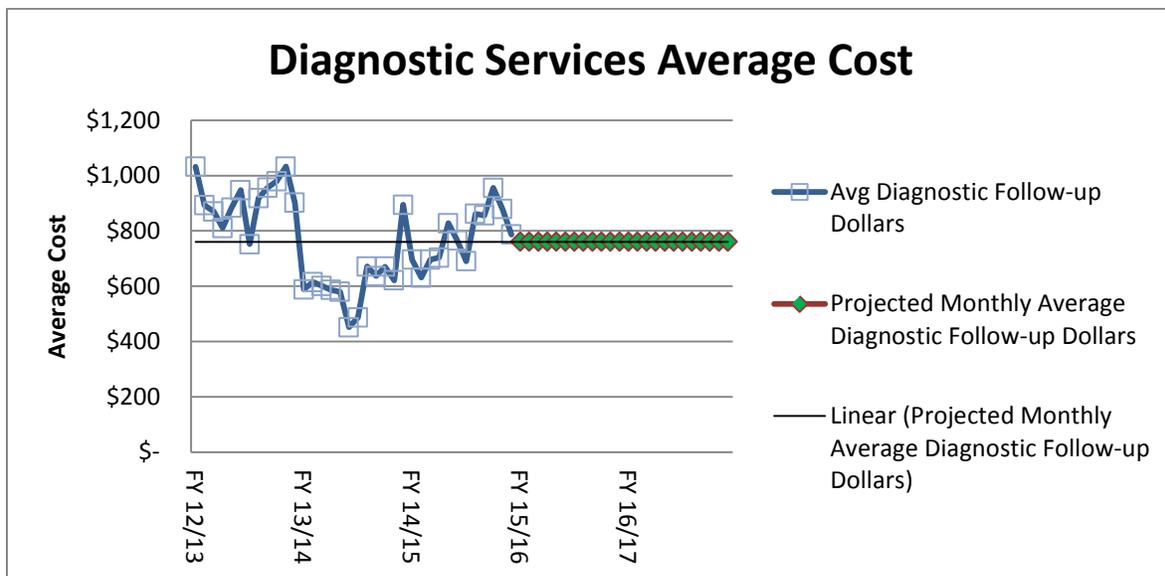
**4. Diagnostic Services:**

Overview- Diagnostic Services are for infants who require extended monitoring while undergoing confirmatory testing and diagnosis. Clinical outcome data is collected on infants once diagnosis is made as a means of tracking, confirming, evaluating, and refining program standards. Services include: coordination with the NBS ASC and GDSP for ongoing medical care, ensuring the establishment of infant treatment plans through specialty care hospitals and university medical centers specializing in the genetic disorders such as sickle cell anemia, cystic fibrosis, PKU, beta thalassemia, alpha thalassemia, and various neurologic, metabolic, and endocrine disorders, etc. Services are provided through Special Care Centers, which are composed of highly specialized medical teams; cost is based on per case reimbursement.

Diagnostic Services Caseload- GDSP estimates current year Diagnostic Services caseload will total 2,249, which is an increase of 159 or 7.61% compared to FY 2014-15 actual Diagnostic Services caseload of 2,090. Diagnostic caseload in FY 2016-17 is estimated at 2,296, which is an increase of 47 or 2.09% compared to the current year estimate. This is due largely to DOF DRU projected increase in the number of live births. The following chart shows the actual Diagnostic Services cases by month, along with our projected numbers for the remainder of the current year and budget year.



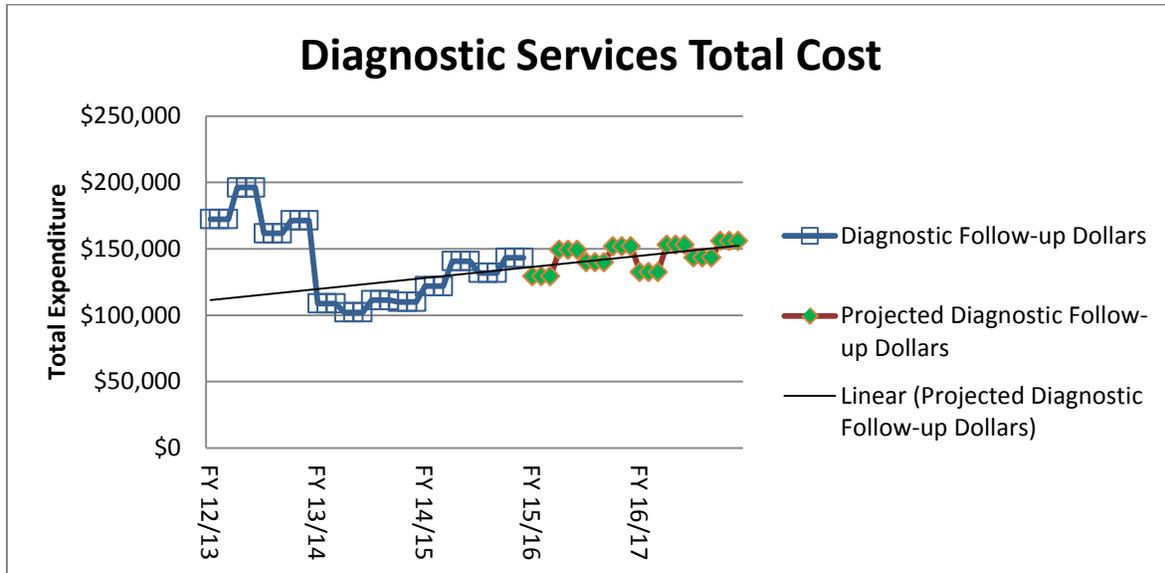
**Diagnostic Services Average Cost-** GDSP estimates current year average Diagnostic Services cost per participant will be \$760.45, which is a decrease of \$11.44 or 1.48% compared to FY 2014-15 actual average Diagnostic Services cost per participant of \$771.89\*. Average Diagnostic Services cost per participant in FY 2016-17 are estimated at \$760.51, which is an increase of \$0.06 or 0.01% compared to the current year estimate. Increase in average cost can be attributed to inflationary increases.



\*\$771.89 is based on an estimate of current year actuals. Due to the billing cycle for these services the actuals are incomplete as encumbrances have not been liquidated.

**Diagnostic Services Total Cost-** GDSP estimates current year Diagnostic Services costs to total \$1,710,251, which is an increase of \$97,001 or 6.01% compared to FY 2014-15 actual Diagnostic Services total costs of \$1,613,250. Diagnostic Services costs in FY 2016-17 are estimated to total \$1,754,305, which is an increase of \$44,054 or 2.58% compared to the

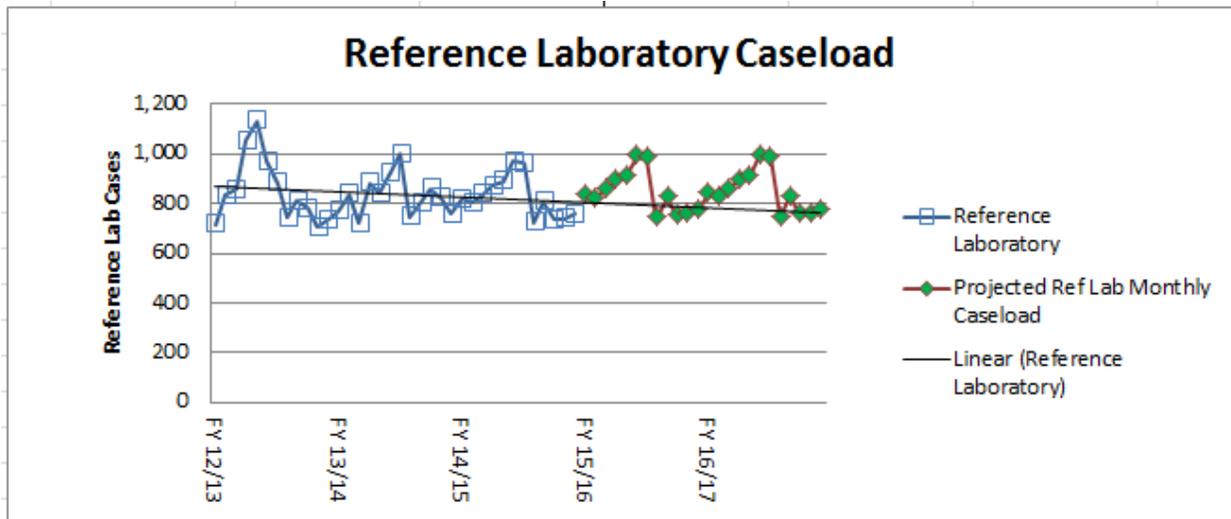
current year estimate. The increase is caused by the projected increase in caseload coupled with the small increase in the projected average Diagnostic Services costs as well as the addition of ALD cases to be followed.



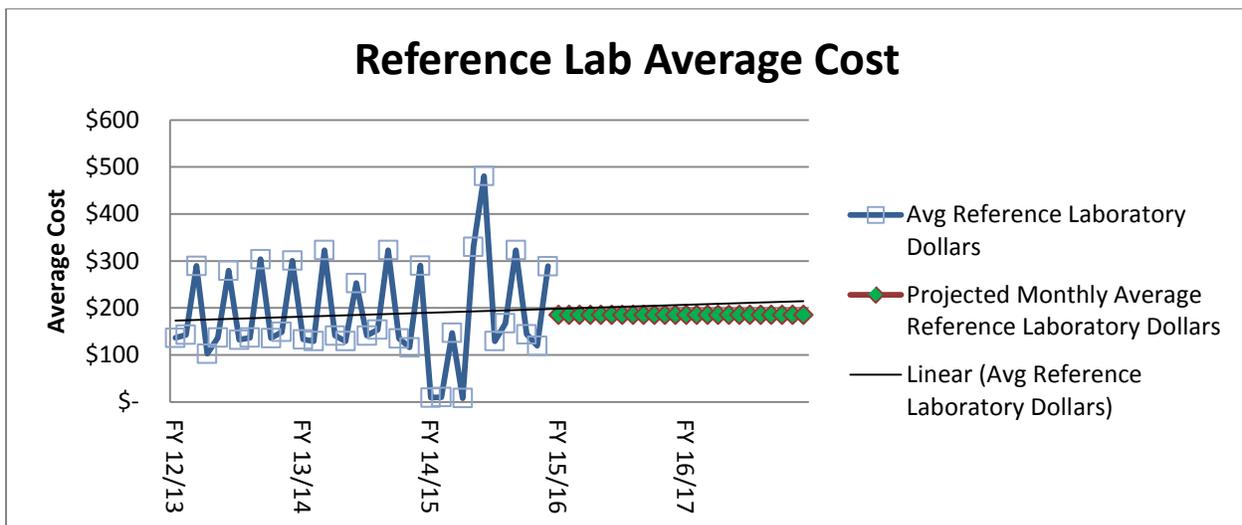
**5. Reference Laboratory Cases:**

Overview- Cases that result in a positive screening test are referred for diagnostic testing at various confirmatory laboratories. Costs include medical and confirmatory diagnostic tests, as well as fixed costs for lab technical support, and expert medical consultation services for rare genetic abnormalities. Reference Laboratories are reimbursed on a cost per test basis.

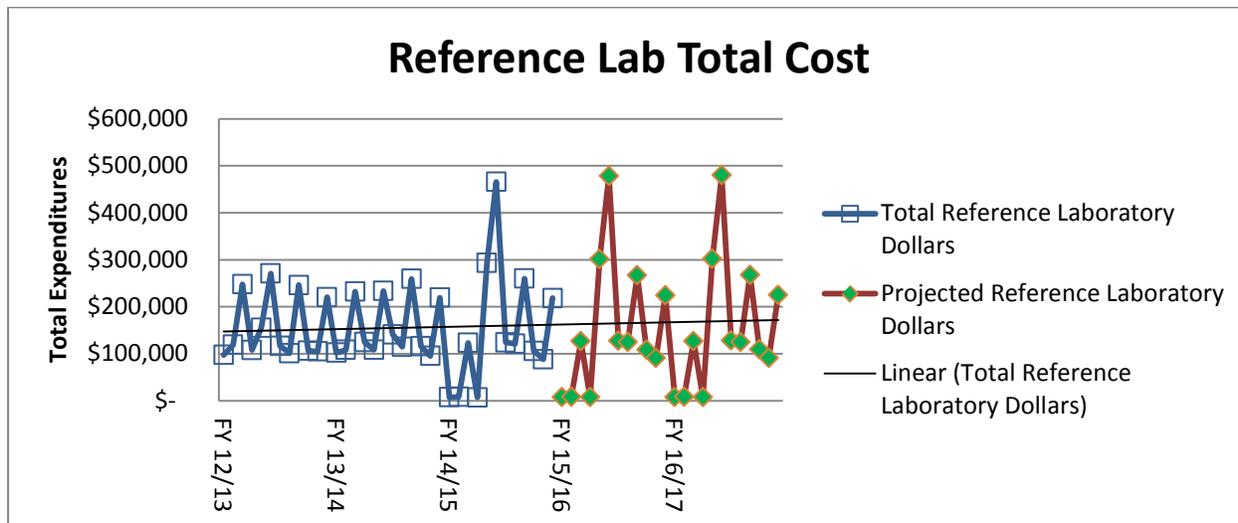
Reference Laboratory Caseload- GDSP estimates current year Reference Laboratory caseload will total 10,104, which is an increase of 196 or 1.98% compared to FY 2014-15 actual Reference Laboratory caseload of 9,908. Reference Laboratory caseload in FY 2016-17 is estimated at 10,140, which is an increase of 36 or 0.36% compared to the current year estimate. This is due largely to DOF DRU projected increase in the number of live births. The following chart shows the actual Reference Laboratory cases by month, along with projected caseload for the remainder of the current year and budget year.



**Reference Laboratory Average Cost-** GDSP estimates current year Reference Laboratory average cost per participant will be \$185.19, which is an increase of \$1.23 or 0.67% compared to FY 2014-15 Reference Laboratory actual average costs per participant of \$183.96. Reference Laboratory average cost per participant in FY 2016-17 is estimated at \$185.19, which is no change compared to the current year estimate.



**Reference Laboratory Total Cost-** GDSP estimates current year Reference Laboratory costs to total \$1,871,181, which is an increase of \$48,523 or 2.66% compared to FY 2014-15 actual Diagnostic Services total costs of \$1,822,658. Reference Laboratory costs in FY 2016-17 are estimated to total \$1,877,854, which is an increase of \$6,673 or 0.36% compared to the current year estimate. The increases are caused by the projected increases in Reference Laboratory caseload, and marginal price increase for reference laboratory services.



**APPENDIX B: PNS Assumptions and Rationale**

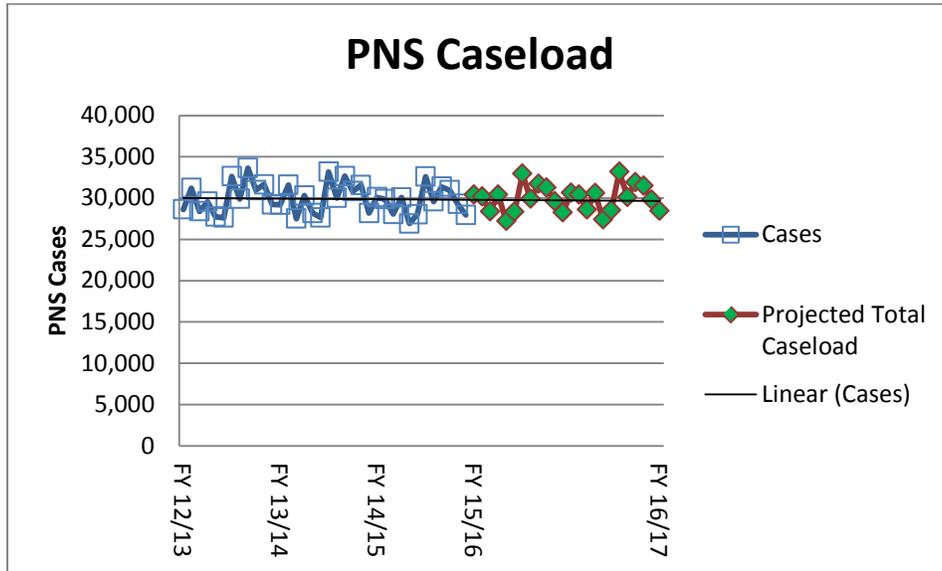
**1. Contract Laboratories:**

Overview- Laboratory testing to screen pregnant women for genetic and congenital disorders, such as Trisomy 21, Trisomy 18, Smith-Lemli-Opitz Syndrome (SLOS), and Neural Tube Defects. Costs include laboratory services for performing prenatal genetic screening tests. The screening test estimates the chance or risk that the fetus has a certain birth defect; the screening provides a risk assessment but not a diagnosis. In prior years the state contracted with seven regional laboratories, currently the state contracts with five regional laboratories that are paid on a per specimen basis.

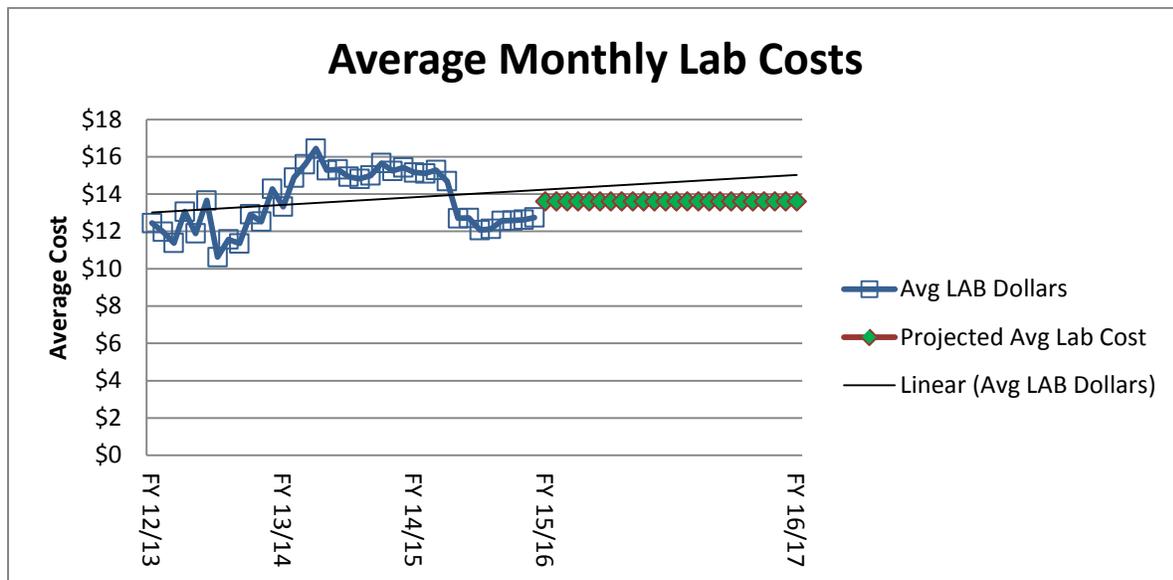
In the past GDSP estimated the number of 1<sup>st</sup> trimester and 2<sup>nd</sup> trimester screens performed separately in the estimate. This is because the average cost of the 1<sup>st</sup> trimester screen was substantially less than the cost of the 2<sup>nd</sup> trimester screens. When GDSP consolidated the laboratories from seven down to five, we evaluated the work associated with testing 1<sup>st</sup> and 2<sup>nd</sup> trimester specimens and found it to be the same. Therefore, during the competitive bidding process, laboratories provided one cost for processing both 1<sup>st</sup> and 2<sup>nd</sup> trimester specimens. As such GDSP will estimate the average cost to provide both screens without differentiating between the two different specimens a participant may provide.

Total Caseload – GDSP estimates current year caseload will total 358,559 which is an increase of 3,780 or 1.1% compared to FY 2014-15 actual total caseload of 354,779. Caseload in FY 2016-17 is estimated at 361,128, which is an increase of 2,569 or 0.7% compared to the current year estimate. The PNS program participation is estimated as a percentage of the DOF/DRU projected number of live births. GDSP estimates that 71.1% (based from a three-year actual average) of the projected births will participate in the PNS program in FY 2015-16, and that the number of participants will remain constant in FY 2016-17. The FY 2016-17 projections do not increase with DOF/DRU birth rates because PNS participation has not remained constant as a percent of DRU birth projections due to women choosing other types of prenatal testing offered

outside of the State program. The following chart shows the actual PNS cases by month, along with our projected numbers for the remainder of the current year and budget year.

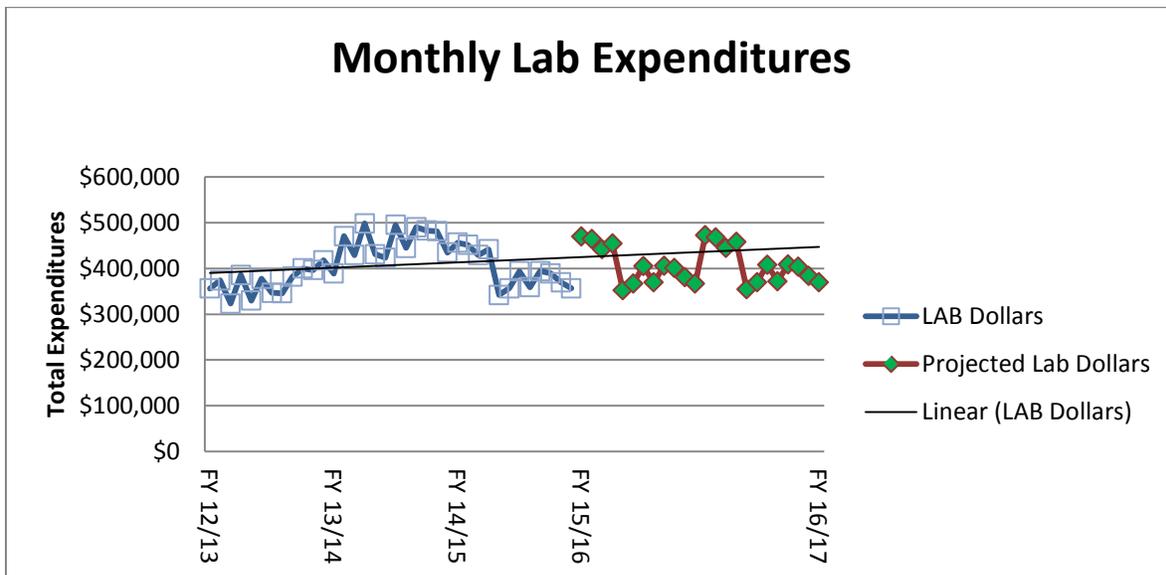


Contract Laboratory Average Cost Projections- GDSP estimates current year average laboratory cost per participant will be \$13.60, which is an increase of \$0.24 or 1.8% compared to FY 2014-15 actual average laboratory cost per participant of \$13.36. Average laboratory cost per participant in FY 2016-17 is estimated at \$13.60, which is no change compared to the current year estimate. Average cost for contract laboratories are expected to remain constant as GDSP negotiated new contracts with the PNS laboratories last year, and slight changes in average cost are due to both current and budget year projected caseload.



Contract Laboratory Total Cost Projections- GDSP estimates current year contract laboratory cost to total \$4,875,395, which is an increase of \$136,562 or 2.9% compared to FY 2014-15

actual contract laboratory costs of \$4,738,834. Laboratory costs in FY 2016-17 are estimated to total \$4,910,324, which is an increase of \$34,929 or 0.7% compared to the current year estimate. The steady costs are attributable to unchanging participation and average cost projections.

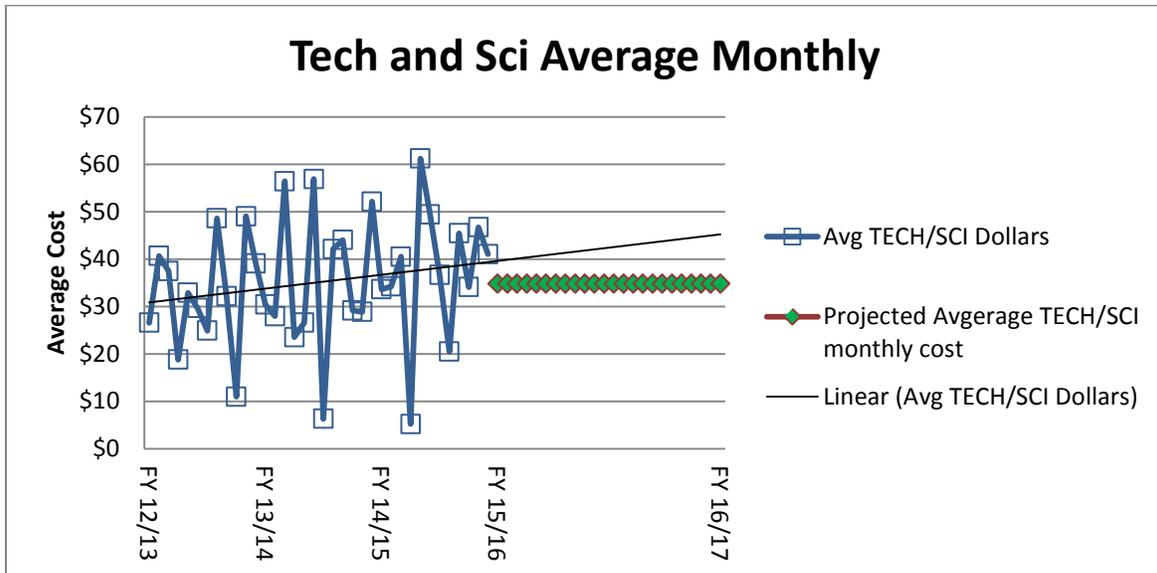


## 2. Technical and Scientific

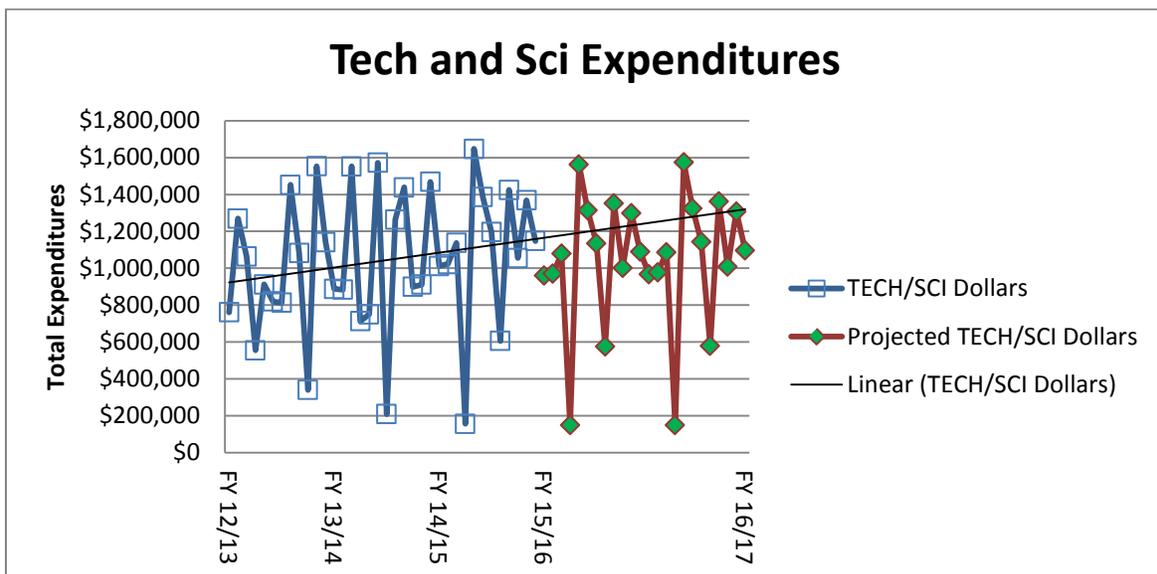
Overview- Costs associated with screening services provided at the laboratory include: reagent kits, limited maintenance and support (as it directly relates to the reagents) of laboratory equipment, supplies, and processing. In addition, there are several costs associated with screening including: blood specimen tubes, laboratory supplies, blood specimen storage, and costs for special packaging for blood specimen transport. Reagent kits, which are the majority of the Technology & Scientific costs, are purchased in lots based on anticipated caseload. Reagents vary in cost depending upon the type of screening performed.

Technical and Scientific Caseload: See Appendix B 1

Technical and Scientific Average Cost- GDSP estimates current year average Technical and Scientific cost per participant will be \$34.82, which is a decrease of \$2.27 or 6.1% compared to FY 2014-15 actual average Technical and Scientific cost per participant of \$37.09. Average laboratory cost per participant in FY 2016-17 is estimated at \$34.82, which is no change compared to the current year estimate. The decrease in average cost in the current year is the result of cost savings realized as a result of laboratory consolidation.



Technical and Scientific Total Cost- GDSP estimates current year Technical and Scientific costs to total \$12,483,407, which is a decrease of \$676,065 or 5.1% compared to FY 2014-15 actual technical and scientific costs of \$13,159,472. Technical and Scientific costs in FY 2016-17 are estimated to total \$12,572,842, which is an increase of \$89,435 or 0.7% compared to the current year estimate. The decrease in the current year is the result of cost savings realized as a result of laboratory consolidation.

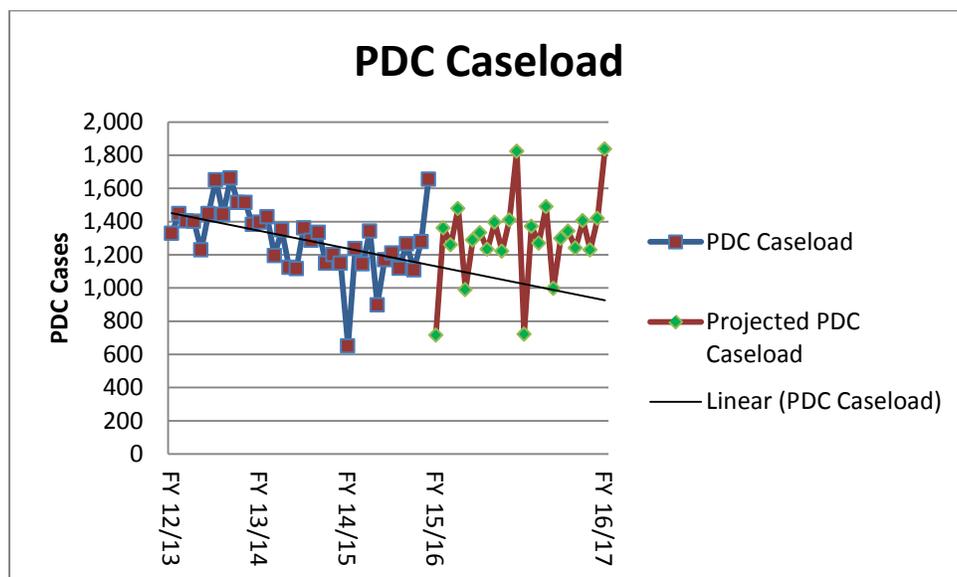


### 3. Prenatal Diagnostic Services Centers

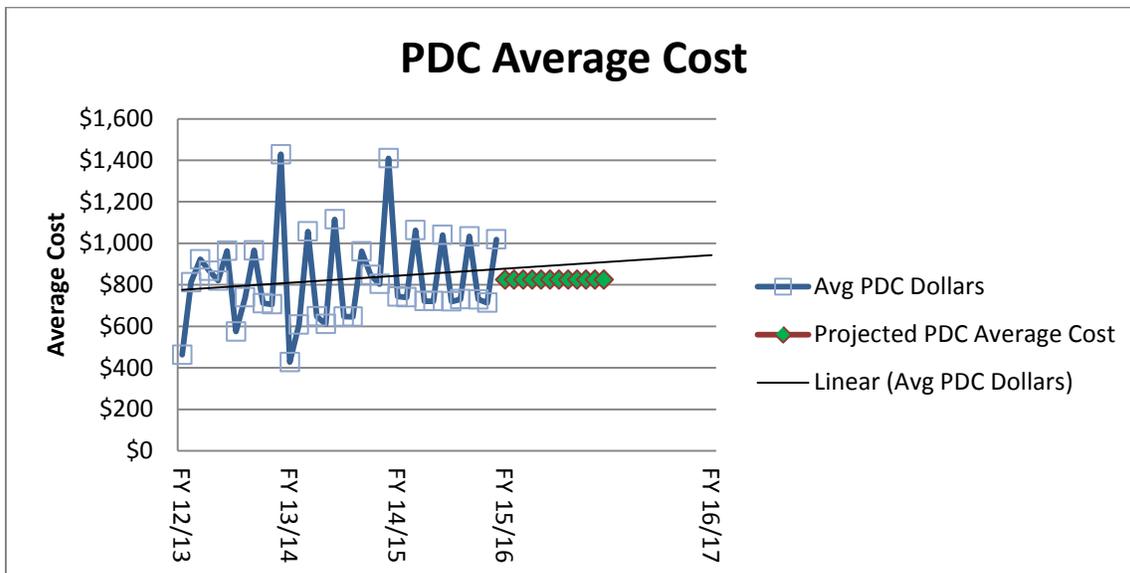
Overview- Women with positive results are provided additional services, which include: confirmatory and diagnostic prenatal testing, genetic counseling, education, coordinated medical care referrals, and coordination and consultation with patient's physician, and specialty

care providers. Services are provided through Prenatal Diagnostic Services Centers and are reimbursed per service type.

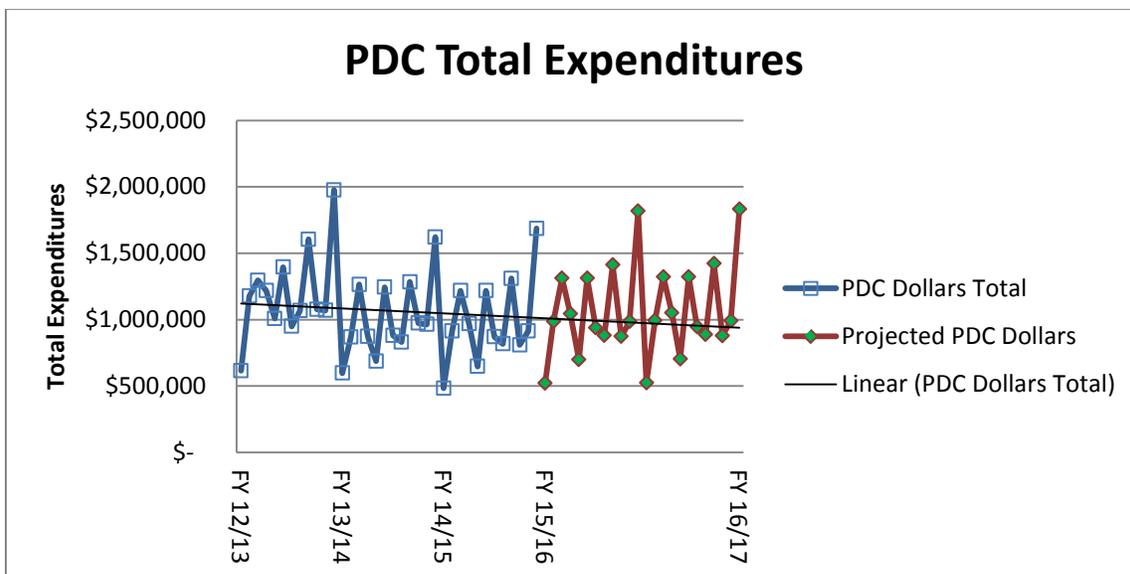
Prenatal Diagnostic Services Centers (PDC) Caseload- GDSP estimates current year PDC caseload will total 15,517, which is an increase of 1,431 or 10.16% compared to the FY 2014-15 actual PDC caseload of 14,086. PDC caseload in FY 2016-17 is estimated to total 15,628, which is an increase of 111 or 0.72% compared to the current year estimate. The increase in current year is caused by a projected uptick in women choosing to further pursue diagnostic care. As the methods for diagnosing pregnancies for genetic diseases increases GDSP anticipates that PDC caseload will increase.



Prenatal Diagnostic Services Average Cost- GDSP estimates current year average PDC cost per participant will be \$823.84, which is a decrease of \$17.88 or 2.1% compared to FY 2014-15 actual average PDC cost per participant of \$841.72. Average laboratory cost per participant in FY 2016-17 is estimated at \$823.84, which is no change compared to the current year estimate. The reduction in average cost in the current year, which is projected to be sustained in the budget year, is the result of changes in the types of procedures used to diagnose genetic diseases. Procedures like Non-Invasive Prenatal Testing and Micro Array can be offered to women in lieu of more invasive and costly procedures, like amniocentesis. Women are choosing these procedures over amniocentesis and similar procedures in larger numbers.



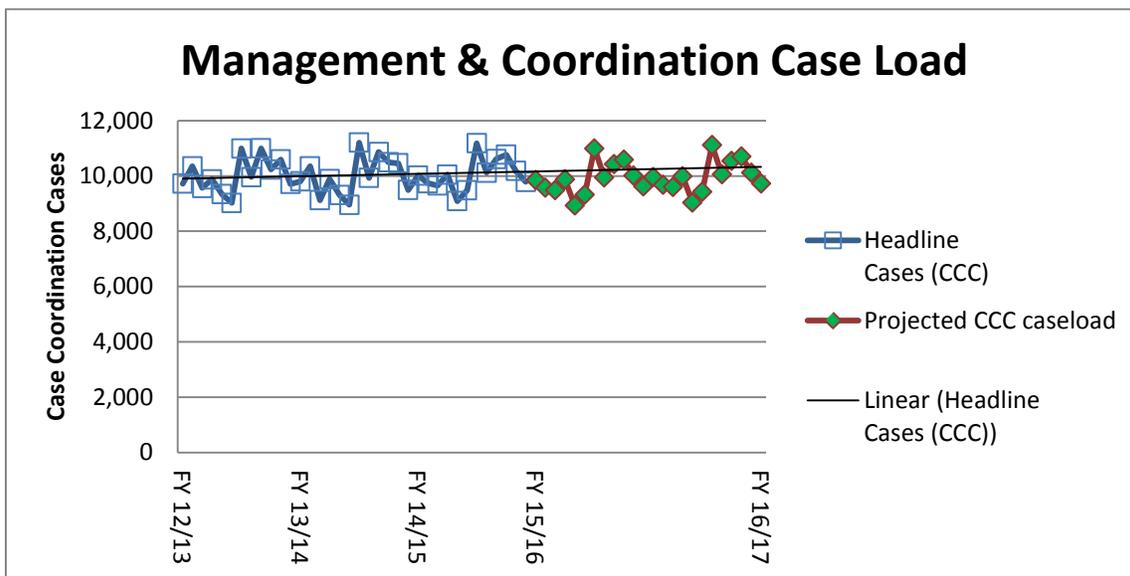
Prenatal Diagnostic Services Total Cost- GDSP estimates current year PDC costs to total \$12,783,458, which is an increase of \$926,933 or 7.82% compared to FY 2014-15 actual PDC total costs of \$11,856,525. PDC costs in FY 2016-17 are estimated to total \$12,875,043, which is an increase of 91,585 or 0.72% compared to the current year estimate. The change in total expenditures is attributable mainly to projected increases in caseload, which results from women opting in to diagnostic services in greater numbers.



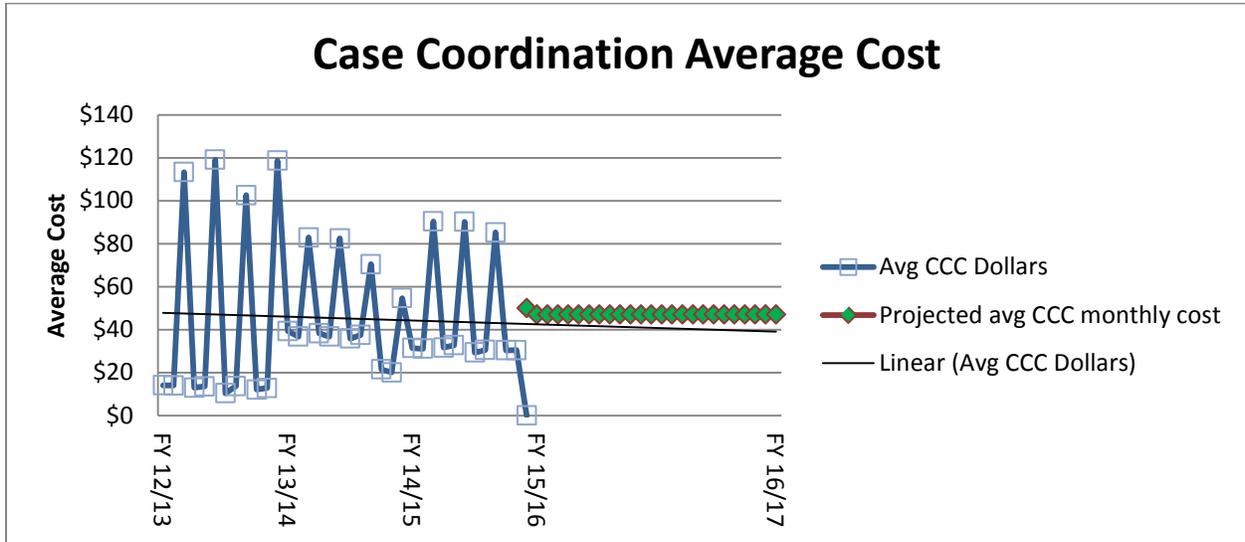
**4. Case Management and Coordination Services:**

Overview- Services provided to pregnant women who screen positive or have questionable results include coordination of first and second trimester screens and ultrasounds, identifying patients whose blood specimens were drawn too early or were inadequate, requiring additional blood draws. The PNS Area Service Centers (ASC) provide clinician and patient education and consultations; make referrals to Prenatal Diagnostic Centers for diagnostic and confirmatory tests, and genetic counseling, and track patients to ensure appointments are kept and patients seen within prescribed timeframes. Coordinators confirm and verify specific patient information as needed with the treating physician offices, and the Prenatal Diagnostic Centers. Costs are fixed for a required core team of medical professionals for the PNS ASC to ensure adequate personnel and infrastructure needs are always in place to provide for all cases referred. Costs associated with these services vary by ASC dependent upon the geographic location and thus the geographic distribution of caseload as well.

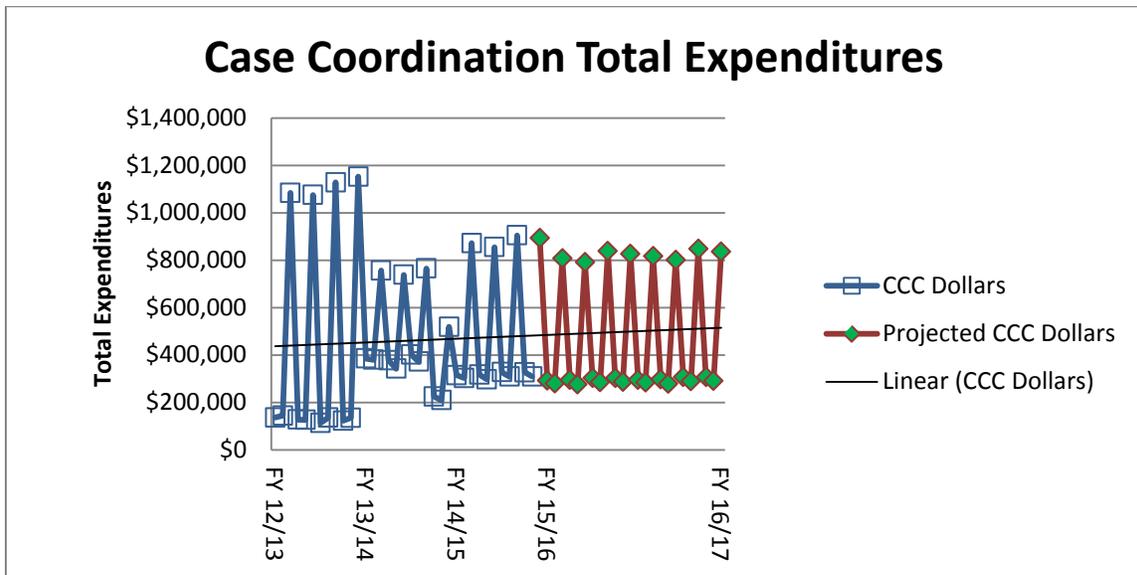
Case Management and Coordination Services (CMCS) Caseload- GDSP estimates current year CMCS caseload will total 118,613, which is a decrease of 2,069 or 1.71% compared to FY 2014-15 actual CMCS caseload of 120,682. CMCS caseload in FY 2016-17 is estimated at 119,932, which is an increase of 1,319 or 1.11% compared to the current year estimate. This is due largely to changes in the caseload, and GDSP noted that the trend for CMCS caseload has remained relatively flat regardless of overall program participation. The following chart shows the actual CMCS cases by month, along with our projected numbers for the remainder of the current year and budget year.



Case Management and Coordination Services (CMCS) Average Cost- GDSP estimates current year average CMCS cost per participant will be \$47.06, which is a decrease of \$2.91 or 5.8% compared to FY 2014-15 actual average CMCS cost per participant of \$49.97. Average cost per participant in FY 2016-17 is estimated at \$47.06, which is no change compared to the current year estimate. The decrease in the current year is attributable to a slight increase in caseload causing a decrease in average cost.



Case Management and Coordination Services (CMCS) Total Cost- GDSP estimates current year CMCS costs to total \$5,582,036, which is a decrease of \$449,032 or 7.45% compared to FY 2014-15 actual CMCS total costs of \$6,031,068. CMCS costs in FY 2016-17 are estimated to total \$5,644,096, which is an increase of \$62,060 or 1.11% compared to the current year estimate. The changes are caused by the increase in average cost noted above coupled with the relatively small increases to CMCS caseload.



**APPENDIX C: Revenue Assumptions**

**NBS Revenue**

The Newborn Screening Program charges a fee of \$112.70. In most cases the fee is paid to directly to GDSP by hospitals. For births that occur outside of a hospital GDSP does invoice the \$112.70 from the practitioner (where applicable) or the family of the infant directly. Since the majority of births happen within a hospital billing and receiving payment for NBS services is greatly streamlined and efficient. Past actual collection amounts indicate that GDSP collects approximately 98% of all revenue related to providing NBS services. As such NBS revenue is estimated using the following formula:

$$\text{\#of Projected Newborns screened} \times \text{Fee} \times 98\%$$

**NBS Revenue Projections**

	A	B	C	D=(A*B*C)
	Fee	Caseload	Collection Rate	Total Revenue
FY 2015-16	\$112.70	493,547	98%	\$54,510,292
FY 2016-17	\$123.70	497,083	98%	\$60,259,384

**PNS Revenue**

The Prenatal Screening Program charges a fee of \$207 to all participating women. Of the total fee, \$197 is deposited into the Genetic Disease Testing Fund (Fund 0203), and \$10 is deposited into the California Birth Defect Monitoring Program Fund (Fund 3114). Unlike NBS which collects revenue from hospitals directly, PNS invoices participants and bills insurance companies (analogous to the way a traditional medical provider would). This system of billing which shares cost between the participant and one or more third party payers makes full, or close to full collection of revenue a challenge for the program. Past collection rates have revealed that PNS collects a higher percentage of anticipated revenue from Medi-Cal enrollees than those enrolled in private insurance plans or the uninsured. PNS receives approximately 98% of all claims submitted to Medi-Cal, and approximately 83% of all claims submitted to private insurance companies and other payers. Approximately 45% of all PNS participants are enrolled in Medi-Cal. PNS revenue is estimated using the following formula:

$$(\text{Fee} \times \text{PNS Participants} \times \text{Medi-Cal Participation Rate} \times \text{Medi-Cal Collection Rate}) + (\text{Fee} \times \text{PNS Participants} \times \text{Private Payer Rate} \times \text{Private Payer Collection Rate})$$

**PNS Revenue Projections**

Fiscal Year	A=( $\$207-\$10$ )	B	C	D=1-C	E	F	G=(B*C)	H=(B*D)	I=(G*A*E)+(H*A*F)
	Fee	Caseload	% Medi-Cal	% Non-Medical	Medi-Cal Collection Rate	Private Insurance Collection Rate	Medi-Cal Cases	Non Medi-Cal Cases	Total Revenue
FY 2015-16	\$197	358,559	45%	55%	98%	83%	161,352	197,207	\$63,395,920
FY 2016-17	\$197	361,128	45%	55%	98%	83%	162,508	198,620	\$63,850,139