

GENETIC DISEASE SCREENING PROGRAM (GDSP)

**Estimate Package
2015-16 May Revision**



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GDSP Program Overview

The California Department of Public Health (CDPH), Genetic Disease Screening Program (GDSP) Estimate provides a revised projection of FY 2014-15 expenditures along with projected costs for FY 2015-16 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

GDSP estimates revised FY 2014-15 expenditures of \$115,518,615, which is a decrease of \$1,221,213 or 1.05% compared to the 2015-16 Governor’s Budget. GDSP estimates revised FY 2015-16 expenditures of \$118,634,018, which is a decrease of \$776,288 or 0.66% compared to the 2015-16 Governor’s Budget.

Table 1 shows the difference between the 2015-16 Governor’s Budget appropriation and the revised FY 2014-15 expenditures and proposed FY 2015-16 expenditures for the GDSP program.

Table 1

Genetic Disease Screening Program: Current Year and Budget Year Budget Summaries Compared to 2015-16 Governor’s Budget

Fund 0203 Genetic Disease Testing Fund	2014 Budget Act	FY 2014-15				FY 2015-16			
		2015-16 Governor's Budget	2015 May Revision	Change from Governor's Budget to May Revision	Percent Change from Governor's Budget to May Revision	2015-16 Governor's Budget	2015 May Revision	Change from Governor's Budget to May Revision	Percent Change from Governor's Budget to May Revision
Total	\$ 116,885,000	\$ 116,739,828	\$ 115,518,615	\$ (1,221,213)	-1.05%	\$ 119,410,306	\$ 118,634,018	\$ (776,288)	-0.66%
State Operations	\$ 28,231,000	\$ 28,792,000	\$ 28,792,000	\$ -	0.00%	\$ 28,922,000	\$ 28,922,000	\$ -	0.00%
Local Assistance	\$ 88,654,000	\$ 87,947,828	\$ 86,726,615	\$ (1,221,213)	-1.39%	\$ 90,488,306	\$ 89,712,018	\$ (776,288)	-0.86%

GDSP Local Assistance Projections

Current Year (FY 2014-15)

The GDSP 2015-16 Governor’s Budget appropriation for GDSP’s local assistance is \$87,947,828. GDSP anticipates revised FY 2014-15 expenditures of \$86,726,615, which is a decrease of \$1,221,213 or 1.39% compared to the 2015-16 Governor’s Budget.

Budget Year (FY 2015-16)

For FY 2015-16, GDSP estimates local assistance expenditures will total \$89,712,018, which is a decrease of \$776,288 or 0.86% compared to the 2015-16 Governor's Budget of \$90,488,306.

The difference between the 2015-16 Governor's Budget and the revised estimated expenditure for current year and budget year is due to an update of Department of Finance (DOF) Demographic Research Unit (DRU) birthrate figures which lowered caseload projections, therefore resulting in lower projected expenditures. Table 2 shows the difference between the 2015-16 Governor's Budget appropriation and the revised FY 2014-15 expenditures and proposed FY 2015-16 expenditures for the GDSP local assistance.

Table 2

Local Assistance Total: Current Year and Budget Year Budget Summaries Compared to 2015-16 Governor's Budget

Fund 0203 Genetic Disease Testing Fund	2014 Budget Act	FY 2014-15				FY 2015-16			
		2015-16 Governor's Budget	2015 May Revision	Change from Governor's Budget to May Revision	Percent Change from Governor's Budget to May Revision	2015-16 Governor's Budget	2015 May Revise	Change from Governor's Budget to May Revision	Percent Change from Governor's Budget to May Revision
Local Assistance Total	\$ 88,654,000	\$ 87,947,828	\$ 86,726,615	\$ (1,221,213)	-1.39%	\$ 90,488,306	\$ 89,712,018	\$ (776,288)	-0.86%
New Born Screening	\$ 35,010,462	\$ 36,838,380	\$ 36,101,084	\$ (737,296)	-2.00%	\$ 37,146,972	\$ 36,357,366	\$ (789,606)	-2.13%
Prenatal Screening	\$ 42,879,713	\$ 40,045,448	\$ 39,561,531	\$ (483,917)	-1.21%	\$ 39,962,334	\$ 39,975,652	\$ 13,318	0.03%
Operational Support	\$ 10,763,825	\$ 11,064,000	\$ 11,064,000	\$ -	0.00%	\$ 13,379,000	\$ 13,379,000	\$ -	0.00%

Future Fiscal Considerations

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

1. **Electronic Medical Records (EMR)** - in the coming years GDSP will adapt its systems and capacities to allow for the implementation and *meaningful use* of EMR. While not a requirement, EMR is encouraged by the federal government and GDSP will move to provide all medical records in electronic format. The fiscal impacts of implementing EMR are unknown at this time, as the scope and complexity of the project are still being determined, however preliminary costs are expected to be \$1.4 million. These include creation of a web portal for prenatal and pediatric clinicians to access records, creation of PDFs of test result records by SIS for availability on the web portal and moving HL7 record transfer for hospitals to the CDPH Gateway to facilitate easier on-boarding of new facilities and system maintenance. GDSP will actively pursue any Federal Grant opportunities that may become available to support the adoption of EMR.
2. **Assembly Bill (AB) 1559; Newborn Screening Program**- This bill requires CDPH to expand statewide screening of newborns to include screening for Adrenoleukodystrophy (ALD) as soon as ALD is added to the federal Recommended Uniform Screening Panel (RUSP). GDSP expects the federal Discretionary Advisory Committee on Heritable Disorders in Newborns and Children to recommend approval of ALD within 2 years. This addition will cost \$1.975 million in upfront planning and preparation costs and \$150,000 per year in ongoing costs. The increase in appropriation for AB 1559 is being requested through a separate BCP. The addition of ALD will require a fee increase of approximately \$11 per participant in FY 2016-17.

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 2014-15 GDSP revised NBS local assistance expenditures total \$36,101,084, which is a decrease of \$737,296 or 2.0% compared to 2015-16 Governor's Budget amount of \$36,838,380.

For FY 2015-16 GDSP estimates that NBS local assistance expenditures will total \$36,357,366, which is a decrease of \$789,606 or 2.13% compared to 2015-16 Governor's Budget amount of \$37,146,972.

The difference between the 2015-16 Governor's Budget and the revised estimated expenditure is due to an update of DOF DRU birthrate figures which lowered caseload projections, therefore resulting in lower projected expenditures. The 2015 May Revision Estimate projects NBS caseload at 491,588, which is a decrease of 12,701 compared to 2014 November Estimate caseload projection for FY 2014-15. For FY 2015-16, the 2015 May Revision Estimate projects NBS caseload at 495,079, which is a decrease of 13,658 compared to 2014 November Estimate caseload projection.

Table 3 shows the difference between the 2015-16 Governor's Budget appropriation and the revised FY 2014-15 expenditures and proposed FY 2015-16 expenditures for the NBS program costs by client type.

Table 3

New Born Screening: Current Year and Budget Year Budget Summaries Compared to 2015-16 Governor's Budget

Fund 0203 Genetic Disease Testing Fund	2014 Budget Act	FY 2014-15				FY 2015-16			
		2015-16 Governor's Budget	2015 May Revision	Change from Governor's Budget to May Revision	Percent Change from Governor's Budget to May Revision	2015-16 Governor's Budget	2015 May Revision	Change from Governor's Budget to May Revision	Percent Change from Governor's Budget to May Revision
Total	\$ 35,010,462	\$ 36,838,380	\$ 36,101,084	\$ (737,296)	-2.00%	\$ 37,146,972	\$ 36,357,366	\$ (789,606)	-2.13%
Contract Laboratory	\$ 7,117,976	\$ 7,060,200	\$ 6,882,232	\$ (177,968)	-2.52%	\$ 7,020,612	\$ 6,832,090	\$ (188,522)	-2.69%
Technical and Scientific	\$ 20,119,363	\$ 22,189,200	\$ 21,629,872	\$ (559,328)	-2.52%	\$ 22,384,560	\$ 21,783,476	\$ (601,084)	-2.69%
Reference Laboratory	\$ 1,693,713	\$ 1,907,400	\$ 1,907,400	\$ -	0.00%	\$ 1,935,000	\$ 1,935,000	\$ -	0.00%
Case Management and Coordination Services	\$ 4,237,368	\$ 4,294,080	\$ 4,294,080	\$ -	0.00%	\$ 4,324,800	\$ 4,324,800	\$ -	0.00%
Diagnostic Services	\$ 1,842,042	\$ 1,387,500	\$ 1,387,500	\$ -	0.00%	\$ 1,482,000	\$ 1,482,000	\$ -	0.00%

PNS Expenditures Projections (See Appendices B1-B4)

For FY 2014-15 GDSP revised PNS local assistance expenditures total \$39,561,531, which is a decrease of \$483,917 or 1.21% compared to 2015-16 Governor's Budget of \$40,045,448. The difference between the 2015-16 Governor's Budget and the revised estimated expenditure is due to an update of DOF DRU birthrate figures which lowered caseload projections, therefore resulting in lower projected expenditures. The 2015 May Revision Estimate projects PNS caseload at 367,550, which is a decrease of 9,496 compared to the 2014 November Estimate caseload projection for FY 2014-15.

For FY 2015-16 GDSP estimates that PNS local assistance expenditures will total \$39,975,652 which is an increase of \$13,318 or 0.03% compared to 2015-16 Governor's Budget amount of \$39,962,334. The difference between the 2015-16 Governor's Budget and the revised estimated expenditures is due to an update of DOF DRU birthrate figures, which lowered caseload projections. The 2015 May Revision Estimate projects PNS caseload at 377,160,

which is a decrease of 3,212 compared to the 2014 November Estimate caseload projection for FY 2015-16, however PNS expenditures are increasing due to a slight increase in average costs from increases in reagent and laboratory costs.

Table 4 shows the difference between the 2015-16 Governor’s Budget appropriation and the revised FY 2014-15 expenditures and proposed FY 2015-16 expenditures for the PNS program costs by client type.

Table 4

Prenatal Screening: Current Year and Budget Year Budget Summaries Compared to 2015-16 Governor’s Budget

Fund 0203 Genetic Disease Testing Fund	2014 Budget Act	FY 2014-15				FY 2015-16			
		2015-16 Governor’s Budget	2015 May Revision	Change from Governor’s Budget to May Revision	Percent Change from Governor’s Budget to May Revision	2015-16 Governor’s Budget	2015 May Revise	Change from Governor’s Budget to May Revision	Percent Change from Governor’s Budget to May Revision
Total	\$ 42,879,713	\$ 40,045,448	\$ 39,561,531	\$ (483,917)	-1.21%	\$ 39,962,334	\$ 39,975,652	\$ 13,318	0.03%
Contract Laboratory	\$ 6,179,011	\$ 5,716,017	\$ 5,572,058	\$ (143,959)	-2.52%	\$ 5,716,017	\$ 5,721,517	\$ 5,500	0.10%
Technical & Scientific	\$ 12,874,873	\$ 13,498,247	\$ 13,158,290	\$ (339,957)	-2.52%	\$ 13,385,133	\$ 13,392,952	\$ 7,818	0.06%
Case Management and Case Services	\$ 6,452,563	\$ 5,640,000	\$ 5,640,000	\$ -	0.00%	\$ 5,670,000	\$ 5,670,000	\$ -	0.00%
Prenatal Diagnostic Services	\$ 17,373,266	\$ 15,191,183	\$ 15,191,183	\$ -	0.00%	\$ 15,191,183	\$ 15,191,183	\$ -	0.00%

Operational Support Projections

Historically GDSP split the Operational Support budget into two distinct categories (“Result Reporting and Fee Collection” and “System Project and Maintenance”) and allocated the costs between NBS and PNS. GDSP’s 2014 Program Review revealed that these costs cut across both programs, and the fee collection activities are interconnected with the IT systems.

For FY 2014-15 GDSP revised operational support expenditures total \$11,064,000, which is no change from the 2015-16 Governor’s Budget amount of \$11,064,000.

In FY 2015-16 GDSP projects operational support expenditures will total \$13,379,000, which is no change compared to the 2015-16 Governor’s Budget of \$13,379,000.

GDSP has identified changes that will reduce the number of false positives without affecting the number of true cases identified through screening. Once fully implemented, GDSP expects these changes to achieve a greater than 75% reduction in the number of newborns requiring additional testing for disorders tested for using tandem mass spectrometry and for congenital adrenal hyperplasia. This means savings in case management, diagnostic services and reference laboratories in addition to significantly reducing parental anxiety. However, these changes will require both computer changes and retraining of hospital staff which requires additional monies in FY15-16. These costs were identified in the 2014 November Estimate and included in the 2015-16 Governor’s Budget. These improvements will likely become cost neutral after two to three years’ of reduced false positives.

Table 5 shows the difference between the 2015-16 Governor’s Budget appropriation and the revised FY 2014-15 expenditures and proposed FY 2015-16 expenditures for the Program Operational Support costs.

Table 5

Operational Support: Current Year and Budget Year Budget Summaries Compared to 2015-16 Governor's Budget

Fund 0203 Genetic Disease Testing Fund	2014 Budget Act	FY 2014-15				FY 2015-16			
		2015-16 Governor's Budget	2015 May Revision	Change from Governor's Budget to May Revision	Percent Change from Governor's Budget to May Revision	2015-16 Governor's Budget	2015 May Revision	Change from Governor's Budget to May Revision	Percent Change from Governor's Budget to May Revision
Operational Support	\$ 10,763,825	\$ 11,064,000	\$ 11,064,000	\$ -	0.00%	\$ 13,379,000	\$ 13,379,000	\$ -	0.00%

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 2014-15, GDSP estimates that State operations expenditures will total \$28,792,000, which is no change compared to 2015-16 Governor's Budget amount of \$28,792,000. In FY 2015-16, GDSP estimates State Operations expenditures will total \$28,922,000, which is no change compared to 2015-16 Governor's Budget amount of \$28,922,000. Table 6 shows the difference between the 2015-16 Governor's Budget appropriation and the revised FY 2014-15 expenditures and proposed FY 2015-16 expenditures for the GDSP State Operations costs.

Table 6

State Operations: Current Year and Budget Year Budget Summaries Compared to 2015-16 Governor's Budget

Fund 0203 Genetic Disease Testing Fund	2014 Budget Act	FY 2014-15				FY 2015-16			
		2015-16 Governor's Budget	2015 May Revision	Change from Governor's Budget to May Revision	Percent Change from Governor's Budget to May Revision	2015-16 Governor's Budget	2015 May Revision	Change from Governor's Budget to May Revision	Percent Change from Governor's Budget to May Revision
State Operations	\$ 28,231,000	\$ 28,792,000	\$ 28,792,000	\$ -	0.00%	\$ 28,922,000	\$ 28,922,000	\$ -	0.00%

Revenue Projections

Combined NBS and PNS Revenue

GDSP has revised revenue estimates for FY 2014-15 totaling \$118,483,044, which is a decrease of \$3,062,376 or 2.52% compared to 2015-16 Governor's Budget amount of \$121,545,420.

For FY 2015-16 GDSP projects revenue will total \$121,364,212, which is a decrease of \$671,588 or 0.55% compared to the 2015-16 Governor's Budget amount of \$122,035,800.

The difference between the 2015-16 Governor's Budget and the revised estimated revenue is due to an update of DOF DRU birthrate figures which lowered caseload projections, therefore resulting in lower projected revenue. The 2015 May Revision Estimate projects NBS caseload at 491,588, which is a decrease of 12,701 compared to 2014 November Estimate caseload projection for FY 2014-15. For FY 2015-16, the 2015 May Revision Estimate projects NBS caseload at 495,079, which is a decrease of 13,658 compared to 2014 November Estimate caseload projection.

The 2015 May Revision Estimate projects PNS caseload at 367,550, which is a decrease of 9,496 compared to the 2014 November Estimate caseload projection for FY 2014-15. For FY 2015-16, the 2015 May Revision Estimate projects PNS caseload at 377,160, which is a decrease of 3,212 compared to the 2014 November Estimate caseload projection.

Revenue Methodology

PNS and NBS each charge a participation fee. 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.

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 81% of the fees owed by individuals with private insurance. In an effort to increase the collection rate from non-Medi-Cal payers CDPH is introducing the attached Trailer Bill Language (TBL). If this TBL is adopted, GDSP anticipates an increase in the non-Medi-Cal fee collection rate to from 81% to 83% in 2015-16.

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

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

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.

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

NBS Revenue (See Appendix C-1)

In FY 2014-15 NBS revenue is expected to total \$54,293,928, which is a decrease of \$1,403,990 or 2.52% compared to 2015-16 Governor's Budget amount of \$55,697,918.

In FY 2015-16 GDSP projects NBS revenue will total \$54,679,495, which is a decrease of \$1,508,803 or 2.69% compared to 2015-16 Governor's Budget of \$56,188,298.

The changes from year to year are caused entirely by projected changes in the NBS caseload. The program participation fee remains at \$112.70, which is charged directly to hospitals or other providers. The collection rate remains unchanged.

PNS Revenue (See Appendix C2)

In FY 2014-15 PNS revenue is expected to total \$64,189,116, which is a decrease of \$1,658,386 or 2.52% compared to the 2015-16 Governor’s Budget amount of \$65,847,502.

In FY 2015-16 GDSP projects PNS revenue will total \$66,684,717, which is an increase of \$837,215 or 1.27% compared to the 2015-16 Governor’s Budget of \$65,847,502.

These decreases are caused by a projected decrease in the PNS caseload for FY 2014-15. GDSP projects an increase in revenue collection in FY 2015-16 due to the afore-mentioned proposed TBL which GDSP anticipates will increase PNS collection efforts.

Table 7 shows the revised current year revenue projections for current year and budget year compared to 2015-16 Governor’s Budget.

Table 7

Genetic Disease Screening Program Revenue: Current Year and Budget Year Revenue Summaries Compared to 2015-16 Governor’s Budget

Fund 0203 Genetic Disease Testing Fund	2014 Budget Act	FY 2014-15				FY 2015-16			
		2015-16 Governor’s Budget	2015 May Revision	Change from Governor’s Budget to May Revision	Percent Change from Governor’s Budget to May Revision	2015-16 Governor’s Budget	2015 May Revision	Change from Governor’s Budget to May Revision	Percent Change from Governor’s Budget to May Revision
Total	\$ 121,494,839	\$ 121,545,420	\$ 118,483,044	\$ (3,062,376)	-2.52%	\$ 122,035,800	\$ 121,364,212	\$ (671,588)	-0.55%
New Born Screening	\$ 55,786,473	\$ 55,697,918	\$ 54,293,928	\$ (1,403,990)	-2.52%	\$ 56,188,298	\$ 54,679,495	\$ (1,508,803)	-2.69%
Prenatal Screening	\$ 65,708,366	\$ 65,847,502	\$ 64,189,116	\$ (1,658,386)	-2.52%	\$ 65,847,502	\$ 66,684,717	\$ 837,215	1.27%

GENETIC DISEASE TESTING FUND
FUND CONDITION REPORT
DOLLARS IN THOUSANDS

	2013-14	2014-15	2015-16
RESOURCES			
BEGINNING BALANCE	\$4,459	\$2,075	\$5,115
Prior Year Adjustment	1,057	0	-
<i>Adjusted Beginning Balance</i>	<u>3,402</u>	<u>2,075</u>	<u>5,115</u>
REVENUES			
4123400 Genetic Disease Testing Fees ^{1/}	106,556	118,483	121,364
4163000 Income from Surplus Investments	5	5	5
4171400 Escheat of Unclaimed Checks & Warrants	70	70	70
TOTALS, REVENUES	<u>106,631</u>	<u>118,558</u>	<u>121,439</u>
TOTAL RESOURCES	\$110,033	\$120,633	\$126,554

EXPENDITURES AND EXPENDITURE ADJUSTMENTS			
4265 Department of Public Health (State Operations)	25,171	28,792	28,922
4265 Department of Public Health (Local Assistance)	82,659	87,947	90,488
May Revision Adjustments (Local Assistance)		-1,221	-776
0840 State Controller (State Operations)	3	0	-
8880 Financial Information System for California (State Operations)	125	0	-
TOTAL EXPENDITURES AND EXPENDITURE ADJUSTMENTS	<u>107,958</u>	<u>115,518</u>	<u>118,634</u>

FUND BALANCE	2,075	5,115	7,920
	2%	4%	7%

REVENUE PROJECTIONS

2014-15

2014-15 NBS FEES BASED ON	491,588	TESTS @ \$112.70	AND 98% Provider ^{2/}	=	\$54,293,928
2014-15 PNS FEES BASED ON	202,153	TESTS @ \$197.00	AND 81% Non Medi-Cal ^{3/}	=	\$32,257,474
2014-15 PNS FEES BASED ON	<u>165,398</u>	TESTS @ \$197.00	AND 98% Medi-Cal ^{4/}	=	<u>\$31,931,641</u>
	367,550				\$64,189,116
GDSP Total					\$118,483,044

2015-16

2015-16 NBS FEES BASED ON	495,079	TESTS @ \$112.70	AND 98% Provider ^{2/}	=	\$54,679,495
2015-16 PNS FEES BASED ON	207,438	TESTS @ \$197.00	AND 83% Non Medi-Cal ^{5/}	=	\$33,918,187
2015-16 PNS FEES BASED ON	<u>169,722</u>	TESTS @ \$197.00	AND 98% Medi-Cal ^{4/}	=	<u>\$32,766,529</u>
	377,160				\$66,684,717
GDSP Total					\$121,364,212

- 1/ Revenue Projections for FY 2013-14 Includes AB 97 Medi-Cal reduction repayment
- 2/ NBS Fees based on 98% hospital and other provider collection rate
- 3/ PNS Fees based on 81% of private payer / insurance collection rate
- 4/ PNS Fees based on 98% Medi-Cal Collection rate
- 5/ PNS Fees based on 83% of private payer / insurance collection rate, 2% increase based on proposed TBL

*The revenue figures above are based on the most current and accurate information, which differ from the figures reflected in 2015-16 Governor's Budget fund condition statement.

Appendices

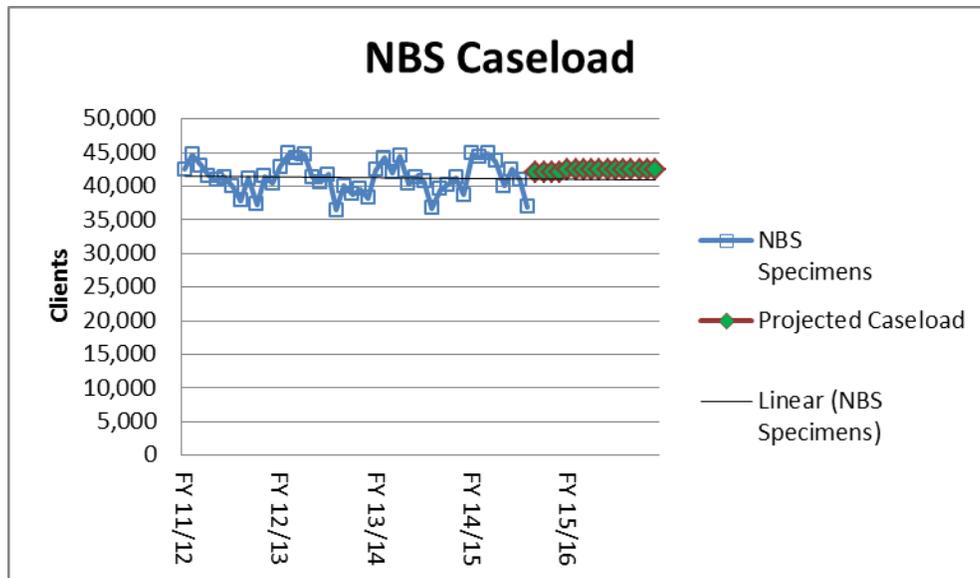
Appendix A: NBS Assumptions and Rationale

1. Contract Laboratories

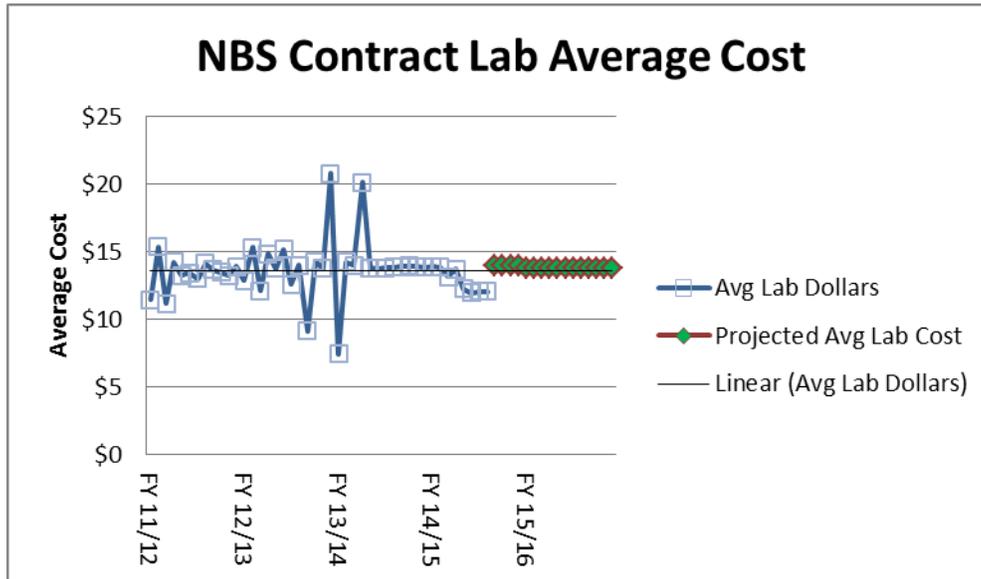
Overview: Laboratory testing of specimens is performed at regional screening laboratories contracted by the state to screen newborns for 75+ specific genetic disorders. Costs include laboratory services for processing genetic screening tests. Screening laboratories ascertain the possible presence of 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. GDSP will be consolidating the number of regional screening laboratories from seven down to five in FY 2014-15. Competitive procurement may affect the average cost per case.

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 491,588, a decrease of 494 or 0.1% compared to the FY 2013-14, actual total caseload of 492,082. Caseload in FY 2015-16 is estimated at 495,079, which is an increase of 3491 or 0.7% compared to the current year estimate. This year over 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 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 \$14.00, which is an increase of \$0.07 or 0.5% compared to the FY 2013-14 actual average laboratory cost per participant of \$13.93. Average laboratory cost per participant in FY 2015-16 is estimated at \$13.80, which is a decrease of \$0.20 or 1.4% compared to the current year estimate. The decrease in cost in budget year is associated with projected savings related to lab consolidation.



Contract Laboratory Total Cost Projections - GDSP estimates current year contract laboratory cost to total \$6,882,232, which is an increase of \$29,775 or .04% compared to FY 2013-14 actual contract laboratory costs of \$6,852,457. Laboratory costs in FY 2015-16 are estimated to total \$6,832,090, a decrease of \$285,886 or 4% compared to the current year estimate. The increase in cost in the current year is caused by the \$0.07 average cost per client increase and the number of projected participants. The decrease in costs in the budget year is the result of lab consolidation, which is anticipated to lower average cost.

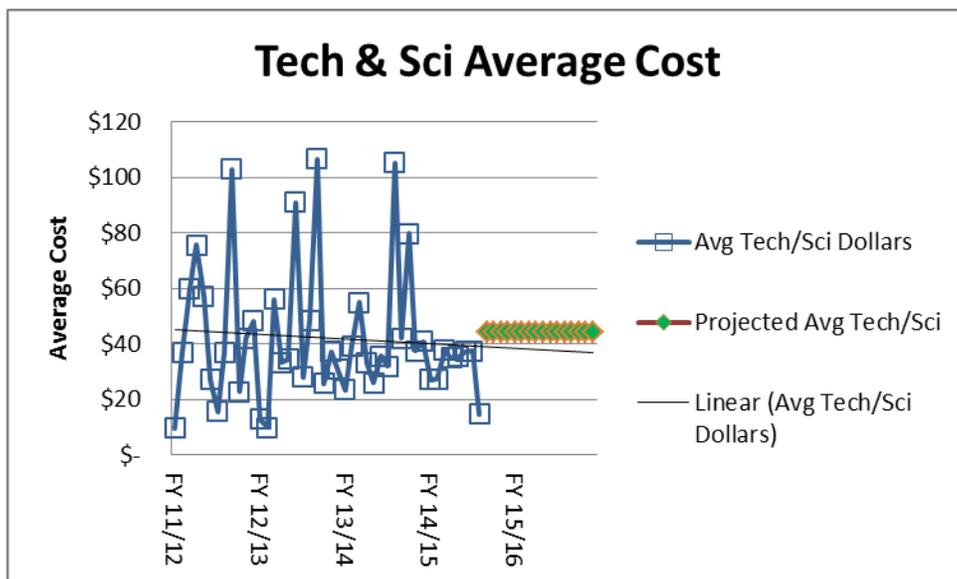
Technical and Scientific

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 \$44.00, a decrease of \$1.04 or 2.32% compared to FY

2013-14 actual average Technical and Scientific cost per participant of \$45.04. Average laboratory cost per participant in FY 2015-16 is estimated at \$44.00, which is no change compared to the current year estimate. The decrease in average cost in the current year is the result of lab consolidation. GDSP anticipates that lab consolidation will save the program approximately \$1.00 per client or \$1,000,000 dollars over current year and budget year.



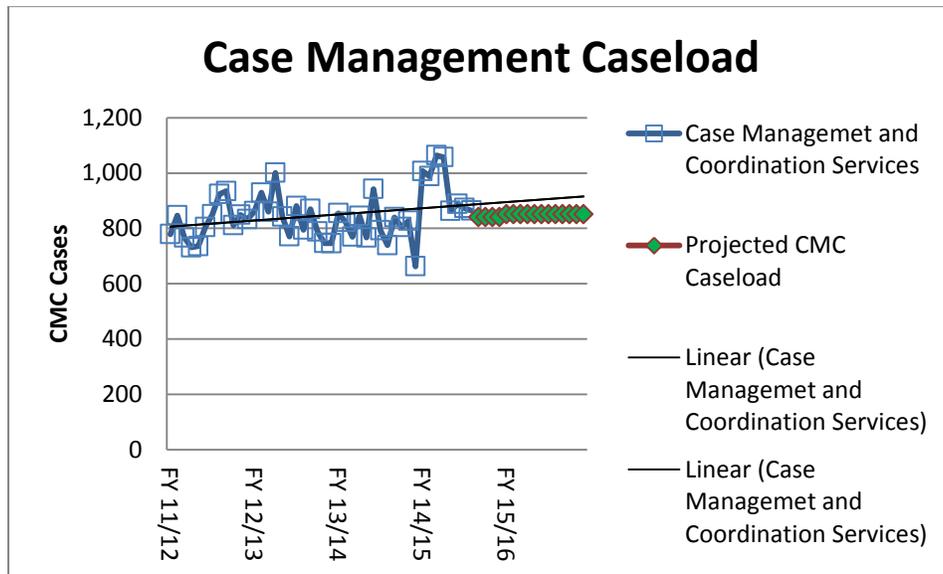
Technical and Scientific Total Cost- GDSP estimates current year Technical and Scientific costs to total \$21,629,872, which is an increase of \$535,069 or 2.4% compared to FY 2013-14 actual technical and scientific costs of \$22,164,941. Technical and Scientific costs in FY 2015-16 are estimated to total \$21,783,476, which is an increase of \$153,604 or 0.7% compared to the current year estimate. The increase in cost for budget year is attributable to projected increases in caseload.

Case Management and Coordination Services:

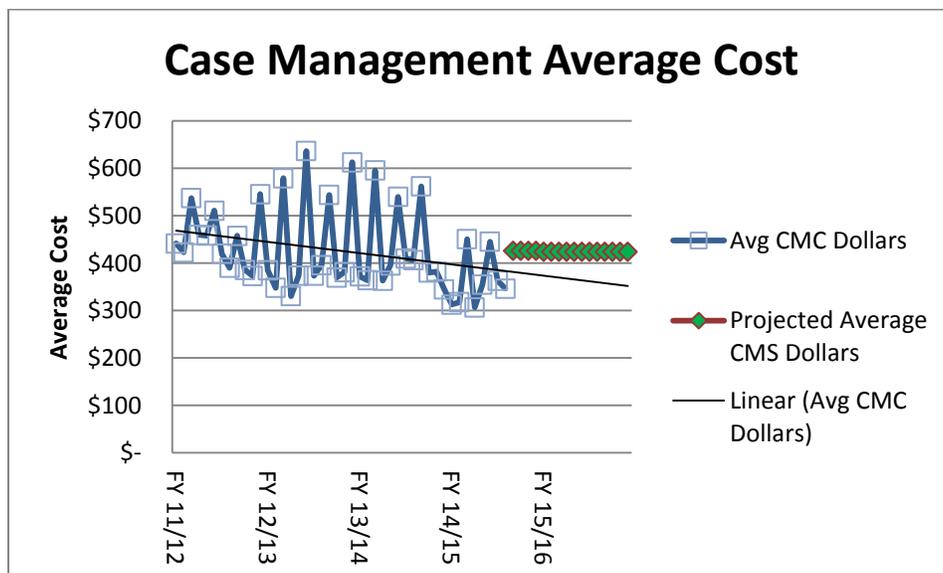
Overview- Services provided to infants who screen initial positive or have questionable screening test results for the 75+ genetic disorders screened. These services include: time-sensitive coordination for specific confirmatory testing, family consultation – including consultation with the infant’s 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 10,080, which is an increase of 411 or 4.3% compared to FY 2013/14 actual CMCS caseload of 9,669. CMCS caseload in FY 2015-16 is estimated at 10,200, which is an increase of 120 or 1.2% compared to the current year estimate. These case load increases are due mainly to projected increases in total caseload. While the trend for CMCS

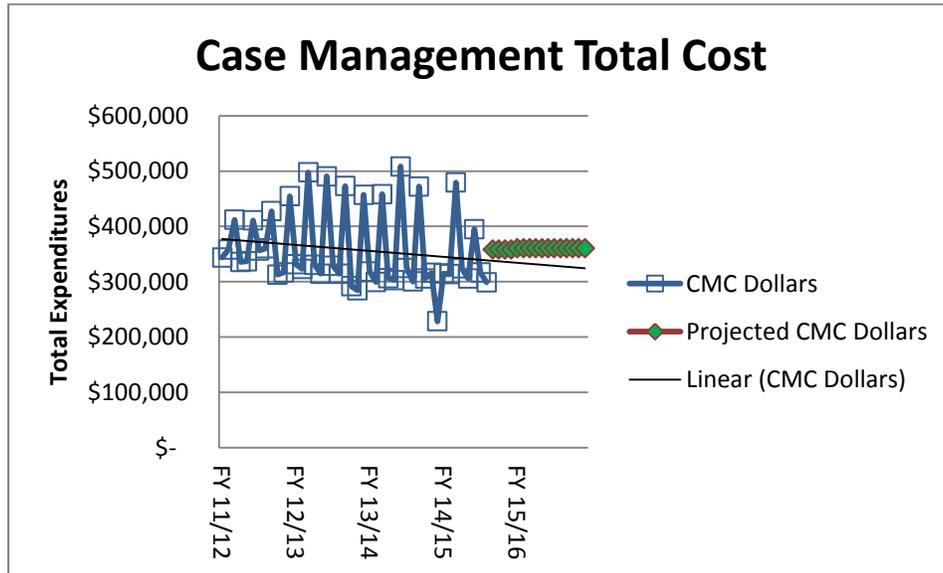
participation has been declining, GDSP does not expect this trend to continue. The following chart shows the actual CMCS cases by month, along with projected numbers for the remainder of the current year and budget year.



Case Management and Coordination Services (CMCS) Average Cost- GDSP estimates current year average CMCS cost per participant will be \$426.00, which is a decrease of \$2.22 or 0.5% compared to FY 2013-14 actual average CMCS cost per participant of \$428.22. Average CMCS cost per participant in FY 2015-16 is estimated at \$424.00, which is a decrease of \$2.00 or 0.5% compared to the current year estimate. The decreases in average cost in current year and budget year are the result of increased caseload. CMCS costs are a combination of fixed costs and incremental (per case) reimbursement. Increased caseload with some fixed costs decreases the average cost.



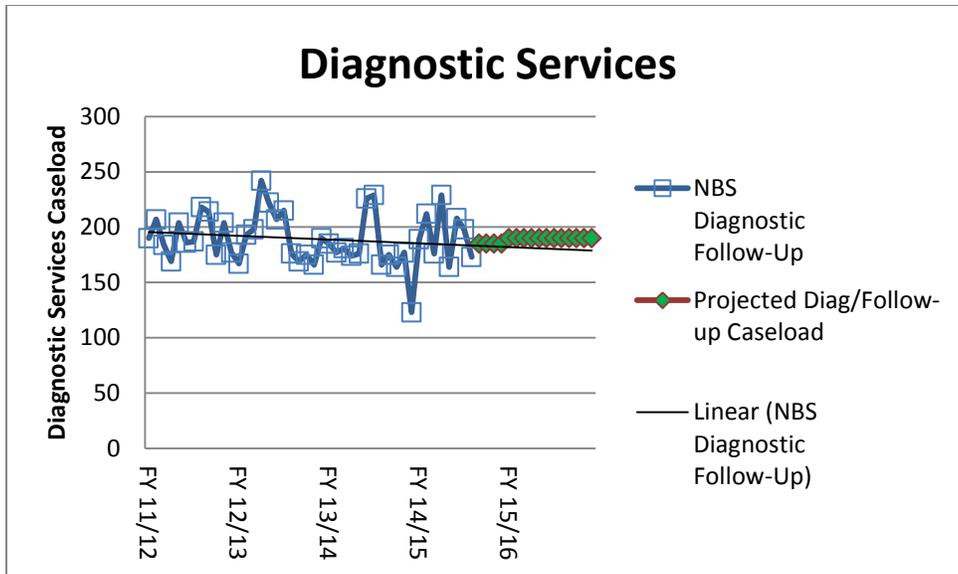
Case Management and Coordination Services (CMCS) Total Cost- GDSP estimates current year CMCS costs to total \$4,294,080, which is an increase of \$153,612 or 3.7% compared to FY 2013-14 actual CMCS total costs of \$4,140,468. CMCS costs in FY 2015-16 are estimated to total \$4,324,800, which is an increase of \$30,720 or 0.7% compared to the current year estimate. The increase is caused by the projected increase in caseload but is partially offset by the small decrease in projected average CMCS costs.



Diagnostic Services:

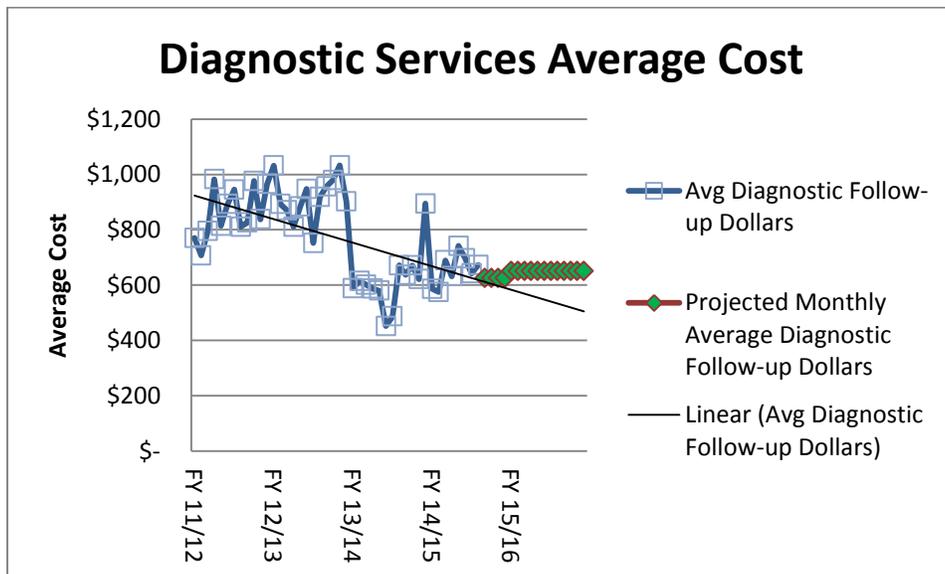
Overview- Diagnostic Services are for infants who require extended monitoring while undergoing confirmatory testing and diagnosis. Clinical outcome data is collected on infants once diagnosis is made as a means of tracking, confirming, evaluating, and refining program standards. Services include: coordination 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 2,220, which is an increase of 67 or 3.1% compared to FY 2013/14 actual Diagnostic Services caseload of 2,153. Diagnostic caseload in FY 2015-16 is estimated at 2,280, which is an increase of 60 or 2.7% compared to the current year estimate. The following chart shows the actual Diagnostic Services cases by month, along with projected numbers for the remainder of the current year and budget year.

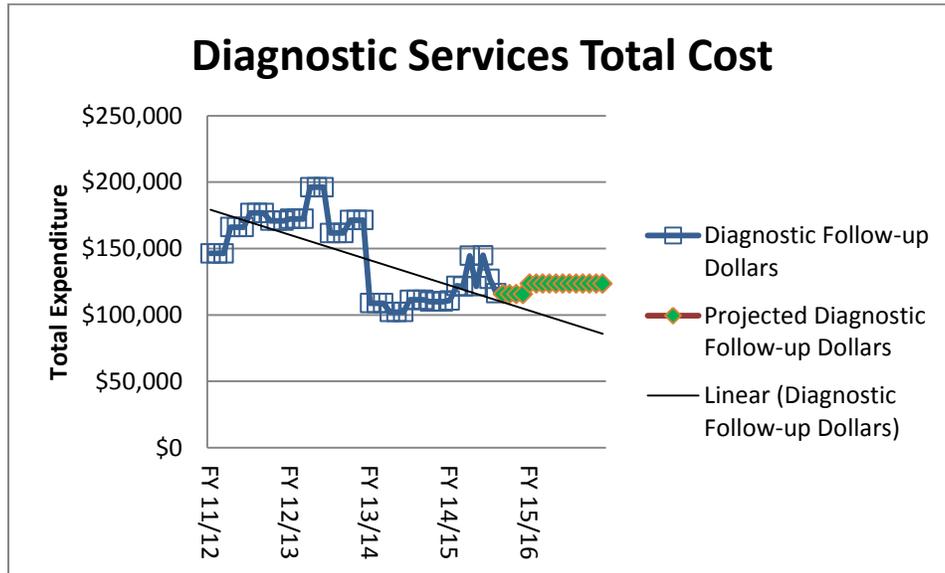


Diagnostic Services Average Cost- GDSP estimates current year average Diagnostic Services cost per participant will be \$625.00, which is an increase of \$22.51 or 3.7% compared to FY 2013-14 actual average Diagnostic Services cost per participant of \$602.49*. Average Diagnostic Services cost per participant in FY 2015-16 are estimated at \$650.00, which is an increase of \$25.00 or 4.0% compared to the current year estimate. Even though the average cost per client has been decreasing in recent months, GDSP does not expect this trend to continue. Cost initially fell as GDSP modified the way it paid for services (i.e. transitioned from paying a flat rate to a fee for service), and as a result of the types of services clients received. GDSP expects this trend will flatten over the next two years.

*\$602.49 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.



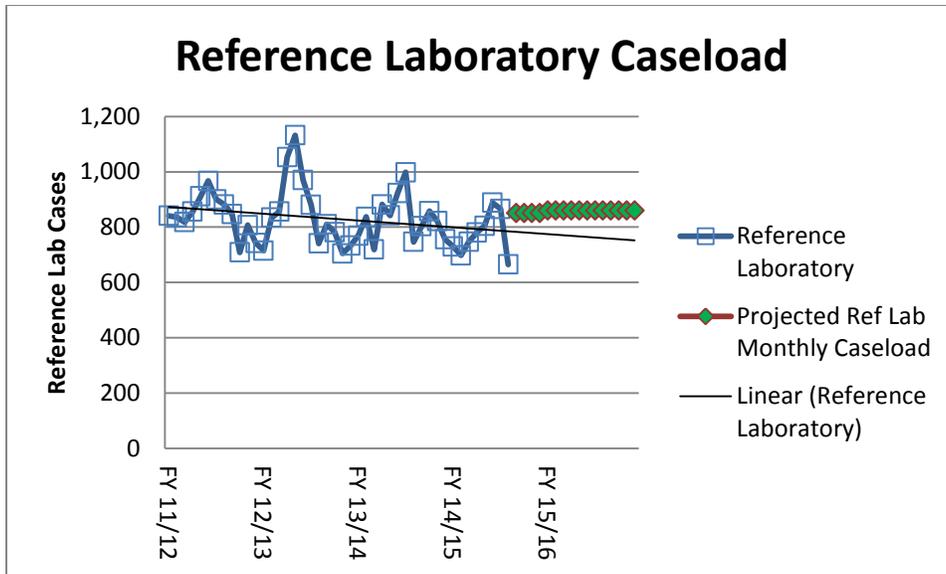
Diagnostic Services Total Cost- GDSP estimates current year Diagnostic Services costs to total \$1,387,500, which is an increase of \$90,330 or 7.0% compared to FY 2013-14 actual Diagnostic Services total costs of \$1,297,170. Diagnostic Services costs in FY 2015-16 are estimated to total \$1,482,000, which is an increase of \$94,500 or 6.81% 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.



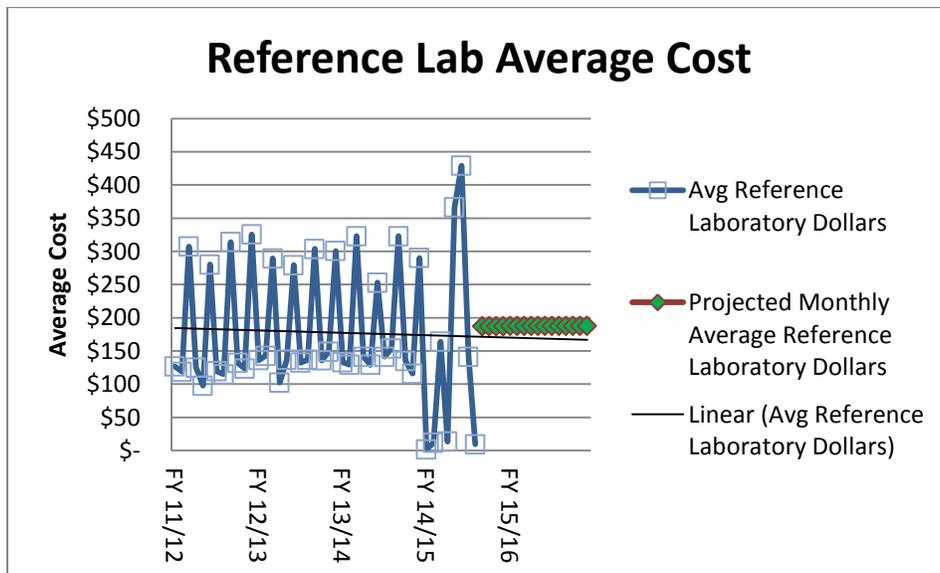
Reference Laboratory Cases:

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.

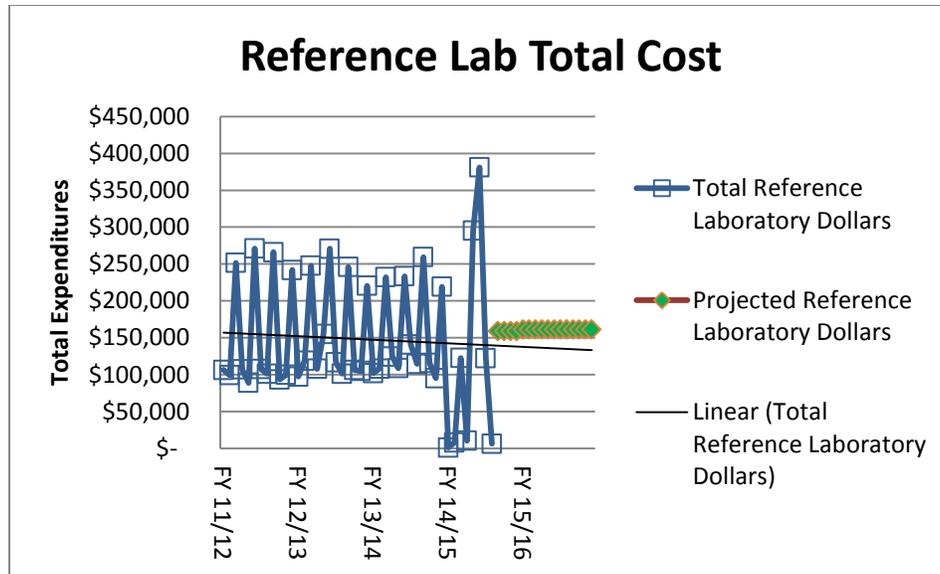
Reference Laboratory Caseload- GDSP estimates current year Reference Laboratory caseload will total 10,200, which is an increase of 244 or 2.5% compared to FY 2013/14 actual Reference Laboratory caseload of 9,956. Reference Laboratory caseload in FY 2015-16 is estimated at 10,320, which is an increase of 120 or 1.2% compared to the current year estimate. 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 \$187.00, which is an increase of \$0.74 or 0.4% compared to FY 2013-14 Reference Laboratory actual average cost per participant of \$186.26. Reference Laboratory average cost per participant in FY 2015-16 is estimated at \$187.50, which is an increase of \$0.50 or 0.3% compared to the current year estimate. These small increases in average cost are the result general price inflation offset by the slight increase in caseload.



Reference Laboratory Total Cost- GDSP estimates current year Reference Laboratory costs to total \$1,907,400, which is an increase of \$52,979 or 2.9% compared to FY 2013-14 actual Diagnostic Services total costs of \$1,854,421. Reference Laboratory costs in FY 2015-16 are estimated to total \$1,935,000, which is an increase of \$27,600 or 1.5% 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.



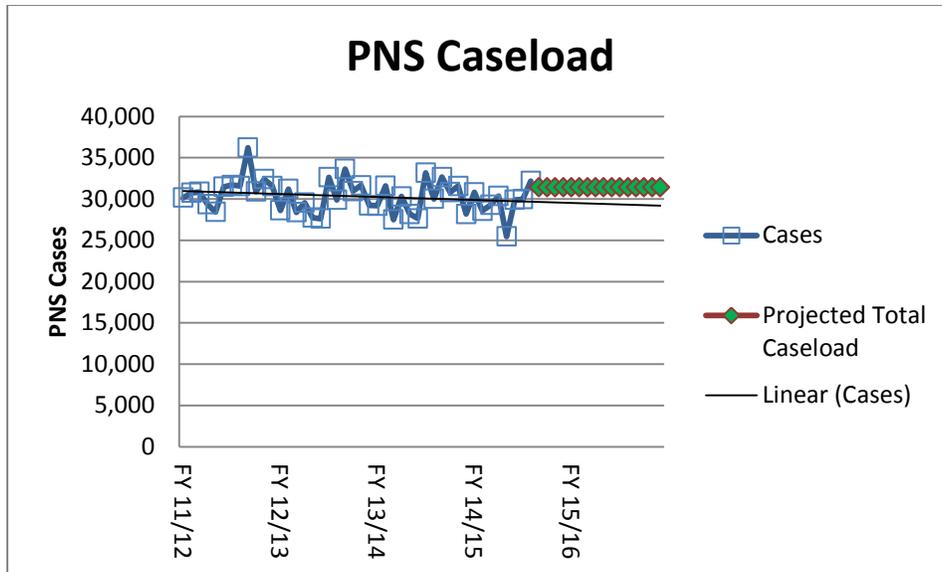
APPENDIX B: PNS Assumptions and Rationale

1. Contract Laboratories:

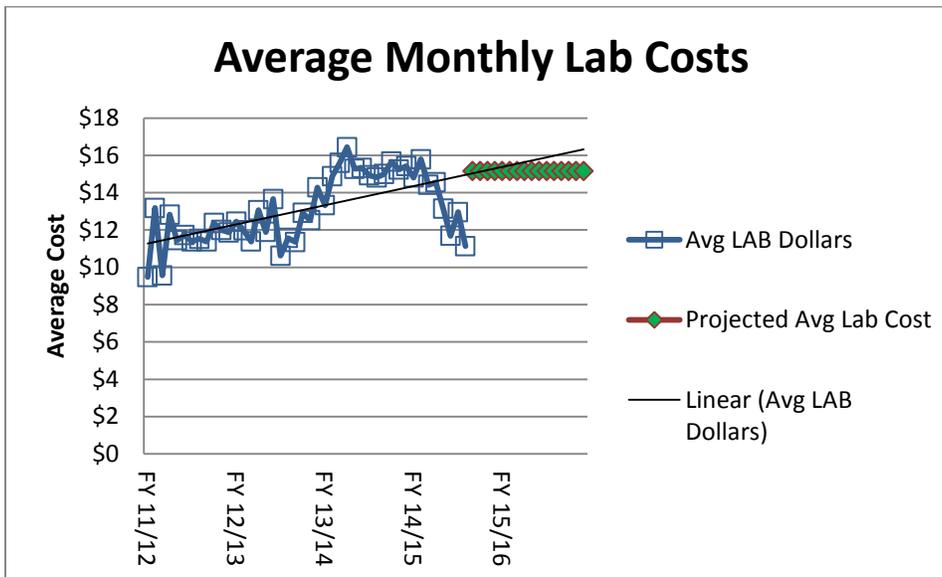
Overview- Laboratory testing to screen pregnant women for genetic and congenital disorders, such as Trisomy 21, Trisomy 18, Smith-Lemli-Opitz Syndrome (SLOS), and Neural Tube Defects. Costs include laboratory services for performing prenatal genetic screening tests. The screening test estimates the chance 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 7 regional laboratories, currently the state contracts with five regional contract laboratories that are paid on a per specimen basis.

In the past GDSP estimated the number of 1st trimester and 2nd trimester screens performed separately in the estimate. This is because the average cost of the 1st trimester screen was substantially less than the cost of the 2nd trimester screens. Currently however the cost of each test is the same, as such GDSP will estimate the average cost to provide both screens without differentiating between the two tests a participant may receive.

Total Caseload – GDSP estimates current year caseload will total 367,550, which is an increase of 6,691 or 1.8% compared to FY 2013/14 actual total caseload of 360,859. Caseload in FY 2015-16 is estimated at 377,160 which is an increase of 9,610 or 2.6% 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 73% of the projected births will participate in the PNS program in FY 2014/15, and that the number of participants will remain constant in FY 2015-16. The FY 2015-16 projections does 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 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 \$15.16, which is no change compared to FY 2013-14 actual average laboratory cost per participant of \$15.16. Average laboratory cost per participant in FY 2015-16 is estimated at \$15.17, which is an increase of \$0.01 compared to current year estimate.



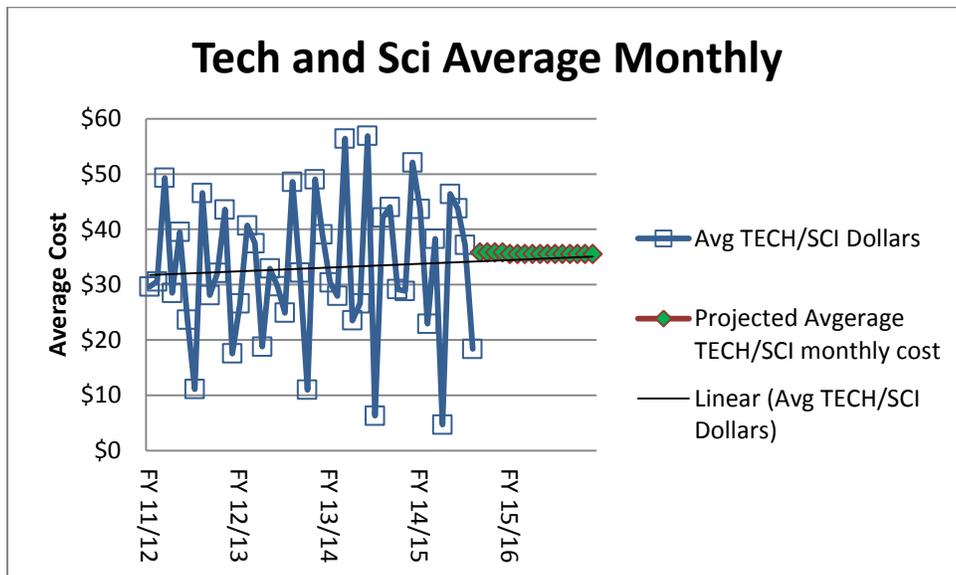
Contract Laboratory Total Cost Projections- GDSP estimates current year contract laboratory cost to total \$5,572,058, which is an increase of \$103,182 or 1.8% compared to FY 2013-14 actual contract laboratory costs of \$5,468,876. Laboratory costs in FY 2015-16 are estimated to total \$5,721,517, which is a decrease of \$149,459 or 2.6% compared to the current year estimate. The costs adjustments are attributable to changing participation and average cost projections.

2. Technical and Scientific

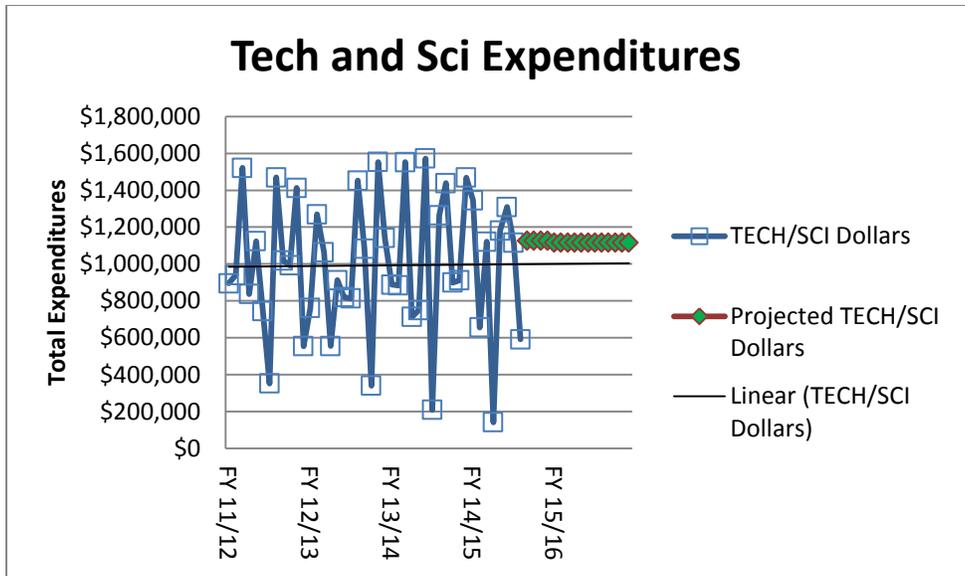
Overview- Costs associated with screening services provided at the laboratory include: reagent kits, limited maintenance and support (as it directly relates to the reagents) of laboratory equipment, supplies, and processing. In addition, there are several costs associated with screening including: blood 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 \$35.80, which is an increase of \$1.03 or 2.9% compared to FY 2013-14 actual average Technical and Scientific cost per participant of \$34.77. Average laboratory cost per participant in FY 2015-16 is estimated at \$35.51, which is an increase of \$0.01 compared to the current year estimate. The increases in average cost in the budget year are the result of an approximate 3.0% cost increase associated with a negotiated contract increase.



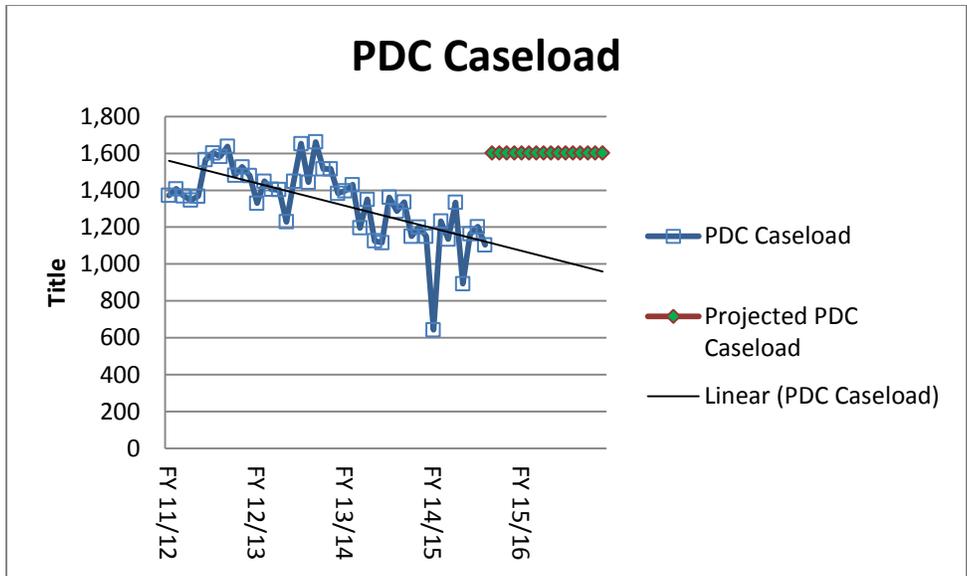
Technical and Scientific Total Cost- GDSP estimates current year Technical and Scientific costs to total \$13,158,290, which is an increase of \$609,484 or 4.6% compared to FY 2013-14 actual technical and scientific costs of \$12,548,806. Technical and Scientific costs in FY 2015-16 are estimated to total \$13,392,952, which is an increase of \$234,662 or 1.7% compared to the current year estimate. The increase in the current and budget year is caused by updated DRU Birth Rate figures, that decreased caseload, coupled with an approximately 3.0% increase in average cost.



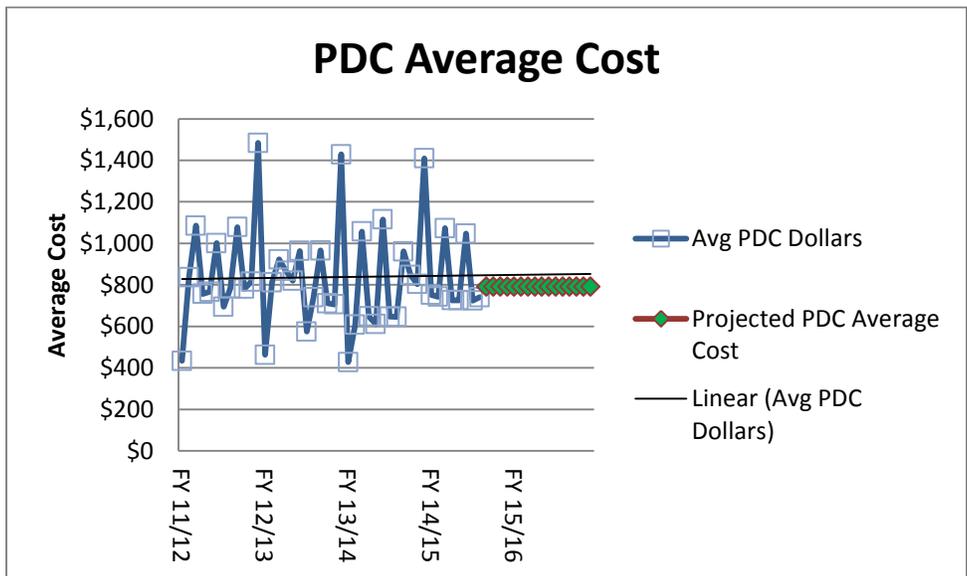
Prenatal Diagnostic Services Centers

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 19,229, which is an increase of 4,130 or 27.4% compared to the FY 2013-14, actual PDC caseload of 15,099. PDC caseload in FY 2015-16 is estimated to total 19,229, which is no change compared to the current year estimate. The increase in current year which is expected to be sustained in the 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.

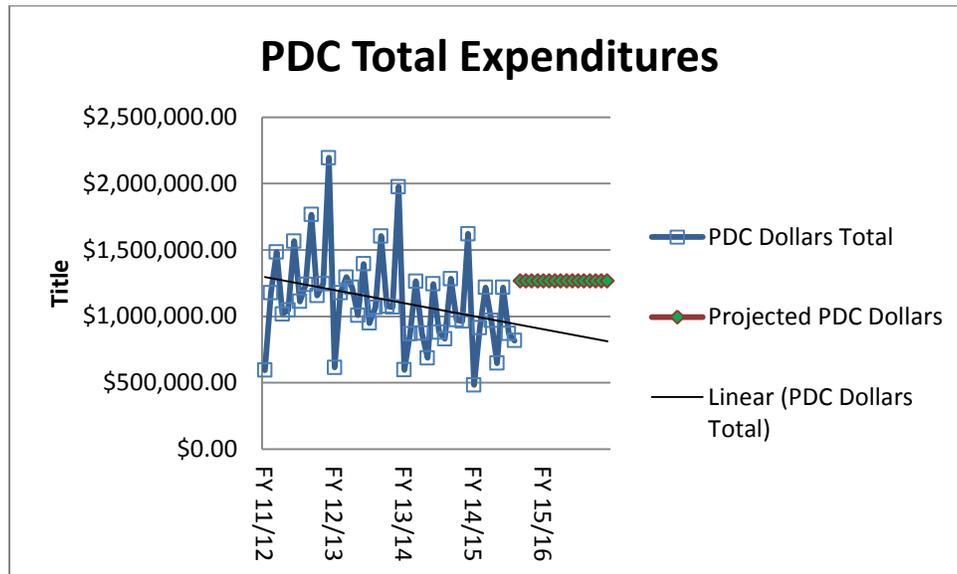


Prenatal Diagnostic Services Average Cost- GDSP estimates current year average PDC cost per participant will be \$790.00, which is a decrease of \$10.82 or 1.4% compared to FY 2013-14 actual average PDC cost per participant of \$800.82. Average laboratory cost per participant in FY 2015-16 is estimated at \$790.00, 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.



Prenatal Diagnostic Services Total Cost- GDSP estimates current year PDC costs to total \$15,191,183, which is an increase of \$3,099,605 or 25.6% compared to FY 2013-14 actual PDC total costs of \$12,091,578. PDC costs in FY 2015-16 are estimated to total \$15,191,183, which is no change 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.

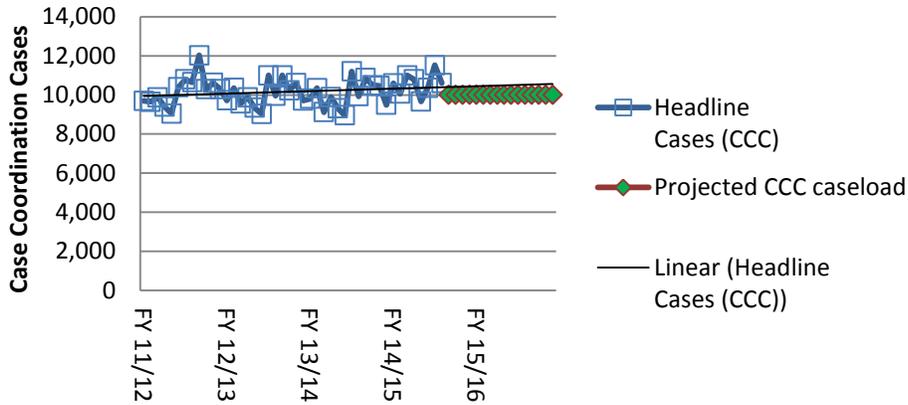


Case Management and Coordination Services:

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.

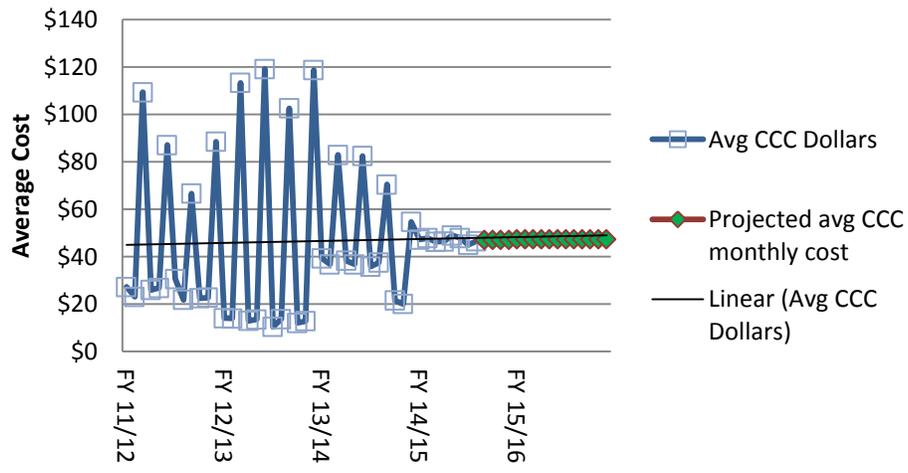
Case Management and Coordination Services (CMCS) Caseload- GDSP estimates current year CMCS caseload will total 120,000, which is an increase of 128 or .1% compared to FY 2013/14 actual CMCS caseload of 119,872. CMCS caseload in FY 2015-16 is estimated at 120,000, which is no change compared to the current year estimate. 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 projected numbers for the remainder of the current year and budget year.

Management & Coordination Case Load

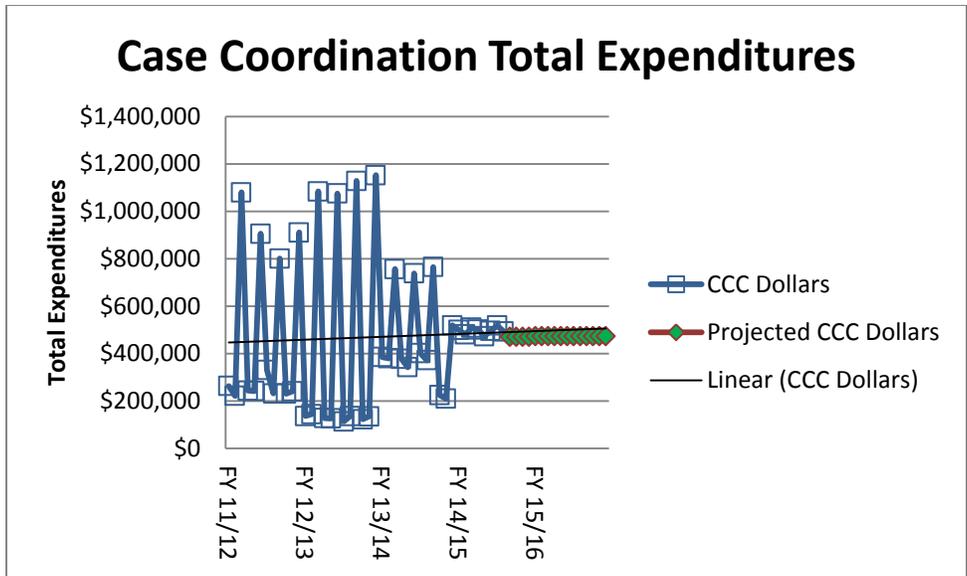


Case Management and Coordination Services (CMCS) Average Cost- GDSP estimates current year average CMCS cost per participant will be \$47.00, which is an increase of \$1.35 or 2.9% compared to FY 2013-14 actual average CMCS cost per participant of \$45.65. Average laboratory cost per participant in FY 2015-16 is estimated at \$47.25, which is an increase of \$0.25 or 0.5% compared to the current year estimate. These increases are attributable to general increases that GDSP has realized in the cost to provide follow-up services.

Case Coordination Average Cost



Case Management and Coordination Services (CMCS) Total Cost- GDSP estimates current year CMCS costs to total \$5,640,000, which is an increase of \$167,373 or 3.1% compared to FY 2013-14 actual CMCS total costs of \$5,472,627. CMCS costs in FY 2015-16 are estimated to total \$5,670,000, which is an increase of \$30,000 or 0.5% 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 2014-15	\$112.70	491,588	98%	\$54,293,928
FY 2015-16	\$112.70	495,079	98%	\$54,679,495

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. GDSP has implemented a new health insurance billing system which will likely lead to improved collection rates and is exploring

potential methods of increasing the collection rate from non-Medi-Cal payers, including the proposed TBL mentioned previously. Analysis of 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 81% of all claims submitted to private insurance companies and other payers. However, with adoption of the proposed TBL GDSP anticipates the PNS collection rates to increase slightly from 81% to 83% in FY 2015-16. 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

	A=(\$207-\$10)	B	C	D=1-C	E	F	G=(B*C)	H=(B*D)	I=(G*A*E)+(H*A*F)
Fiscal Year	Fee	Caseload	% Medi-Cal	% Non-Medical	Medi-Cal Collection Rate	Private Insurance Collection Rate	Medi-Cal Cases	Non Medi-Cal Cases	Total Revenue
FY 2014-15	\$197	367,550	45%	55%	98%	81%	165,398	202,153	\$64,189,116
FY 2015-16	\$197	377,160	45%	55%	98%	83%	169,722	207,438	\$66,684,717