

Genetic Disease Screening Program (GDSP)

Fiscal Year 2018-19

November Estimate



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A. Program Overview

The California Department of Public Health (CDPH), Genetic Disease Screening Program (GDSP) Estimate provides a revised projection of Fiscal Year (FY) 2017-18 expenditures along with projected costs for FY 2018-19 Local Assistance and State Operations budget for GDSP.

The CDPH/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.

B. Combined State Operations and Local Assistance Overview

The CDPH/GDSP 2017 Budget Act appropriation is \$131.6 million, of which \$104.7 million is for Local Assistance and \$26.9 million is for State Operations. CDPH/GDSP estimates revised FY 2017-18 expenditures of \$132.4 million, which is an increase of \$796,000 compared to the 2017 Budget Act. The increase is a result of various baseline adjustments. The combined State Operations and Local Assistance budget expenditures for FY 2018-19 total \$132.9 million, which is an increase of \$1.3 million or 1 percent compared to the 2017 Budget Act.

Table 1 shows the difference between the 2017 Budget Act appropriation and the revised FY 2017-18 expenditures and proposed FY 2018-19 expenditures for CDPH/GDSP.

In FY 2018-19, an increase in State Operations of \$2.2 million is needed to fund 15 positions to address the routine testing and ongoing workload associated with the addition of Pompe disease and mucopolysaccharidosis type I (MPS-I) in compliance with Senate Bill (SB) 1095 (Chapter 363, Statutes of 2016) to expand statewide screening of newborns to include screening of any disease that is detectable in blood samples within two years of the disease being adopted by the federal Recommended Uniform Screening Panel (RUSP). In addition, CDPH/GDSP will transfer \$460,000 from Local Assistance to State Operations to perform the routine and ongoing workload associated with second-tier testing. State Operations is also increased by \$538,000 as a result of various baseline adjustments, decreased by \$302,000 to remove a one-time appropriation increase, and removal of a one-time \$330,000 transfer from Local Assistance to State Operations authorized in the 2017 Budget Act.

An increase of \$1.5 million in Local Assistance expenditure authority will be required to purchase the consumables, supplies, and reagents related to the ongoing screening and testing activities of Pompe and MPS-I. These additional ongoing costs will require a NBS fee increase of \$12 per specimen effective July 1, 2018. Other changes to Local Assistance in FY 2018-19 include the restoration of \$330,000 for the one-time transfer to State Operations for 2nd tier testing in FY 2017-18. Additionally, Local Assistance will be reduced by \$3.1 million, as a result of the proposed transfer of \$460,000 to State Operations for the ongoing workload related to the 2nd tier testing, removal of the \$2.3 million SB 1095 one-time appropriation increase from FY 2017-18, and \$380,000 in savings from implementing 2nd tier testing.

Table 1
GDSP: Current Year and Budget Year Budget Summaries Compared to 2017 Budget Act

Fund 0203 Genetic Disease Testing Fund	FY 2017-18 Budget Act	FY 2017-18			FY 2018-19		
		November Estimate FY 2017-18	Change from Budget Act	Percent Change from Budget Act	November Estimate FY 2018-19	Change from Budget Act	Percent Change from Budget Act
Total	\$ 131,586,000	\$ 132,382,000	\$ 796,000	0.6%	\$ 132,924,000	\$ 1,338,000	1.0%
State Operations	\$ 26,854,000	\$ 27,650,000	\$ 796,000	3.0%	\$ 29,451,000	\$ 2,597,000	9.7%
Local Assistance	\$ 104,732,000	\$ 104,732,000	\$ -	0.0%	\$ 103,473,000	\$ (1,259,000)	-1.2%

C. Local Assistance Expenditure Projections

Current Year (FY 2017-18)

The CDPH/GDSP 2017 Budget Act appropriation for CDPH/GDSP's Local Assistance is \$104.7 million. CDPH/GDSP anticipates the November Estimate for FY 2017-18 expenditures to be the same at \$104.7 million, which is no change compared to the 2017 Budget Act.

Budget Year (FY 2018-19)

For FY 2018-19, CDPH/GDSP estimates Local Assistance expenditures will total \$103.5 million, which is a decrease of \$1.3 million or 1.2 percent compared to the 2017 Budget Act. CDPH/GDSP requests an increase in expenditure authority of \$1.5 million for the purchase of consumables, supplies, and reagents related to the ongoing screening and testing activities related to Pompe disease and MPS-I as required by SB 1095 (Chapter 393, Statutes of 2016). The \$330,000 one-time transfer to State Operations related to 2nd tier testing, authorized in the 2017 Budget Act, will be restored to Local Assistance in the budget year; however, Local Assistance will be reduced by \$3.1 million. The decrease in Local Assistance is a result of a permanent transfer of \$460,000 to State Operations for the ongoing workload related to the 2nd tier testing, removal of one-time funding of \$2.3 million from FY 2017-18, and the projected savings of \$380,000 from implementing 2nd tier testing.

Table 2 shows the difference between the 2017 Budget Act appropriation and the revised FY 2017-18 expenditures and proposed FY 2018-19 expenditures for the CDPH/GDSP Local Assistance.

Table 2
Local Assistance Total: Current Year and Budget Year Budget Summaries Compared to 2017 Budget Act

Fund 0203 Genetic Disease Testing Fund	FY 2017-18 Budget Act	FY 2017-18			FY 2018-19		
		November Estimate FY 2017-18	Change from Budget Act	Percent Change from Budget Act	November Estimate FY 2018-19	Change from Budget Act	Percent Change from Budget Act
Local Assistance Total	\$ 104,732,000	\$ 104,732,000	\$ -	0.0%	\$ 103,473,000	\$ (1,259,000)	-1.2%
NBS	\$ 41,259,000	\$ 40,097,000	\$ (1,162,000)	-2.8%	\$ 40,984,000	\$ (275,000)	-0.7%
PNS	\$ 34,224,000	\$ 35,184,000	\$ 960,000	2.8%	\$ 35,016,000	\$ 792,000	2.3%
Operational Support	\$ 29,249,000	\$ 29,451,000	\$ 202,000	0.7%	\$ 27,473,000	\$ (1,776,000)	-6.1%

Future Fiscal Considerations

Beyond FY 2017-18 CDPH/GDSP foresees two developments that may impact the program's budget and operations:

Senate Bill (SB) 1095: Newborn Screening Program

SB 1095 amends Sections 124977 and 125001 of the Health and Safety Code and requires the CDPH/ GDSP to expand statewide screening of newborns to include screening for any disease that is detectable in blood samples within two years of the disease being adopted by the federal RUSP.

Screening for additional diseases will require start-up costs, additional laboratory equipment, changes to the Screening Information System (SIS), the follow-up systems, the addition of new confirmatory testing, and additional personnel. Furthermore, as additional diseases are added to the federal RUSP, there will be a need to request additional expenditure authority necessary to plan, prepare for, and implement the additional required screening (for any new diseases). If CDPH/GDSP is unable to absorb the additional spending authority within its current revenue, a fee increase may be needed.

CDPH/GDSP adopted two new disorders, Pompe disease and MPS-I in FY 2016-17; however, screening is not set to commence until August 2018. Currently, Spinal Muscular Atrophy (SMA) is being considered for addition to the RUSP this year which may require CDPH/GDSP to add SMA screening within two years or by FY 2019-20. This could potentially impact FY 2018-19 expenditures and revenues. However, the timing of when a new disorder is added is not certain and this will remain as a future fiscal impact.

Expenditure Methodology / Key Drivers of Cost

The CDPH/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/GDSP 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 CDPH/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 CDPH/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 2017-18 CDPH/GDSP revised NBS Local Assistance expenditures total \$40.1 million, which is a decrease of \$1.2 million or 2.8 percent compared to 2017 Budget Act amount of \$41.3 million. Although caseload is slightly increasing due to a higher percentage of expected NBS cases, the current year decrease can be attributed to lower average costs in the Contract Laboratories and Technical and Scientific categories.

For FY 2018-19 CDPH/GDSP estimates that NBS Local Assistance expenditures will total \$40.1 million, which is a decrease of \$275,000 or 0.7 percent compared to the 2017 Budget Act amount of \$41.3 million. The reductions in the budget year funding are associated with a decrease in caseload, one-time adjustments, and savings from implementing 2nd tier testing and screening for SB 1095.

Table 3 shows the difference between the 2017 Budget Act appropriation and the revised FY 2017-18 expenditures and proposed FY 2018-19 expenditures for the Newborn Screening program costs by client type.

Table 3

NBS: Current Year and Budget Year Budget Summaries Compared to 2017 Budget Act

Fund 0203 Genetic Disease Testing Fund	FY 2017-18 Budget Act	FY 2017-18			FY 2018-19		
		November Estimate FY 2017-18	Change from Budget Act	Percent Change from Budget Act	November Estimate FY 2018-19	Change from Budget Act	Percent Change from Budget Act
Total	\$ 41,259,000	\$ 40,097,000	\$ (1,162,000)	-2.8%	\$ 40,984,000	\$ (275,000)	-0.7%
Lab Dollars	\$ 7,907,000	\$ 7,004,000	\$ (903,000)	-11.4%	\$ 6,971,000	\$ (936,000)	-11.8%
Tech Sci	\$ 25,466,000	\$ 24,428,000	\$ (1,038,000)	-4.1%	\$ 25,280,000.00	\$ (186,000)	-0.7%
Reference Lab	\$ 1,836,000	\$ 1,686,000	\$ (150,000)	-8.2%	\$ 1,866,000.00	\$ 30,000	1.7%
CMCS	\$ 4,354,000	\$ 4,841,000	\$ 487,000	11.2%	\$ 4,772,000.00	\$ 418,000	9.6%
Diagnostic Services	\$ 1,696,000	\$ 2,138,000	\$ 442,000	26.1%	\$ 2,095,000.00	\$ 399,000	23.5%

PNS Expenditures Projections (See Appendices B1-B4)

For FY 2017-18 CDPH/GDSP revised PNS Local Assistance expenditures total \$35.2 million, which is an increase of \$960,000 or 2.8 percent compared to the 2017 Budget Act amount of \$34.2 million.

For FY 2018-19 CDPH/GDSP estimates that PNS Local Assistance expenditures will total \$35.0 million, which is an increase of \$792,000 or 2.3 percent compared to the 2017 Budget Act amount. Although caseload is declining, the main reason for the increase in costs in the current year and budget year are due to expected increases in the Technical and Scientific category.

Table 4 shows the difference between the 2017 Budget Act and the revised FY 2017-18 expenditures and proposed FY 2018-19 expenditures for the Prenatal Screening program costs by client type.

Table 4

PNS: Current Year and Budget Year Budget Summaries Compared to 2017 Budget Act

Fund 0203 Genetic Disease Testing Fund	FY 2017-18 Budget Act	FY 2017-18			FY 2018-19		
		November Estimate FY 2017-18	Change from Budget Act	Percent Change from Budget Act	November Estimate FY 2018-19	Change from Budget Act	Percent Change from Budget Act
Total	\$ 34,224,000	\$ 35,184,000	\$ 960,000	2.8%	\$ 35,016,000	\$ 792,000	2.3%
Contract Lab	\$ 4,706,000	\$ 4,512,000	\$ (194,000)	-4.1%	\$ 4,490,000	\$ (216,000)	-4.6%
Tech & Sci	\$ 12,118,000	\$ 13,280,000	\$ 1,162,000	9.6%	\$ 13,217,000	\$ 1,099,000	9.1%
CMCS	\$ 5,967,000	\$ 6,101,000	\$ 134,000	2.2%	\$ 6,072,000	\$ 105,000	1.8%
PDC	\$ 11,433,000	\$ 11,291,000	\$ (142,000)	-1.2%	\$ 11,237,000	\$ (196,000)	-1.7%

Operational Support Projections

For FY 2017-18 CDPH/GDSP estimates that Operational Support expenditures will total \$29.5 million, which is an increase of \$202,000 compared to the 2017 Budget Act. The increase is due to additional expenses related to laboratory equipment software modifications.

In FY 2018-19 CDPH/GDSP projects Operational Support expenditures will total \$27.5 million, which is a decrease of \$1.8 million or 6.1 percent compared to the 2017 Budget Act. The reductions in Operational Support are due to one-time adjustments for equipment and system upgrades from FY 2017-18 for implementing SB 1095 and 2nd tier testing.

Table 5 shows the difference between the 2017 Budget Act and the revised FY 2017-18 expenditures and proposed FY 2018-19 expenditures for the Program Operational Support costs.

Table 5

Operational Support: Current Year and Budget Year Budget Summaries Compared to 2017 Budget Act

Fund 0203 Genetic Disease Testing Fund	FY 2017-18 Budget Act	FY 2017-18			FY 2018-19		
		November Estimate FY 2017-18	Change from Budget Act	Percent Change from Budget Act	November Estimate FY 2018-19	Change from Budget Act	Percent Change from Budget Act
Operational Support	\$ 29,249,000	\$ 29,451,000	\$ 202,000	0.7%	\$ 27,473,000	\$ (1,776,000)	-6.1%

D. State Operations Expenditure Projections

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 2017-18, CDPH/GDSP estimates that State Operations expenditures will total \$27.7 million, which is a change of \$796,000 compared to the 2017 Budget Act. The increase is due to various baseline adjustments.

In FY 2018-19, CDPH/GDSP estimates State Operations expenditures will total \$29.5 million, which is a change of \$2.6 million or 9.7 percent compared to the 2017 Budget Act. The net increase in budget year is associated with the request to increase State Operations expenditure authority by \$2.2 million to fund 15 positions for the routine testing and ongoing workload associated with the addition of Pompe disease and MPS-I, a transfer of \$460,000 from Local Assistance to State Operations to fund 3 positions for the routine and ongoing workload for second tier testing, restoring the one-time transfer of \$330,00 to Local Assistance from State Operations, and an increase of \$538,000 due to various baseline adjustments.

Table 6 shows the difference between the 2017 Budget Act and the revised FY 2017-18 expenditures and proposed FY 2018-19 expenditures for the GDSP State Operations costs.

Table 6

State Operations: Current Year and Budget Year Budget Summaries Compared to 2017 Budget Act

Fund 0203 Genetic Disease Testing Fund	FY 2017-18 Budget Act	FY 2017-18			FY 2018-19		
		November Estimate FY 2017-18	Change from Budget Act	Percent Change from Budget Act	November Estimate FY 2018-19	Change from Budget Act	Percent Change from Budget Act
State Operations	\$ 26,854,000	\$ 27,650,000	796,000	2.96%	\$ 29,451,000	\$ 2,597,000	9.7%

E. Revenue Projections

Combined NBS and PNS Revenue

CDPH/GDSP has revised revenue estimates for FY 2017-18 totaling \$126.7 million, which is a decrease of \$633,000 or 0.5 percent compared to the 2017 Budget Act amount of \$127.3 million.

For FY 2018-19 CDPH/GDSP projects revenue will total \$131.7 million, which is an increase of \$4.4 million or 3.4 percent compared to the 2017 Budget Act amount of \$127.3 million.

All other assumptions and calculations remain unchanged from the 2017 Budget Act.

Revenue Estimate Methodology

Effective July 1, 2016, PNS charges a fee of \$221.60, \$211.60 of which is deposited into the Genetic Disease Testing Fund (Fund 0203), with the remaining \$10 deposited into the Birth Defects Monitoring Program (BDMP) Fund (Fund 3114). Effective July 1, 2018, CDPH/GDSP will require a PNS fee increase of \$4 to increase the fee deposited to BDMP Fund from \$10 to \$14. The new PNS fee will be \$225.60. CDPH/GDSP collects PNS fees from individual participants, private insurers, and Medi-Cal.

For PNS, CDPH/GDSP is able to collect approximately 98% of all fees owed on behalf of Medi-Cal patients (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 \$130.25. Effective July 1, 2018, CDPH/GDSP will require a fee increase of \$12 to support the increase in expenditures needed to perform the routine and ongoing workload for Pompe disease and MPS-I. The new NBS fee will be \$142.25. Unlike PNS, where CDPH/GDSP bills patients and collects fees from insurers, CDPH/GDSP collects NBS revenue from hospitals and providers directly, which is possible because NBS is a mandated service. As such the billing for NBS services is more streamlined resulting in a 98% collection rate. CDPH/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 2017-18 NBS revenue is expected to total \$61.3 million, which is an increase of \$223,000 or 0.4 percent compared to the 2017 Budget Act amount of \$61.1 million.

In FY 2018-19 CDPH/GDSP projects NBS revenue will total \$66.7 million, which is an increase of \$5.6 million or 9.1 percent compared to the 2017 Budget Act amount of \$61.1 million.

PNS Revenue (See Appendix C2)

In FY 2017-18 PNS revenue is expected to total \$65.3 million, which is a decrease of \$856,000 or 1.3 percent compared to the 2017 Budget Act amount of \$66.2 million.

In FY 2018-19 CDPH/GDSP projects PNS revenue will total \$65.0 million, which is a decrease of \$1.2 million or 1.8 percent compared to the 2017 Budget Act amount of \$66.2 million.

The decrease in both current year and budget year is attributed to the decrease in projected caseload.

Table 7 shows the revised current year revenue projections for current year and budget year compared to 2017 Budget Act.

Table 7

GDSP Revenue: Current Year and Budget Year Revenue Summaries Compared to 2017 Budget Act

Fund 0203 Genetic Disease Testing Fund	FY 2017-18 Budget Act	FY 2017-18			FY 2018-19		
		November Estimate FY 2017-18	Change from Budget Act	Percent Change from Budget Act	November Estimate FY 2018-19	Change from Budget Act	Percent Change from Budget Act
Total	\$ 127,296,000	\$ 126,663,000	\$ (633,000)	-0.5%	\$ 131,686,000	\$ 4,390,000	3.4%
NBS	\$ 61,124,000	\$ 61,347,000	\$ 223,000	0.4%	\$ 66,680,000	\$ 5,556,000	9.1%
PNS	\$ 66,172,000	\$ 65,316,000	\$ (856,000)	-1.3%	\$ 65,006,000	\$ (1,166,000)	-1.8%

Fund Condition Statement

**GENETIC DISEASE TESTING FUND
FUND CONDITION REPORT
DOLLARS IN THOUSANDS**

	2016-17	2017-18	2018-19
RESOURCES			
BEGINNING BALANCE	\$20,917	\$21,761	\$14,311
Prior Year Adjustment	-2,806	0	0
<i>Adjusted Beginning Balance</i>	<u>18,111</u>	<u>21,761</u>	<u>14,311</u>
REVENUES			
121100 Genetic Disease Testing Fees ^{1/}	127,384	126,663	131,686
150300 Income from Surplus Investments	43	45	45
161000 Escheat of Unclaimed Checks & Warrants	2	2	2
TOTALS, REVENUES	<u>127,429</u>	<u>126,710</u>	<u>131,733</u>
TOTAL RESOURCES	\$145,540	\$148,471	\$146,044

EXPENDITURES AND EXPENDITURE ADJUSTMENTS			
4265 Department of Public Health (State Operations)	22,072	27,650	29,451
4265 Department of Public Health (Local Assistance)	99,947	104,732	103,473
8880 Financial Information System for California (State Operations)	36	34	3
9892 Supplemental Pension Payments (State Operations)			202
9900 Statewide General Admin Expenditures (State Ops - Pro Rata)	<u>1,724</u>	<u>1,744</u>	<u>1,101</u>
TOTAL EXPENDITURES AND EXPENDITURE ADJUSTMENTS	123,779	134,160	134,230

FUND BALANCE	21,761	14,311	11,814
	18%	11%	9%

REVENUE PROJECTIONS

2017-18

2017-18 NBS FEES BASED ON	480,607 TESTS @ \$130.25 AND 98% Provider ^{1/}	=	\$61,347,000
2017-18 PNS FEES BASED ON	189,163 TESTS @ \$211.60 AND 83% Non Medi-Cal ^{2/}	=	\$33,222,000
2017-18 PNS FEES BASED ON	<u>154,770 TESTS @ \$211.60 AND 98% Medi-Cal ^{3/}</u>	=	<u>\$32,094,000</u>
	343,933		\$65,316,000

GDSP Total

\$126,663,000

2018-19

2018-19 NBS FEES BASED ON	478,321 TESTS @ \$142.25 AND 98% Provider ^{1/}	=	\$66,680,000
2018-19 PNS FEES BASED ON	188,263 TESTS @ \$211.60 AND 83% Non Medi-Cal ^{2/}	=	\$33,064,000
2018-19 PNS FEES BASED ON	<u>154,033 TESTS @ \$211.60 AND 98% Medi-Cal ^{3/}</u>	=	<u>\$31,942,000</u>
	342,296		\$65,006,000

GDSP Total

\$131,686,000

- 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**New Assumptions/ Premises****Proposed Trailer Bill Language: Birth Defects Monitoring Program Fund**

Background: CDPH administers California's GDSP, which includes the Prenatal Screening Program and the Newborn Screening Program. Both programs screen for genetic disorders that are, for the most part, preventable or remediable by early intervention. They provide clinical oversight for the follow-up services, which include genetic counseling and confirmatory testing, including ultrasound and diagnostic procedures. The PNS Program charges a fee of \$221.60 and \$10 of that fee is deposited into the Birth Defects Monitoring Program Fund (Fund 3114). The \$10 was specified by Assembly Bill 2599 (Chapter 680, Statutes of 2008) and has remained unchanged since its adoption in 2008. It is the sole source of funding for the California Birth Defects Monitoring Program (CBDMP).

The \$10 fee allows the CBDMP to provide birth defects surveillance in ten California counties. With the current \$10 fee structure, the Birth Defects Monitoring Program Fund is running an operational deficit and will need a small increase in the PNS fees deposited to BDMP fund of approximately \$4 in order to continue CBDMP operations.

Description of Change: CDPH/GDSP will require a fee increase to the PNS fee from \$221.60 to approximately \$225.60 per case, effective July 1, 2018. CDPH proposes accompanying trailer bill language to amend Health and Safety Code Section 124977 (b)(4)(B) to provide the Director of the California Department of Public Health the authority to periodically adjust the fee charged for these activities in order to meet the costs of the program.

Discretionary: No

Reason for Adjustment/ Change: The CBDMP has the statutory requirement to conduct birth defect surveillance throughout the state. Specifically, Health and Safety Code sections 103825-103835 direct BDMP to: maintain an ongoing birth defects monitoring program statewide, track birth defects and trends, evaluate whether environmental hazards are associated with birth defects, investigate other possible birth defect causes, develop birth defect prevention strategies, and conduct interview studies about causes. To ensure fund solvency for the CBDMP there is a need to increase the PNS fee by approximately \$4. This will increase the fee deposited to the California Birth Defects Monitoring Program Fund from \$10 to approximately \$14.

Fiscal Impact (Range) and Fund Source(s): A \$4 fee increase in PNS fees that is deposited to the Birth Defects Monitoring Program Fund (Fund 3114).

Budget Change Proposal: New Genetic Disorders (SB 1095) and Second Tier Testing***Newborn Screening for New Genetic Disorders (Pompe Disease and Mucopolysaccharidosis type I)***

Background: SB 1095 (Chapter 393, Statutes of 2016) was chaptered on September 16, 2016. This bill established Health and Safety Code section 125001(d) and required the CDPH/GDSP to expand statewide screening of newborns by adding new tests within two years of the disease screen being adopted by the federal RUSP. At the time the bill was enrolled, there were two disorders on the RUSP that were not on the California Newborn Screening panel, MPS-I and Pompe disease, which were added to the RUSP in 2016 and 2015, respectively. Therefore, as specified in state statutes, CDPH is required to add these disorders to the California NBS panel by August 26, 2018.

The 2017 Budget Act included \$2.25 million in one-time Local Assistance expenditure authority and \$139,000 in State Operation expenditure authority to plan, prepare for, and add the additional required screenings to the NBS panel to meet the August 2018 deadline. These increases only cover costs for the initial start-up activities related to enhancements for the Screening Information System and support of initial testing method development.

Description of Change: Once the disorders are added to the NBS panel in August 2018, the CDPH/GDSP will still need to perform routine testing of the new disorders, and fully evaluate, validate and approve the Food and Drug Administration (FDA) test kit before it is rolled out to the regional laboratories to perform the actual screening workload. The FDA kit is not expected to be approved until the end of 2019. Even after approval of the FDA kit and rollout to the regional laboratories, CDPH/GDSP will need to perform repeat testing on sample sizes to ensure accurate quality control review and patient result reporting.

CDPH/GDSP is requesting 15 positions to address the routine testing and ongoing workload associated with the addition of Pompe disease and MPS-I. An increase in Local Assistance expenditure authority will be required beginning FY 2018-19 to purchase the consumables, supplies, and reagents related to the ongoing screening and testing activities.

Discretionary: No

Reason for Adjustment/ Change: Passage of SB 1095 required CDPH/GDSP to add Pompe disease and MPS-I within two years. Screening is set to commence August 2018 and will require an increase in expenditures needed to perform the routine and ongoing workload for MPS-I and Pompe disease screening.

Fiscal Impact (Range) and Fund Source(s): Approximately \$2.23 million in State Operations expenditure authority and an increase of \$1.5 million in Local Assistance expenditure authority in FY 2018-19. These additional ongoing costs will require a NBS fee increase of approximately \$12 per specimen, effective July 1, 2018. The fund source is the Genetic Disease Testing Fund (Fund 0203).

Genetic Disease Laboratory Second Tier Testing - Workload

Background: The CDPH/GDSP works to improve the quality of testing by preventing false negative tests and keeping false positive test rates as low as possible. Incorporating new testing strategies to reduce false positive test rates to prevent unnecessary stress and anxiety for parents is vital. By coupling the primary screening method with a second linked test that is more specific than the original method, CDPH can improve diagnostic specificity (fewer false positives) without reducing sensitivity (the rate of false negatives). A second-tier test uses the same blood specimen from the original test, eliminating that additional burden to families or hospital personnel, and measures additional metabolites that either strongly supports the presumption of a true positive case or shows that the patient does not have the disorder.

Using second-tier testing to increase positive predictive values of screening assays is a common standard of practice in most newborn screening laboratories. The effectiveness of second-tier testing on decreasing overall costs for the NBS Program has been tested and validated, and the results have been published by many researchers.

The 2017 Budget Act included a one-time increase of \$300,000 State Operations expenditure authority, and a one-time transfer of \$330,000 from Local Assistance to State Operations expenditure authority, for the purchase of mass spectrometry equipment and testing method development. These one-time increases provided expenditure authority for the initial start-up activities for second-tier testing.

Description of Change: CDPH/GDSP is requesting a permanent shift of \$460,000 from Local Assistance to State Operations to fund 3 positions to perform the ongoing second-tier testing work that will begin in FY 2018-19.

Discretionary: Yes

Reason for Adjustment/ Change: The increase in State Operation expenditure authority is needed to perform the routine and ongoing workload for second-tier testing.

Fiscal Impact (Range) and Fund Source(s): A transfer of \$460,000 expenditure authority from Local Assistance to State Operations from the Genetic Disease Testing Fund (Fund 0203).

Existing (Significantly Changed) Assumptions/Premises

There are no Existing (Significantly Changed) Assumptions/Premises

Unchanged Assumptions/Premises**Budget Change Proposal - Newborn Screening Program (SB 1095)**

Background: SB 1095 was chaptered on September 16, 2016. This bill amended sections 124977 and 125001 of the Health and Safety Code and required the CDPH/GDSP to expand statewide screening of newborns to include screening for any disease that is detectable in blood samples within two years of the disease being adopted by the federal RUSP.

Description of Change: CDPH/GDSP expanded the screening of newborns' blood samples to include screening for new diseases as those diseases are adopted by the RUSP, so planning and preparation will need to begin prior to screening. Screening for additional diseases will require additional laboratory equipment, changes to the SIS, the follow-up systems, the addition of new confirmatory testing, and possibly additional personnel.

Discretionary: No

Reason for Adjustment/ Change: As a result of the passage of SB 1095, CDPH is required to add to the newborn screening panel any disease as soon as the disease is adopted by the federal RUSP. In FY 2018-19 CDPH/GDSP will begin screening for MPS-I and Pompe disease.

Fiscal Impact (Range) and Fund Source(s): The 2017 Budget Act included \$2.25 million in one-time Local Assistance expenditure authority and \$139,000 in State Operations expenditure authority to plan, prepare for, and add MPS-I and Pompe disease to the NBS panel to meet the August 2018 deadline. The fund source is the Genetic Disease Testing Fund (Fund 0203).

Genetic Disease Laboratory Second Tier Testing

Background: The CDPH/GDSP works to improve the quality of testing by preventing false negative tests and keeping false positive test rates as low as possible. Incorporating new testing strategies to reduce false positive test rates to prevent unnecessary stress and anxiety for parents is vital. By coupling the primary screening method with a second linked test that is more specific than the original method, CDPH can improve diagnostic specificity (fewer false positives) without reducing sensitivity (the rate of false negatives). A second-tier test uses the same blood specimen from the original test, eliminating that additional burden to families or hospital personnel, and measures additional metabolites that either strongly supports the presumption of a true positive case or shows that the patient does not have the disorder.

Using second-tier testing to increase positive predictive values of screening assays is a common standard of practice in most newborn screening laboratories. The effectiveness of second-tier testing on decreasing overall costs for the NBS Program has been tested and validated, and the results have been published by many researchers. It was estimated that cost savings associated with Second-Tier Testing beginning FY 2018-19 would be approximately \$380,000 annually in California.

Description of Change: The 2017 Budget Act included a one-time increase of \$300,000 in State Operations expenditure authority, and a one-time transfer of \$330,000 from Local Assistance to State Operations expenditure authority, for the purchase of mass spectrometry equipment and testing method development. These one-time increases only provided resources for the initial start-up activities for second-tier testing.

Discretionary: Yes

Reason for Adjustment/ Change: By reducing the number of false-positives results, performing second tier testing will reduce overall expenditures and lead to less unnecessary stress, anxiety, and concern for families. This process will bring the highest positive predictive values with the least number of false negatives and false positives, without the need to collect a second sample.

Fiscal Impact (Range) and Fund Source(s): State Operations expenditure authority in FY 2017-18 reflects a one-time increase of \$302,000 and a one-time transfer of \$330,000 expenditure authority from Local Assistance to State Operations. It is estimated that cost savings associated with Second-Tier Testing beginning FY 2018-19 would be \$380,000 annually. The fund source is the Genetic Disease Testing Fund (Fund 0203).

Discontinued Assumptions/Premises

Increase Appropriation in Local Assistance: Operational Support for Enhancements and Maintenance and Operations (M&O) for Screening Information System (SIS) and Accounts Receivable (AR) System; Data Center Transition; and Accounts Receivable Vendor Transition

In FY 2016-17 Local Assistance expenditure authority was increased by \$10.7 million. The fund source is the Genetic Disease Testing Fund (0203).

Transition In-House Patient Billing to an Outsourcing Vendor

Outsource vendor, Sutherland, went live with patient billing on July 1, 2016. Current GDSP staff were phased out from the Call Center on June 30, 2017 and transferred to other sections within GDSP.

GS \$Mart Loan Repayment

GS \$Mart Loans were approved and CDPH/GDSP received additional expenditure authority in State Operations for the purchase of software and hardware required for the SIS transition, as well as the equipment to screen for ALD.

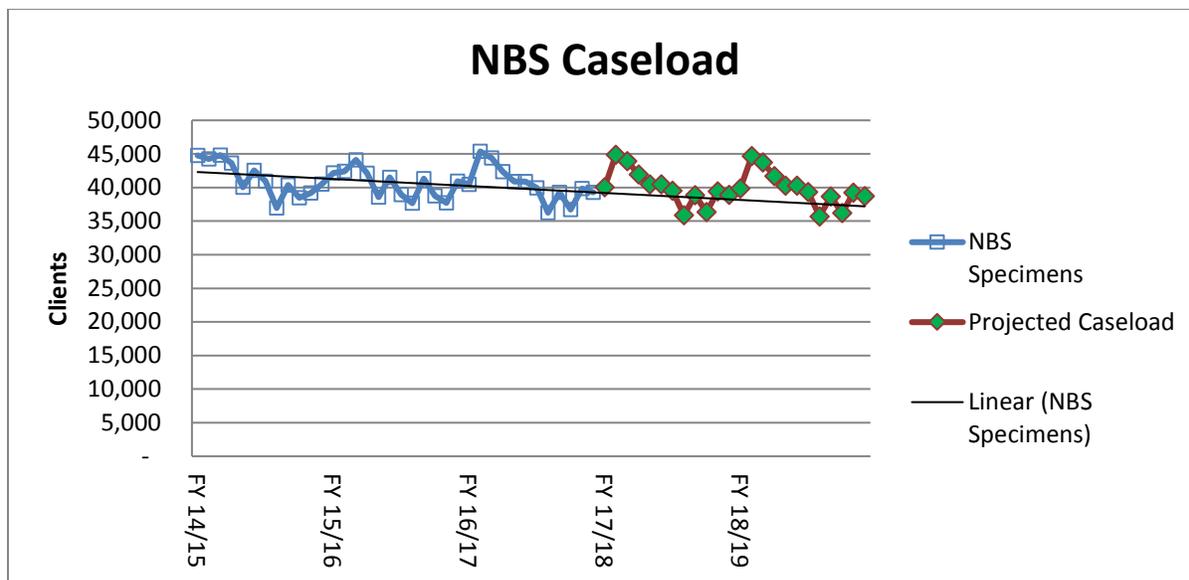
Appendices

Appendix A: Newborn Screening Program Assumptions and Rationale

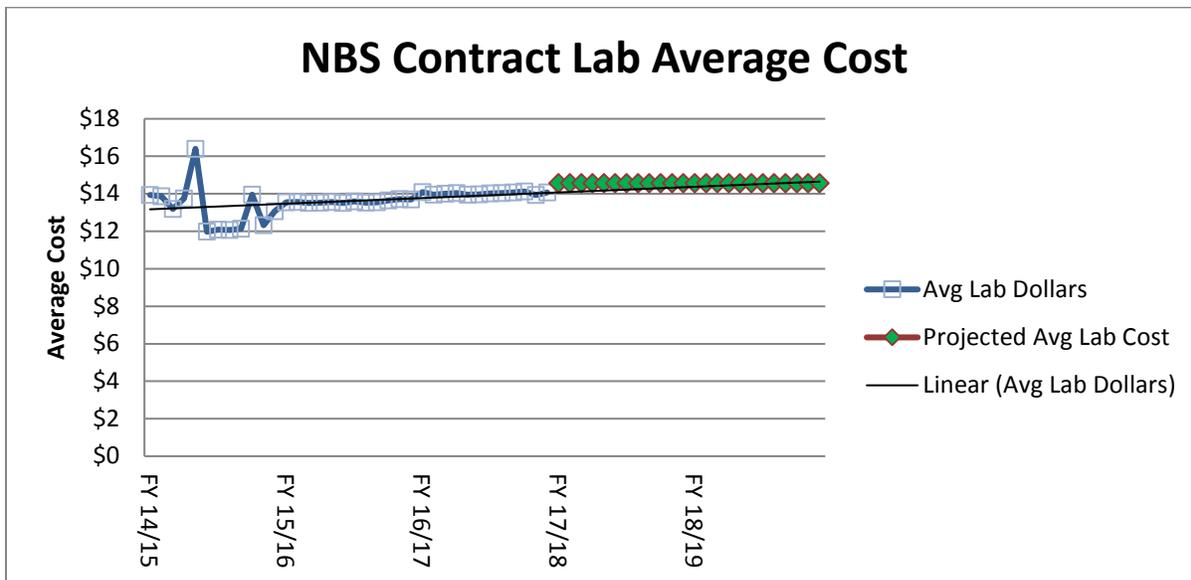
1. Contract Laboratories

Overview: Laboratory testing of specimens is performed at regional screening laboratories contracted by the state to screen newborns for over 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 99.4 percent of the DOF/DRU projected births will participate in the NBS program.

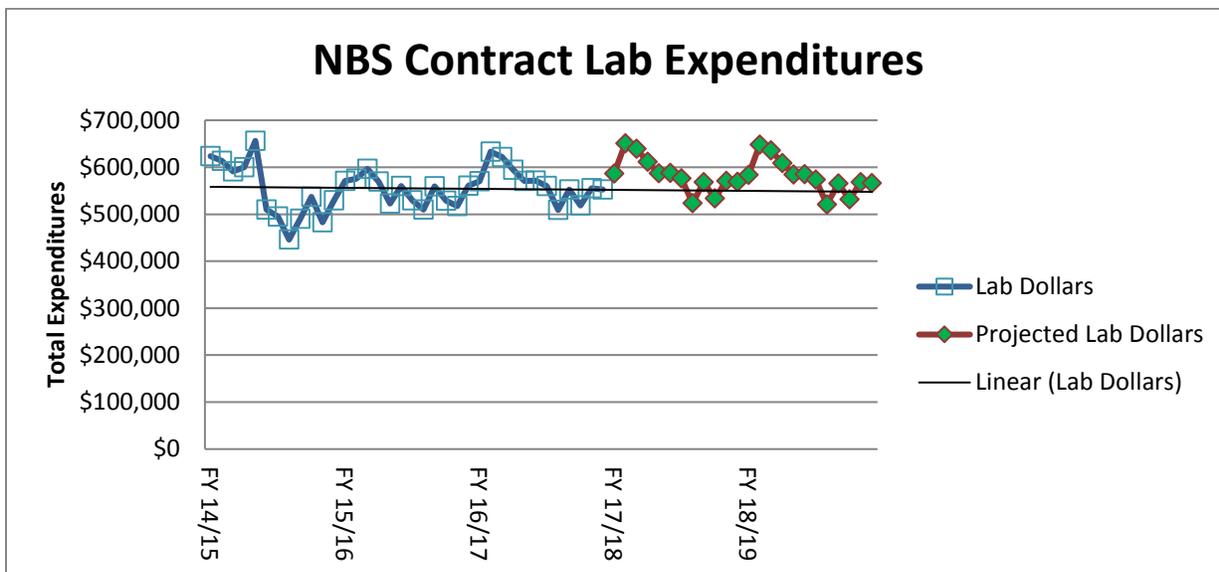
Total Caseload: CDPH/GDSP estimates current year caseload will total 480,607, a decrease of 5,133 or 1.1 percent compared to the FY 2016-17 actual total caseload of 485,740. Caseload in FY 2018-19 is estimated at 478,321, which is a decrease of 2,287 or 0.5 percent compared to the current year estimate. The decrease in both current year and budget year is due to the DOF/DRU’s projected decrease in the number of live births, CDPH/GDSP assumes that 99.4 percent 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: CDPH/GDSP estimates current year average laboratory cost per participant will be \$14.57, which is an increase of \$0.55 or 3.9 percent compared to the FY 2016-17 actual average laboratory cost per participant of \$14.02. Average laboratory cost per participant in FY 2018-19 is estimated at \$14.57, which has no change compared to the current year estimate.



Contract Laboratory Total Cost Projections: CDPH/GDSP estimates current year contract laboratory cost to total \$7.0 million, which is an increase of \$194,000 or 2.9 percent compared to FY 2016-17 actual contract laboratory costs of \$6.8 million. Laboratory costs in FY 2018-19 are estimated to total \$7.0 million, which is a decrease of \$33,000 or 0.5 compared to the current year estimate. The increase in cost in the current year is caused by the cost per client increase.

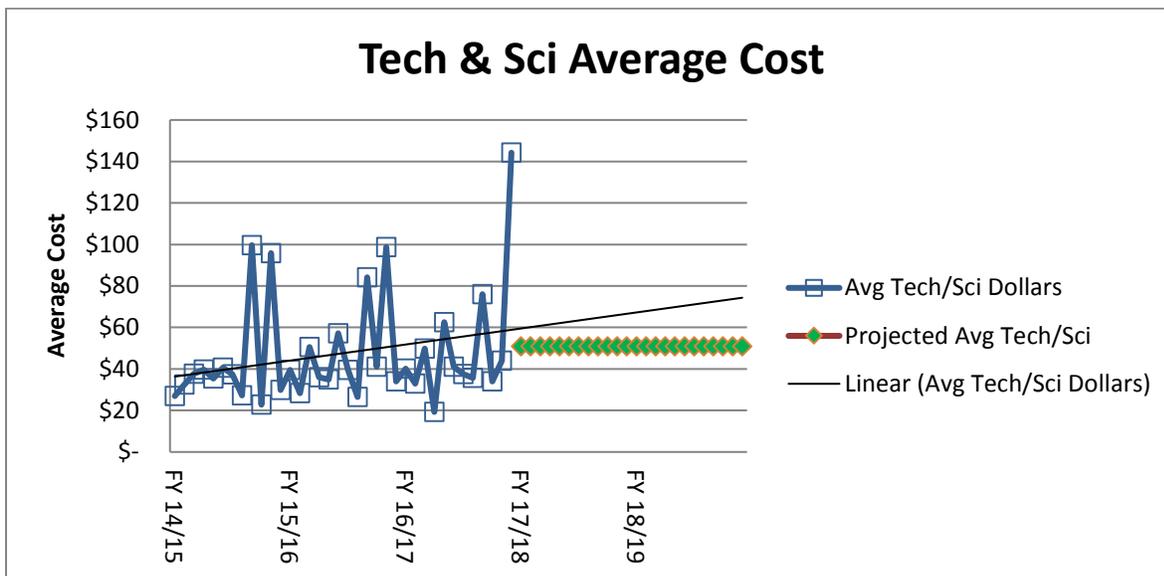


2. Technical and Scientific

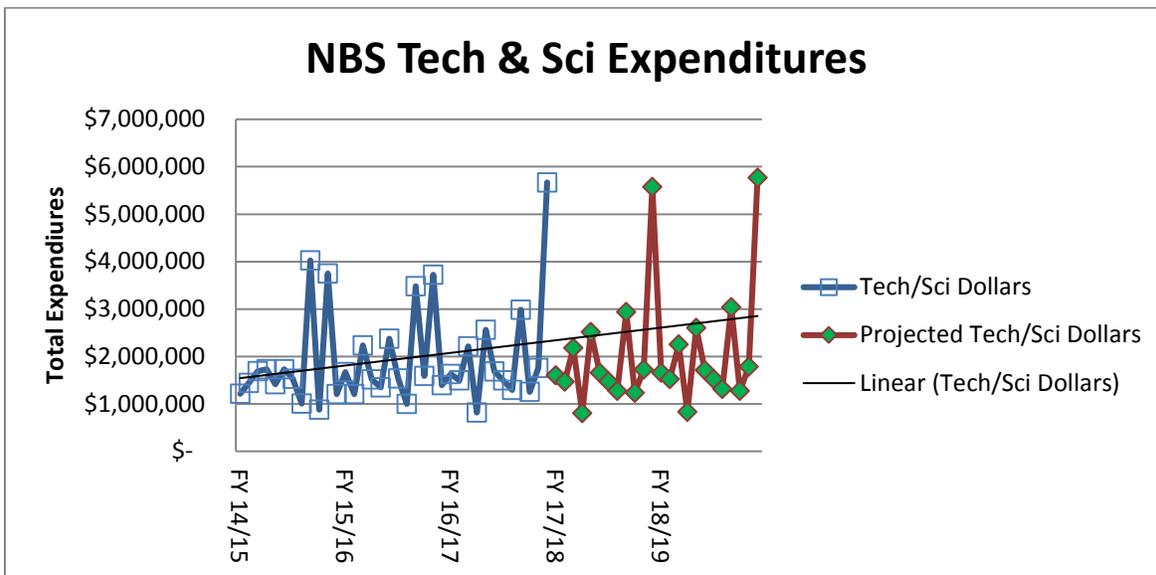
Overview: Costs associated with specimen screening include: reagents kits, supplies, processing, and limited maintenance and support (as it directly relates to the reagents) of laboratory equipment that is with the contract laboratories. In addition, there are minimal fixed costs associated with specimen 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: CDPH/GDSP estimates current year average Technical and Scientific cost per participant will be \$50.83, a decrease of \$0.30 or 0.60 percent compared to FY 2016-17 actual average Technical and Scientific cost per participant of \$51.13. Average Technical and Scientific cost per participant in FY 2018-19 is estimated at \$50.83, which is no change compared to the current year estimate. The increase in average cost in the current year is the result of increases in the cost of reagents.



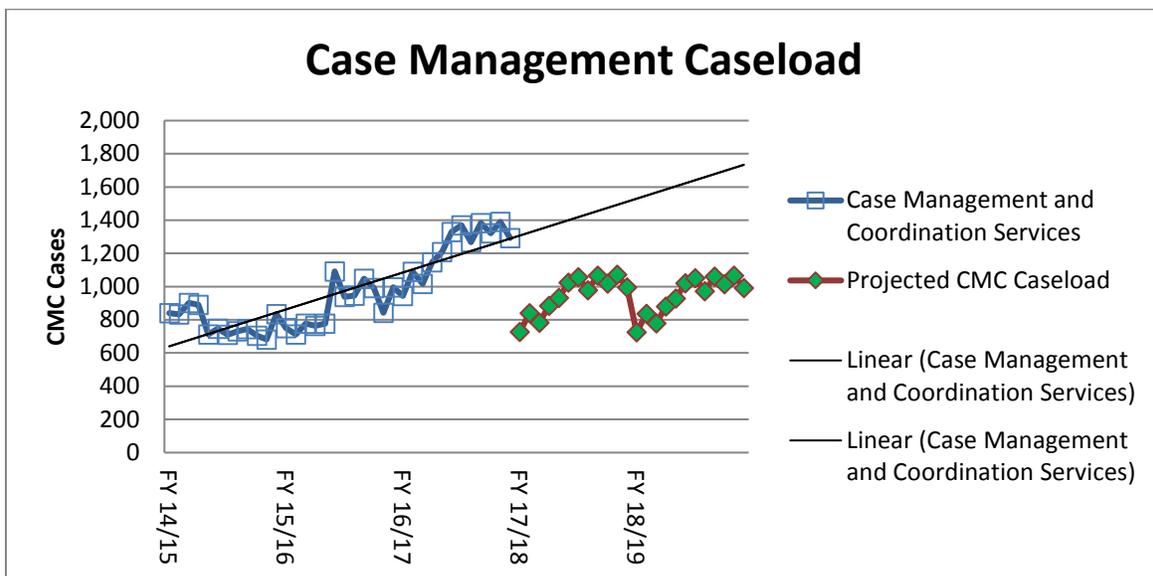
Technical and Scientific Total Cost: CDPH/GDSP estimates current year Technical and Scientific costs to total \$24.4 million, which is a decrease of \$408,000 or 1.64 percent compared to FY 2016-17 actual technical and scientific costs of \$24.8 million. Technical and Scientific costs in FY 2018-19 are estimated to total \$25.3 million, which is an increase of \$852,000 or 3.49 percent compared to the current year estimate. The current year decrease in cost is attributable to case load decrease. The anticipated increase in FY 2018-19 is attributable to the purchase of consumables, supplies, and reagents for Pompe disease and MPS-I.



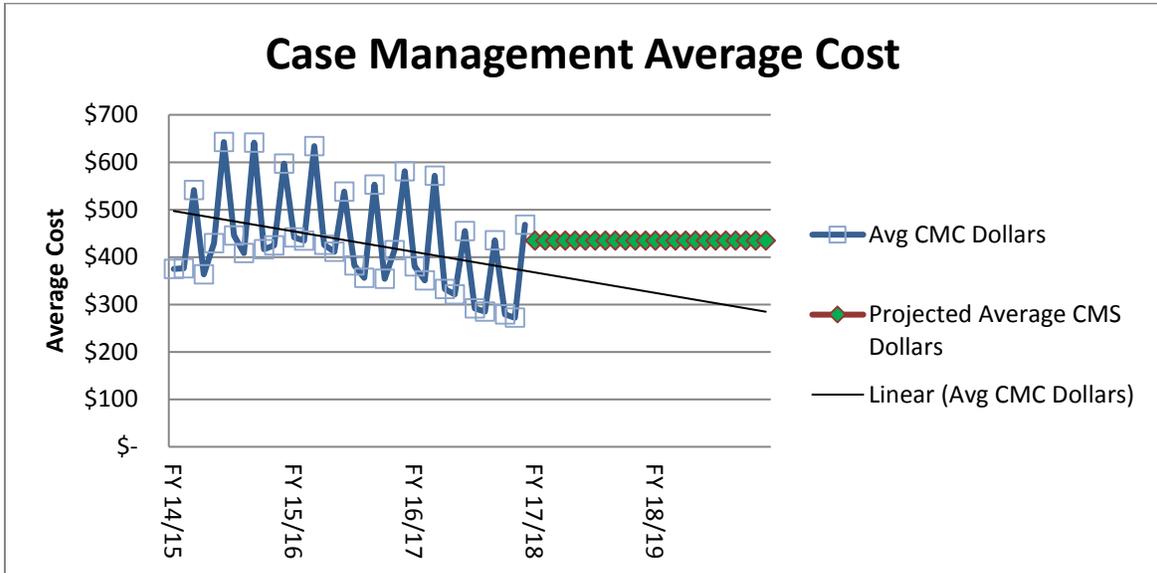
3. Case Management and Coordination Services:

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: CDPH/GDSP estimates current year CMCS caseload will total 11,383, which is a decrease of 3,376 or 22.9 percent compared to FY 2016-17 actual CMCS caseload of 14,759. CMCS caseload in FY 2018-19 is estimated at 11,329, which is a decrease of 54 or 0.5 percent compared to the current year estimate. The decrease in both current year and budget year is attributable to the decrease in projected caseload which is based on the prior three fiscal years’ percentages of infants who screen initial positive or have questionable screening test results .

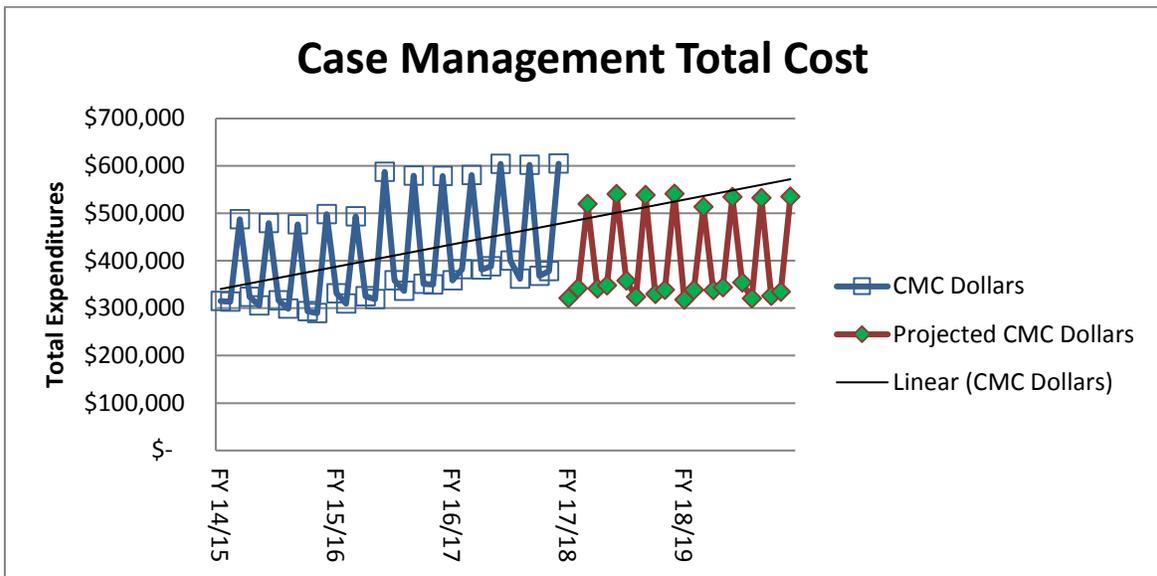


Case Management and Coordination Services (CMCS) Average Cost: CDPH/GDSP estimates current year average CMCS cost per participant will be \$434.92, which is an increase of \$68.35 or 18.6 percent compared to FY 2016-17 actual average CMCS cost per participant of \$366.57*. With the reduction of the number 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 2018-19 is estimated at \$434.92, which is no change compared to the current year estimate. CMCS costs are a combination of fixed costs and incremental (per case) reimbursement.



*\$366.57 is based on an estimate of prior year actuals. Due to the billing cycle for these services the actuals are incomplete as encumbrances have not been liquidated.

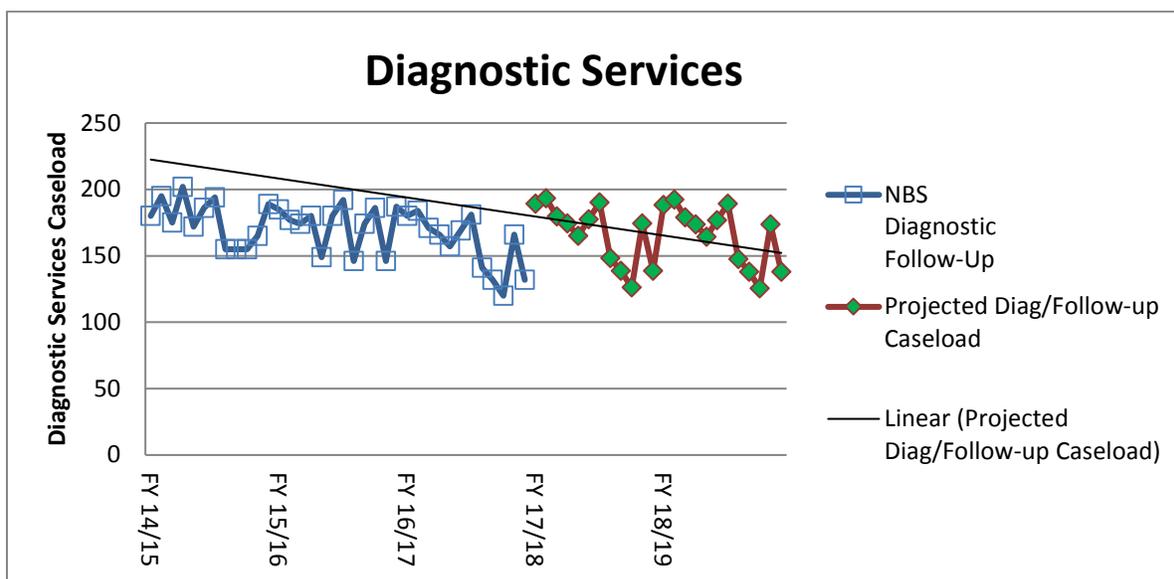
Case Management and Coordination Services (CMCS) Total Cost: CDPH/ GDSP estimates current year CMCS costs to total \$4.8 million, which is a decrease of \$569,000 or 10.5 percent compared to FY 2016-17 actual CMCS total costs of \$5.4 million. CMCS costs in FY 2018-19 are estimated to total \$4.8 million, which is a decrease of \$69,000 or 1.4 percent compared to the current year estimate. The decrease in both current year and budget year is caused by the projected decrease in caseload.



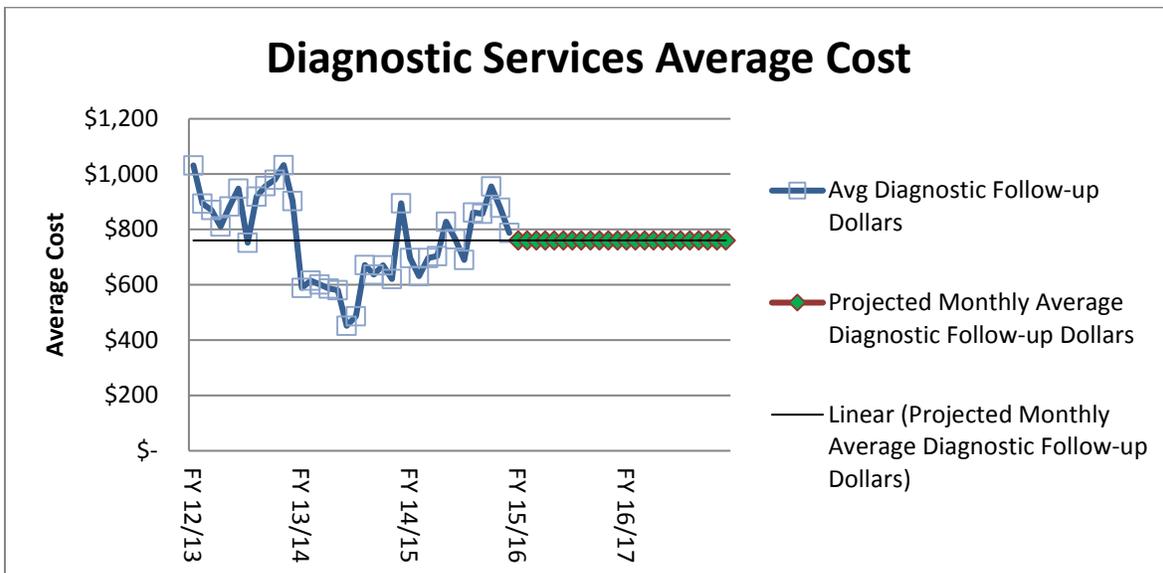
4. Diagnostic Services:

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: CDPH/GDSP estimates current year Diagnostic Services caseload will total 1,995, which is an increase of 96 or 5.1 percent compared to FY 2016-17 actual Diagnostic Services caseload of 1,899. Diagnostic caseload in FY 2018-19 is estimated at 1,986, which is a decrease of 9 or 0.5 percent compared to the current year estimate. This is due largely to DOF DRU projected decrease 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.

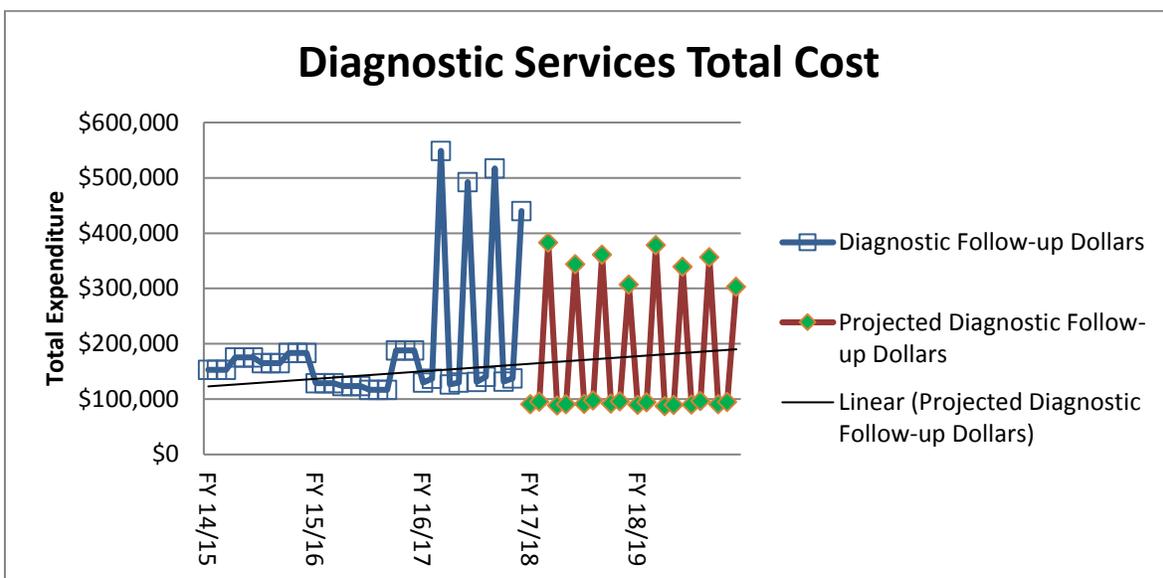


Diagnostic Services Average Cost: CDPH/GDSP estimates current year average Diagnostic Services cost per participant will be \$1,126.38, which is a decrease of \$486 or 30.14 percent compared to FY 2016-17 actual average Diagnostic Services cost per participant of \$1,612.34*. Average Diagnostic Services cost per participant in FY 2018-19 are estimated at \$1,126.38, which is no change compared to the current year estimate. Decrease in average cost can be attributed to inflationary decreases.



*\$1,612.34 is based on an estimate of prior year actuals. Due to the billing cycle for these services the actuals are incomplete as encumbrances have not been liquidated.

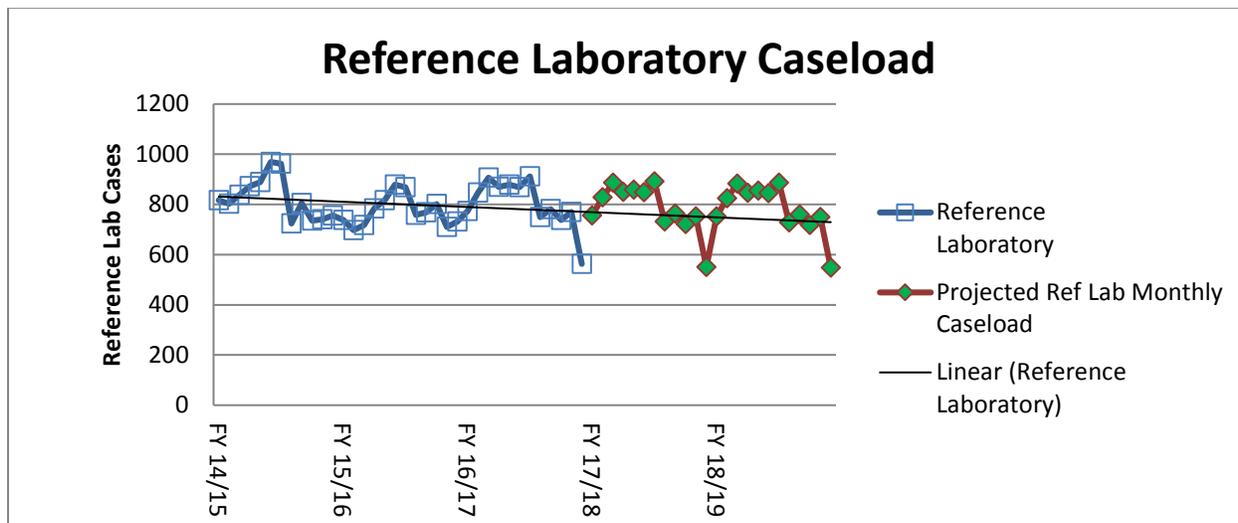
Diagnostic Services Total Cost: CDPH/GDSP estimates current year Diagnostic Services costs to total \$2.1 million, which is a decrease of \$924,000 or 30.2% compared to FY 2016-17 actual Diagnostic Services total costs of \$3.1 million. Diagnostic Services costs in FY 2018-19 are estimated to total \$2.1 million, which is a decrease of \$43,000 or 2.0 percent compared to the current year estimate. The decrease is caused by the decrease in the projected average Diagnostic Services costs



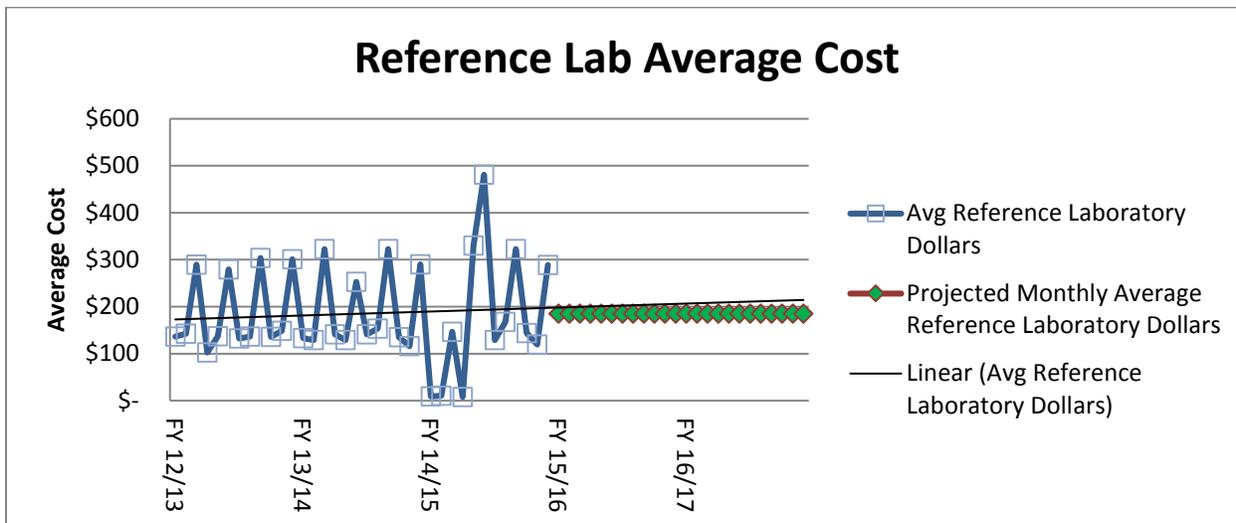
5. Reference Laboratory Cases:

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: CDPH/GDSP estimates current year Reference Laboratory caseload will total 9,436, which is a decrease of 221 or 2.29 percent compared to FY 2016-17 actual Reference Laboratory caseload of 9,657. Reference Laboratory caseload in FY 2018-19 is estimated at 9,391, which is a decrease of 45 or 0.48 percent compared to the current year estimate. This is due largely to DOF DRU projected decrease 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.

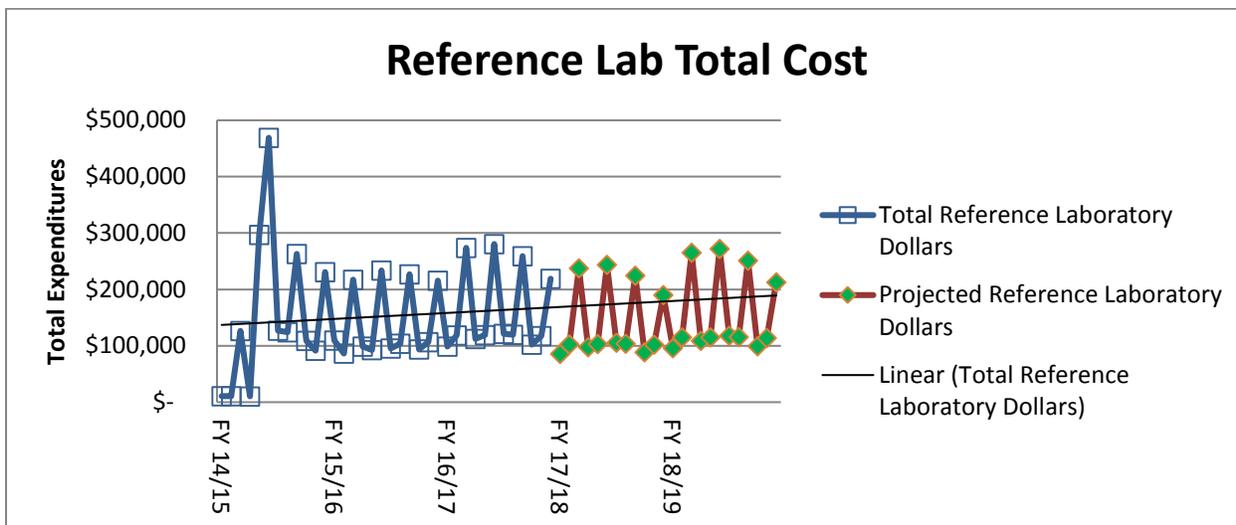


Reference Laboratory Average Cost: CDPH/GDSP estimates current year Reference Laboratory average cost per participant will be \$190.34, which is a decrease of \$10.70 or 5.3 percent compared to FY 2016-17 Reference Laboratory actual average costs per participant of \$201.04*. Reference Laboratory average cost per participant in FY 2018-19 is estimated at \$190.34, which is no change compared to the current year estimate.



*\$201.04 is based on an estimate of prior year actuals. Due to the billing cycle for these services the actuals are incomplete as encumbrances have not been liquidated.

Reference Laboratory Total Cost: CDPH/GDSP estimates current year Reference Laboratory costs to total \$1.7 million, which is a decrease of \$255,000 or 13.2 percent compared to FY 2016-17 actual Diagnostic Services total costs of \$1.9 million. The decrease is caused by the projected decrease in Reference Laboratory caseload, and marginal price decrease for reference laboratory services. Reference Laboratory costs in FY 2018-19 are estimated to total \$1.9 million, which is an increase of \$180,000 or 10.7 percent compared to the current year estimate. The increase is due to the increase in expenditures related to Pompe disease and MPS-I.

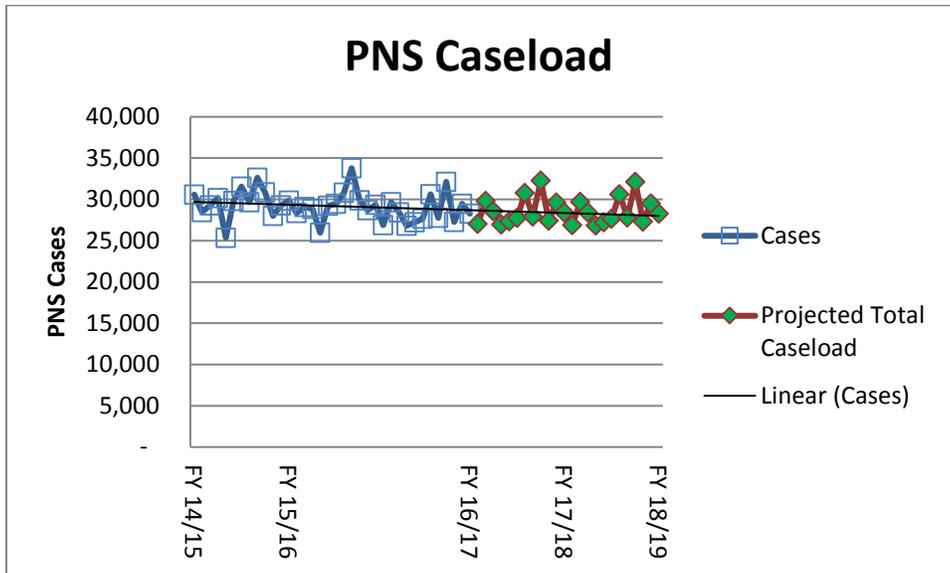


APPENDIX B: Prenatal Screening Program Assumptions and Rationale**1. Contract Laboratories:**

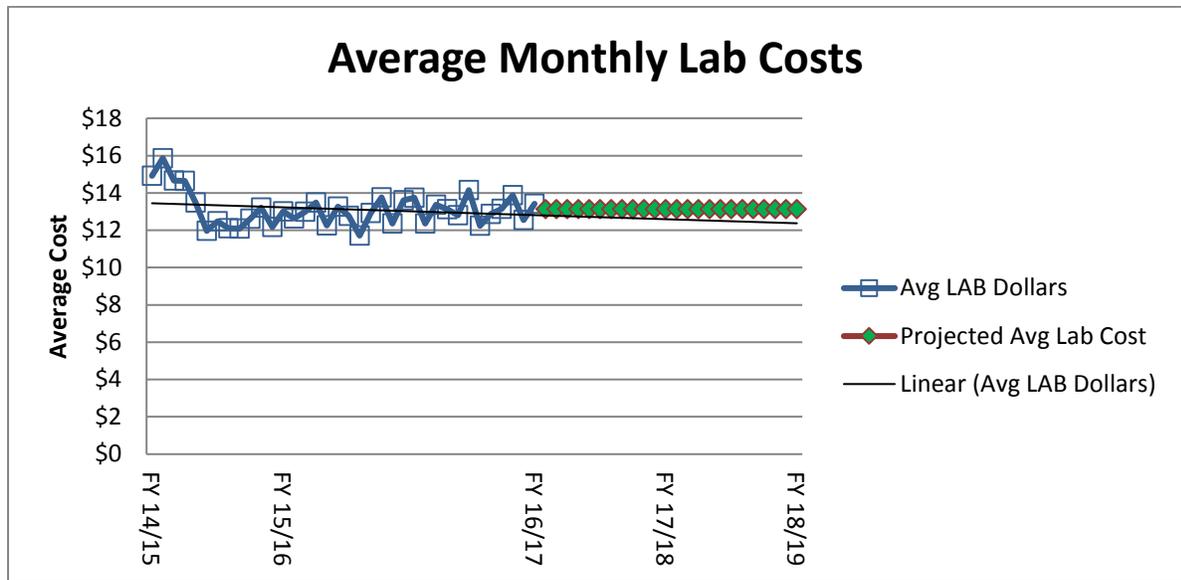
Overview: Laboratory testing to screen pregnant women for genetic and congenital disorders, such as Trisomy 21, Trisomy 18, Smith-Lemli-Opitz Syndrome (SLOS), and Neural Tube Defects. Costs include laboratory services for performing prenatal genetic screening tests. The screening test estimates the chance 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 CDPH/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. When GDSP consolidated the laboratories from seven down to five, we evaluated the work associated with testing 1st and 2nd trimester specimens and found it to be the same. Therefore, during the competitive bidding process, laboratories provided one cost for processing both 1st and 2nd 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.

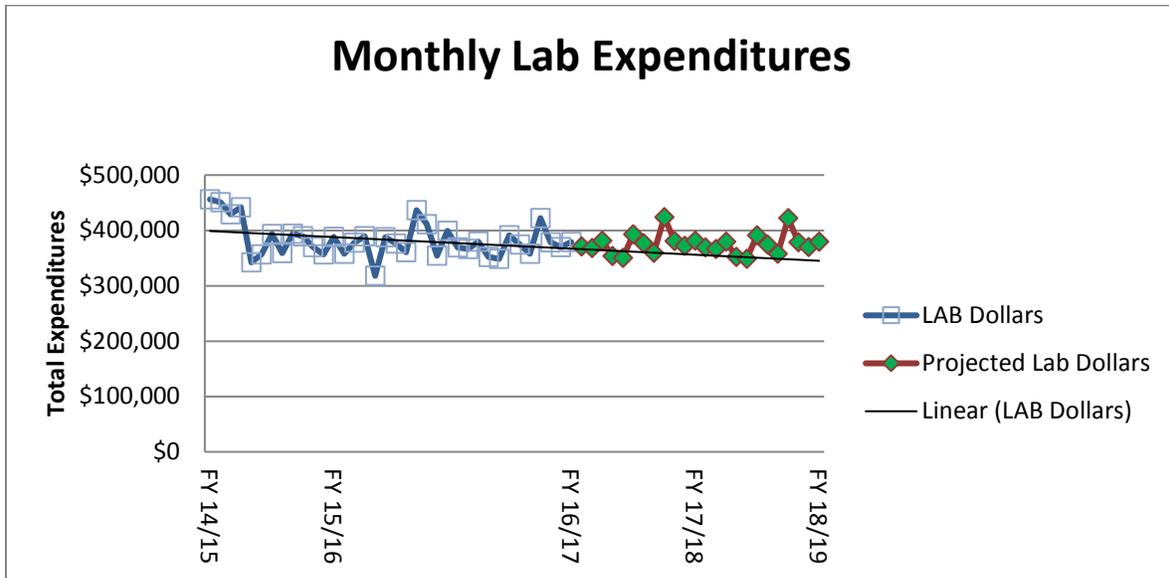
Total Caseload: CDPH/GDSP estimates current year caseload will total 343,933 which is an increase of 1,815 or 0.5 percent compared to FY 2016-17 actual total caseload of 342,118. Caseload in FY 2018-19 is estimated at 342,297, which is a decrease of 1,636 or 0.5 percent compared to the current year estimate. 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 2017-16, and that the number of participants will remain constant in FY 2018-19. The FY 2018-19 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: CDPH/GDSP estimates current year average laboratory cost per participant will be \$13.12, which is no change compared to FY 2016-17 actual average laboratory cost per participant of \$13.12. Average laboratory cost per participant in FY 2018-19 is estimated at \$13.12, which is also no change compared to the current year estimate. Average cost for contract laboratories are expected to remain constant as CDPH/GDSP negotiated new contracts with the PNS laboratories



Contract Laboratory Total Cost Projections: CDPH/GDSP estimates current year contract laboratory cost to total \$4.5, which is an increase of \$23,000 or 0.5 percent compared to FY 2016-17 actual contract laboratory costs of \$4.5 million. Laboratory costs in FY 2018-19 are estimated to total \$4.5 million, which is a decrease of \$22,000 or 0.5 percent compared to the current year estimate. The steady costs are attributable to unchanging participation and average cost projections.

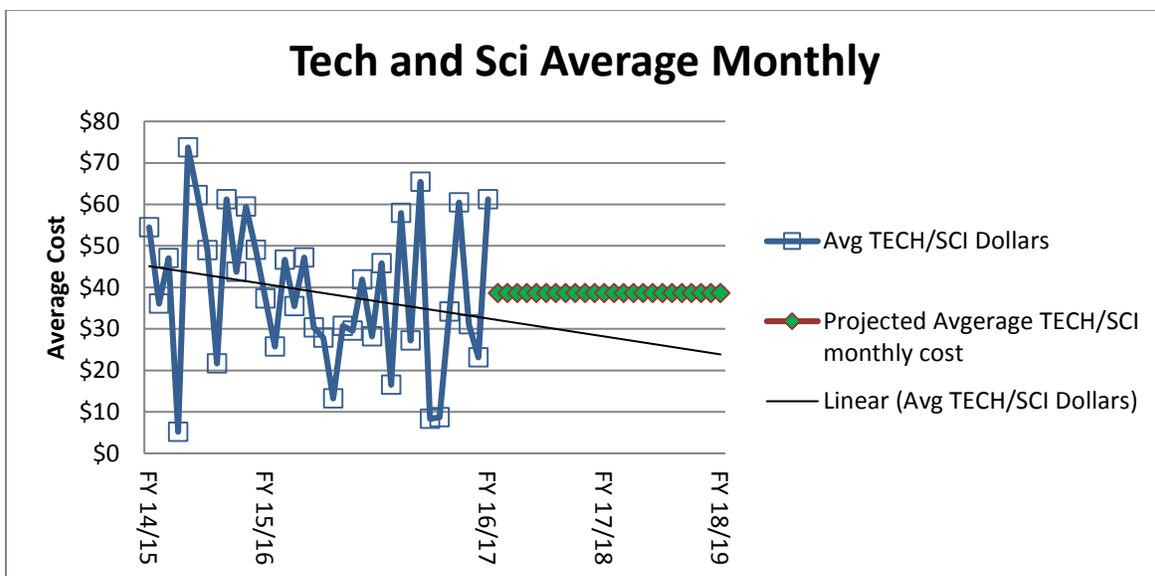


2. Technical and Scientific

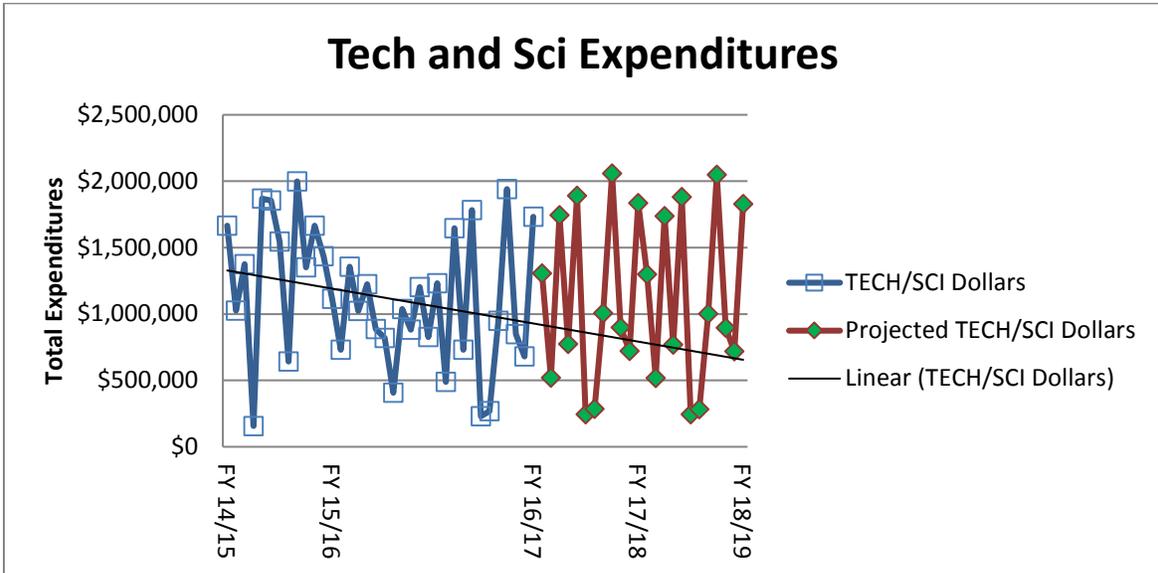
Overview: Costs associated with screening services provided at the laboratory include: reagent kits, limited maintenance and support (as it directly relates to the reagents) of laboratory equipment, supplies, and processing. In addition, there are several costs associated with screening including: blood 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: CDPH/GDSP estimates current year average Technical and Scientific cost per participant will be \$38.61, which is an increase of \$2.01 or 5.5 percent compared to FY 2016-17 actual average Technical and Scientific cost per participant of \$36.61. Average laboratory cost per participant in FY 2018-19 is estimated at \$38.61, which is no change compared to the current year estimate. The increase in average cost in the current year is the result of increase in projected caseload.



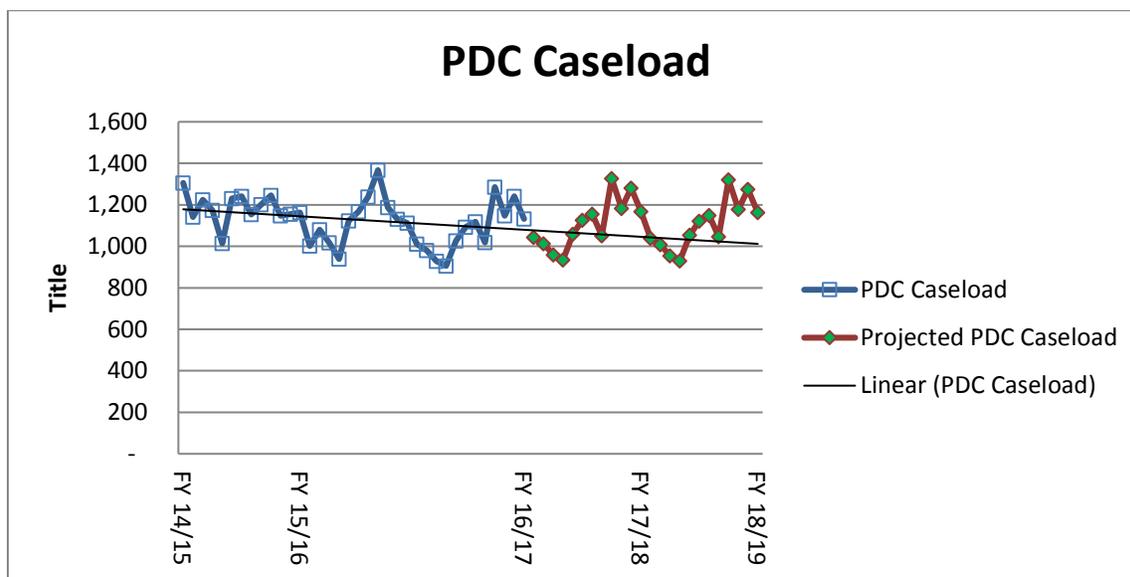
Technical and Scientific Total Cost: CDPH/GDSP estimates current year Technical and Scientific costs to total \$13.3 million, which is an increase of \$755,000 or 6.0 percent compared to FY 2016-17 actual technical and scientific costs of \$12.5 million. The increase is due to the increase of the average cost per case. Technical and Scientific costs in FY 2018-19 are estimated to total \$13.2 million, which is a decrease of \$63,000 or 0.5 percent compared to the current year estimate. The decrease is due to the decrease in the projected caseload.



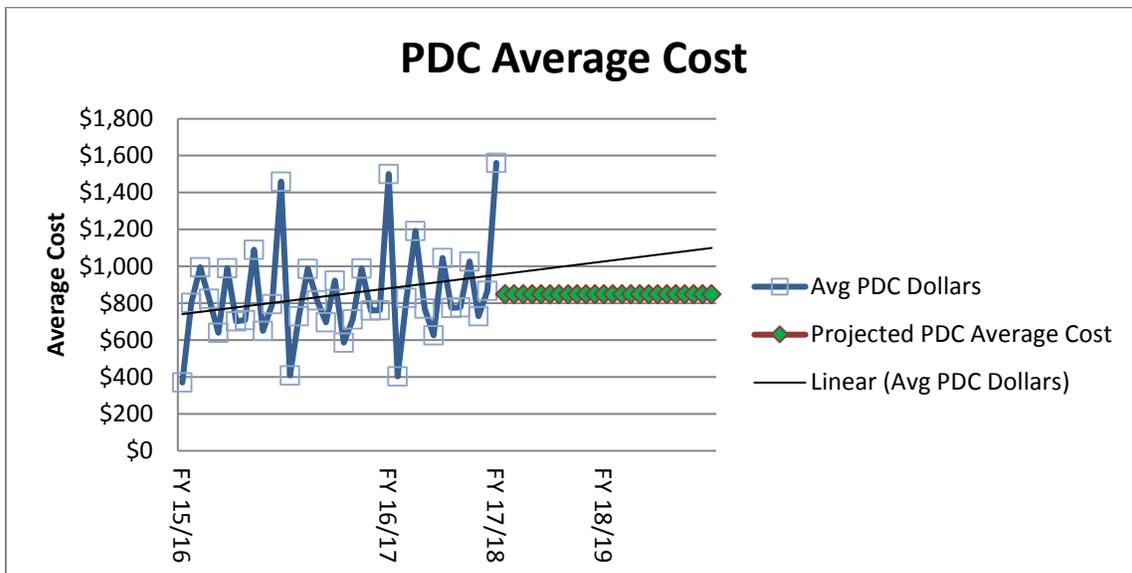
3. Prenatal Diagnostic Services Centers

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.

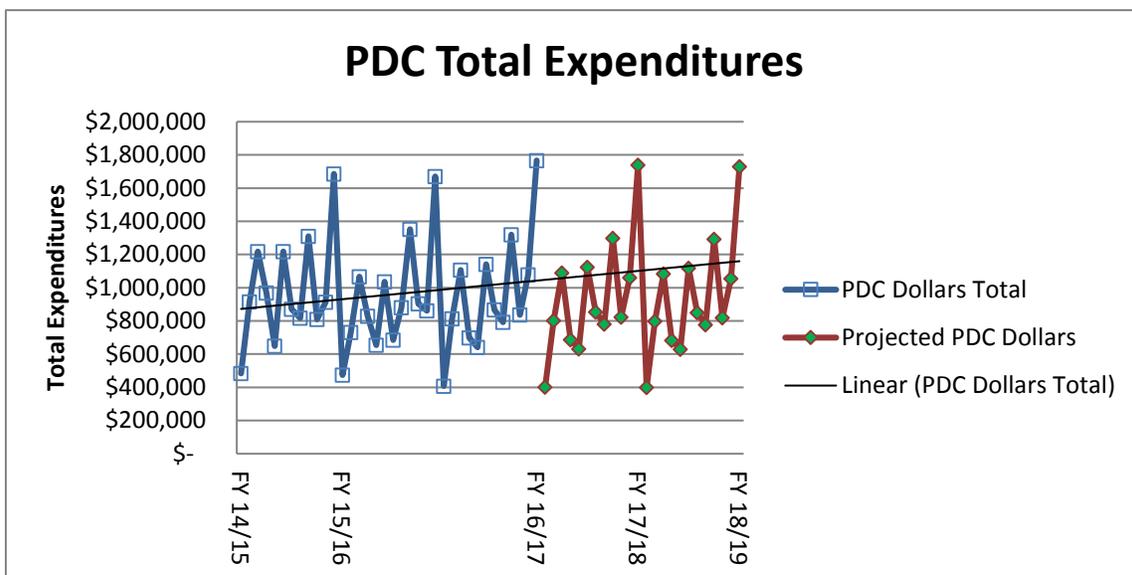
Prenatal Diagnostic Services Centers (PDC) Caseload: CDPH/GDSP estimates current year PDC caseload will total 13,299, which is an increase of 410 or 3.2 percent compared to the FY 2016-17 actual PDC caseload of 12,889. PDC caseload in FY 2018-19 is estimated to total 13,236, which is a decrease of 63 or 0.5 percent 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: CDPH/GDSP estimates current year average PDC cost per participant will be \$849, which is a decrease of \$41.06 or 4.6 percent compared to FY 2016-17 actual average PDC cost per participant of \$890.06. Average laboratory cost per participant in FY 2018-19 is estimated at \$849, 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.



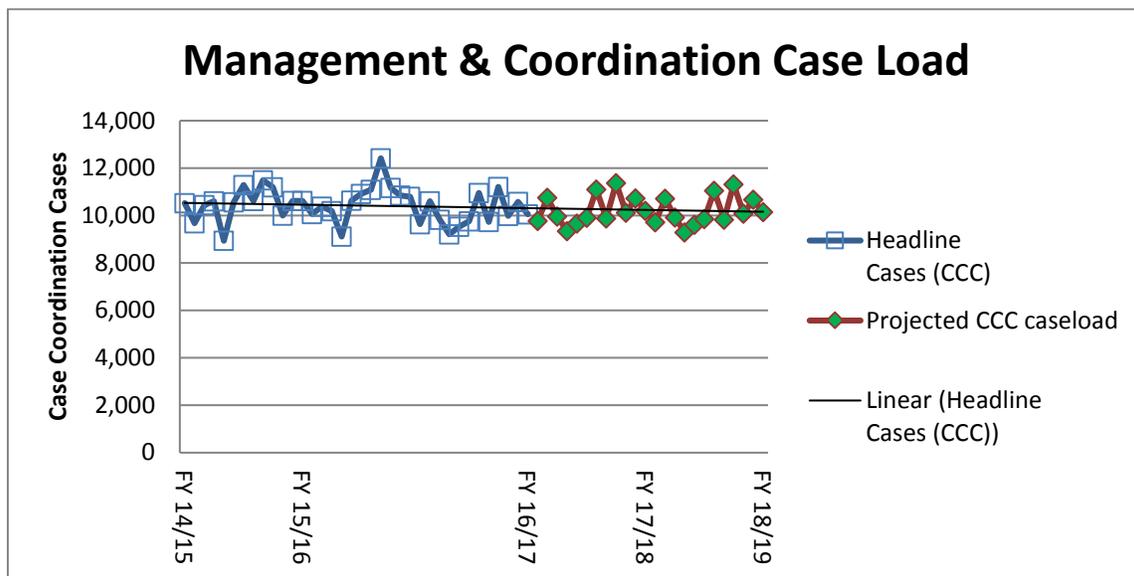
Prenatal Diagnostic Services Total Cost: CDPH/GDSP estimates current year PDC costs to total \$11.3 million, which is a decrease of \$181,000 or 1.6 percent compared to FY 2016-17 actual PDC total costs of \$11.5 million. PDC costs in FY 2018-19 are estimated to total \$11.2 million, which is a decrease of \$54,000 or 0.5 percent compared to the current year estimate. The change in total expenditures is attributable mainly to projected decreases in caseload.



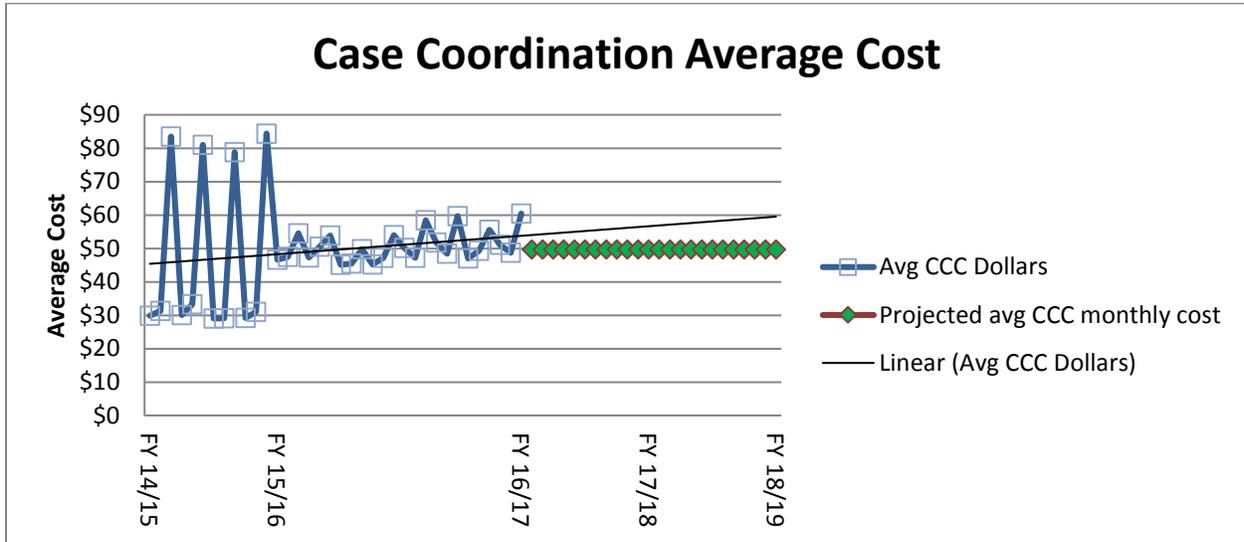
4. Case Management and Coordination Services:

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.

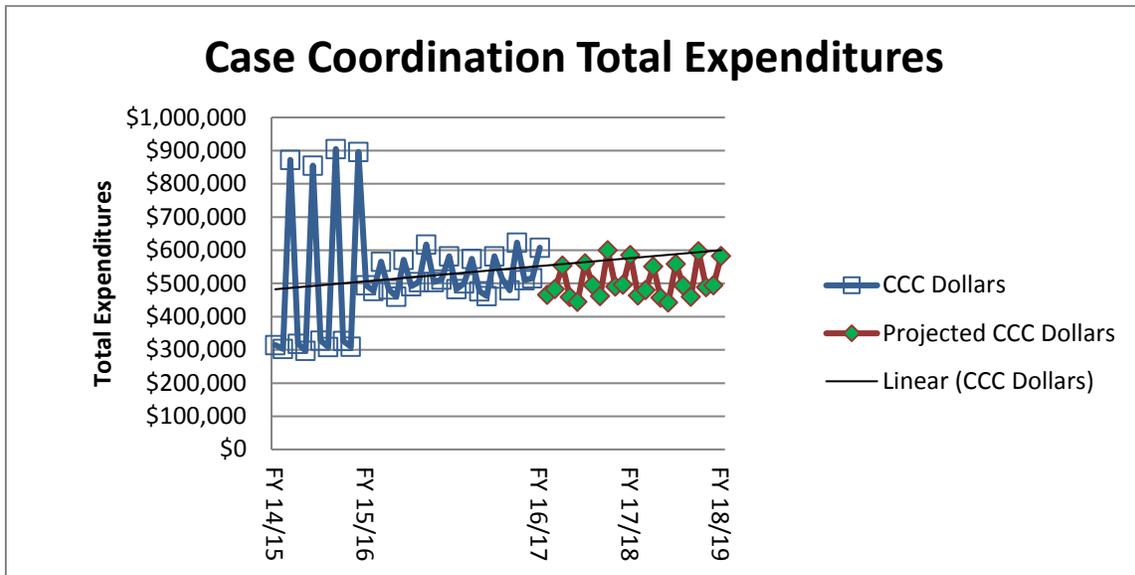
Case Management and Coordination Services (CMCS) Caseload: CDPH/GDSP estimates current year CMCS caseload will total 122,792, which is an increase of 1,732 or 1.4 percent compared to FY 2016-17 actual CMCS caseload of 121,060. CMCS caseload in FY 2018-19 is estimated at 122,208, which is a decrease of 584 or 0.5 percent 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: CDPH/GDSP estimates current year average CMCS cost per participant will be \$49.69, which is a decrease of \$2.59 or 5.0 percent compared to FY 2016-17 actual average CMCS cost per participant of \$52.28. Average cost per participant in FY 2018-19 is estimated at \$49.69, 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: CDPH/GDSP estimates current year CMCS costs to total \$6.1 million, which is a decrease of \$228,000 or 3.6 percent compared to FY 2016-17 actual CMCS total costs of \$6.3 million. CMCS costs in FY 2018-19 are estimated to total \$6.1 million, which is a decrease of \$29,000 or 0.48 percent compared to the current year estimate. The changes are caused by the decrease in average cost noted above.



APPENDIX C: Revenue Assumptions

NBS Revenue

The Newborn Screening Program charges a fee of \$130.25 currently. Effective July 1, 2018, the NBS fee will increase by \$12 and the new fee would be \$142.25. 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 \$130.25 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 2017-18	\$130.25	480,607	98%	\$61,347,125
FY 2018-19	\$142.25	478,321	98%	\$66,680,282

PNS Revenue

The Prenatal Screening Program charges a fee of \$221.60 to all participating women. Of the total fee, \$211.60 is deposited into the Genetic Disease Testing Fund (Fund 0203), and \$10 is deposited into the California Birth Defect Monitoring Program Fund (Fund 3114). Effective July 1, 2018, PNS fee will increase by \$4 to ensure solvency for the CBDMP. The new PNS fee would be \$225.60. 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

	A=(S207-S10)	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 2017-18	\$211.60	343,933	45%	55%	98%	83%	154,770	189,163	\$65,316,672
FY 2018-19	\$211.60	342,297	45%	55%	98%	83%	154,033	188,263	\$65,005,892