

# **GENETIC DISEASE SCREENING PROGRAM**

**2020-21  
May Revision Estimate**



**Sonia Y. Angell, MD, MPH**  
*Director and State Public Health Officer*

**California Department of Public Health**

**TABLE OF CONTENTS**

<b>I. Estimate</b>	<b>3</b>
<b>A. Program Overview</b>	<b>3</b>
<b>B. Combined State Operations and Local Assistance Expenditure Overview</b>	<b>3</b>
<b>C. Local Assistance Expenditure</b>	<b>3</b>
i. Projections Current Year	3
ii. Budget Year	4
iii. Expenditure Estimate Methodology	4
iv. Newborn Screening Expenditure Projections	5
v. Prenatal Screening Expenditures Projections	6
vi. Operational Support Expenditures Projections	6
<b>D. State Operations Expenditure Projections</b>	<b>6</b>
<b>E. Revenue Projections</b>	<b>7</b>
i. Combined Newborn Screening/Prenatal Screening Revenue	7
ii. Revenue Estimate Methodology	7
iii. Newborn Screening Revenue	8
iv. Prenatal Screening Revenue	8
<b>II. Fund Condition Statement</b>	<b>9</b>
<b>III. General Assumptions</b>	<b>10</b>
1. Future Fiscal Issues	10
2. New Assumptions/ Premises	12
3. Existing (Significantly Changed) Assumptions/Premises	12
4. Unchanged Assumptions/Premises	12
5. Discontinued Assumptions/Premises	14
<b>IV. Appendix A: NBS Assumptions and Rationale</b>	<b>15</b>
1. Contract Laboratories	15
2. Technical and Scientific	17
3. Case Management and Coordination	18
4. Diagnostic Services:	20
5. Reference Laboratory Cases:	22
<b>V. APPENDIX B: PNS Program Assumptions and Rationale</b>	<b>24</b>
1. Contract Laboratories:	24
2. Technical and Scientific	26
3. Prenatal Diagnostic Services Centers	27
4. Case Management and Coordination Services:	29

<b>VI. APPENDIX C: Revenue Projections .....</b>	<b>32</b>
<b>1. Newborn Screening Revenue.....</b>	<b>32</b>
<b>2. Prenatal Screening Revenue.....</b>	<b>32</b>

**I. Estimate****A. Program Overview**

The California Department of Public Health (CDPH), Genetic Disease Screening Program (GDSP) May Revision Estimate provides a revised projection of 2019-20 expenditures along with projected costs for 2020-21 Local Assistance and State Operations budget for GDSP.

GDSP's 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 their newborns out of 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. Screenings that meet or exceed a specified risk threshold are identified and further testing and genetic counseling/diagnostic services are offered at no additional expense to the participant.

**B. Combined State Operations and Local Assistance Expenditure Overview**

GDSP's 2020-21 Governor's Budget appropriation for 2019-20 is \$143 million of which \$111.6 million is for Local Assistance and \$31.4 million is for State Operations. GDSP estimates 2019-20 expenditures will be \$142.1 million of which \$31.4 million is for State Operations and \$110.7 million is for Local Assistance. Overall, this is a decrease of \$893,000 or 0.62% compared to the 2020-21 Governor's Budget.

GDSP's 2020-21 Governor's Budget appropriation for 2020-21 is \$142.6 million. GDSP estimates 2020-21 budget expenditures will be \$141.3 million of which \$31.7 million is for State Operations and \$109.7 million is for Local Assistance. Overall, this is a decrease of \$1.2 million or 0.86 percent compared to the 2020-21 Governor's Budget.

Table 1 displays the difference between GDSP's 2020-21 Governor's Budget appropriation, the revised 2019-20 expenditures and proposed 2020-21 expenditures.

**Table 1**  
Genetic Disease Screening Program: Current Year and Budget Year Budget Summaries Compared to 2020-21 Governor's Budget

Fund 0203 Genetic Disease Testing Fund	2019 Budget Act	FY 2019-20				FY 2020-21			
		2020-21 Governor's Budget	2020 May Revision	Change from Governor's Budget to May Revision	Percent Change from Governor's Budget to May Revision	2020-21 Governor's Budget	2020 May Revision	Change from Governor's Budget to May Revision	Percent Change from Governor's Budget to May Revision
Total	\$ 142,975,000	\$ 142,975,000	\$ 142,082,000	\$ (893,000)	-0.62%	\$ 142,566,000	\$ 141,335,000	\$ (1,231,000)	-0.86%
State Operations	\$ 31,351,000	\$ 31,351,000	\$ 31,351,000	\$ -	0.00%	\$ 31,679,000	\$ 31,679,000	\$ -	0.00%
Local Assistance	\$ 111,624,000	\$ 111,624,000	\$ 110,731,000	\$ (893,000)	-0.80%	\$ 110,887,000	\$ 109,656,000	\$ (1,231,000)	-1.11%

**C. Local Assistance Expenditure****1. Projections Current Year (2019-20)**

The 2019-20 Governor's Budget appropriation for GDSP's Local Assistance is \$111.6 million. GDSP anticipates revised 2019-20 Local Assistance expenditures of \$110.7 million, which is a decrease of \$893,000 or 0.80 percent compared to the 2020-21 Governor's Budget. The decrease is due to the decline in caseload results based on Department of Finance's Demographic Research Unit's (DRU) projection of live births.

## 2. Budget Year (2020-21)

For 2020-21, GDSP estimates Local Assistance expenditures will total \$109.7 million, which is a decrease of \$1.2 million or 1.11 percent compared to the 2020-21 Governor's Budget amount of \$110.9 million. The decrease is attributed to caseload reductions based on DRU's projection of live births.

Table 2 displays the difference between the 2020-21 Governor's Budget appropriation, the revised 2019-20 expenditures and proposed 2020-21 expenditures for GDSP Local Assistance.

Table 2

Local Assistance Total: Current Year and Budget Year Budget Summaries Compared to 2020-21 Governor's Budget

Fund 0203 Genetic Disease Testing Fund	2019 Budget Act	FY 2019-20				FY 2020-21			
		2020-21 Governor's Budget	2020 May Revision	Change from Governor's Budget to May Revision	Percent Change from Governor's Budget to May Revision	2020-21 Governor's Budget	2020 May Revision	Change from Governor's Budget to May Revision	Percent Change from Governor's Budget to May Revision
Local Assistance Total	\$ 111,624,000	\$ 111,624,000	\$ 110,731,000	\$ (893,000)	-0.80%	\$ 110,887,000	\$ 109,656,000	\$ (1,231,000)	-1.11%
Newborn Screening	\$ 45,343,000	\$ 45,883,000	\$ 45,635,000	\$ (248,000)	-0.54%	\$ 47,576,000	\$ 47,234,000	\$ (342,000)	-0.72%
Prenatal Screening	\$ 35,937,000	\$ 35,397,000	\$ 34,752,000	\$ (645,000)	-1.82%	\$ 35,911,000	\$ 35,022,000	\$ (889,000)	-2.48%
Operational Support	\$ 30,344,000	\$ 30,344,000	\$ 30,344,000	\$ -	0.00%	\$ 27,400,000	\$ 27,400,000	\$ -	0.00%

## 3. Expenditure Methodology / Key Drivers of Cost

GDSP Local Assistance expenditures are split into three areas: PNS, NBS and Operational Support. Operational Support costs do not fluctuate greatly with changes in caseload. For both PNS and NBS program 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, GDSP projects NBS and

PNS caseloads and multiplies them by their respective projected average cost plus the baseline cost. This total is then added to the Operational Support costs.

- 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 + applicable baseline cost
  - Diagnostic Services cases x Diagnostic Services average cost + applicable baseline cost
  - Reference laboratory cases x Reference laboratory average cost
- PNS total costs equal the sum of:
  - Total clients tested x Contract laboratory average cost
  - Total clients tested x Technology and Scientific average cost
  - Case Management cases x Case Management and Coordination average cost + applicable baseline cost
  - Diagnostic Services cases x Diagnostic Services average cost
- Operational Support Costs are the sum of various service contracts that support GDSP including Information Technology and courier services.

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

#### 4. NBS Expenditure Projections (See Appendices A1-A5)

For 2019-20, GDSP estimates NBS Local Assistance expenditures will total \$45.6 million, which is virtually no change compared to the 2020-21 Governor's Budget of \$45.9 million. For 2020-21, GDSP estimates that NBS Local Assistance expenditures will total \$47.2 million, which is a slight decrease of \$342,000 or 0.72 percent to the 2020-21 Governor's Budget of \$47.6 million.

Table 3 displays the 2020-21 Governor's Budget appropriation, the revised 2019-20 expenditures and proposed 2020-21 expenditures for NBS costs by client type.

**Table 3**  
Newborn Screening: Current Year and Budget Year Budget Summaries Compared to 2020-21 Governor's Budget

Fund 0203 Genetic Disease Testing Fund	2019 Budget Act	FY 2019-20				FY 2020-21			
		2020-21 Governor's Budget	2020 May Revision	Change from Governor's Budget to May Revision	Percent Change from Governor's Budget to May Revision	2020-21 Governor's Budget	2020 May Revision	Change from Governor's Budget to May Revision	Percent Change from Governor's Budget to May Revision
<b>Total</b>	<b>\$ 45,343,000</b>	<b>\$ 45,883,000</b>	<b>\$ 45,635,000</b>	<b>\$ (248,000)</b>	<b>-0.54%</b>	<b>\$ 47,576,000</b>	<b>\$ 47,234,000</b>	<b>\$ (342,000)</b>	<b>-0.72%</b>
Lab Dollars	\$ 6,942,000	\$ 6,875,000	\$ 6,836,000	\$ (39,000)	-0.57%	\$ 7,188,000	\$ 7,132,000	\$ (56,000)	-0.78%
Tech & Sci	\$ 27,493,000	\$ 27,493,000	\$ 27,338,000	\$ (155,000)	-0.56%	\$ 28,354,000	\$ 28,133,000	\$ (221,000)	-0.78%
Reference Lab	\$ 2,426,000	\$ 2,426,000	\$ 2,411,000	\$ (15,000)	-0.62%	\$ 2,513,000	\$ 2,494,000	\$ (19,000)	-0.76%
CMCS	\$ 6,031,000	\$ 6,202,000	\$ 6,177,000	\$ (25,000)	-0.40%	\$ 6,807,000	\$ 6,783,000	\$ (24,000)	-0.35%
Diagnostic Services	\$ 2,451,000	\$ 2,887,000	\$ 2,873,000	\$ (14,000)	-0.48%	\$ 2,714,000	\$ 2,692,000	\$ (22,000)	-0.81%

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

For 2019-20, GDSP estimates PNS Local Assistance expenditures will total \$34.8 million, which is a slight decrease compared to the 2020-21 Governor's Budget of \$35.4 million. For 2020-21, GDSP estimates PNS Local Assistance expenditures will total \$35 million, which is a decrease of \$889,000 or 2.48 percent compared to the 2020-21 Governor's Budget of \$35.9 million.

The net decrease in the current year and budget year is due to the projected decline in caseload results based on DRU's projection of live births.

Table 4 shows the 2020-21 Governor's Budget appropriation, the revised 2019-20 expenditures and proposed 2020-21 expenditures for PNS program costs by client type.

**Table 4**

Prenatal Screening: Current Year and Budget Year Budget Summaries Compared to 2020-21 Governor's Budget

Fund 0203 Genetic Disease Testing Fund	2019 Budget Act	FY 2019-20				FY 2020-21			
		2020-21 Governor's Budget	2020 May Revision	Change from Governor's Budget to May Revision	Percent Change from Governor's Budget to May Revision	2020-21 Governor's Budget	2020 May Revision	Change from Governor's Budget to May Revision	Percent Change from Governor's Budget to May Revision
Total	\$ 35,937,000	\$ 35,397,000	\$ 34,752,000	\$ (645,000)	-1.82%	\$ 35,911,000	\$ 35,022,000	\$ (889,000)	-2.48%
Contract Lab	\$ 4,685,000	\$ 4,621,000	\$ 4,313,000	\$ (308,000)	-6.67%	\$ 4,952,000	\$ 4,608,000	\$ (344,000)	-6.95%
Tech & Sci	\$ 12,862,000	\$ 12,686,000	\$ 12,668,000	\$ (18,000)	-0.14%	\$ 12,627,000	\$ 12,574,000	\$ (53,000)	-0.42%
CMCS	\$ 6,389,000	\$ 6,586,000	\$ 6,346,000	\$ (240,000)	-3.64%	\$ 6,633,000	\$ 6,393,000	\$ (240,000)	-3.62%
PDC	\$ 12,001,000	\$ 11,504,000	\$ 11,425,000	\$ (79,000)	-0.69%	\$ 11,699,000	\$ 11,447,000	\$ (252,000)	-2.15%

**6. Operational Support Projections**

For 2019-20, GDSP revised operational support expenditures total was \$30.3 million which is no change compared to the 2020-21 Governor's Budget.

In 2020-21, GDSP projects operational support expenditures will total \$27.4 million, which is no change compared to the 2020-21 Governor's Budget.

Table 5 displays the difference between the 2020-21 Governor's Budget appropriation, the revised 2019-20 expenditures and proposed 2020-21 expenditures for Operational Support costs.

**Table 5**

Operational Support: Current Year and Budget Year Budget Summaries Compared to 2020-21 Governor's Budget

Fund 0203 Genetic Disease Testing Fund	2019 Budget Act	FY 2019-20				FY 2020-21			
		2020-21 Governor's Budget	2020 May Revision	Change from Governor's Budget to May Revision	Percent Change from Governor's Budget to May Revision	2020-21 Governor's Budget	2020 May Revision	Change from Governor's Budget to May Revision	Percent Change from Governor's Budget to May Revision
Operational Support	\$ 30,344,000	\$ 30,344,000	\$ 30,344,000	\$ -	0.00%	\$ 27,400,000	\$ 27,400,000	\$ -	0.00%

**D. State Operations Expenditure Projections**

In 2019-20, GDSP estimates State Operations expenditures will total \$31.4 million, which is no change from the 2020-21 Governor's Budget amount of \$31.4 million.

In 2020-21, GDSP estimates State Operations expenditures will total \$31.7 million, which is no change compared to the 2020-21 Governor's Budget amount of \$31.7 million.



Table 6 displays the difference between the 2020-21 Governor's Budget appropriation, the revised 2019-20 expenditures and proposed 2020-21 expenditures for GDSP State Operations costs.

**Table 6**

State Operations: Current Year and Budget Year Budget Summaries Compared to 2020-21 Governor's Budget

Fund 0203 Genetic Disease Testing Fund	2019 Budget Act	FY 2019-20				FY 2020-21			
		2020-21 Governor's Budget	2020 May Revision	Change from Governor's Budget to May Revision	Percent Change from Governor's Budget to May Revision	2020-21 Governor's Budget	2020 May Revision	Change from Governor's Budget to May Revision	Percent Change from Governor's Budget to May Revision
State Operations	\$ 31,351,000	\$ 31,351,000	\$ 31,351,000	\$ -	0.00%	\$ 31,679,000	\$ 31,679,000	\$ -	0.00%

## E. Revenue Projections

### 1. Combined NBS and PNS Revenue

GDSP has revised revenue estimates for 2019-20 totaling \$127.6 million, which is a decrease of \$2.2 million or 1.71 percent compared to the 2020-21 Governor's Budget amount of \$129.8 million. For 2020-21, GDSP projects revenue will total \$142.7 million, which is a decrease of \$2.4 million or 1.66 percent compared to the 2020-21 Governor's Budget amount of \$145.1 million.

The May Revision Estimate projects the 2019-20 NBS caseload at 453,146, which is a decrease of 2,582 cases or 0.57 percent compared to the 2020-21 Governor's Budget caseload projection of 455,729. For 2020-21, the May Revision Estimate projects the NBS caseload at 450,344, which is a decrease of 3,525 cases or 0.78 percent compared to the 2020-21 Governor's Budget caseload projection of 453,869.

The May Revision Estimate projects the 2019-20 PNS caseload at 313,363, which is a decrease of 9,139 cases or 2.83 percent compared to the 2020-21 Governor's Budget caseload projection of 322,502 cases. For 2020-21, the May Revision Estimate projects the PNS caseload at 312,801, which is a decrease of 8,806 cases or 2.74 percent compared to the 2020-21 Governor's Budget caseload projection of 321,607.

### 2. Revenue Methodology

The PNS and NBS programs each charge a fee for screening services provided to clients.

The PNS program charges a fee of \$221.60. \$211.60 is deposited into the Genetic Disease Testing Fund (Fund 0203) and the remaining ten dollars is deposited into the Birth Defects Monitoring Program Fund (Fund 3114).

GDSP invoices and collects PNS payments from individual participants, private insurers and Medi-Cal. Within a two-year collection period, GDSP is able to collect approximately 98 percent of all fees owed on behalf of Medi-Cal clients (which is approximately 55 percent of the total caseload) and approximately 94 percent of the fees owed by individuals with private insurances. GDSP uses the following formula to estimate revenue generated from PNS fees:



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

NBS participants are charged a fee of \$142.25. Effective July 1, 2020, NBS fees will increase by \$35 resulting to a new fee of \$177.25. The increase will be used to support the expenditures related to higher contract rates for Spinal Muscular Atrophy (SMA) screening and costs associated with a rise in referrals for case management/coordination and diagnostic services. Unlike PNS, wherein GDSP bills patients and collects fees from insurers, GDSP collects the bulk of NBS revenue directly from hospitals. Only home births, where specimens are collected outside of the hospital, are billed to the newborns' parents or their insurance company. As such, the billing for NBS services is much more streamlined resulting in a 99 percent collection rate over a two-year collection period. GDSP uses the following formula to estimate revenue generated from NBS fees:

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

### 3. NBS Revenue (See Appendix C-1)

In 2019-20, NBS revenue is expected to total \$63.8 million, which is a slight decrease from the 2020-21 Governor's Budget amount of \$64.2 million.

In 2020-21, GDSP projects NBS revenue will total \$79 million, which is a decrease of \$619,000 or 0.78 percent compared to the 2020-21 Governor's Budget of \$79.6 million.

The fluctuation in the current year is tied to the billable caseload. The net decrease in the budget year is due to the reduction in billable caseload along with the fee increase of \$35.

### 4. PNS Revenue (See Appendix C2)

In 2019-20, PNS revenue is expected to total \$63.8 million, which is a decrease of \$1.9 million or 2.83 percent compared to the 2020-21 Governor's Budget amount of \$65.6 million.

In 2020-21, GDSP projects PNS revenue will total \$63.7 million, which is a decrease of \$1.8 million or 2.74 percent compared to the 2020-21 Governor's Budget of \$65.5 million.

The decrease in both current year and budget year is due to the decline in billable caseload.

Table 7 displays the revised current year revenue projections for current year and budget year compared to 2020-21 Governor's Budget.

**Table 7**  
Genetic Disease Screening Program Revenue: Current Year and Budget Year Revenue Summaries Compared to 2020-21 Governor's Budget

Fund 0203 Genetic Disease Testing Fund	2019 Budget Act	FY 2019-20				FY 2020-21			
		2020-21 Governor's Budget	2020 May Revision	Change from Governor's Budget to May Revision	Percent Change from Governor's Budget to May Revision	2020-21 Governor's Budget	2020 May Revision	Change from Governor's Budget to May Revision	Percent Change from Governor's Budget to May Revision
<b>Total</b>	<b>\$ 129,361,000</b>	<b>\$ 129,827,000</b>	<b>\$ 127,603,000</b>	<b>\$ (2,224,000)</b>	<b>-1.71%</b>	<b>\$ 145,110,000</b>	<b>\$ 142,698,000</b>	<b>\$ (2,412,000)</b>	<b>-1.66%</b>
Newborn Screening	\$ 64,148,000	\$ 64,179,000	\$ 63,815,000	\$ (364,000)	-0.57%	\$ 79,644,000	\$ 79,025,000	\$ (619,000)	-0.78%
Prenatal Screening	\$ 65,213,000	\$ 65,648,000	\$ 63,788,000	\$ (1,860,000)	-2.83%	\$ 65,466,000	\$ 63,673,000	\$ (1,793,000)	-2.74%

**II. Fund Condition Statement****GENETIC DISEASE TESTING FUND**  
FUND CONDITION REPORT  
DOLLARS IN THOUSANDS

	2018-19	2019-20	2020-21
<b>RESOURCES</b>			
BEGINNING BALANCE	\$26,494	\$30,775	\$14,070
Prior Year Adjustment	4,512	0	0
Adjusted Beginning Balance	31,006	30,775	14,070
<b>REVENUES</b>			
121100 Genetic Disease Testing Fees <sup>1/</sup>	125,211	127,603	142,698
150300 Income from Surplus Investments	451	451	451
161000 Escheat of Unclaimed Checks & Warrants	1	1	1
TOTALS, REVENUES	125,663	128,055	143,150
<b>TOTAL RESOURCES</b>	\$156,669	\$158,830	\$157,220
<b>EXPENDITURES AND EXPENDITURE ADJUSTMENTS</b>			
4265 Department of Public Health (State Operations)	29,849	31,351	31,679
4265 Department of Public Health (Local Assistance)	94,740	110,731	109,656
8880 Financial Information System for California (State Operations)	3	-4	0
9800 Employee Compensation (State Operations)	0	913	957
Control Section 3.60 Retirement	0	233	233
Lease Revenue Debt Service Adjustment	0	1	4
9892 Supplemental Pension Payments (State Operations)	202	496	496
9900 Statewide General Admin Exp (ProRata) (State Operations)	1,100	1,039	1,268
9920 Loan Transfer to Other Funds	0	0	3,000
<b>TOTAL EXPENDITURES AND EXPENDITURE ADJUSTMENTS</b>	<b>125,894</b>	<b>144,760</b>	<b>147,293</b>
<b>FUND BALANCE</b>	30,775 24%	14,070 10%	9,927 7%

**REVENUE PROJECTIONS****2019-20**

2019-20 NBS FEES BASED ON	453,146 TESTS @	\$142.25	AND 99% Provider <sup>1/</sup>	=	\$63,815,000
2019-20 PNS FEES BASED ON	141,013 TESTS @	\$211.60	AND 94% Non Medi-Cal <sup>2/</sup>	=	\$28,048,000
2019-20 PNS FEES BASED ON	172,350 TESTS @	\$211.60	AND 98% Medi-Cal <sup>3/</sup>	=	\$35,740,000
	313,363				\$63,788,000
<b>GDSP Total</b>					<b>\$127,603,000</b>

**2020-21**

2020-21 NBS FEES BASED ON	450,344 TESTS @	\$177.25	AND 99% Provider <sup>1/</sup>	=	\$79,025,000
2020-21 PNS FEES BASED ON	140,760 TESTS @	\$211.60	AND 94% Non Medi-Cal <sup>2/</sup>	=	\$27,998,000
2020-21 PNS FEES BASED ON	172,040 TESTS @	\$211.60	AND 98% Medi-Cal <sup>3/</sup>	=	\$35,675,000
	312,801				\$63,673,000
<b>GDSP Total</b>					<b>\$142,698,000</b>

- 1/ NBS Fees based on 99% hospital and other provider collection rate  
2/ PNS Fees based on 94% of private payer / insurance collection rate for  
3/ PNS Fees based on 98% Medi-Cal Collection rate

### III. General Assumptions

#### Future Fiscal Issues

##### **Senate Bill (SB) 1095: Newborn Screening Program**

**Background:** Senate Bill (SB) 1095 (Chapter 393, Statutes of 2016) amends Sections 124977 and 125001 of the Health and Safety Code (H&S Code) and requires 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 Recommended Uniform Screening Panel (RUSP).

**Description of Change:** Screening for additional diseases will require start-up costs, additional laboratory equipment, additional personnel, changes to the Screening Information System (SIS), the follow-up systems and the addition of new confirmatory testing.

**Discretionary:** No

**Reason for Adjustment/ Change:** Passage of SB 1095 requires 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.

**Fiscal Impact (Range) and Fund Source(s):** Expenditures may increase by approximately \$1 million to \$2.5 million per year for any new disorder adopted by the federal RUSP. This range is only an estimate and is based on costs from the last two additions to the Newborn Screening panel – Mucopolysaccharidosis Type 1 (MPS-I) and Pompe disease. Furthermore, as additional diseases are added to the federal RUSP, there may be one-time resources needed to plan, prepare for, and implement the other required screening. GDSP will assess the fund reserve to ensure the program is able to absorb the increase in expenditures and determine if, and when, a fee increase is needed. The fund source is the Genetic Disease Testing Fund (GDTF) (Fund 0203).

##### **Modernization of the California PNS Program**

**Background:** A new screening test known as “Cell-free DNA” (cfDNA) has been developed and became available to the public in 2011 and over time has demonstrated value for prenatal screening. With cfDNA testing, it is now possible to detect fetal DNA circulating freely in a pregnant woman’s blood. The cfDNA screening can be used to detect the same chromosome abnormalities as the current PNS program’s conventional biochemical screening but with a significantly lower false positive rate. It can also detect an additional chromosome abnormality for which the current screening does not evaluate (e.g., Trisomy 13).

Health and Safety Code section 125055 (g)(1) states that CDPH “shall expand prenatal screening to include all tests that meet or exceed the current standard of care as recommended by nationally recognized medical or genetic organizations.” A statement from the American College of Medical Genetics and Genomics indicated that cfDNA has been rapidly integrated into prenatal care and new evidence strongly suggests that it “can replace

conventional screening for Patau (Trisomy 13), Edwards, and Down Syndrome across the maternal age spectrum.” This new technology may be the standard of care and should be offered to all women in California, regardless of income, education, or ability to pay.

Description of Change: The California PNS program plans to replace GDSP's current conventional biochemical screening for chromosome abnormalities with cfDNA screening. GDSP's testing for neural tube defects will remain part of the overall screening process. The proposed changes would require the California PNS program to initiate the following activities in preparation for the new screening launch expected to take place in July 2022: redesign the Test Request Forms for providers to order prenatal screening; redesign numerous screening protocols to administer the new test to all California individuals who seek prenatal screening; develop new health education materials; establish a contract for new laboratories to carry out cfDNA screening; develop new fee structures for case management services provided by Case Coordination Centers and follow-up services provided by the Prenatal Diagnosis Centers (PDCs); redesign the SIS to accommodate the new screening results transmitted from the cfDNA laboratories, redesign of test result mailers, develop new algorithms to designate a case as screen-positive and the subsequent referral mechanisms to refer high risk cases to the PDCs for follow-up services. These screening launch preparation activities are estimated to cost \$4 million. The actual laboratory screening replacement is expected to be contracted out to private laboratories and estimates indicate the costs will increase net PNS program expenditures by approximately \$21 million annually beginning 2022-23. The net increase factors in projected savings from the improved accuracy of cfDNA testing resulting in lower false positives and fewer invasive diagnostic procedures.

Discretionary: Yes

Reason for Adjustment/ Change: The cfDNA screening yields a much better chromosome abnormality detection rate than the PNS Program's current screening methodology, with a significantly lower false positive rate. A lower false positive rate means that fewer women are flagged as being high risk for having a baby with a chromosome abnormality. This translates to a much lower referral rate for follow-up diagnostic services that will result in less anxiety for families and fewer invasive prenatal diagnostic procedures (chorionic villus sampling and amniocentesis) which are associated with a slightly higher risk of fetal loss and unnecessary stress for pregnant individuals who face a decision to undergo these invasive procedures.

Additionally, unlike current practice, cfDNA screening would be universally offered to all pregnant individuals throughout California without disparities associated with private-sector use, geographic location, race, ethnicity, age, or ability to pay.

Fiscal Impact (Range) and Fund Source(s): In addition to one-time start-up costs of \$4 million in 2021-22, Local Assistance expenditures are estimated to increase by approximately \$21 million annually beginning 2022-23. Additionally, GDSP estimates the need for six positions and an \$879,000 increase in State Operations expenditure authority in 2021-22 and ongoing to update California PNS program testing procedures. The fund source is the GDTF (Fund 0203).

Further details on any fee increases and identifiable impacts to the Medi-Cal program from this proposal are currently under review.

### **New Assumptions/ Premises**

There are no New Assumptions/Premises

### **Existing (Significantly Changed) Assumptions/Premises**

There are no Existing (Significantly Changed) Assumptions/Premises.

### **Unchanged Assumptions/Premises**

### **Newborn Screening Fee Increase**

Background: Senate Bill (SB) 1095 (Chapter 393, Statutes of 2016) established H&S Code section 125001(d) and required the CDPH NBS program to expand statewide screening of newborns by adding new tests within two years of any disease testing being adopted by the federal RUSP. Since this mandate was introduced, the CDPH NBS program has added screening for two additional disorders to the NBS panel in August 2018 – mucopolysaccharidoses (MPS) Type I and Pompe disease requiring NBS fee increases in July 2018 to support the additional expenditures.

On July 2, 2018, SMA was added to the federal RUSP by the Secretary of Health and Human Services. This requires GDSP to implement newborn screening for the disorder in California within two years of that date.

This addition will allow California to meet the national standard of care as recommended by the federal Advisory Committee on Heritable Disorders in Newborns and Children, the US Department of Health and Human Services and will bring the NBS program into alignment with the most up-to-date research, technology, laboratory, public health standards and practices, as well as H&S Code section 125001(d). Similar to MPS Type I and Pompe disease, GDSP will need to increase fees to offset the additional expenditures of screening for SMA.

Additionally, over the past two years, GDSP has been experiencing an increase in the contracted rates for screening which can be attributed to normal costs of conducting business. GDSP has experienced an increased rate in referrals for case management and coordination and diagnostic services. Additional contract rate increases with regional testing laboratories for Adrenoleukodystrophy rollout, area service centers, specialized follow-up centers, and diagnostic testing labs, as well as scientific supply companies are expected in budget year. These rate and caseload increases were included in prior, current, and budget year estimates, and although additional budget authority was authorized, fees were not increased to offset the additional expenditures.

Description of Change: The 2019 Budget Act includes the necessary additional expenditure authority (\$4.3 million in 2019-20, and \$2.6 million in 2020-21 and ongoing) to support SMA screening. A fee increase of approximately nine dollars will be needed to offset these costs.



An additional fee increase of approximately \$26 will be needed to offset the increased expenditures related to higher contract rates for screening and higher costs associated with increased referrals for case management/coordination and diagnostic services.

Discretionary: No

Reason for Adjustment/ Change: SB 1095 requires 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. The higher screening rates can be attributed to standard increasing costs of conducting business. The increases in case management, coordination and diagnostic services are likely an unplanned impact from the increasing numbers of disorders that are being screened under the NBS program.

Fiscal Impact (Range) and Fund Source(s): An increase in revenues of approximately \$15.2 million annually beginning 2020-21 due to a \$35 NBS fee increase that will be approved through the rulemaking process. The fund source is the GDTF (Fund 0203).

### **Accounts Receivables (AR) Collection Rate Change for PNS and NBS**

Background: In 2016-17, GDSP fully transitioned its in-house patient billing process to an outsourced vendor, Sutherland Healthcare Solutions (SHS). With the in-house process using call center staff, GDSP had an approximate 83 percent collection rate within two years collection time. Over the two previous fiscal years when patient billing process was outsourced, the collection rate increased to 90 percent within the two years collection time from non-Medi-Cal insurers for PNS. This rate was used for GDSP's 2019-20 estimates for revenue projections. CDPH contracted with SHS due to its powerful billing system, customer care expertise, extensive knowledge of healthcare policy and programs and state of the art technology. The goal was to accelerate revenue collections, reduce the overall risk and cost to collect and reduce uncollectable accounts.

As the patient billing collection rate progresses under a new AR system (outsourced vendor), the client billing collection rate increased from 98 percent to 99 percent. During the transition process of removing patient billing from the existing AR system, GDSP staff worked on improving the processes of client billing by sending out invoices electronically via secured email rather than sending by mail. In the same year that GDSP transitioned the patient billing process to SHS, GDSP staff received requests from 20 large hospital providers indicating preference to electronic billing via email than paper invoices. This new process helped GDSP not only increase the collection rate to 99 percent but it also reduced the timeline of collecting revenue from one year to six months. The remaining one percent belongs to one hospital provider that filed for bankruptcy and since it was an unsecured claim, the court scheduled the Chapter 9 to be paid out beginning in 2025 through 2029. Eventually, once the bankruptcy case is finalized, the remaining balance will be discharged from accountability.

Description of Change: Since GDSP contracted with Sutherland for PNS billing and collection, the collection rate for non-Medi-Cal participants has improved from 84 percent to 94 percent. The NBS collection rate has improved from 98 percent to 99 percent.



Discretionary: Yes

Reason for Adjustment/ Change: The rate of collection for PNS non-Medi-Cal participants as well as NBS participants needs to be updated to reflect accurate revenue figures.

Fiscal Impact (Range) and Fund Source(s): An annual increase for PNS in projected revenues is \$1.2 million. The annual increase for NBS in projected revenues is \$654,000. The fund source is the GDTF (Fund 0203).

### **Discontinued Assumptions/Premises**

There are no Discontinued Assumptions/Premises.

## Appendices

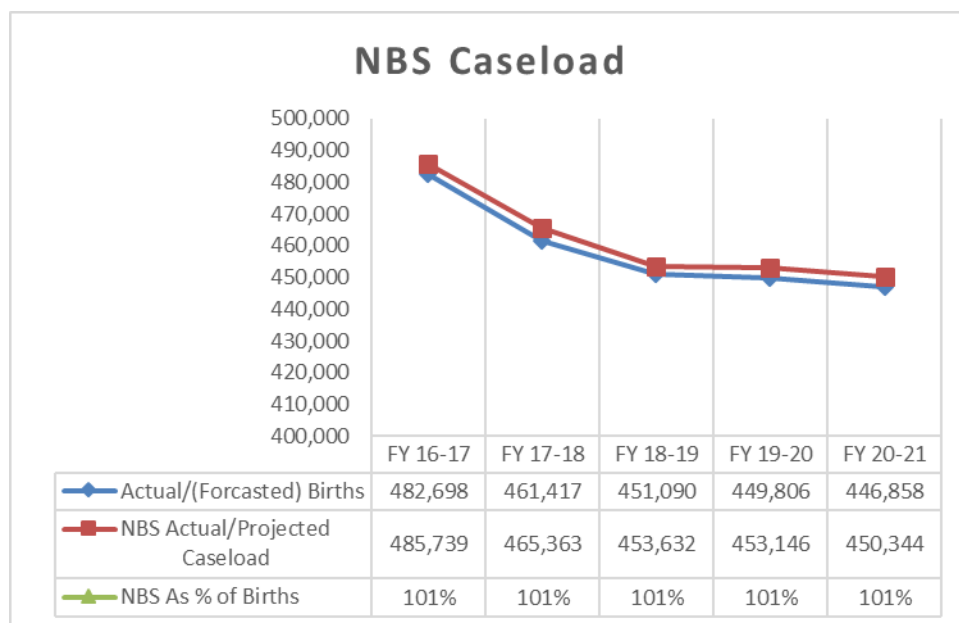
### IV. Appendix A: NBS Assumptions and Rationale

#### 1. Contract Laboratories

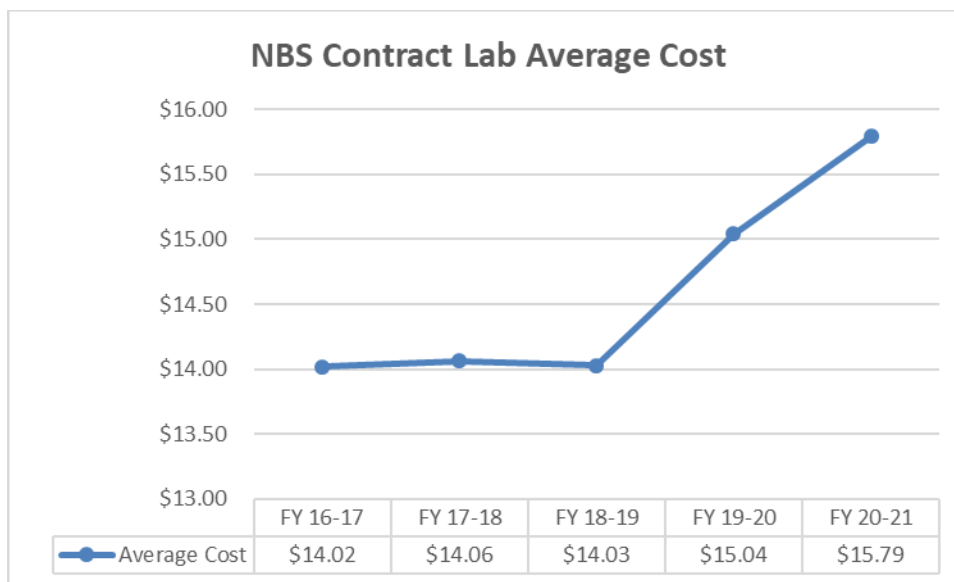
Overview: Laboratory testing of specimens is performed at regional screening laboratories contracted by the state to screen newborns for at least 75 specific genetic disorders. Costs include laboratory services for processing genetic screening tests. Screening laboratories ascertain the possible presence of a birth defect or a congenital disorder; a screening test is not diagnostic and 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 laboratories that are paid on a per specimen basis.

Costs associated with contracted laboratories and technical and scientific supplies are both driven by the total number of clients the NBS program serves. The total caseload is determined as a percentage of the DRU's projected number of live births. This estimate assumes that 100 percent of DRU's projected births will participate in the NBS program in 2019-20 and 2020-21.

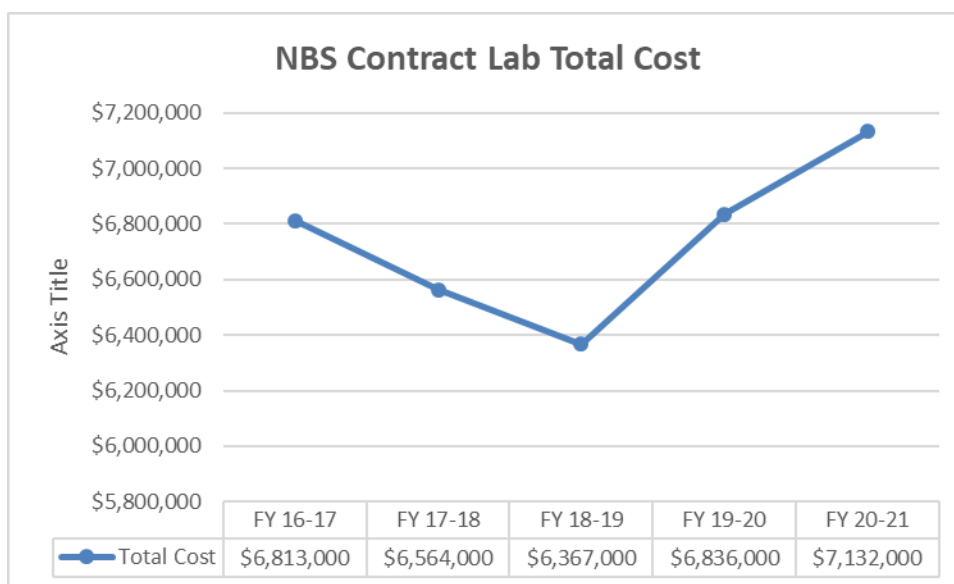
**Total Caseload** – GDSP estimates current year caseload will total 453,146, a decrease of 486 or 0.11 percent compared to the 2018-19 actual total caseload of 453,632. Caseload in 2020-21 is estimated at 450,344, which is a decrease of 2,802 or 0.62 percent compared to the current year estimate. This year-over-year change is due to DRU's projected number of live births. GDSP assumes that up to 99 percent 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 costs per participant will be \$15, which is an increase of one dollar or 7.22 percent compared to the 2018-19 actual average laboratory cost per participant of \$14. Average laboratory cost per participant in 2020-21 is estimated at \$15.80, which is an increase of 80 cents or 4.99 percent compared to the current year estimate. The rise in the current year and the budget year is due to the increased costs of the laboratory contracts.



**Contract Laboratory Total Cost Projections** – GDSP estimates current year contract laboratory costs to total \$6.8 million which is an increase of \$469,000 or 7.37 percent compared to 2018-19 actual contract laboratory costs of \$6.4 million. 2020-21 contract laboratory costs are projected to be \$7.1 million which is an increase of \$296,000 or 4.33 percent compared to the current year.

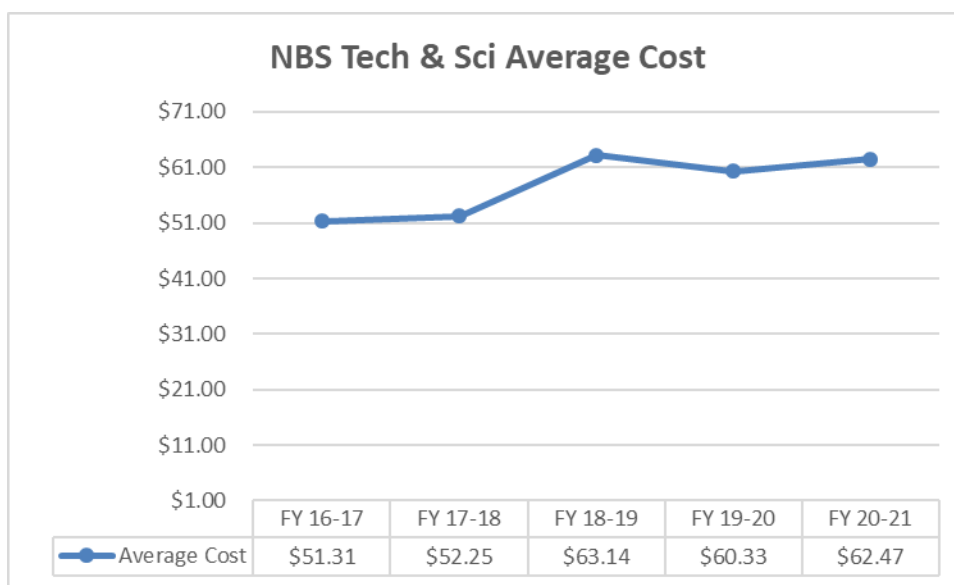


## 2. Technical and Scientific

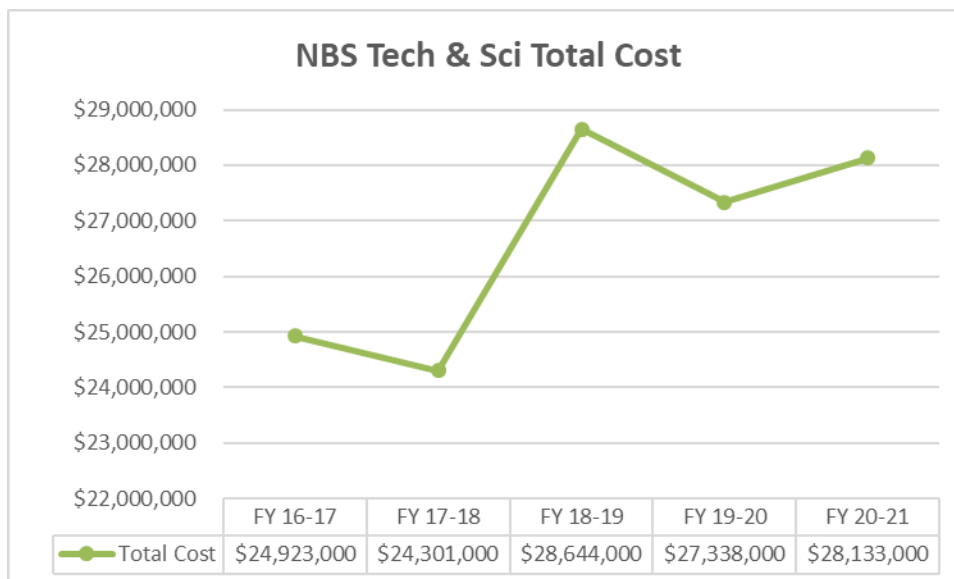
**Overview:** Costs associated with specimen screening include: reagents kits, supplies, processing and limited maintenance and support (as it directly relates to the reagents) of laboratory equipment that is with the contract laboratories. In addition, there are minimal fixed costs associated with specimen 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 and 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 \$60.30, which is a decrease of \$2.80 or 4.46 percent compared to 2018-19 actual average cost per participant of \$63.10. Average laboratory cost per participant in 2020-21 is estimated at \$62.50 which is an increase of \$2.10 or 3.55 percent compared to the current year estimate.



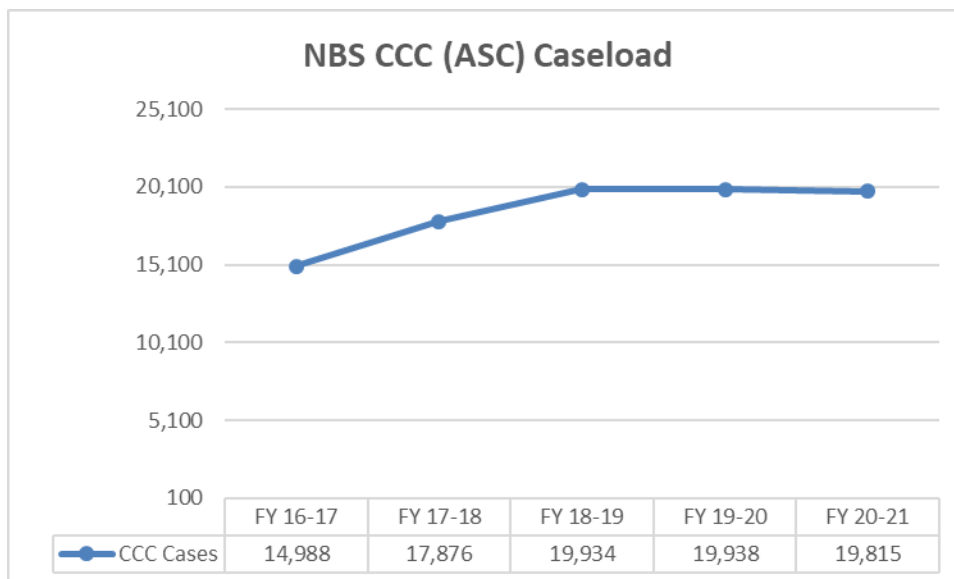
**Technical and Scientific Total Cost** – GDSP estimates current year technical and scientific costs to total \$27.3 million which is a decrease of \$1.3 million or 4.56 percent compared to 2018-19 actual costs of \$28.6 million. For 2020-21, the technical and scientific costs are estimated to be \$28.1 million which is an increase of \$795,000 or 2.91 percent compared to the current year. The current year decrease in costs is tied to the fluctuation of caseloads. The average cost decreases with an increase in the consumables and reagents needed for screening disorders. The budget year increase in average cost is tied to the declining caseloads.



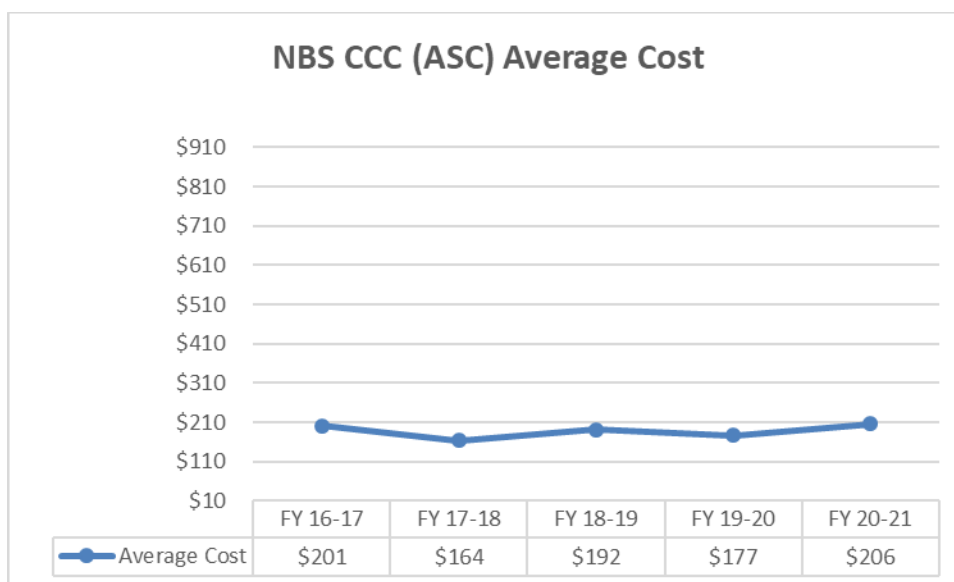
### 3. Case Management and Coordination Services (CMCS):

Overview- Services are provided to infants who screen an initial positive or have questionable screening test results for the 75 plus genetic disorders tested. 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 ASCs 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 services 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.

CMCS Caseload – GDSP estimates current year CMCS caseload will total 19,938 which is a slight increase of four or 0.02 percent compared to 2018-19 actual CMCS caseload of 19,934. The increase is attributed to the newest disorders added to the screening panel. CMCS caseload in 2020-21 is estimated at 19,815 which is a decrease of 123 or 0.62 percent compared to the current year estimate.



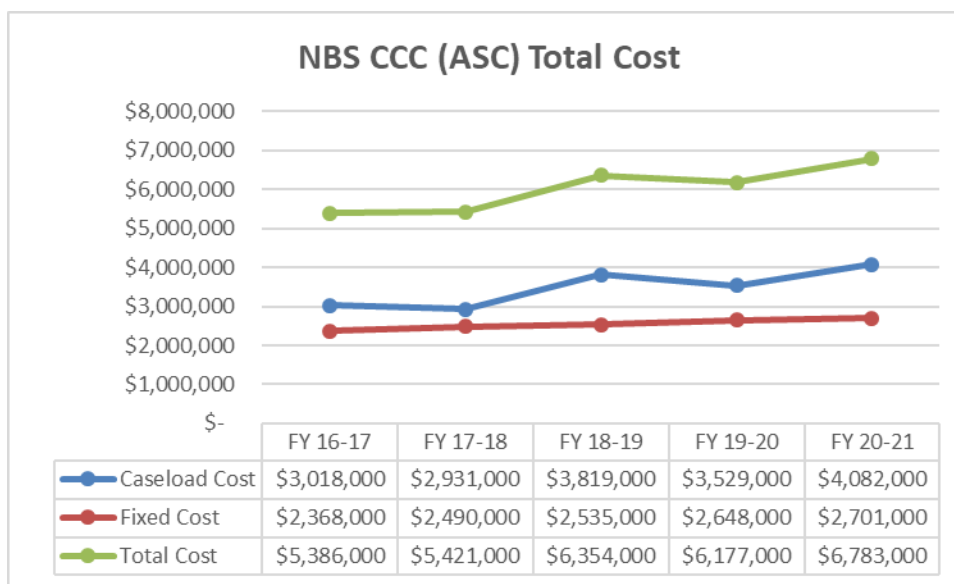
**CMCS Average Cost** - GDSP estimates current year average CMCS cost per participant will be \$177, which is a decrease of \$14.60 or 7.61 percent compared to 2018-19 actual average cost of \$191.60. Average CMCS cost per participant in 2020-21 is estimated at \$206 which is an increase of \$29 or 16.38 percent compared to the current year estimate. CMCS costs are a combination of fixed costs and incremental (per case) reimbursement. Fluctuation in the average cost is tied directly to the total cost and additional specialized follow-up centers for SMA testing.



**CMCS Total Cost** – GDSP estimates current year CMCS costs to total \$6.2 million which is a decrease of \$177,000 or 2.79 percent compared to 2018-19 actual CMCS costs of \$6.4 million. CMCS costs in 2020-21 are estimated to total \$6.8 million which is an increase of \$606,000 or 9.81 percent compared to the current year estimate.



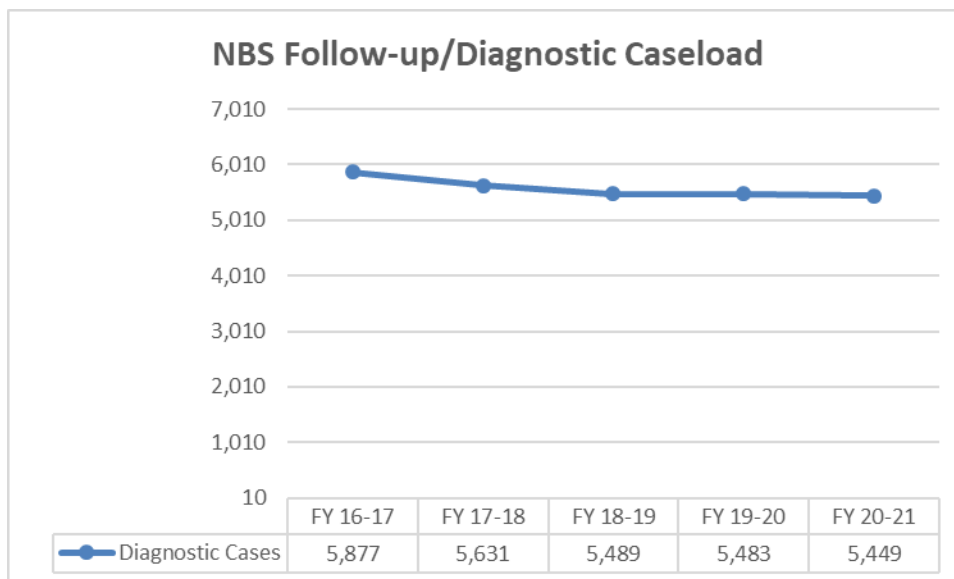
The reduction in current year reflects the projected decrease in data correction on newborn records and an increase in expenditures in 2020-21 is due to the projected number of positive cases attributed to the new screening for SMA. In addition, GDSP considered a combination of increased fixed costs and incremental (per case) reimbursement which includes administrative costs, rent, equipment, travel and administrative staff.



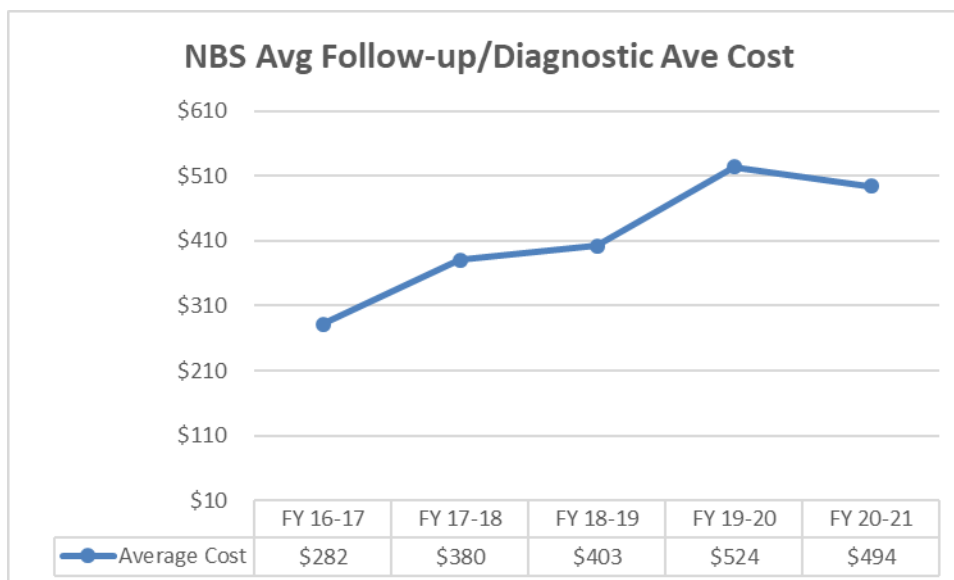
#### 4. Diagnostic Services:

**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 ASCs 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, 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 caseload will total 5,483, which is a slight decrease of six or 0.11 percent compared to 2018-19 actual caseload of 5,489. Diagnostic caseload in 2020-21 is estimated at 5,449 which is a decrease of 34 or 0.62 percent compared to the current year estimate. The change in the current year and the budget year is due to the fluctuation in caseloads based on DRU's projection of live births. The following chart shows the actual diagnostic services cases along with projected numbers for the remainder of the current year and budget year.

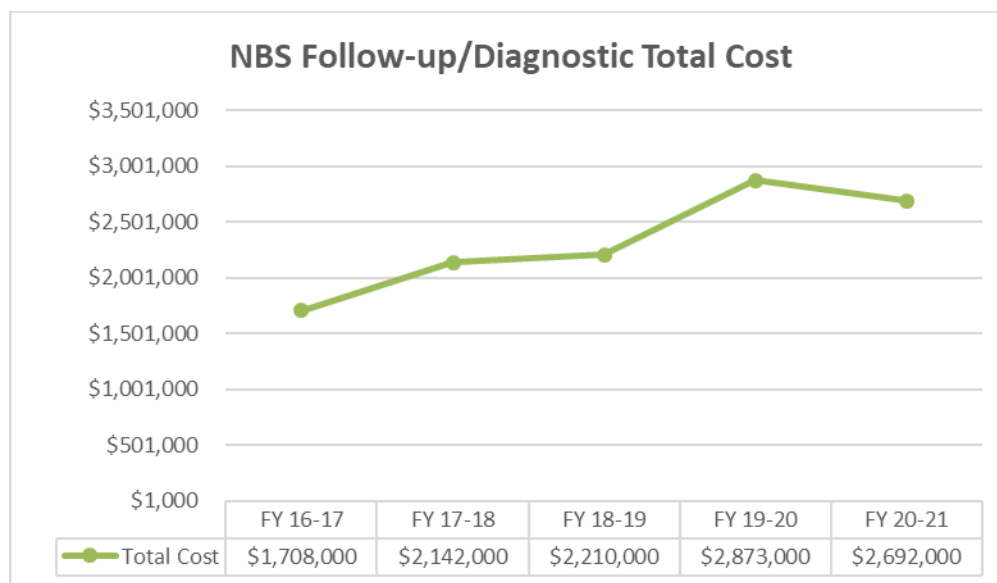


**Diagnostic Services Average Cost** – GDSP estimates current year average diagnostic services cost per participant will be \$524 which is an increase of \$121 or 30.15 percent compared to 2018-19 actual average diagnostic services cost per participant of \$402. Average diagnostic services cost per participant in 2020-21 are estimated at \$494 which is a decrease of \$30 or 5.73 percent compared to the current year estimate. The increase in current year is tied to the rise in total costs and growth in caseload. The reduction in the budget year is tied to the decrease in total cost and decline in caseload.



**Diagnostic Services Total Cost** - GDSP estimates current year diagnostic services costs to total \$2.9 million which is an increase of \$663,000 or 30 percent compared to 2018-19 actual costs of \$2.2 million. Diagnostic services costs in 2020-21 are estimated to total \$2.7 million which is a decrease of \$181,000 or 6.30 percent

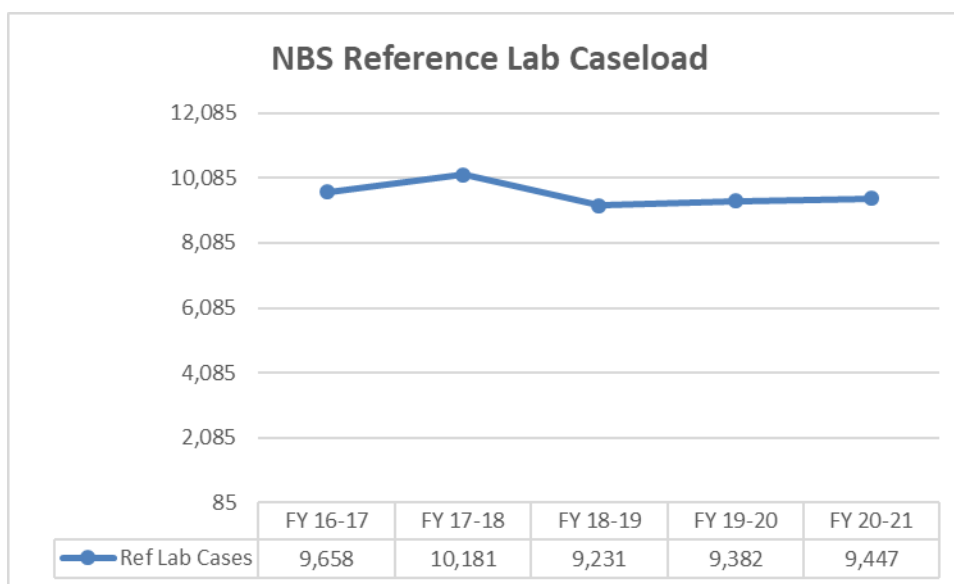
compared to the current year estimate. The rise in current year total cost is attributable to the contract increases and growth in caseload. The reduction in budget year total cost is due to the decline in caseload.



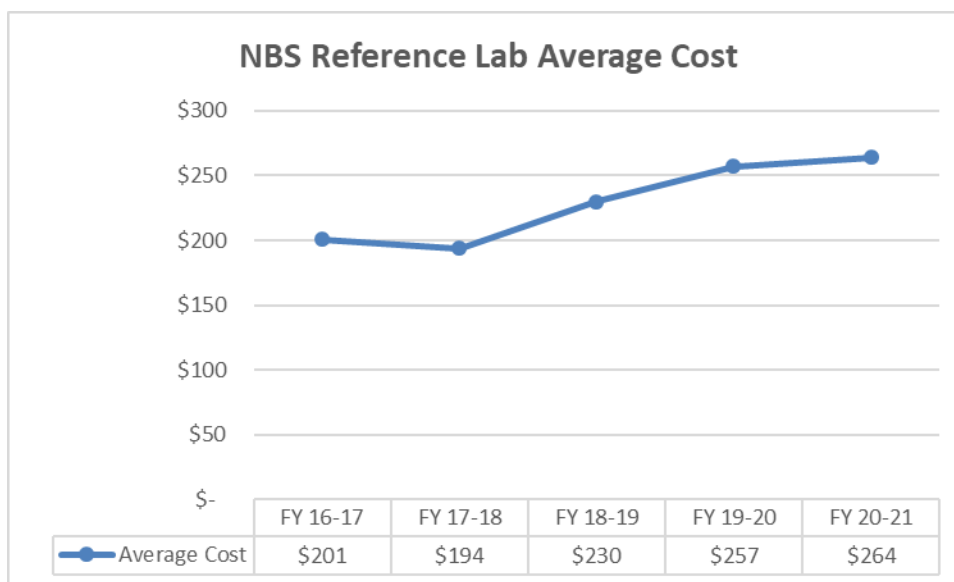
## 5. Reference Laboratory Cases:

**Overview-** Cases that result in a positive screening tests 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 9,382 which is an increase of 151 or 1.63 percent compared to 2018-19 actual caseload of 9,231. Reference Laboratory caseload in 2020-21 is estimated at 9,447 which is an increase of 65 or 0.69 percent compared to the current year estimate. The increases are due to the growth in projected caseload. The following chart shows the actual reference laboratory cases along with projected caseload for the remainder of the current year and budget year.

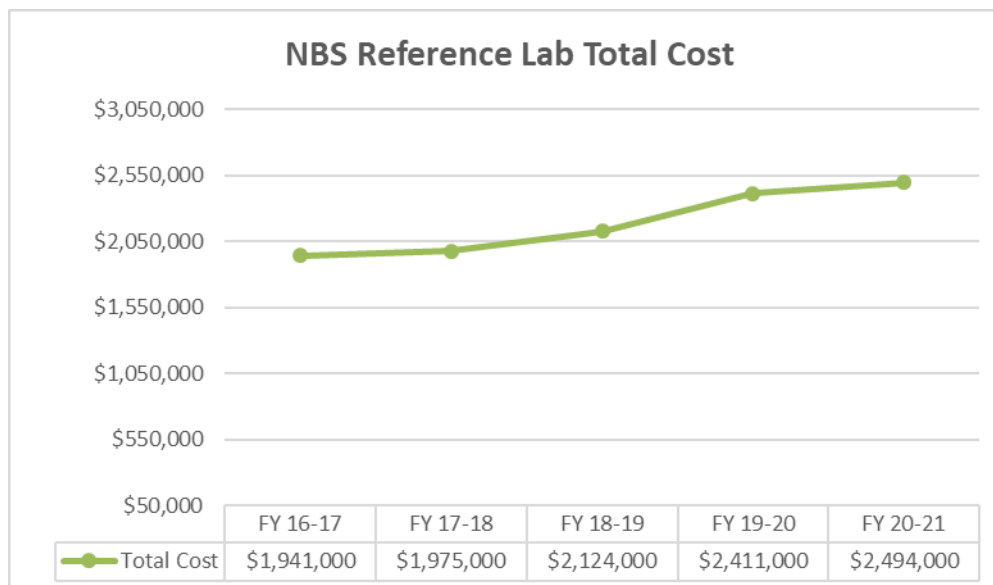


**Reference Laboratory Average Cost** – GDSP estimates current year reference laboratory average cost per participant will be \$257 which is an increase of \$26 or 11.69 percent compared to 2018-19 actual average cost per participant of \$230.10. Reference laboratory average cost per participant in 2020-21 is estimated at \$264 which is an increase of seven dollars or 2.73 percent compared to the current year estimate. Fluctuation is tied to the total costs.



**Reference Laboratory Total Cost** – GDSP estimates current year reference laboratory costs to total \$2.4 million which is an increase of \$287,000 or 13.51 percent compared to 2018-19 actual total costs of \$2.1 million. Reference laboratory costs in 2020-21 are estimated to total \$2.5 million which is an increase of \$83,000 or 3.44 percent compared to the current year estimate. The increase is attributed to the additional cost

for adding confirmatory DNA sequencing for new disorders and contract increases for sickle cell trait follow-up.



## V. APPENDIX B: PNS Program Assumptions and Rationale

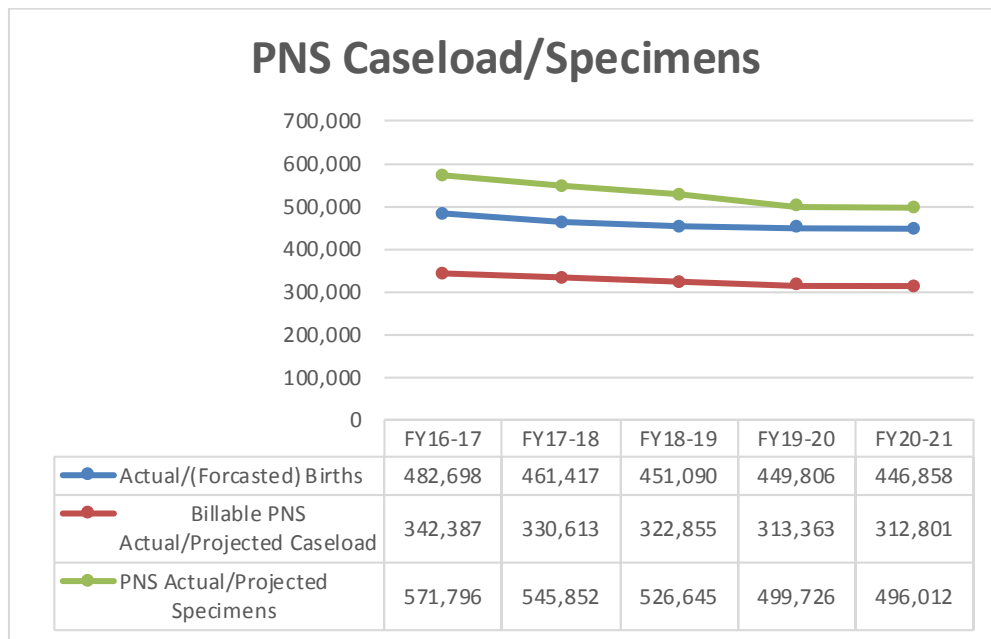
### 1. Contract Laboratories:

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

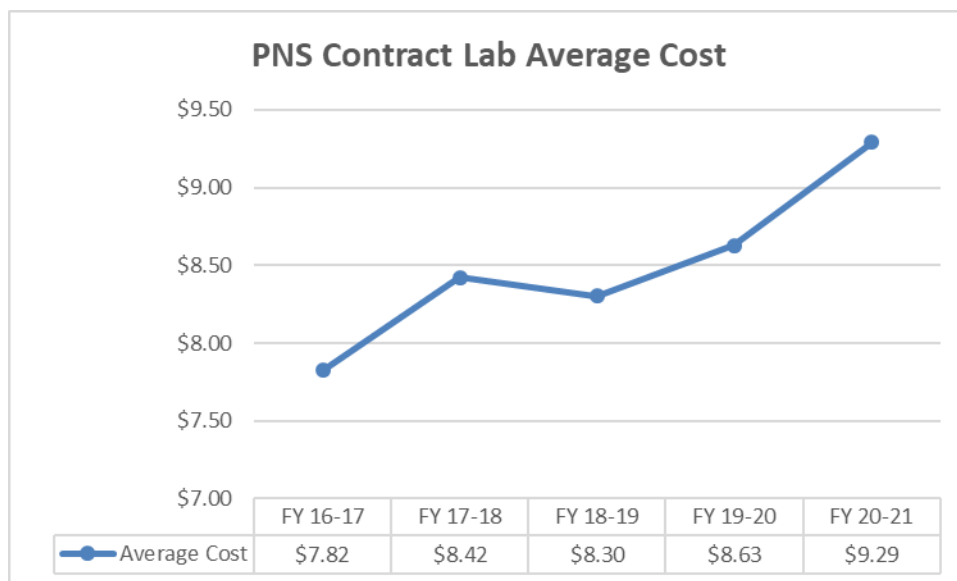
In the past GDSP estimated the number of first trimester and second trimester screens separately. This is because the average cost of the first trimester screen was substantially less than the cost of the second trimester screen. Currently, the cost of each test is the same, as such, GDSP will estimate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

**Total Specimen Caseload** – GDSP estimates current year specimen caseload will total 499,726 which is a decrease of 26,919 or 5.11 percent compared to 2018-19 actual total caseload of 526,645. Caseload in 2020-21 is estimated at 496,012 which is a decrease of 3,712 or 0.74 percent compared to the current year estimate. The PNS program participation is estimated based on a percentage of DRU's projected number of live births. GDSP estimates that 70 percent (based from a three-year actual average) of the projected births will participate in the PNS program in 2019-20 and that the number of participants will remain constant in 2020-21. The 2020-21 projections does not increase based on DRU's projected 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 along with projected numbers for the remainder of the current year and budget year.

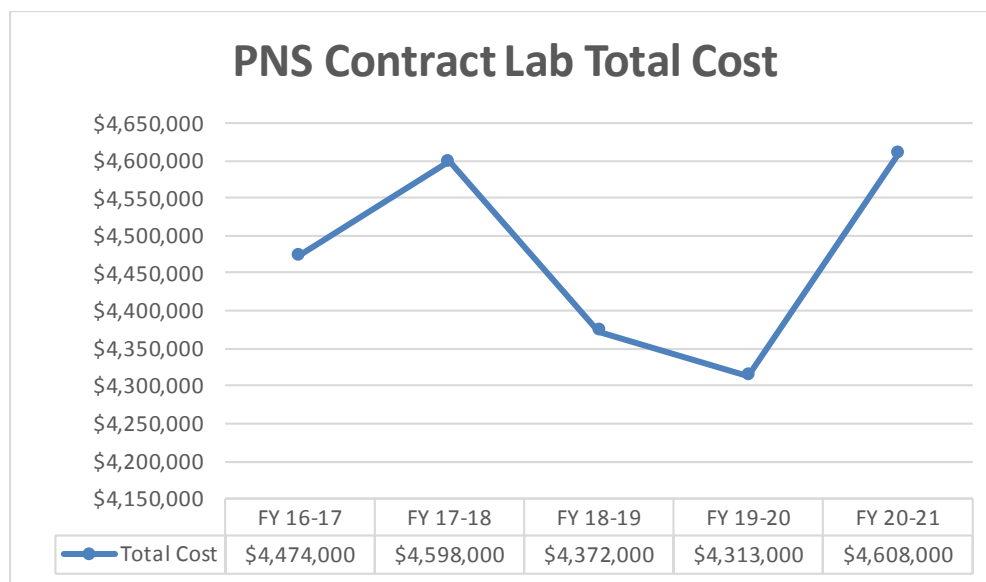


**Contract Laboratory Average Cost Projections** – GDSP estimates current year average laboratory cost per participant will be \$8.60 which is an increase of 30 cents or 3.96 percent compared to 2018-19 actual average laboratory cost per participant of \$8.30. Average laboratory cost per participant in 2020-21 is estimated at \$9.30 which is an increase of 70 cents or 7.65 percent compared to current year estimate. Fluctuation in average cost is attributed to a corresponding fluctuation in specimen caseload.





**Contract Laboratory Total Cost Projections** – GDSP estimates current year contract laboratory cost to total \$4.3 million which is a decrease of \$59,000 or 1.35 percent compared to 2018-19 actual contract laboratory costs of \$4.4 million. Laboratory costs in 2020-21 are estimated to total \$4.6 million which is an increase of \$295,000 or 6.84 percent compared to the current year estimate. Fluctuation in total cost is attributed to a corresponding fluctuation in specimen caseload.

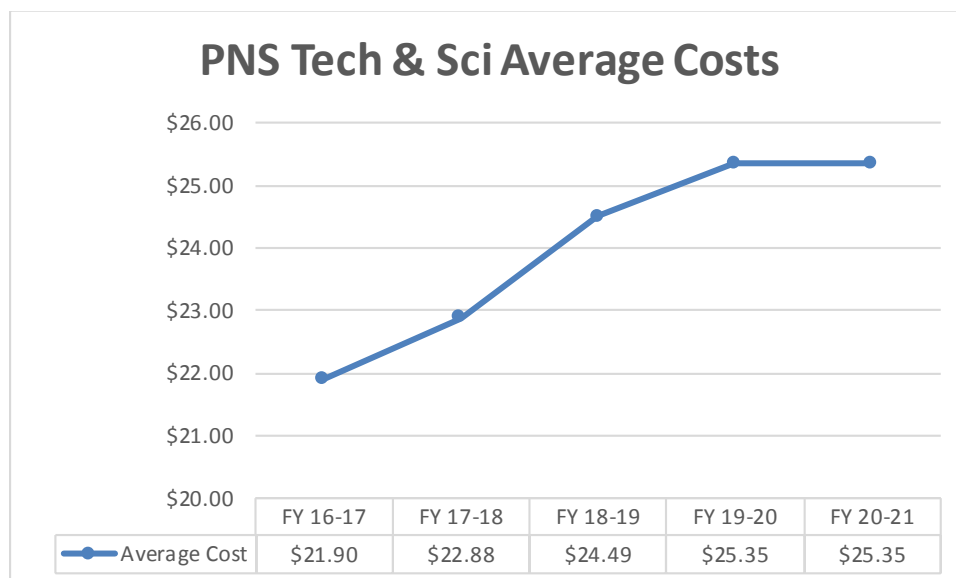


## 2. Technical and Scientific

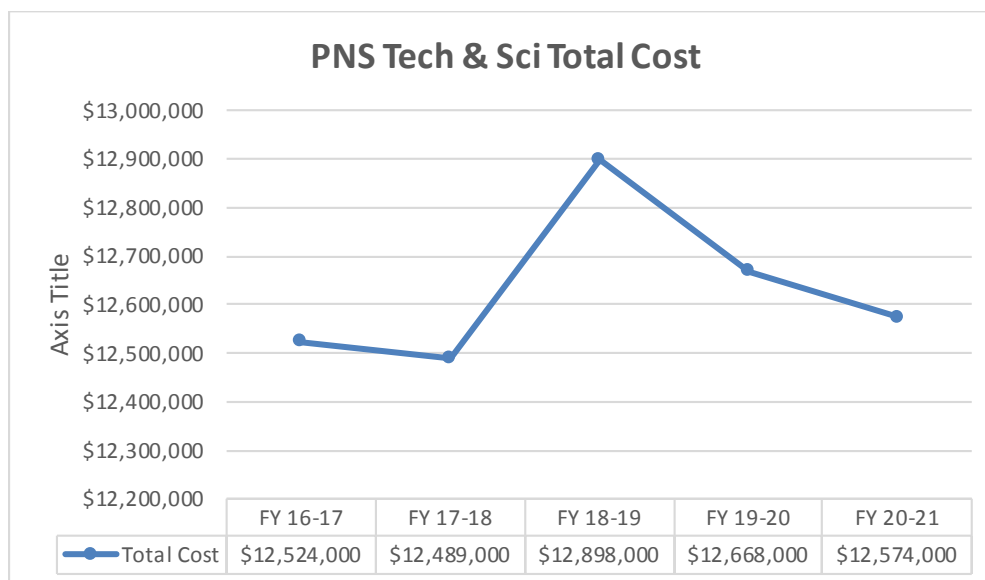
**Overview** - Costs associated with screening services provided at the laboratory include: reagent kits, limited maintenance and support (as it directly relates to the reagents) of laboratory equipment, supplies, and processing. In addition, there are several costs associated with screening including: 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 and 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 \$25.40 which is an increase of 90 cents or 3.51 percent compared to 2018-19 actual average cost per participant of \$24.50. The increase in the current year is attributed to the rise in total cost of reagents, supplies and consumables; and is tied to the total projected specimens tested. Average laboratory cost per participant in 2020-21 is estimated at \$25.40 which is no change compared to the current year estimate.



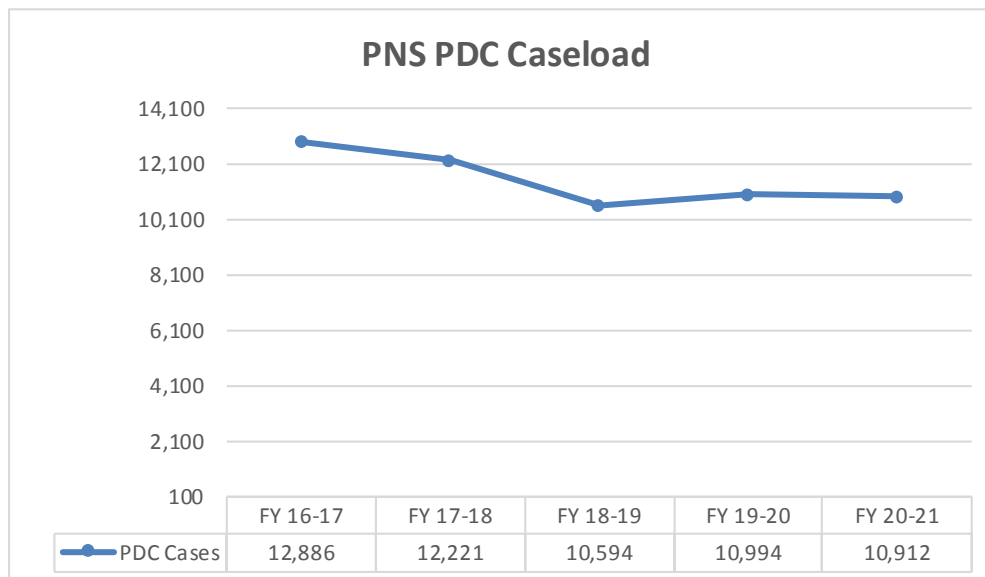
**Technical and Scientific Total Cost** – GDSP estimates current year technical and scientific costs to total \$13 million which reflects no change compared to 2018-19 actual costs of \$13 million. Technical and scientific costs in 2020-21 are estimated to total \$13 million which is also no change compared to the current year estimate. Fluctuations in total costs are tied to caseload and increase in costs of reagents, supplies and consumables.



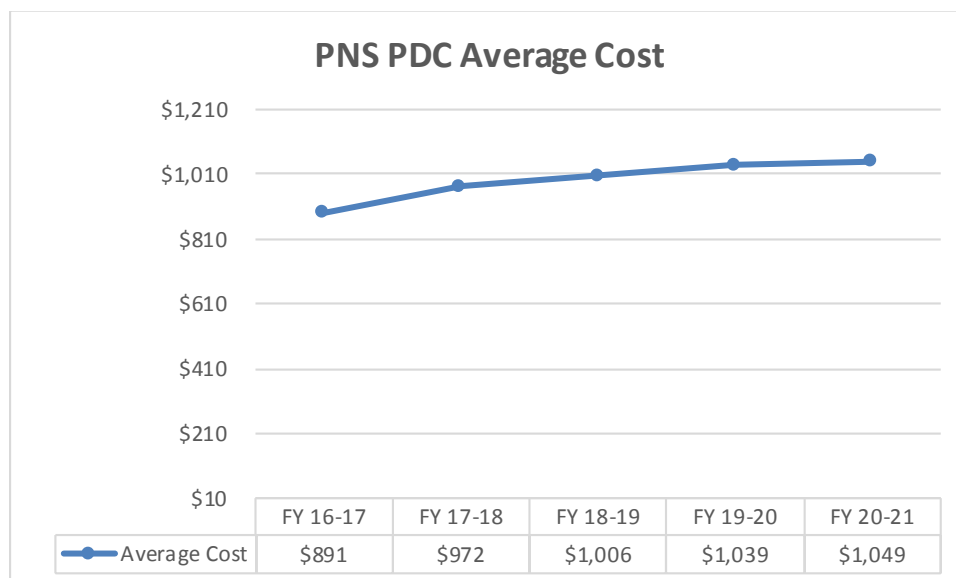
### 3. Prenatal Diagnostic Services Centers

**Overview** - Women with positive results are provided additional services which include: confirmatory and diagnostic prenatal testing, genetic counseling, education, coordinated medical care referrals, coordination and consultation with patient's physician and specialty care providers. Services are provided through Prenatal Diagnostic Services Centers (PDSC) and are reimbursed per service type.

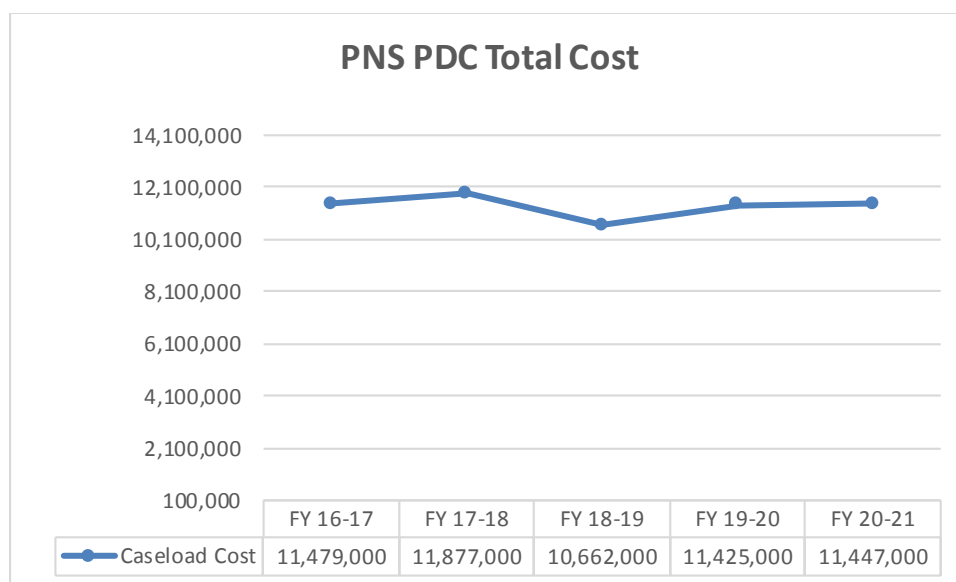
**PDSC Caseload** – GDSP estimates current year PDSC caseload will total 10,994 which is an increase of 400 or 3.78 percent compared to the 2018-19 actual caseload of 10,594. The increase is caused by a projected uptick in women choosing to further pursue diagnostic care. PDSC caseload in 2020-21 is estimated to total 10,912 which is a decrease of 82 or 0.74 percent compared to the current year estimate.



**Prenatal Diagnostic Services Average Cost** – GDSP estimates current year average cost per participant will be \$1,039.20 which is an increase of \$32.80 or 3.26 percent compared to 2018-19 actual average cost per participant of \$1,006.40. Average cost per participant in 2020-21 is estimated at \$1,049 which is an increase of \$9.80 or 0.94 percent compared to the current year estimate. The rise in average cost in the current year is the result of increased costs in the types of procedures used to diagnose genetic diseases. The rise in average cost in the budget year is due to increased contract costs. Procedures like Non-Invasive Prenatal Testing and Micro Array can be offered to women in lieu of more invasive and costly procedures such as amniocentesis. Women who would previously have declined prenatal diagnostic services are now choosing these non-invasive procedures.



**Prenatal Diagnostic Services Total Cost** – GDSP estimates current year costs to total \$11.4 million which is an increase of \$763,000 or 7.16 percent compared to 2018-19 actual total costs of \$10.7 million. Prenatal diagnostic costs in 2020-21 are estimated to total \$11.4 million which is no change compared to the current year estimate. The change in total expenditures is attributable mainly to increase contract costs and a fluctuation in projected caseload.

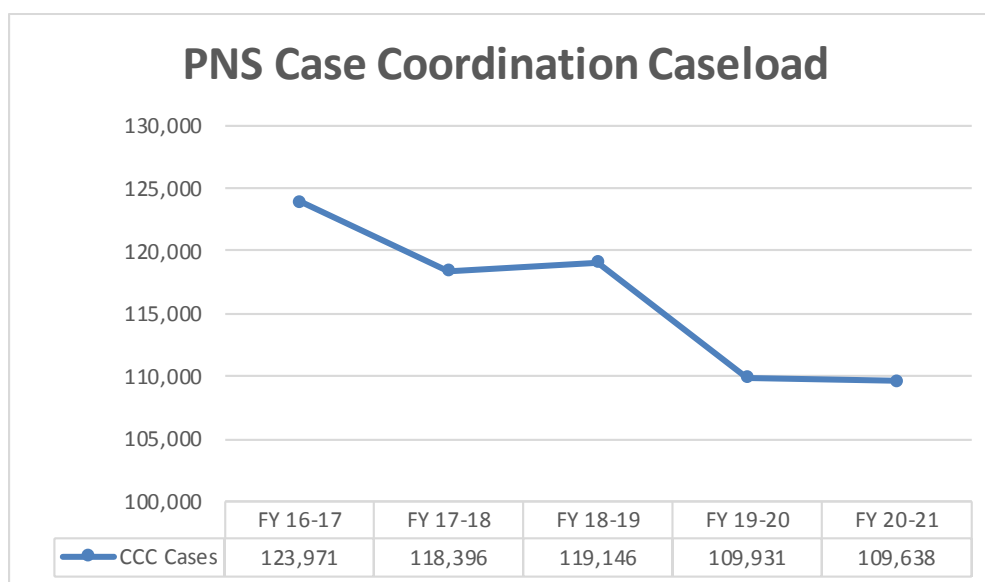


#### 4. Case Management and Coordination Services:

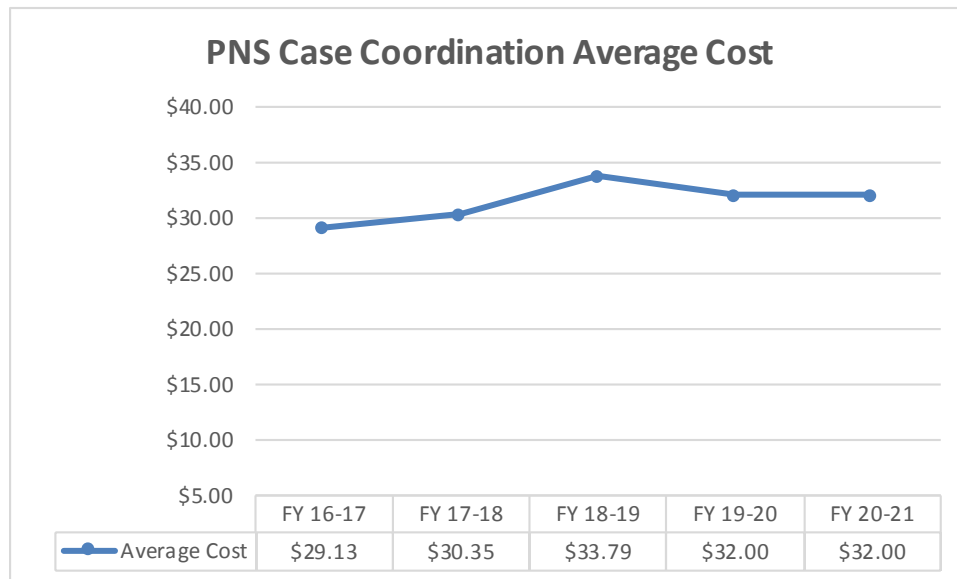
**Overview** - Services provided to pregnant women who screen positive or have questionable results include coordination of first and second trimester screens and ultrasounds, identification of patients whose blood specimens were drawn too early or were inadequate requiring additional blood draws. The PNS ASCs provide clinician and patient education, consultations and referrals to PDSCs for diagnostic and confirmatory

tests, genetic counseling and track patients to ensure appointments are kept and patients are seen within prescribed timeframes. Coordinators confirm and verify specific patient information as needed with the treating physician offices and the PDSCs. Costs are fixed for a required core team of medical professionals for the PNS ASCs 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.

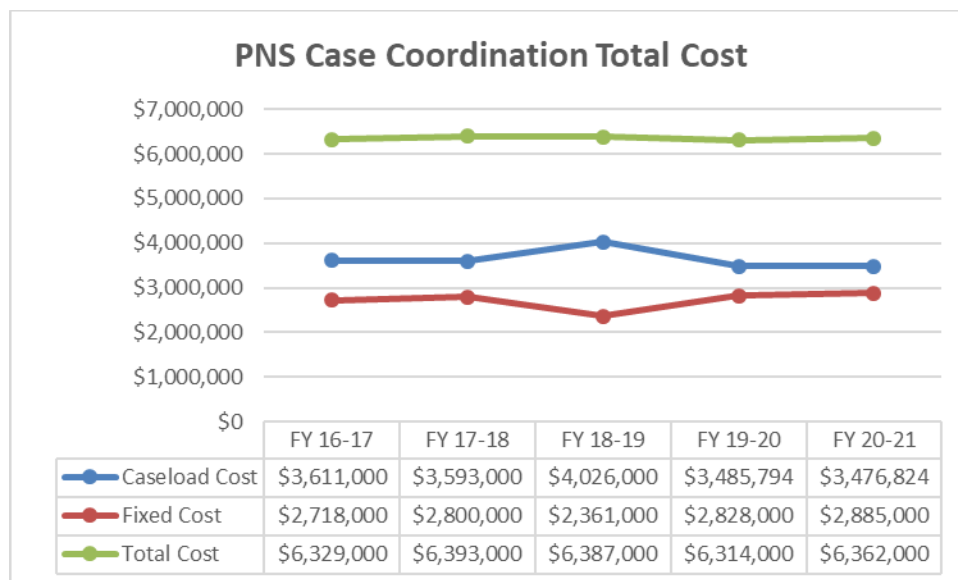
**CMCS Caseload** – GDSP estimates current year CMCS caseload will total 109,931 which is a decrease of 9,215 or 7.73 percent compared to 2018-19 actual caseload of 119,146. CMCS caseload in 2020-21 is estimated at 109,638 which is decrease of 292 or 0.27 percent compared to the current year estimate. This is largely due to changes in the DRU based caseload. The following chart shows the actual CMCS cases by month along with projected numbers for the remainder of the current year and budget year.



**CMCS Average Cost** - GDSP estimates current year average CMCS cost per participant will be \$32 which is a decrease of \$1.80 or 5.30 percent compared to 2018-19 actual average cost per participant of \$33.80. Average CMCS cost per participant in 2020-21 is estimated at \$32 which is no change compared to the current year estimate. The changes in the average costs are attributable to the fluctuation in total costs.



**CMCS Total Cost** – GDSP estimates current year CMCS costs to total \$6.3 million which is a decrease of \$41,000 or 0.64 percent compared to 2018-19 actual total costs of \$6.4 million. CMCS costs in 2020-21 are estimated to total \$6.4 million which is an increase of \$47,000 or 0.74 percent compared to the current year estimate. The fluctuation in total cost is attributed to a corresponding fluctuation in specimen caseload.





**VI. APPENDIX C: Revenue Projections****1. NBS Revenue**

In most cases the NBS fee is paid directly to CDPH GDSP by hospitals. Effective July 1, 2020, NBS fees will increase by \$35 resulting to a new fee of \$177.25. For births that occur outside of a hospital, GDSP invoices the infant's family or their insurance company. Since the majority of births happen within a hospital, billing and collection is more streamlined and efficient than PNS. Past actual collection amounts indicate that GDSP collects approximately 99 percent of all revenue related to providing NBS services. The collection rate remains unchanged. As such NBS revenue is estimated using the following formula:

$$\# \text{of Projected Newborns screened} \times \text{Fee} \times 99\%$$

**NBS Revenue Projections**

	Fee	Caseload	Collection Rate	Total Revenue
FY 2019-20	\$142.25	453,146	99%	\$63,815,000
FY 2020-21	\$177.25	450,344	99%	\$79,025,000

**2. 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 GDTF (Fund 0203) and ten dollars is deposited into the California Birth Defect Monitoring Program Fund (Fund 3114). Unlike NBS, which collects revenue from hospitals directly, PNS invoices participants and bills insurance companies (analogous to the way a traditional medical provider would). This system of billing which shares cost between the participant and one or more third party payers makes full or close to full collection of revenue a challenge for the program. Past collection rates have revealed that PNS collects a higher percentage of anticipated revenue from Medi-Cal enrollees than those enrolled in private insurance plans or the uninsured. PNS receives approximately 98 percent of all claims submitted to Medi-Cal, and approximately 94 percent of all claims submitted to private insurance companies and other payers. Approximately 55 percent 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=(\$221.60-\$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 2019-20	\$211.60	313,363	55%	45%	98%	94%	172,350	141,013	\$63,788,000
FY 2020-21	\$211.60	312,801	55%	45%	98%	94%	172,040	140,760	\$63,673,000