

Genetic Disease Screening Program (GDSP)

Fiscal Year 2021-22

November Estimate



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I. Estimate**A. Program Overview**

The California Department of Public Health (CDPH), Genetic Disease Screening Program (GDSP) Estimate provides a revised projection of 2020-21 expenditures along with projected costs for 2021-22 Local Assistance and State Operations budget for CDPH/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 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. Expenditure Overview

The CDPH/GDSP 2020 Budget Act appropriation is \$142.5 million of which \$109.7 million is for Local Assistance and \$32.9 million is for State Operations. The CDPH/GDSP estimates 2020-21 expenditures of \$139.6 million, which is a decrease of \$1.8 million or 1.2 percent compared to the 2020 Budget Act. The combined State Operations and Local Assistance budget expenditures for 2021-22 total \$145.2 million, which is an increase of \$2.7 million or 1.9 percent compared to the 2020 Budget Act. This increase consists of a 2021-22 Budget Change Proposal to support a major redesign of the PNS program which includes an additional \$449,000 in State Operations authority needed for staffing and a one-time increase of \$3.9 million in Local Assistance attributed to the one-time cost for cfDNA, specifically increasing technical configurations and redesigns, and educational materials. Another factor for the change in budget year is a \$1.6 million decrease in Local Assistance expenditures due to caseload fluctuations derived from the Department of Finance Demographic Research Unit's (DRU) projection of live births.

Table 1 shows the difference between the 2020 Budget Act appropriation and the revised 2020-21 expenditures and proposed 2021-22 expenditures for CDPH/GDSP.

TABLE 1 GDSP: Current Year and Budget Year Budget Summaries Compared to 2020 Budget Act							
Fund 0203 Genetic Disease Testing Fund	2020 Budget Act	FY 2020-21			FY 2021-22		
		November Estimate FY 2020-21	Change from Budget Act	Percent Change from Budget Act	November Estimate FY 2021-22	Change from Budget Act	Percent Change from Budget Act
Total	\$ 142,529,000	\$ 140,758,000	\$ (1,771,000)	-1.2%	\$ 145,261,000	\$ 2,732,000	1.9%
State Operations	\$ 32,873,000	\$ 32,873,000	\$ -	0.0%	\$ 33,322,000	\$ 449,000	1.4%
Local Assistance	\$ 109,656,000	\$ 107,885,000	\$ (1,771,000)	-1.6%	\$ 111,939,000	\$ 2,283,000	2.1%

Current Year (2020-21)

The 2020 Budget Act appropriation for CDPH/GDSP's Local Assistance is \$109.7 million in 2020-21. The CDPH/GDSP estimates 2020-21 Local Assistance expenditures will total \$107.9 million, which is a decrease of \$1.8 million or 1.6 percent compared to the 2020 Budget Act. The net decrease in Local Assistance is attributed to an overall decrease in the DRU's projection of live births.

Budget Year (2021-22)

For 2021-22, CDPH/GDSP estimates Local Assistance expenditures will total \$111.9 million, which is an increase of \$2.3 million or 2.1 percent compared to the 2020 Budget Act amount of \$109.7 million. The net increase in Local Assistance is attributed to an increase of \$3.9 million from the BCP request for cfDNA screening implementation and a \$1.6 million decrease due to a lower projection of birth rates than the 2020-21 rate used in the 2020 Budget Act.

Table 2 shows the difference between the 2020 Budget Act appropriation and the revised 2020-21 expenditures and proposed 2021-22 expenditures for CDPH/GDSP Local Assistance.

TABLE 2

Local Assistance Total: Current Year and Budget Year Budget Summaries Compared to 2020 Budget Act

Fund 0203 Genetic Disease Testing Fund	2020 Budget Act	FY 2020-21			FY 2021-22		
		November Estimate FY 2020-21	Change from Budget Act	Percent Change from Budget Act	November Estimate FY 2021-22	Change from Budget Act	Percent Change from Budget Act
Local Assistance Total	\$ 109,656,000	\$ 107,885,000	\$ (1,771,000)	-1.6%	\$ 111,939,000	\$ 2,283,000	2.1%
NBS	\$ 47,234,000	\$ 46,091,000	\$ (1,143,000)	-2.4%	\$ 46,594,000	\$ (640,000)	-1.4%
PNS	\$ 35,022,000	\$ 34,394,000	\$ (628,000)	-1.8%	\$ 34,021,000	\$ (1,001,000)	-2.9%
Operational Support	\$ 27,400,000	\$ 27,400,000	\$ -	0.0%	\$ 31,324,000	\$ 3,924,000	14.3%

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, CDPH projects NBS and PNS caseloads/specimens and multiplies them by their respective projected average cost, plus the baseline cost. They are then 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 + 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 2020-21, CDPH/GDSP estimates NBS Local Assistance expenditures to total \$46.1 million, which is a decrease of \$1.1 million or 2.4 percent compared to the 2020 Budget Act of \$47.2 million. The decrease can be attributed to decreases in caseload in the Technical and Scientific, Reference Laboratory, and Case Management and Coordination Services categories compared to the caseload rates used in the 2020 Budget Act.

For 2021-22, CDPH/GDSP estimates that NBS Local Assistance expenditures will total \$46.6 million, which is a net decrease of \$640,000 or 1.4 percent compared to the 2020 Budget Act of \$47.2 million. The decrease can be attributed to a lower projection of birth rates than the 2020-21 rate used in the 2020 Budget Act.

Table 3 shows the 2020 Budget Act appropriation and the revised 2020-21 expenditures and proposed 2021-22 expenditures for the Newborn Screening Program costs by cost center type.

TABLE 3

NBS: Current Year and Budget Year Budget Summaries Compared to 2020 Budget Act

Fund 0203 Genetic Disease Testing Fund	2020 Budget Act	FY 2020-21			FY 2021-22		
		November Estimate FY 2020-21	Change from Budget Act	Percent Change from Budget Act	November Estimate FY 2021-22	Change from Budget Act	Percent Change from Budget Act
Total	\$ 47,234,000	\$ 46,091,000	\$ (1,143,000)	-2.4%	\$ 46,594,000	\$ (640,000)	-1.4%
Lab Dollars	\$ 7,132,000	\$ 7,254,000	\$ 122,000	1.7%	\$ 7,468,000	\$ 336,000	4.7%
Tech Sci	\$ 28,133,000	\$ 27,605,000	\$ (528,000)	-1.9%	\$ 27,705,000	\$ (428,000)	-1.5%
Reference Lab	\$ 2,494,000	\$ 2,484,000	\$ (10,000)	-0.4%	\$ 2,496,000	\$ 2,000	0.1%
CMCS	\$ 6,783,000	\$ 6,023,000	\$ (760,000)	-11.2%	\$ 6,174,000	\$ (609,000)	-9.0%
Diagnostic Services	\$ 2,692,000	\$ 2,725,000	\$ 33,000	1.2%	\$ 2,751,000	\$ 59,000	2.2%

PNS Expenditures Projections (See Appendices B1-B4)

For 2020-21, CDPH/GDSP estimates PNS Local Assistance expenditures total \$34.4 million, which is a decrease of \$628,000 or 1.8 percent compared to the 2020 Budget Act.

For 2021-22, CDPH /GDSP estimates that PNS Local Assistance expenditures will total \$34 million, which is a decrease of \$1 million or 2.9 percent compared to the 2020 Budget Act.

The net decreases in both current year and budget year are due to fewer cases being referred to Prenatal Diagnostic Centers. This decrease is occurring even though there are slight contract rate increases in the Technical and Scientific and Case Management and Coordination Services categories.

Table 4 displays the 2020 Budget Act appropriation, the revised 2020-21 expenditures and proposed 2021-22 expenditures for the Prenatal Screening program costs by client type.

TABLE 4

PNS: Current Year and Budget Year Budget Summaries Compared to 2020 Budget Act

Fund 0203 Genetic Disease Testing Fund	2020 Budget Act	FY 2020-21			FY 2021-22		
		November Estimate FY 2020-21	Change from Budget Act	Percent Change from Budget Act	November Estimate FY 2021-22	Change from Budget Act	Percent Change from Budget Act
Total	\$ 35,022,000	\$ 34,394,000	\$ (628,000)	-1.8%	\$ 34,021,000	\$ (1,001,000)	-2.9%
Contract Lab	\$ 4,608,000	\$ 4,551,000	\$ (57,000)	-1.2%	\$ 4,597,000	\$ (11,000)	-0.2%
Tech & Sci	\$ 12,574,000	\$ 13,274,000	\$ 700,000	5.6%	\$ 13,061,000	\$ 487,000	3.9%
CMCS	\$ 6,393,000	\$ 6,586,000	\$ 193,000	3.0%	\$ 6,633,000	\$ 240,000	3.8%
PDC	\$ 11,447,000	\$ 9,983,000	\$ (1,464,000)	-12.8%	\$ 9,730,000	\$ (1,717,000)	-15.0%

Operational Support Projections

For 2020-21, the CDPH/GDSP revised operational support expenditures total was \$27.4 million, which is no change compared to the 2020 Budget Act.

In 2021-22, CDPH/GDSP projects operational support expenditures will total \$31.3 million, which is an increase of \$3.9 million or 14.3 percent compared to the 2020 Budget Act. The net change in Operational Support is due to a one-time increase in funding requested through a 2021-22 BCP for cfDNA database upgrades and technical configurations, and educational materials.

Table 5 displays the difference between the 2020 Budget Act appropriation, the revised 2020-21 expenditures and proposed 2021-22 expenditures for Program Operational Support costs.

Operational Support: Current Year and Budget Year Budget Summaries Compared to 2020 Budget Act

Fund 0203 Genetic Disease Testing Fund	2020 Budget Act	FY 2020-21			FY 2021-22		
		November Estimate FY 2020-21	Change from Budget Act	Percent Change from Budget Act	November Estimate FY 2021-22	Change from Budget Act	Percent Change from Budget Act
Operational Support	\$ 27,400,000	\$ 27,400,000	\$ -	0.0%	\$ 31,324,000	\$ 3,924,000	14.3%

D. State Operations Expenditure Projections

In 2020-21, CDPH/GDSP estimates State Operations expenditures will total \$32.9 million, which is no change compared to the 2020 Budget Act amount of \$32.9 million.

In 2021-22, CDPH/GDSP estimates State Operations expenditures will total \$33.3 million, which is an increase of \$449,000 or 1.4 percent from the 2020 Budget Act amount of \$32.9 million. The increased cost is attributed to a 2021-22 BCP request for additional cfDNA staffing resources.

Table 6 displays the difference between the 2020 Budget Act appropriation and the revised 2020-21 expenditures and proposed 2021-22 expenditures for the CDPH/GDSP State Operations costs.

TABLE 6

State Operations: Current Year and Budget Year Budget Summaries Compared to 2020 Budget Act

Fund 0203 Genetic Disease Testing Fund	2020 Budget Act	FY 2020-21			FY 2021-22		
		November Estimate FY 2020-21	Change from Budget Act	Percent Change from Budget Act	November Estimate FY 2021-22	Change from Budget Act	Percent Change from Budget Act
State Operations	\$ 32,873,000	\$ 32,873,000	\$ -	0.00%	\$ 33,322,000	\$ 449,000	1.4%

E. Revenue Projections

Combined NBS and PNS Revenue

CDPH/GDSP has revised revenue estimates for 2020-21 totaling \$142 million, which is a decrease of \$657,000 or 0.5 percent compared to the 2020 Budget Act amount of \$142.7 million. The decrease in revenue for the current year is due to reduced caseload compared to 2020-21 rates in the 2020 Budget Act. For 2021-22, CDPH/GDSP projects revenue will total \$142.5 million, which is a slight increase of \$195,000 or 0.1 percent compared to the 2020 Budget Act amount of \$142.7 million.

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, of which \$211.60 is deposited into the Genetic Disease Testing Fund (Fund 0203). The remaining \$10 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. 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. CDPH/GDSP uses the following formula to estimate revenue generated from PNS fees:

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

On July 1, 2020, fees for NBS participants were increased, \$177.25. The increase was needed in part to support the increase in expenditures to perform the routine and ongoing workload for Spinal Muscular Atrophy (SMA) screening. Unlike PNS, where CDPH/GDSP bills patients and collects fees from insurers, CDPH/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 screening services is much more streamlined resulting in a 99 percent 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 C1) In 2020-21, NBS revenue is expected to total \$78 million, which is a decrease of \$1 million or 1.4 percent compared to the 2020 Budget Act of \$79.0 million.

The decrease in revenue for the current year is due to the decrease in projected caseload.

In 2021-22, GDSP projects NBS revenue will total \$78.2 million, which is a decrease of \$790,000 or 1 percent compared to the 2020 Budget Act of \$79.0 million.

The decrease in revenue for the budget year is again due to the decrease in projected caseload.

PNS Revenue (See Appendix C2) In 2020-21, PNS revenue is expected to total \$64 million, which is an increase of \$415,000 or 0.7 percent compared to the 2020 Budget Act amount of \$63.7 million.

In 2021-22, CDPH/GDSP projects PNS revenue will total \$64.3 million, which is an increase of \$595,000 or 0.9 percent compared to the 2020 Budget Act of \$63.7 million.

Despite a decrease in projected births from the 2020 Budget Act, there is a very slight increasing trend in utilization of the PNS program.

Table 7 shows the revised current year revenue projections for current year and budget year compared to 2020 Budget Act.

TABLE 7

GDSP Revenue: Current Year and Budget Year Revenue Summaries Compared to 2020 Budget Act

Fund 0203 Genetic Disease Testing Fund	2020 Budget Act	FY 2020-21			FY 2021-22		
		November Estimate FY 2020-21	Change from Budget Act	Percent Change from Budget Act	November Estimate FY 2021-22	Change from Budget Act	Percent Change from Budget Act
Total	\$ 142,698,000	\$ 142,041,000	\$ (657,000)	-0.5%	\$ 142,503,000	\$ (195,000)	-0.1%
NBS	\$ 79,025,000	\$ 77,953,000	\$ (1,072,000)	-1.4%	\$ 78,235,000	\$ (790,000)	-1.0%
PNS	\$ 63,673,000	\$ 64,088,000	\$ 415,000	0.7%	\$ 64,268,000	\$ 595,000	0.9%

GENETIC DISEASE TESTING FUND
FUND CONDITION REPORT
DOLLARS IN THOUSANDS

	2019-20	2020-21	2021-22
RESOURCES			
BEGINNING BALANCE	\$30,775	\$11,810	\$8,781
Prior Year Adjustment	0	0	0
Adjusted Beginning Balance	30,775	11,810	8,781
REVENUES			
121100 Genetic Disease Testing Fees ^{1/}	125,343	142,041	142,503
150300 Income from Surplus Investments	451	451	451
161000 Escheat of Unclaimed Checks & Warrants	1	1	1
TOTALS, REVENUES	125,795	142,493	142,955
TOTAL RESOURCES	\$156,570	\$154,303	\$151,736
EXPENDITURES AND EXPENDITURE ADJUSTMENTS			
4265 Department of Public Health (State Operations)	31,351	31,679	32,128
4265 Department of Public Health (Local Assistance)	110,731	107,885	111,939
8880 Financial Information System for California (State Operations)	-4	0	0
9800 Employee Compensation (State Operations)	913	957	957
Control Section 3.60 Retirement	233	233	233
Lease Revenue Debt Service Adjustment	1	4	4
9892 Supplemental Pension Payments (State Operations)	496	496	496
9900 Statewide General Admin Exp (ProRata) (State Operations)	1,039	1,268	1,268
9920 Loan Transfer to Other Funds	0	3,000	0
TOTAL EXPENDITURES AND EXPENDITURE ADJUSTMENTS	144,760	145,522	147,025
FUND BALANCE	11,810	8,781	4,711
	8%	6%	3%

REVENUE PROJECTIONS**2020-21**

2020-21 NBS FEES BASED ON	444,234 TESTS @	\$177.25	AND 99% Provider ^{1/}	=	\$77,953,000
2020-21 PNS FEES BASED ON	141,677 TESTS @	\$211.60	AND 94% Non Medi-Cal ^{2/}	=	\$28,180,000
2020-21 PNS FEES BASED ON	173,161 TESTS @	\$211.60	AND 98% Medi-Cal ^{3/}	=	\$35,908,000
	314,838				\$64,088,000
GDSP Total					\$142,041,000

2021-22

2021-22 NBS FEES BASED ON	445,840 TESTS @	\$177.25	AND 99% Provider ^{1/}	=	\$78,235,000
2021-22 PNS FEES BASED ON	142,074 TESTS @	\$211.60	AND 94% Non Medi-Cal ^{2/}	=	\$28,259,000
2021-22 PNS FEES BASED ON	173,646 TESTS @	\$211.60	AND 98% Medi-Cal ^{3/}	=	\$36,009,000
	315,720				\$64,268,000
GDSP Total					\$142,503,000

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 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 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 \$2 million to \$4 million per year for any new disorder adopted by the 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 RUSP, there may one-time resources needed to plan, prepare for, and implement the additional required screening. Public Health/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).

2021-22 Budget Change Proposal: Improving the California Prenatal Screening (PNS) Program (screening launch)

Background: A new screening methodology has been developed and over time has demonstrated improved performance for prenatal screening. It is called “cell-free DNA” (cfDNA) screening, referring to the fact that fetal DNA can be detected in a pregnant woman’s blood. cfDNA screening involves the extraction of maternal and fetal cells from a pregnant individual’s blood sample and can be used to detect the same

chromosome abnormalities as the current PNS program plus an additional chromosome abnormality for which the program does not currently screen (i.e., trisomy 13). This new efficient in terms of false positive and detection rates resulting in fewer pregnant women being referred for diagnostic follow-up services.

Health and Safety Code section 125055 (g)(1) states that Public Health “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 position statement from the American College of Medical Genetics and Genomics (ACMG) 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 (trisomy 18), and Down syndromes (trisomy 21) across the maternal age spectrum.” This new technology is becoming the standard of care for prenatal screening 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 and neural tube defects with cfDNA screening (for chromosome abnormalities) and a simpler biochemical screen (separate from the cfDNA screen) for neural tube defects. A number of pre-launch screening costs will be incurred in 2021-22 and are identified in the New Assumptions/Premises section. The actual laboratory screening replacement is expected to commence 2022-23 and will be contracted out to private laboratories. The new laboratory screening process will require a \$20.2 million annual increase in Local Assistance expenditure authority in 2022-23 and ongoing. This factors in expected annual savings of approximately \$9 million due to decreases in CCC and PDC referrals that will reduce chromosomal abnormality follow-up services by 91 percent.

Discretionary?: Yes

Reason for Adjustment/ Change: The cfDNA screening yields a much better chromosome abnormality detection rate than the PNS Program’s current biochemical screening methodology, with a significantly lower false positive rate. A lower false positive rate means that fewer pregnant women are flagged as being at 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, 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.

Even with the rollout of cfDNA s collected from all women in the creening, a separate specimen would still need to be second trimester in order to test for neural tube defects.

Fiscal Impact (Range) and Fund Source(s): An increase in Local Assistance expenditures of \$20.2 million in 2022-23 and ongoing.

As part of the plans to improve the PNS program and ensure appropriate fees are charged to support the program and its new screening activities, a change in the fee structure will be necessary beginning 2022-23. CDPH will charge a fee of \$221.60 for cfDNA, which is the same amount that is charged for the current PNS biochemical screening. However, the NTD screening test in the second trimester which is currently included in the PNS biochemical screening fees will now require a new separate fee of \$75 and will be established through the rulemaking process. These fee structure changes will generate sufficient revenue to offset the additional laboratory screening costs.

The fund source is the Genetic Disease Testing Fund (Fund 0203).

New Assumptions/ Premises

2021-22 Budget Change Proposal: Improving the California Prenatal Screening (PNS) Program (pre-screening launch activities)

Background: A new screening methodology has been developed and over time has demonstrated improved performance for prenatal screening. It is called “Cell-free DNA” (cfDNA) screening, referring to the fact that fetal DNA can be detected in a pregnant woman’s blood. cfDNA screening involves the extraction of maternal and fetal cells from a pregnant individual’s blood sample and can be used to detect the same chromosome abnormalities as the current PNS program plus an additional chromosome abnormality for which the program does not currently screen (e.g., trisomy 13). This new test is more efficient in terms of false positive and detection rates resulting in fewer women being referred for diagnostic follow-up services.

Health and Safety Code section 125055 (g)(1) states that Public Health “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 position statement from the ACMGG 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 syndromes 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 screening 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: 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); and redesign the SIS to accommodate the new screening results transmitted from the cfDNA laboratories, including redesign of test result mailers, 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 be a one-time cost \$3.9 million.

CDPH will also need approximately three positions and \$449,000 in State Operations expenditure authority in 2021-22 and annually thereafter. These additional resources are necessary to provide education and outreach prior to the cfDNA screening launch in July 2022 and monitoring after screening launch.

The laboratory screening replacement costs which will be incurred in 2022-23 and ongoing are detailed in the Future Fiscal Issues section.

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.

Even with the rollout of cfDNA screening, a separate specimen would still need to be collected from all women in the second trimester in order to test for neural tube defects.

Fiscal Impact (Range) and Fund Source(s):

\$449,000 increase in State Operations expenditure in 2021-22 and ongoing and a one-time expenditure increase of \$3.9 million in Local Assistance in 2021-22. Current revenue levels in

the Genetic Disease Testing Fund (Fund 0203) are sufficient to offset the expenditure increases in 2021-22.

Existing (Significantly Changed) Assumptions/Premises

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

Unchanged Assumptions/Premises

There are no Unchanged Assumptions/Premises.

Discontinued Assumptions/Premises

Newborn Screening Fee Increase

Why is Change Needed/ Reason for Adjustment: The NBS fee increase of \$35 was implemented on July 1, 2020. The new NBS fee is \$176.25

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

Why is Change Needed/ Reason for Adjustment: Collection rates of 94 percent for PNS non-Medi-Cal patients, 98 percent for PNS Medi-Cal patients, and 99 percent for Client billing are now being used to reflect accurate revenue figures.

IV. Appendices

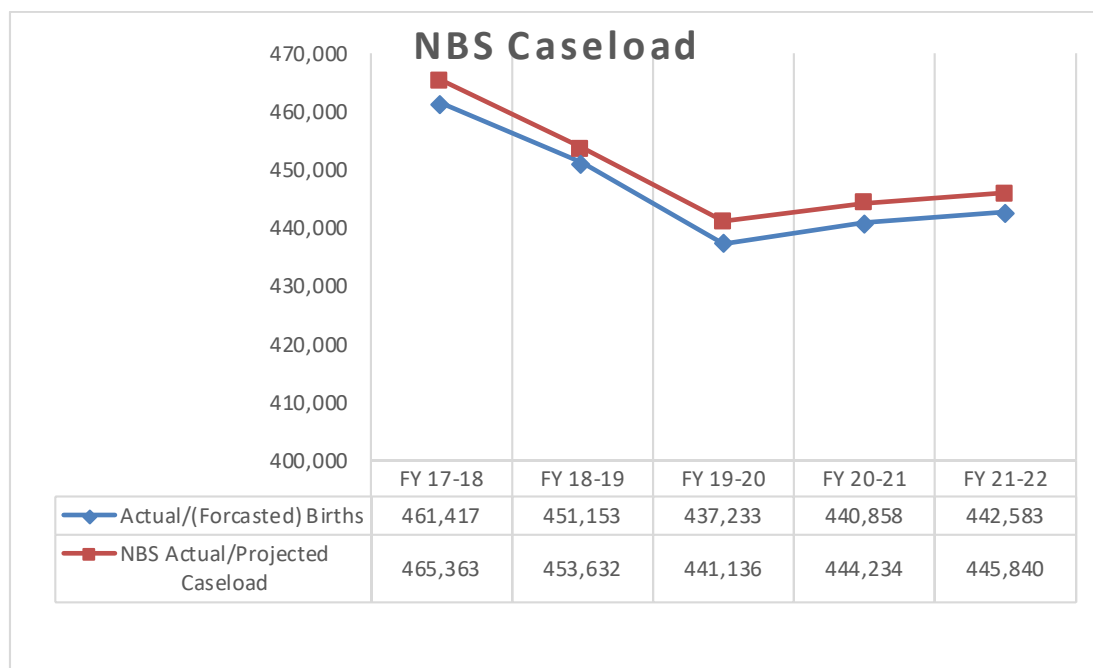
Appendix A: NBS Assumptions and Rationale

1. Contract Laboratories

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

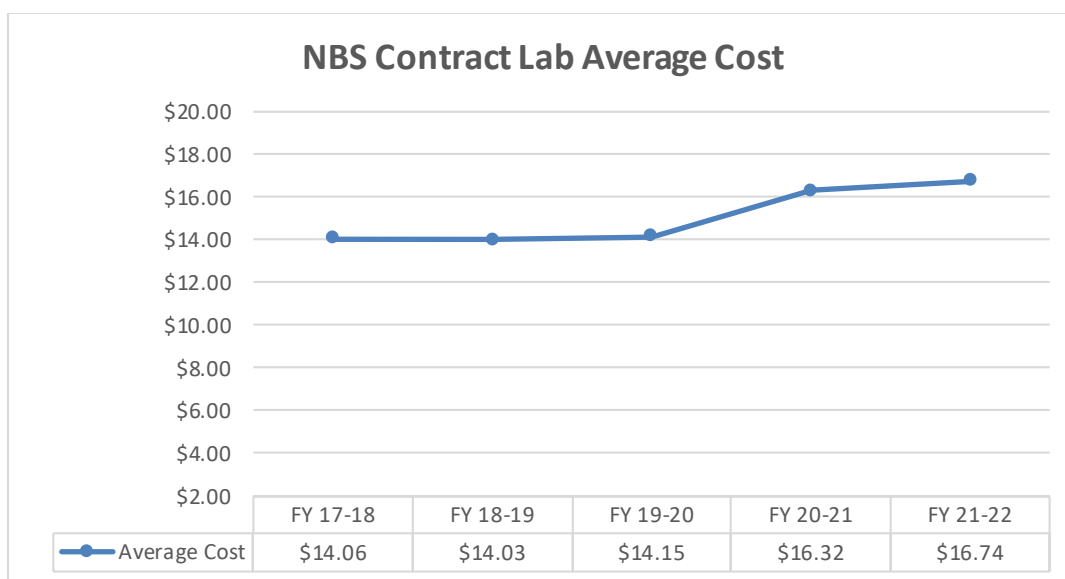
Costs associated with Contract Laboratories and Technical and Scientific supplies are both driven by the total number of clients NBS serves. The total caseload is determined as a percentage of the DRU's projected number of live births. This estimate assumes that 100 percent of the DOF/DRU projected births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

Total Caseload –CDPH/GDSP estimates current year caseload will total 444,234, an increase of 3,098 or 0.7 percent compared to the 2019-20 actual total caseload of 441,136. Caseload in 2021-22 is estimated at 445,840, which is an increase of 1,606 or 0.4 percent compared to the current year estimate. This year over year change is due to the DOF/DRU's projected number of live births. The following chart shows the actual NBS cases by fiscal year, along with our projected numbers for the remainder of the current year and budget year.

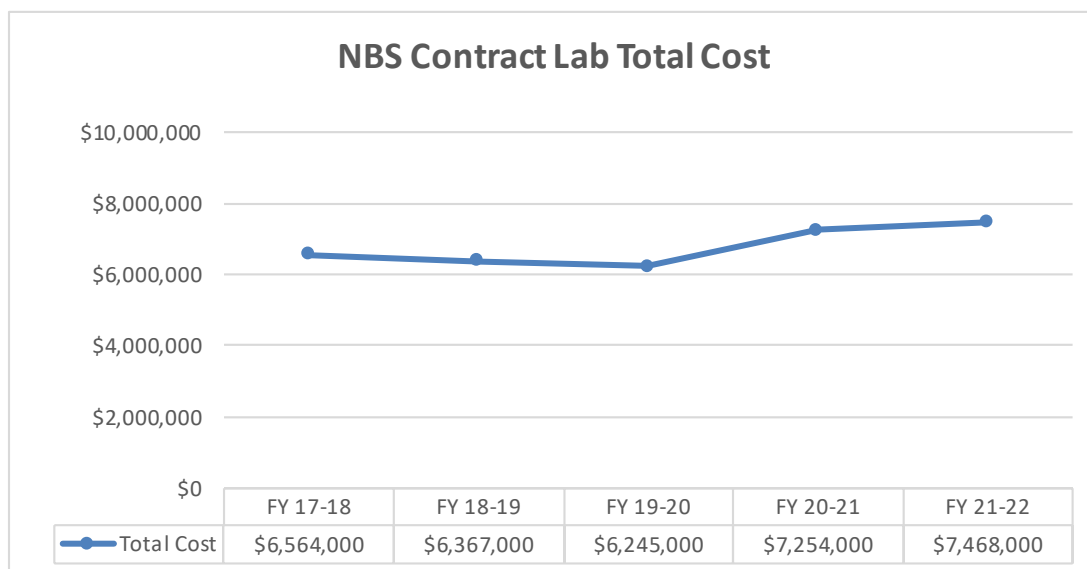


Appendix A.1

Contract Laboratory Average Cost Projections – CDPH/GDSP estimates current year average laboratory cost per participant will be \$16.32, which is an increase of \$2.17 or 15.4 percent compared to the 2019-20 actual average laboratory cost per participant of \$14.15. Average laboratory cost per participant in 2021-22 is estimated at \$16.74, which is an increase of \$0.42 or 2.6 percent compared to the current year estimate. The increase is due to the increased cost rate of the laboratory contracts.



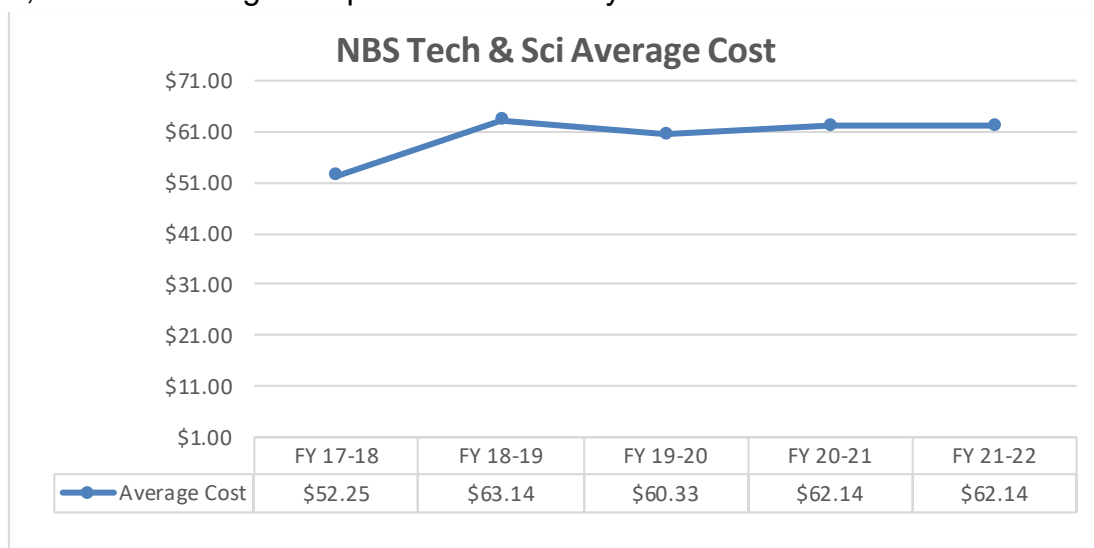
Contract Laboratory Total Cost Projections – CDPH/GDSP estimates current year contract laboratory costs to total \$7.3 million, which is an increase of \$1 million or 16.2 percent compared to 2019-20 actual contract laboratory costs of \$6.2 million. 2021-22 contract laboratory costs are projected to be \$7.5 million, which is an increase of \$214,000 or 3 percent compared to the current year.



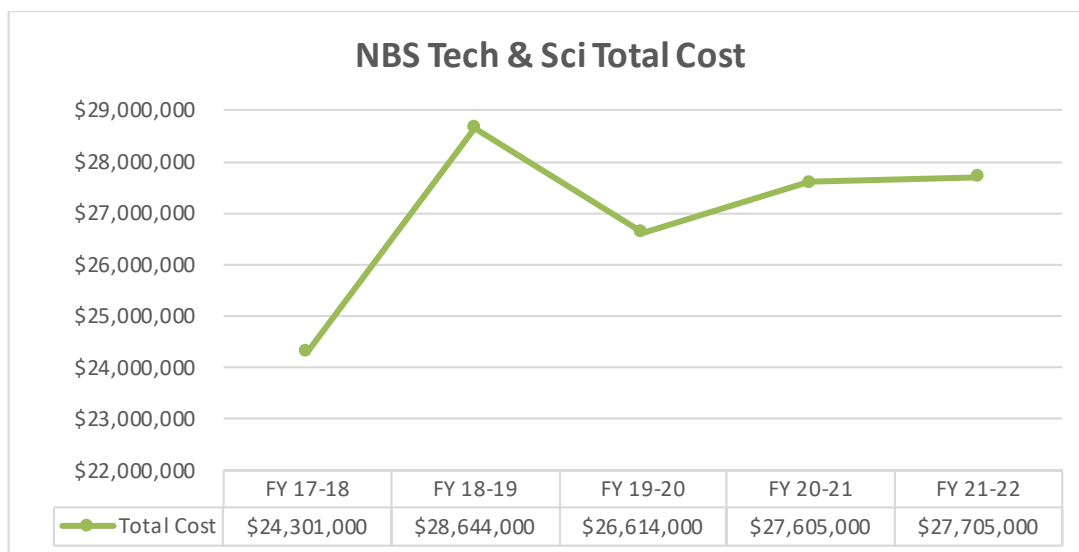
2. Technical and Scientific Overview: Costs associated with specimen screening include reagents kits, supplies, processing, and limited maintenance and support of laboratory equipment. In addition, there are minimal fixed costs associated with specimen screening including: laboratory supplies, blood specimen filter paper, blood specimen storage, and costs for special packaging for blood specimen transport, etc. Reagent test kits, which make up 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 – CDPH/GDSP estimates current year average Technical and Scientific cost per participant will be \$62.14, which is an increase of \$1.81 or 3 percent compared to 2019-20 actual average Technical and Scientific cost per participant of \$60.33. Average Technical and Scientific cost per participant in 2021-22 is estimated at \$62.14, which no change compared to the current year estimate.



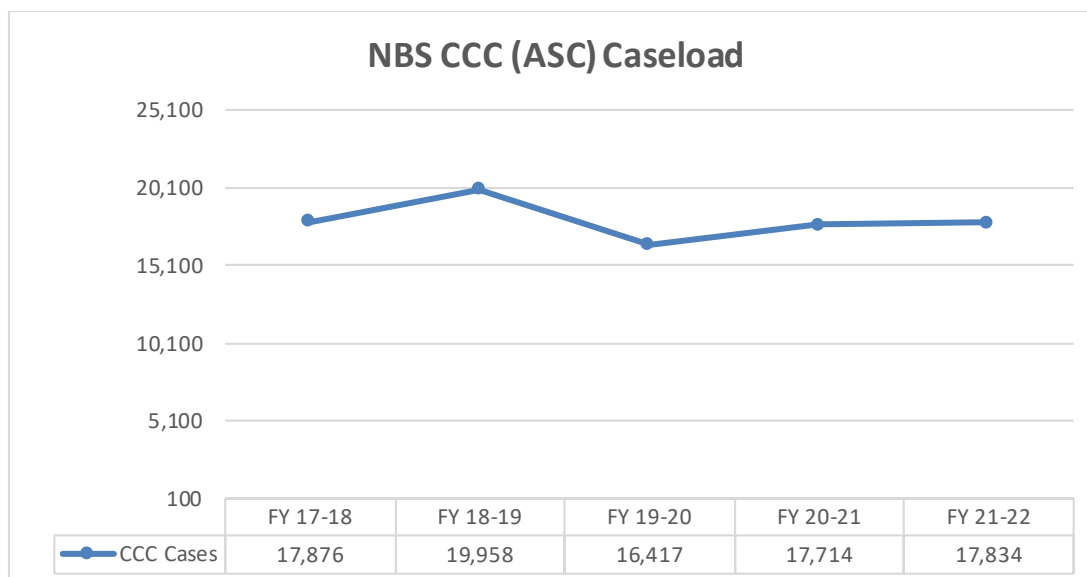
Technical and Scientific Total Cost – CDPH/GDSP estimates current year Technical and Scientific costs to total \$27.6 million, which is an increase of \$991,000 or 4 percent compared to 2019-20 actual technical and scientific costs of \$26.6 million. For 2021-22 the Technical and Scientific costs is estimated to be \$27.7 million, which is an increase of \$100,000 million or 0.4 percent compared to the current year. The current year increase in cost is tied to the fluctuations of caseload. The budget year increase in average cost is tied to the increase cost in purchases of consumables, supplies and reagents needed for screening disorders.



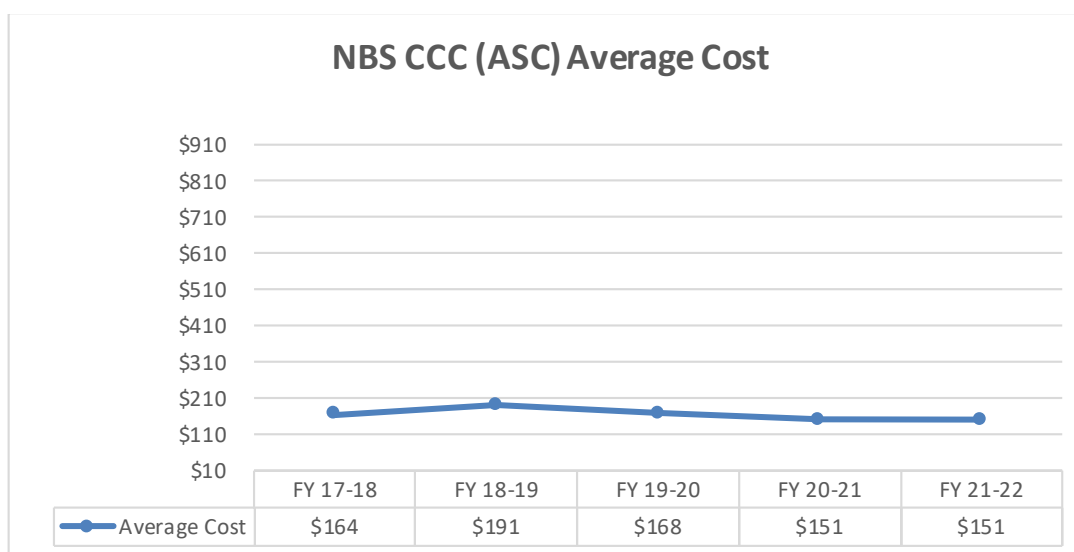
3. Case Management and Coordination Services:

Overview- Services provided to infants who screen initial positive or have questionable screening test results for the 75+ genetic disorders screened. These services include time-sensitive coordination for specific confirmatory testing, family consultation – including consultation with the infant’s pediatrician, genetic disease counseling, family educational services, and coordinated care referrals to specialized medical institutions. The NBS Area Service Centers (ASC) provide critical coordination and tracking services to ensure appropriate diagnostic measures are completed, and that affected infants are provided with appropriate medical care and receive treatment within a critical timeframe. The ASCs are reimbursed based on caseload and the type of service performed along with a monthly base allocation; 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 17,714, which is an increase of 1,297 or 8 percent compared to 2019-20 actual CMCS caseload of 16,417. CMCS caseload in 2021-22 is estimated at 17,834, which is an increase of 120 or 1 percent compared to the current year estimate.

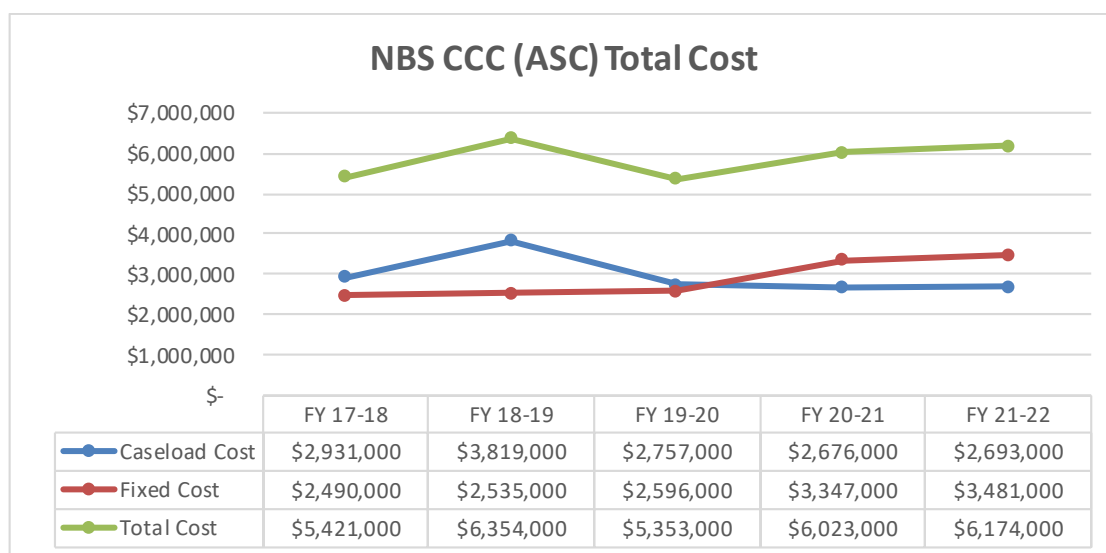


Case Management and Coordination Services (CMCS) Average Cost - CDPH/GDSP estimates current year average CMCS cost per participant will be \$151, which is a decrease of \$17 or 10 percent compared to 2019-20 actual average CMCS cost per participant of \$168. Average CMCS cost per participant in 2021-22 is estimated at \$151, which is no change compared to the current year estimate. The decrease in the average cost is tied directly to the fluctuations in the total cost and additional specialized follow-up centers for the ongoing newborn testing.



Case Management and Coordination Services (CMCS) Total Cost - CDPH/GDSP estimates current year CMCS costs to total \$6 million, which is an increase of \$670,000 or 13 percent compared to 2019-20 actual CMCS total costs of \$5.4 million. CMCS costs in 2021-22 are estimated to total \$6.2 million, which is an increase of \$151,000 or 3 percent compared to the

current year estimate. The increase in current year reflects the projected increase in data correction on newborn records, and an increase in ongoing expenditures in 2021-22 due to the projected number of positive cases attributed to the implemented screening for SMA. In addition, we considered a combination of increased fixed costs, and incremental (per case) reimbursement, which includes administrative costs, rent, equipment, travel and administrative staff.

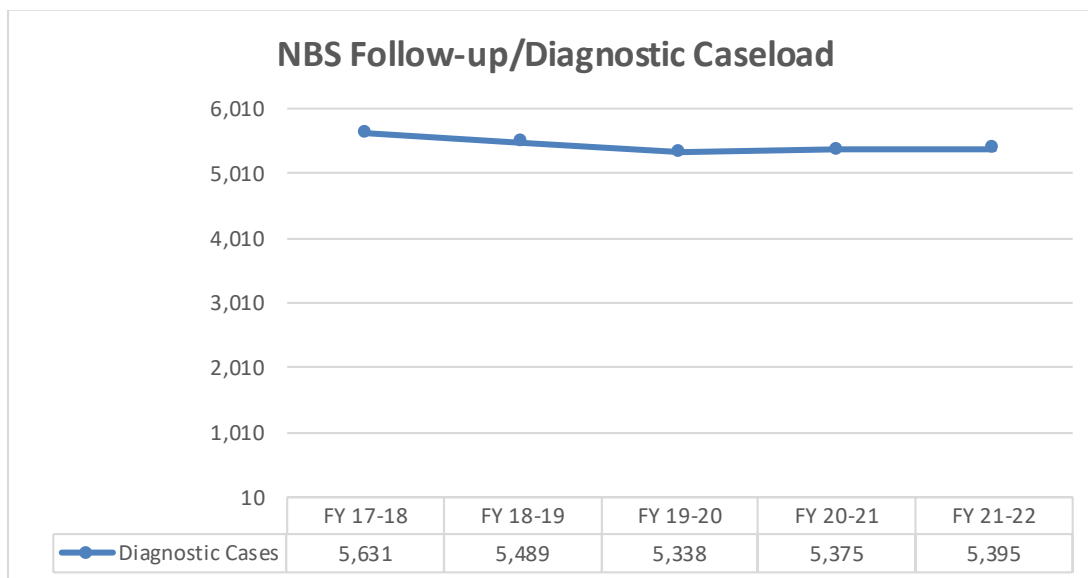


4. Diagnostic Services:

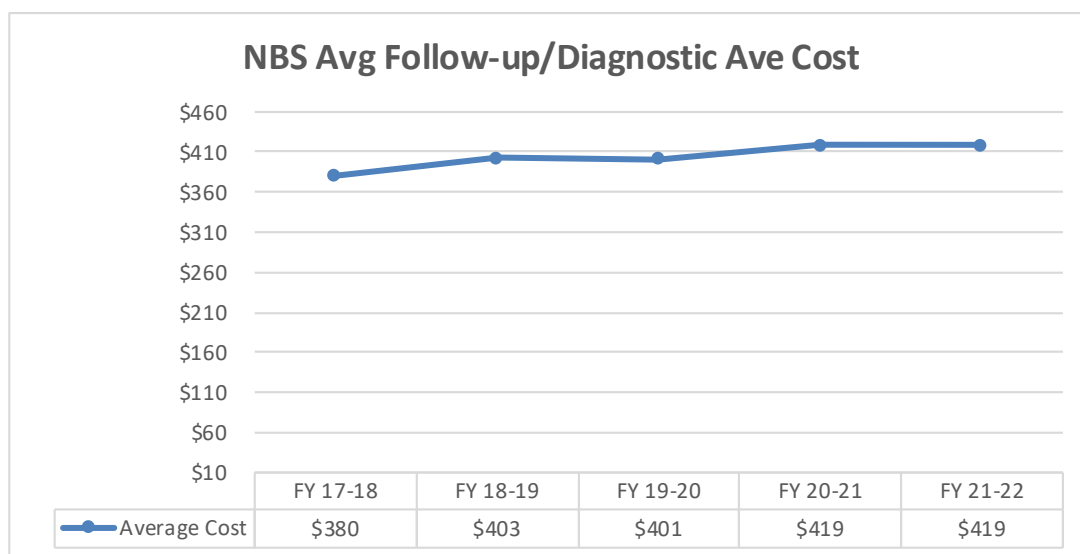
Overview- Diagnostic Services are for infants who require extended monitoring while undergoing confirmatory testing and diagnosis. Clinical outcome data is collected on infants once diagnosis is made as a means of tracking, confirming, evaluating, and refining program standards. Services include: coordination with the NBS, ASC and Public Health/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 and a small base allocation.

Diagnostic Services Caseload – CDPH/GDSP estimates current year Diagnostic caseload will total 5,375, based on projected new referral cases and annual patient summary cases, which is an increase of 37 or 1 percent compared to 2019-20 actual Diagnostic Services caseload of 5,338. Diagnostic caseload in 2021-22 is estimated at 5,395, which is a slight increase of 19 or 0.4 percent compared to the current year estimate. Fluctuations are tied to overall DRU-based caseload. In addition, we considered a combination of increased fixed costs, and incremental

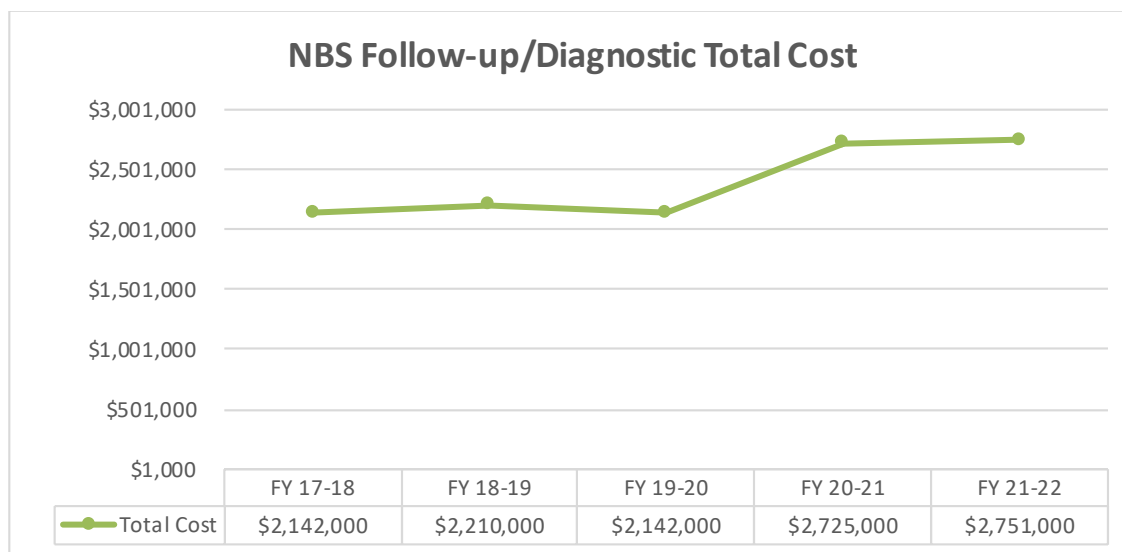
(per case) reimbursement, which includes administrative costs, rent, equipment, travel and administrative staff.



Diagnostic Services Average Cost - CDPH/GDSP estimates current year average Diagnostic Services cost per participant will be \$419, calculated based on projected new referral cases and annual patient summary cases, which is an increase of \$17 or 4 percent compared to 2019-20 actual average Diagnostic Services cost per participant of \$401. The Average Diagnostic Services cost per participant in 2021-22 are estimated at \$419, which is no change compared to the current year average cost. The increase in current year is tied to the rise in total costs, slight increase in caseload and increase in fixed cost.



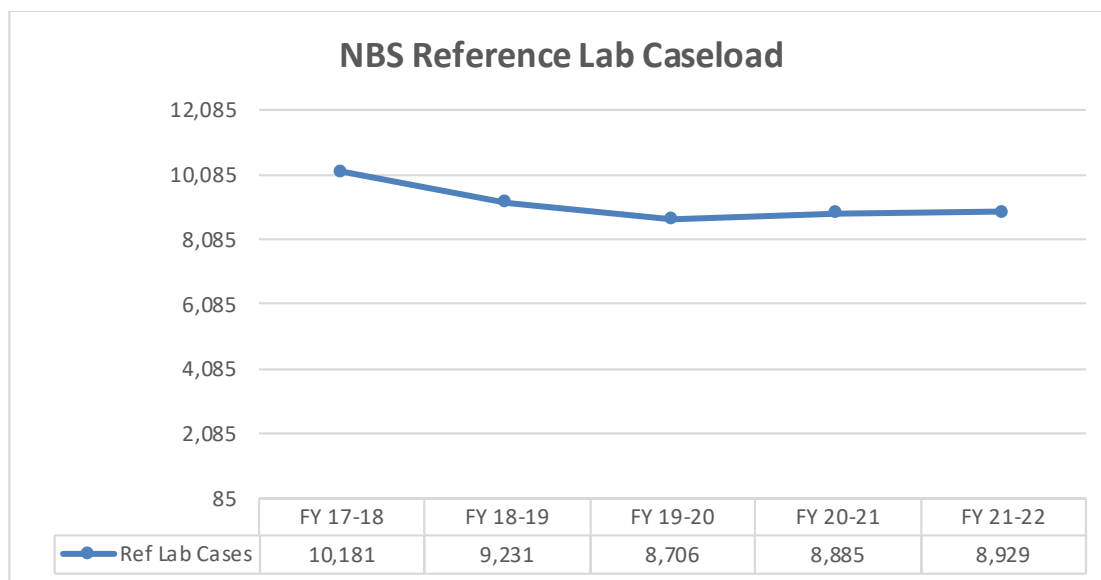
Diagnostic Services Total Cost - CDPH/GDSP estimates current year Diagnostic Services costs to total \$2.7 million, which is an increase of \$583,000 or 27 percent compared to 2019-20 actual Diagnostic Services total costs. Diagnostic Services costs in 2021-22 are estimated to total \$2.7 million, which is an increase of \$26,000 or 1 percent compared to the current year estimate. The rise in current year total cost is attributed to the slight increase in caseload, increase cost rate and increase fixed cost.



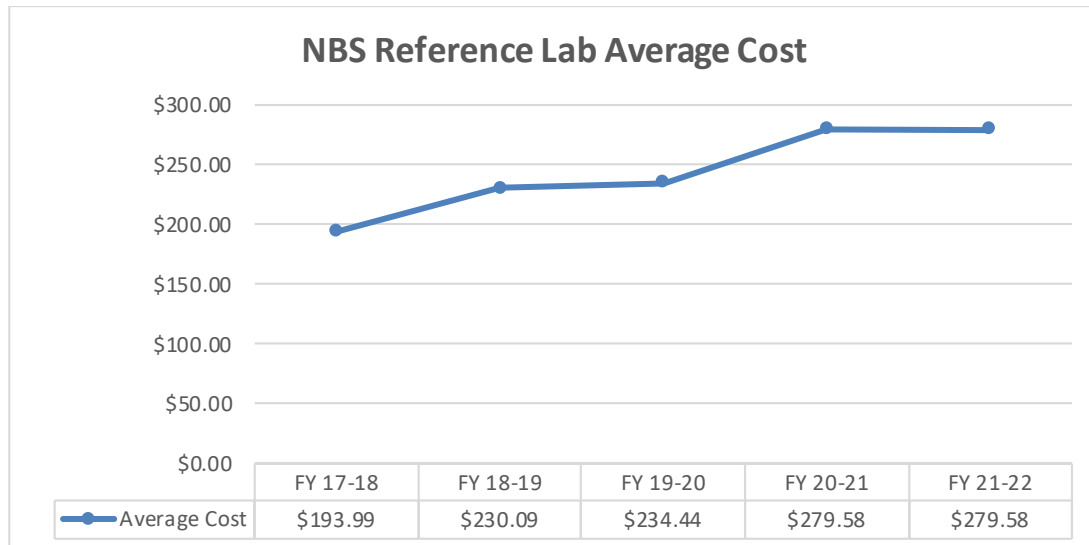
5. Reference Laboratory Cases:

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.

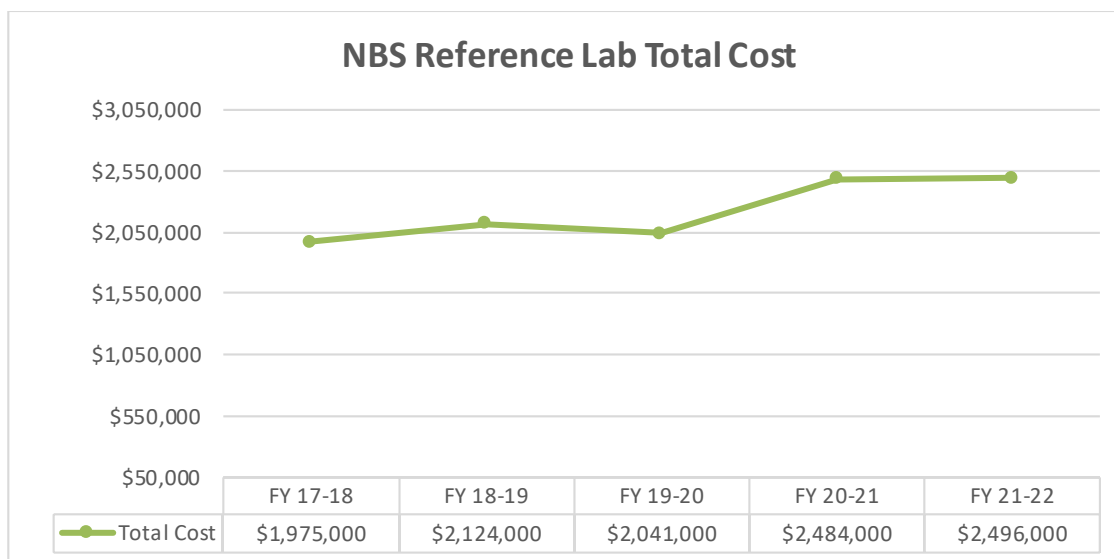
Reference Laboratory Caseload – CDPH/GDSP estimates current year Reference Laboratory caseload will total 8,885, which is an increase of 179 or 2 percent compared to 2019-20 actual Reference Laboratory caseload of 8,706. Reference Laboratory caseload in 2021-22 is estimated at 8,929, which is an increase of 45 or 1 percent compared to the current year estimate.



Reference Laboratory Average Cost – CDPH/GDSP estimates current year Reference Laboratory average cost per participant will be \$279.58, which is an increase of \$45.15 or 19 percent compared to 2019-20 Reference Laboratory actual average cost per participant of \$234. Reference Laboratory average cost per participant in 2021-22 is estimated at \$279.58, which is no change compared to the current year estimate. Fluctuation in caseload is tied to the total costs.



Reference Laboratory Total Cost – CDPH/GDSP estimates current year Reference Laboratory costs to total \$2.5 million, which is an increase of \$443,000 or 22 percent compared to 2019-20 actual Diagnostic Services total costs of \$2 million. Reference Laboratory costs in 2021-22 are estimated to total \$2.5 million, which is an increase of \$12,000 or 0.5 percent compared to the current year estimate. The increase in current year is attributed to the additional cost for adding confirmatory DNA sequencing for new disorders and contract increases for sickle cell trait follow-up, and fluctuations in caseloads.



APPENDIX B: Prenatal Screening Program Assumptions and Rationale

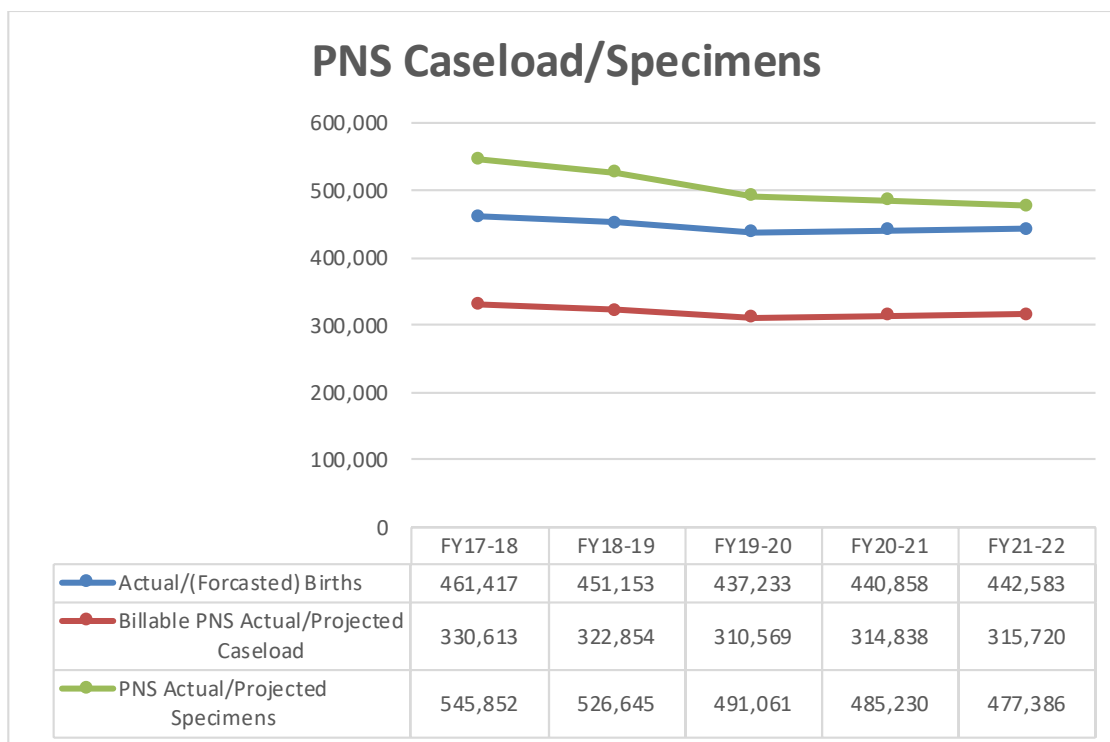
1. Contract Laboratories:

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 contract 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. Currently, the regional laboratory cost of each test is the same, as such GDSP will estimate the average cost to provide both screens without differentiating between the two tests a participant may receive.

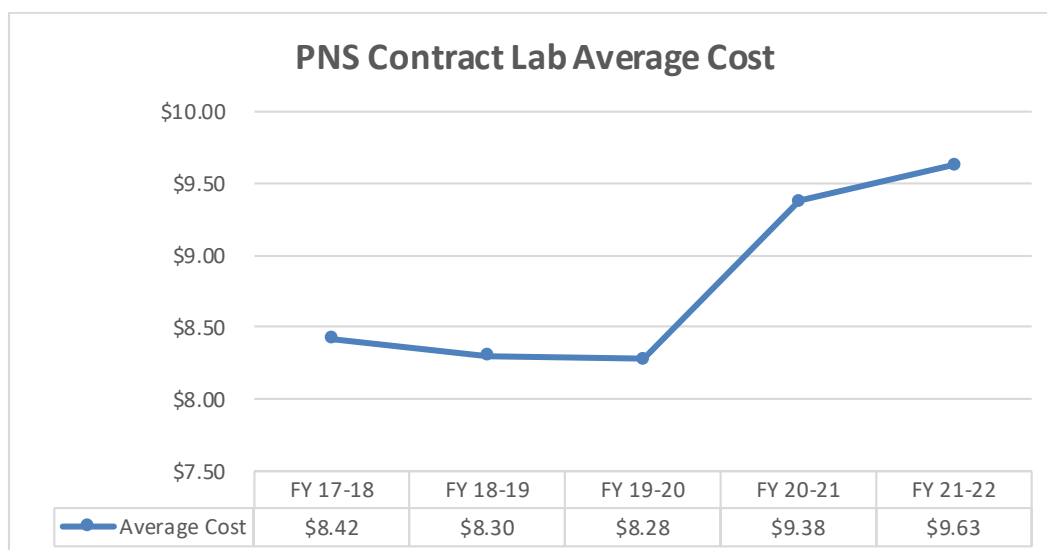
Total Caseload/Specimens – CDPH/GDSP estimates current year specimens will total 485,230, which is a decrease of 5,831 or 1.2 percent compared to 2019-20, actual total specimens of 491,061. Specimens in 2021-22 is estimated at 477,386 which is a decrease of 7,844 or 1.6 percent compared to the current year estimate. The PNS program participation is estimated as a percentage of the DOF/DRU projected number of live births.

CDPH/GDSP estimates that 71 percent (based from a three-year actual average) of the projected births will participate in the PNS program in 2020-21, and that the number of participants will remain constant in 2021-22. The 2020-21 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 year, along with our projected numbers for the remainder of the current year and budget year.

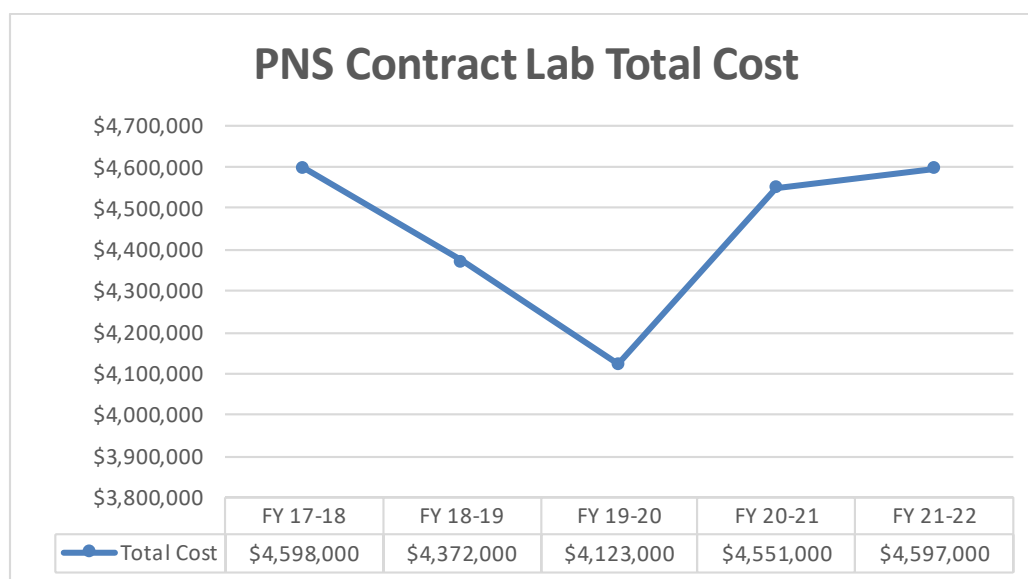


Appendix B.1

Contract Laboratory Average Cost Projections – CDPH/GDSP estimates current year average laboratory cost per participant will be \$9.38, which is an increase of \$1 or 13 percent compared to 2019-20 actual average laboratory cost per participant of \$8.28. Average laboratory cost per participant in 2021-22 is estimated at \$9.63, which is an increase of \$0.25 or three percent compared to current year estimate. The increase in current and budget year is due to an increase in contract rates.



Contract Laboratory Total Cost Projections – CDPH/GDSP estimates current year contract laboratory cost to total \$4.6 million, which is an increase of \$428,000 or 10 percent compared to 2019-20 actual contract laboratory costs of \$4 million. Laboratory costs in 2021-22 are estimated to total \$5 million, which is an increase of \$46,000 or one percent compared to the current year estimate. The increase in current and budget year is due to an increase in contract rates.

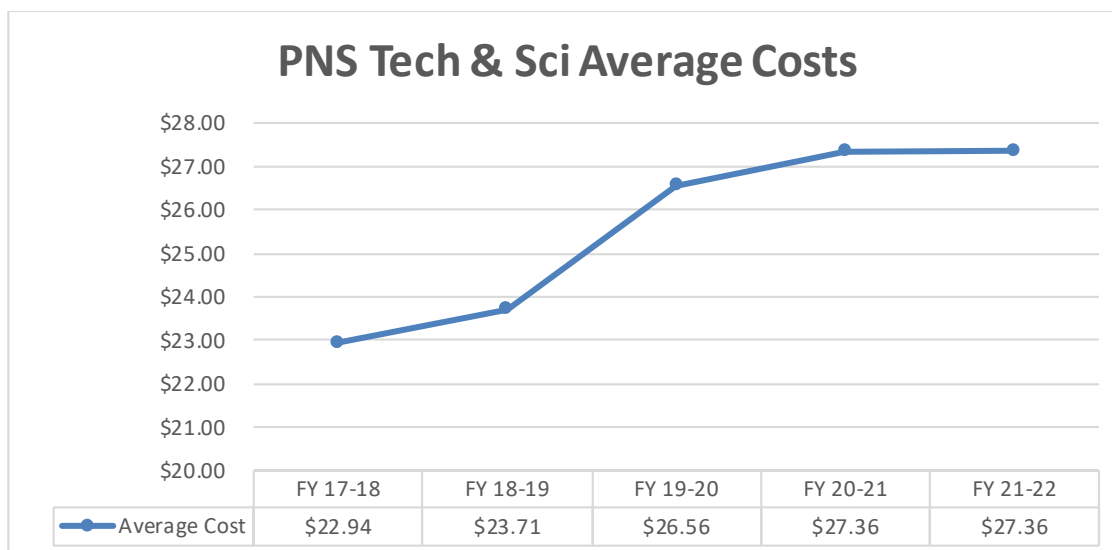


2. Technical and Scientific

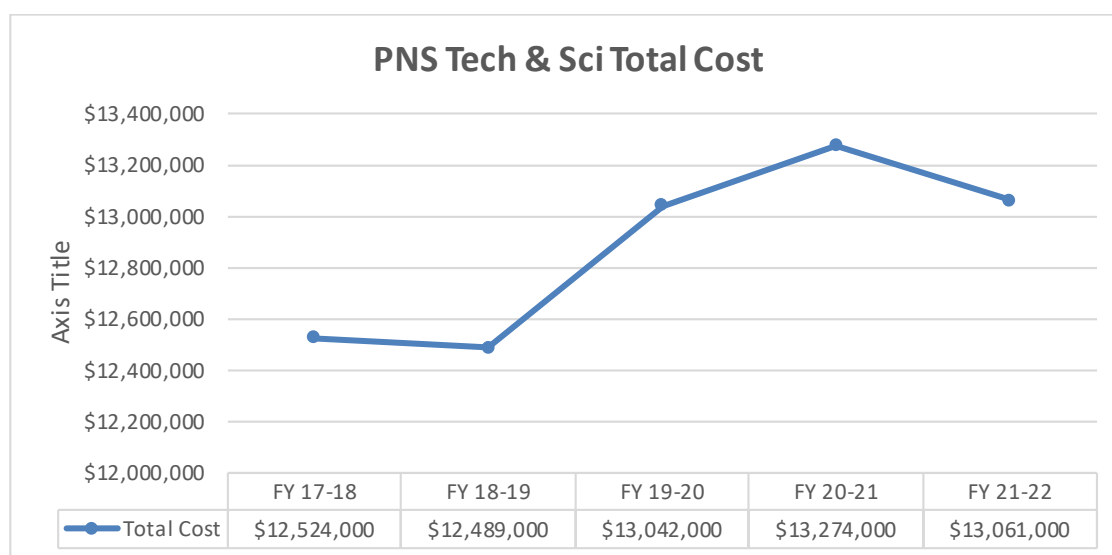
Overview - Costs associated with screening services provided at the laboratory include: reagent kits, limited maintenance and support (as it directly relates to the reagents) of laboratory equipment, supplies, and processing. In addition, there are several costs associated with screening including: blood 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 specimens. 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 \$27.36, which is an increase of \$1 or three percent compared to 2019-20 actual average Technical and Scientific cost per specimen of \$26.56. Average laboratory cost per specimen in 2021-22 is estimated at \$27.36, which is no change compared to the current year estimate. The increase in the current year is attributed to the increase in total cost and is tied to the total projected specimens tested.



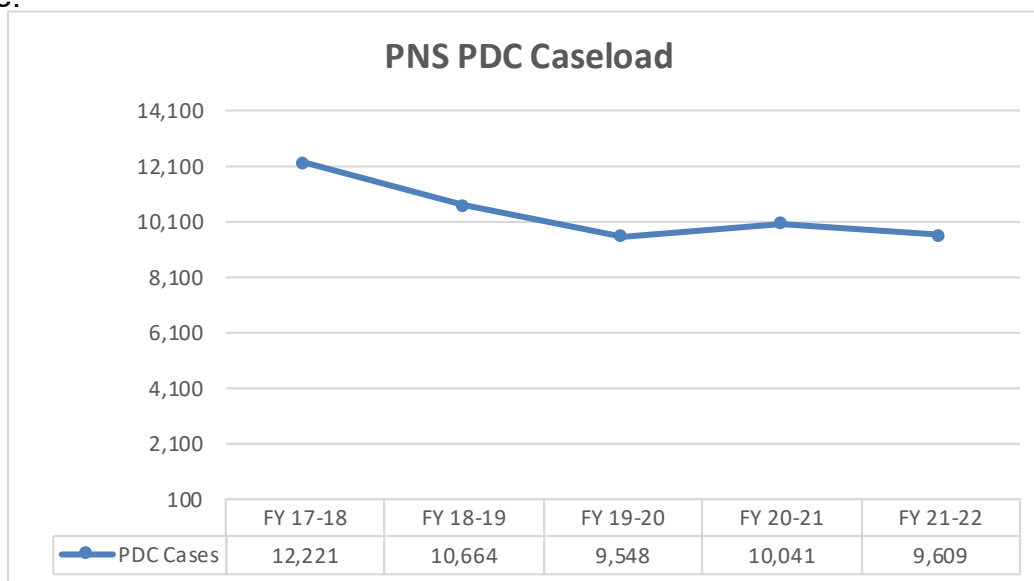
Technical and Scientific Total Cost – CDPH/GDSP estimates current year Technical and Scientific costs to total \$13.3 million, which is an increase of \$232,000 or two percent compared to 2019-20 actual technical and scientific costs of \$13 million. Technical and Scientific costs in 2021-22 are estimated to total \$13.1 million, which is decrease of \$213,999 or 1.6 percent compared to the current year estimate. Fluctuation in total cost is tied to the projected specimens and increase in costs of reagents, supplies, and consumables.



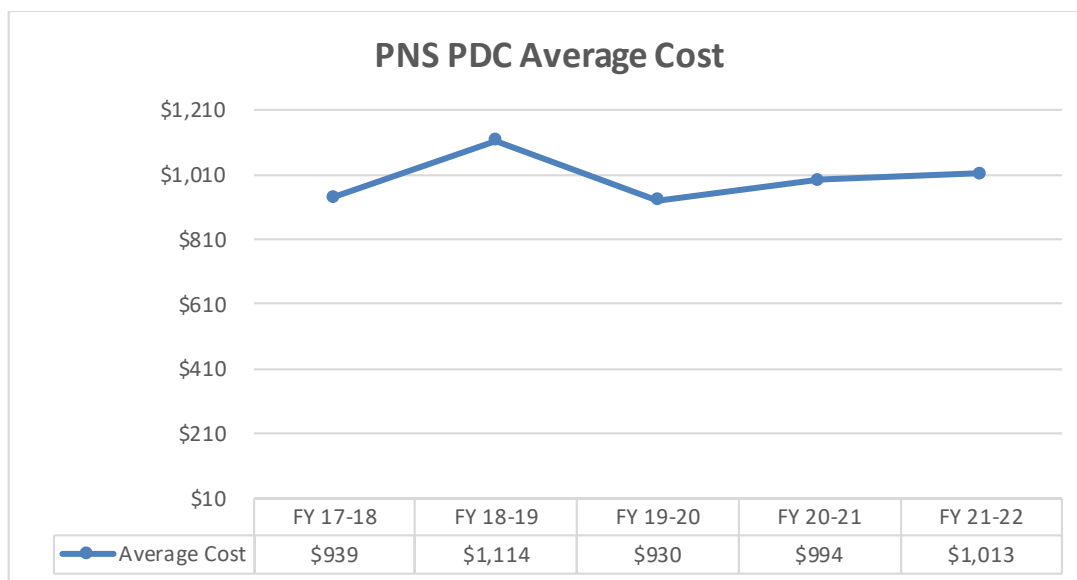
3. Prenatal Diagnostic Services Centers

Overview - Women with positive results are provided additional services, which include: confirmatory and diagnostic prenatal testing, genetic counseling, education, coordinated medical care referrals, 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.

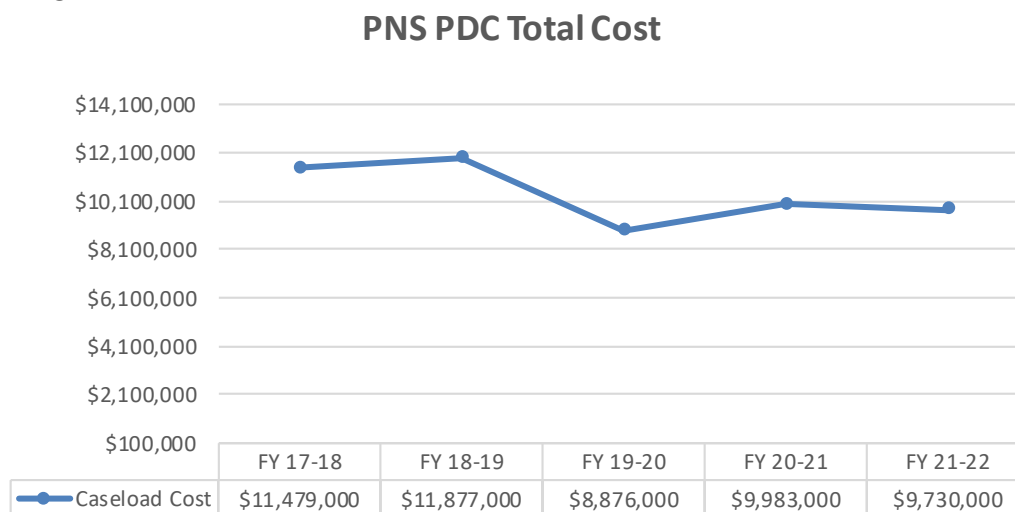
Prenatal Diagnostic Services Centers (PDC) Caseload – CDPH/GDSP estimates current year PDC caseload will total 10,041, which is an increase of 493 or five percent compared to the 2019-20 actual PDC caseload of 9,548. The increase is caused by a projected uptick in women choosing to further pursue diagnostic care. PDC caseload in 2021-22 is estimated to total 9,609, which is a decrease of 432 or four percent compared to the current year estimate.



Prenatal Diagnostic Services Average Cost – CDPH/GDSP estimates current year average PDC cost per participant will be \$994.22, which is an increase of \$65 or seven percent compared to 2019-20 actual average PDC cost per participant of \$929.62. Average laboratory cost per participant in 2021-22 is estimated at \$1,013, which is an increase of \$18.31 or two percent compared to the current year estimate. The rise in average cost in the current year is due to the fluctuations in the projected caseloads and budget year is due to a decrease in the projected participation and referrals. Additionally, increased contract costs as a 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 such as amniocentesis. Women who would previously have declined prenatal diagnostic services are now choosing these non-invasive procedures.



Prenatal Diagnostic Services Total Cost – CDPH/GDSP estimates current year PDC costs to total \$10 million, which is an increase of \$1 million or 12 percent compared to 2019-20 actual PDC total costs of \$8.9 million. PDC costs in 2021-22 are estimated to total \$9.7 million, which is a decrease of \$253,000 or three percent compared to the current year estimate. The change in total expenditures is attributable mainly to fluctuating projected PDC caseload.

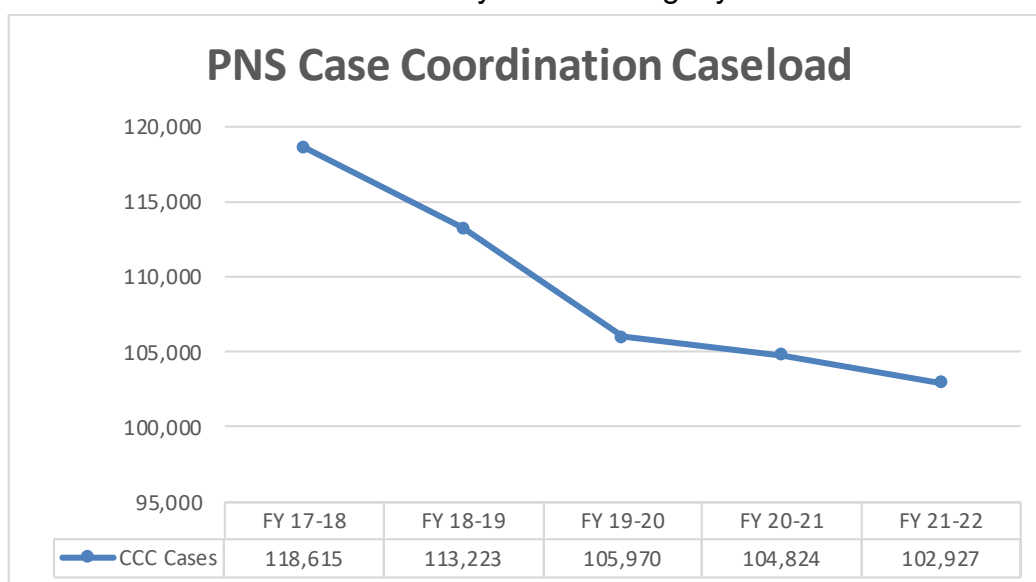


4. Case Management and Coordination Services:

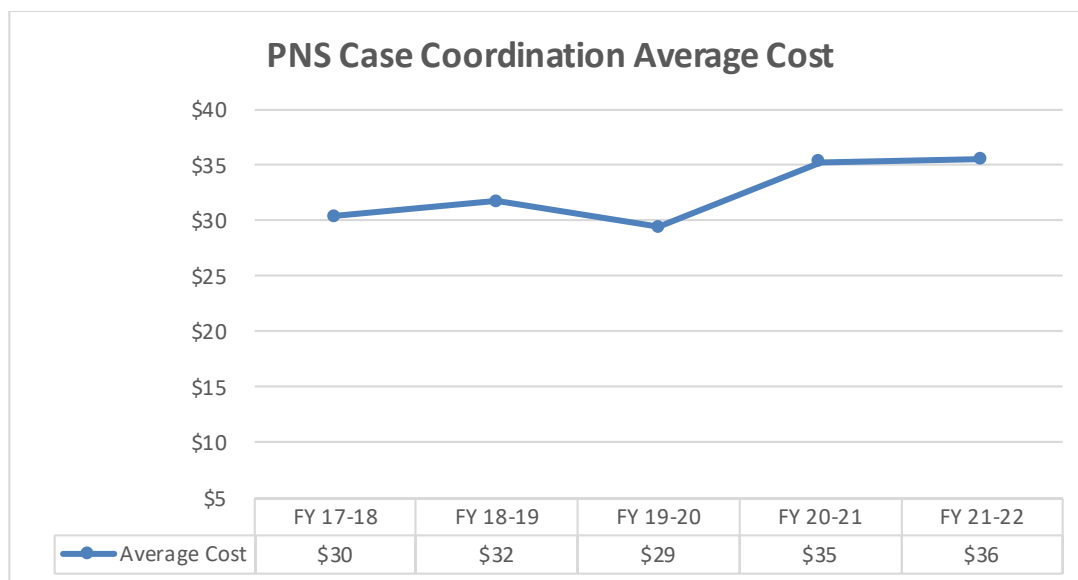
Overview - Services provided to pregnant women who screen positive or have questionable results include coordination of first and second trimester screens and ultrasounds, identifying patients whose blood specimens were drawn too early or were inadequate, requiring additional blood draws. The PNS Case Coordination Centers (CCCs) 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. The CCCs are reimbursed based on caseload and the type of service performed along with a monthly base allocation. Base allocation costs vary by CCC dependent upon the geographic location.

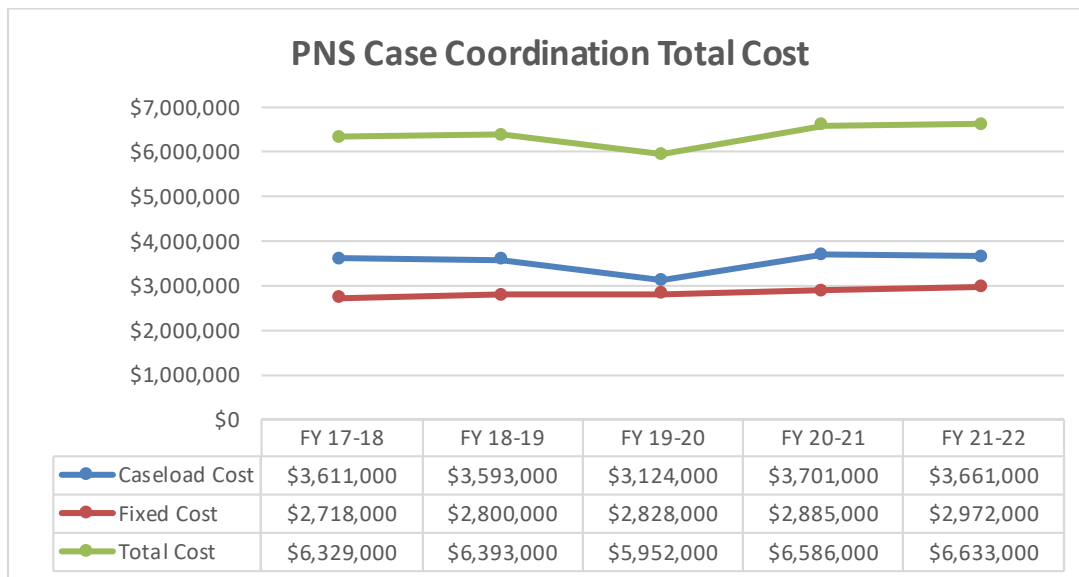
Case Management and Coordination Services (CMCS) Caseload - CDPH/GDSP estimates current year CMCS caseload will total 104,824, which is a decrease of 1,146 or one percent compared to 2019-20 actual CMCS caseload of 105,970. CMCS caseload in 2021-22 is estimated at 102,927, which is a decrease of 1,897 or 1.8 percent compared to the current year estimate. This is due largely 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.



Case Management and Coordination Services Average Cost - CDPH/GDSP estimates current year average CMCS cost per participant will be \$35.31, which is an increase of \$6 or 20 percent compared to 2019-20 actual average CMCS cost per participant of \$29.48. The increase in the current year is attributable to increase in contract rates. Average CMCS cost per participant in 2021-22 is estimated at \$35.57, which is an increase of \$0.26 or 0.7 percent compared to the current year estimate. The increase in average cost is attributable to the increase in fixed cost.



Case Management and Coordination Services Total Cost - CDPH/GDSP estimates current year CMCS costs to total \$6.6 million, which is an increase of \$634,000 or 11 percent compared to 2019-20 actual CMCS total costs of \$6 million. CMCS costs in 2021-22 are estimated to total \$6.6 million, which is an increase of \$47,000 or one percent compared to the current year estimate. The increase in both current year and budget year is attributable to the increase in contract rates and slight increase in fixed cost causing an increase in the total cost.



APPENDIX C: Revenue Projections

1. NBS Revenue

Newborn Screening Program charges a fee of \$177.25. In most cases, the fee is paid to directly to CDPH/GDSP by hospitals. For births that occur outside of a hospital, CDPH/GDSP invoice the appropriate fee to the family of the infant or their insurance company. 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 CDPH/GDSP collects approximately 98 percent of all revenue related to providing NBS services. Since last year, the collection rate has increased to 99 percent. As such, NBS revenue is estimated using the following formula:

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

percent NBS Revenue Projections

	A	B	C	D=(A*B*C)
	Fee	Caseload	Collection Rate	Total Revenue
2020-21	\$177.25	444,234	99%	\$77,953,000
2021-22	\$177.25	445,840	99%	\$78,235,000

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 \$10 is deposited into the California Birth Defect Monitoring Program Fund (Fund 3114). Unlike NBS which collects revenue from hospitals directly, PNS invoices participants and bills insurance companies (analogous to the way a traditional medical provider would). This system of billing which shares cost between the participant and one or more third party payers makes full, or close to full collection of revenue a challenge for the program. Past collection rates have revealed that PNS collects a higher percentage of anticipated revenue from Medi-Cal enrollees than those enrolled in private insurance plans or the uninsured. PNS receives approximately 98 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
2020-21	\$211.60	314,838	55%	45%	98%	94%	173,161	141,677	\$64,088,082
2021-22	\$211.60	315,720	55%	45%	98%	94%	173,646	142,074	\$64,267,693