

**Genetic Disease Screening Program
(GDSP)**

Fiscal Year 2024-25

May Revision Estimate



**Tomás J. Aragón, MD, MPH, DrPH
Director and State Public Health Officer**

California Department of Public Health

TABLE OF CONTENTS

I. ESTIMATES	1
A. PROGRAM OVERVIEW	1
B. EXPENDITURE OVERVIEW	1
C. LOCAL ASSISTANCE EXPENDITURE PROJECTIONS	2
CURRENT YEAR (2023-24)	2
BUDGET YEAR (2024-25)	2
EXPENDITURE METHODOLOGY (KEY DRIVERS OF COST)	3
NBS EXPENDITURE PROJECTIONS (SEE APPENDICES A1-A5)	4
PNS EXPENDITURES PROJECTIONS (SEE APPENDICES B1-B4)	5
OPERATIONAL SUPPORT PROJECTIONS	6
D. STATE OPERATIONS EXPENDITURE PROJECTIONS	6
E. REVENUE PROJECTIONS	7
COMBINED NBS AND PNS REVENUE	7
REVENUE METHODOLOGY	7
NBS REVENUE (SEE APPENDIX C1)	9
PNS REVENUE (SEE APPENDIX C2)	9
II. FUND CONDITION STATEMENT	10
III. GENERAL ASSUMPTIONS	11
FUTURE FISCAL ISSUES	11
NEW ASSUMPTIONS/ PREMISES	12
EXISTING (SIGNIFICANTLY CHANGED) ASSUMPTIONS/PREMISES	12
UNCHANGED ASSUMPTIONS/PREMISES	12
DISCONTINUED ASSUMPTIONS/PREMISES	16
IV. APPENDIX A: NEWBORN SCREENING PROGRAM (NBS) ASSUMPTIONS AND RATIONALE	17
CONTRACT LABORATORIES	17
TECHNICAL AND SCIENTIFIC	19
CASE MANAGEMENT AND COORDINATION SERVICES:	21
DIAGNOSTIC SERVICES	23
REFERENCE LABORATORIES	25
V. APPENDIX B: PRENATAL SCREENING PROGRAM (PNS) ASSUMPTIONS AND RATIONALE	28
CELL-FREE DNA (CFDNA)	28
CONTRACT LABORATORIES	29
TECHNICAL AND SCIENTIFIC	34
PRENATAL DIAGNOSTIC SERVICES CENTERS	36
CASE MANAGEMENT AND COORDINATION SERVICES	38
VI. APPENDIX C: REVENUE PROJECTIONS	42
NBS REVENUE	42
PNS REVENUE	42

ESTIMATES

PROGRAM OVERVIEW

The California Department of Public Health (CDPH), Genetic Disease Screening Program (GDSP) May Revision Estimate provides a revised projection of 2023-24 expenditures along with a projected 2024-25 budget for Local Assistance and State Operations expenditures.

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 pregnant individuals who desire to participate. The screening test provides pregnant individuals 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.

EXPENDITURE OVERVIEW

The CDPH/GDSP 2024-25 Governor's Budget appropriation for 2023-24 is \$167.8 million, of which \$129.1 million is for Local Assistance and \$38.7 million is for State Operations. The CDPH/GDSP's May Revision estimates 2023-24 expenditure will be \$164.8 million, of which \$126.1 million is for Local Assistance and \$38.7 million is for State Operations. There is no change to the State Operations expenditures. Local Assistance expenditures are decreasing by \$3 million, which is attributed to lower Prenatal Screening (PNS) Program and Newborn Screening (NBS) Program caseload than previously projected in the Governor's Budget as a result of declining birth rates. In addition, PNS Program caseload is further declining due to additional monthly participation data reflected in the Unchanged Assumption – Methodology Change in Projecting PNS Caseload.

The CDPH/GDSP's 2024-25 Governor's Budget appropriation for 2024-25 is \$181.5 million, of which \$142.8 million is for Local Assistance and \$38.8 million is for State Operations. The CDPH/GDSP's May Revision estimates 2024-25 expenditure will be \$176.8 million, of which \$138 million is for Local Assistance and \$38.8 million is for State Operations. There is no change to the State Operations expenditures.

Local Assistance expenditures are decreasing by \$4.7 million which is attributed to lower Prenatal Screening Program and Newborn Screening Program caseload than previously projected in the Governor's Budget as a result of declining birth rates. In addition, PNS Program caseload is further declining due to additional monthly participation data reflected in the Unchanged Assumption – Methodology Change in Projecting PNS Caseload.

Table 1 shows the difference between the 2024-25 Governor's Budget appropriation, the revised 2023-24 expenditures and proposed 2024-25 expenditures for CDPH/GDSP.

Table 1: Genetic Disease Screen Program Current Year and Budget Year Summaries Compared to 2024-25 Governor's Budget

Fund 0203 Genetic Disease Testing Fund	2023 Budget Act	FY 2023-24				FY 2024-25			
		2024-25 Governor's Budget	2024-25 May Revision	Change from Governor's Budget to May Revision	Percent Change from Governor's Budget to May Revision	2024-25 Governor's Budget	2024-25 May Revision	Change from Governor's Budget to May Revision	Percent Change from Governor's Budget to May Revision
Total	187,608,000	167,770,000	164,782,000	-2,988,000	-1.8%	181,545,000	176,806,000	-4,739,000	-2.6%
State Operations	38,066,000	38,670,000	38,670,000	0	0.0%	38,761,000	38,761,000	0	0.0%
Local Assistance	149,542,000	129,100,000	126,112,000	-2,988,000	-2.3%	142,784,000	138,045,000	-4,739,000	-3.3%

LOCAL ASSISTANCE EXPENDITURE PROJECTIONS

CURRENT YEAR (2023-24)

The 2024-25 Governor's Budget appropriation for CDPH/GDSP's Local Assistance is \$129.1 million in 2023-24. The CDPH/GDSP's May Revision estimates 2023-24 Local Assistance expenditures will total \$126.1 million, which is a decrease of \$3 million or 2.3 percent compared to the 2024-25 Governor's Budget. The decrease in Local Assistance can be attributed to the decrease in PNS and NBS Program projected caseload. This is a result of the Department of Finance Demographic Research Units (DRU) declining projection of live births as well as a further decline in PNS Program caseload from the methodology change.

BUDGET YEAR (2024-25)

For 2024-25, the CDPH/GDSP estimates the revised Local Assistance expenditures will total \$138 million, which is a decrease of \$4.7 million or 3.3 percent compared to the 2024-25 Governor's Budget appropriation of \$142.8 million. The overall decrease can be attributed to the lower than previously projected number of live births as well as a further decline in PNS Program caseload from the methodology change.

Table 2 shows the difference between the 2024-25 Governor's Budget appropriation and the revised 2023-24 expenditures and proposed 2024-25 expenditures for CDPH/GDSP Local Assistance.

Table 2: Local Assistance Current Year and Budget Year Summaries Compared to 2024-25 Governor's Budget

Fund 0203 Genetic Disease Testing Fund	2023 Budget Act	FY 2023-24				FY 2024-25			
		2024-25 Governor's Budget	2024-25 May Revision	Change from Governor's Budget to May Revision	Percent Change from Governor's Budget to May Revision	2024-25 Governor's Budget	2024-25 May Revision	Change from Governor's Budget to May Revision	Percent Change from Governor's Budget to May Revision
Local Assistance Total	149,542,000	129,100,000	126,112,000	-2,988,000	-2.3%	142,784,000	138,045,000	-4,739,000	-3.3%
Newborn Screening	50,182,000	44,052,000	42,427,000	-1,625,000	-3.7%	49,047,000	46,678,000	-2,369,000	-4.8%
Prenatal Screening	61,697,000	47,385,000	46,022,000	-1,363,000	-2.9%	63,429,000	61,059,000	-2,370,000	-3.7%
Operational Support	37,663,000	37,663,000	37,663,000	0	0.0%	30,308,000	30,308,000	0	0.0%

EXPENDITURE METHODOLOGY (KEY DRIVERS OF COST)

The CDPH/GDSP Local Assistance expenditures are split into three areas: PNS, NBS and Operational Support. Operational Support costs 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/specimens 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 specimen tested x Contract laboratory average cost
 - Total specimen 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 CDPH/GDSP, including Information Technology (IT) and courier services.

Below, the projections are summarized 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 are presented in the appendices.

NBS EXPENDITURE PROJECTIONS (SEE APPENDICES A1-A5)

For 2023-24, CDPH/GDSP's May Revision estimates NBS Local Assistance expenditures will total \$42.4 million, which is a decrease of \$1.6 million or 3.7 percent compared to the 2024-25 Governor's Budget of \$44.1 million. The decrease is attributed to the decrease in DRU's projection of live births as compared to the Governor's Budget.

For 2024-25, CDPH/GDSP's May Revision estimates NBS Local Assistance expenditures will total \$46.7 million, which is a decrease of \$2.4 million or 4.8 percent compared to the 2024-25 Governor's budget of \$49 million. The overall decrease in Newborn Screening expenditures is due to DRU's projection of live births, which is lower than the previous projection in the Governor's Budget.

Table 3 shows the 2024-25 Governor's Budget appropriation and the revised 2023-24 and 2024-25 expenditures for the Newborn Screening Program costs by cost center type.

Table 3: Newborn Screening Current Year and Budget Year Summaries Compared to 2024-25 Governor's Budget

Fund 0203 Genetic Disease Testing Fund	2023 Budget Act	FY 2023-24				FY 2024-25			
		2024-25 Governor's Budget	2024-25 May Revision	Change from Governor's Budget to May Revision	Percent Change from Governor's Budget to May Revision	2024-25 Governor's Budget	2024-25 May Revision	Change from Governor's Budget to May Revision	Percent Change from Governor's Budget to May Revision
Total	50,182,000	44,052,000	42,427,000	-1,625,000	-3.7%	49,047,000	46,678,000	-2,369,000	-4.8%
Contract Lab	8,425,000	7,561,000	7,485,000	-76,000	-1.0%	7,754,000	7,626,000	-128,000	-1.7%
Tech Sci	29,772,000	25,141,000	23,661,000	-1,480,000	-5.9%	29,657,000	27,552,000	-2,105,000	-7.1%
Reference Lab	2,705,000	2,486,000	2,461,000	-25,000	-1.0%	2,612,000	2,570,000	-42,000	-1.6%
CMCS	6,930,000	6,513,000	6,469,000	-44,000	-0.7%	6,757,000	6,697,000	-60,000	-0.9%
Diagnostic Services	2,350,000	2,351,000	2,351,000	0	0.0%	2,267,000	2,233,000	-34,000	-1.5%

PNS EXPENDITURES PROJECTIONS (SEE APPENDICES B1-B4)

For 2023-24, the CDPH/GDSP's May Revision estimates PNS Local Assistance expenditures to total \$46 million, which is a net decrease of \$1.4 million or 2.9 percent compared to the 2024-25 Governor's Budget of \$47.4 million. The overall net decrease in the current year is attributed to the decrease in caseload due to declining births as well as additional monthly participation data reflected in caseload projections. In the Governor's Budget only 3 months of data were included to forecast the PNS participation trend (55 percent of births). In this May Revision, 7 months of data were used to forecast the PNS participation trend which has now decreased to approximately 52 percent of births. These expenditure decreases are partially offset by an increased cost in technical and scientific expenditures due to new procurements for quality control improvement processes and supplies and consumables cost increases in the Genetic Disease Laboratory Branch.

For 2024-25, the CDPH/GDSP's May Revision estimates PNS Local Assistance expenditures will total \$61.1 million, which is a decrease of \$2.4 million or 3.7 percent compared to the 2024-25 Governor's Budget of 63.4 million. The overall net decrease in the budget year is attributed to the decrease in caseload due to the declining births as well as additional monthly participation data reflected in caseload projections. In the Governor's Budget only 3 months of data were included to forecast the PNS participation trend (55 percent of births). In the May Revision, 7 months of data were used to forecast the PNS participation trend which has now decreased to approximately 52 percent of births. These expenditure decreases are partially offset by an increased cost in technical and scientific expenditures due to new procurements for quality control improvement processes and supplies and consumables cost increases in the Genetic Disease Laboratory Branch.

Table 4 displays the 2024-25 Governor's Budget appropriation, the revised 2023-24 expenditures and proposed 2024-25 expenditures for the Prenatal Screening program costs by client type.

Table 4: Prenatal Screening Current Year and Budget Year Summaries Compared to 2024-25 Governor's Budget

Fund 0203 Genetic Disease Testing Fund	2023 Budget Act	FY 2023-24				FY 2024-25			
		2024-25 Governor's Budget	2024-25 May Revision	Change from Governor's Budget to May Revision	Percent Change from Governor's Budget to May Revision	2024-25 Governor's Budget	2024-25 May Revision	Change from Governor's Budget to May Revision	Percent Change from Governor's Budget to May Revision
Total	61,697,000	47,385,000	46,022,000	-1,363,000	-2.9%	63,429,000	61,059,000	-2,370,000	-3.7%
cfDNA	43,949,000	31,912,000	30,372,000	-1,540,000	-4.8%	43,315,000	40,965,000	-2,350,000	-5.4%
Contract Lab	2,970,000	3,192,000	3,070,000	-122,000	-2.9%	3,288,000	3,156,000	-132,000	-4.0%
Tech & Sci	2,100,000	1,951,000	3,547,000	1,596,000	81.8%	2,010,000	3,631,000	1,621,000	80.6%
CMCS	6,058,000	5,382,000	4,339,000	-1,043,000	-19.4%	5,680,000	5,429,000	-251,000	-4.4%
PDC	6,620,000	4,948,000	4,694,000	-254,000	-5.1%	9,136,000	7,878,000	-1,258,000	-13.8%

OPERATIONAL SUPPORT PROJECTIONS

For 2023-24, the CDPH/GDSP's revised Operational Support expenditures total is \$37.7 million, which is no change from the 2024-25 Governor's Budget.

For 2024-25, the CDPH/GDSP projects operational support expenditures will total \$30.3 million, which is no change from the 2024-25 Governor's Budget.

Table 5 displays the difference between the 2024-25 Governor's Budget appropriation, the revised 2023-24 expenditures and proposed 2024-25 expenditures for Program Operational Support costs.

Table 5: Operational Support Current Year and Budget Year Summaries Compared to 2024-25 Governor's Budget

Fund 0203 Genetic Disease Testing Fund	2023 Budget Act	FY 2023-24				FY 2024-25			
		2024-25 Governor's Budget	2024-25 May Revision	Change from Governor's Budget to May Revision	Percent Change from Governor's Budget to May Revision	2024-25 Governor's Budget	2024-25 May Revision	Change from Governor's Budget to May Revision	Percent Change from Governor's Budget to May Revision
Operational Support	37,663,000	37,663,000	37,663,000	0	0.0%	30,308,000	30,308,000	0	0.0%

STATE OPERATIONS EXPENDITURE PROJECTIONS

For 2023-24, the CDPH/GDSP's May Revision estimates State Operations expenditures will total \$38.7 million, which is no change from the 2024-25 Governor's Budget.

For 2024-25, the CDPH/GDSP's May Revision estimates State Operations expenditures will total \$38.8 million, which is no change from the 2024-25 Governor's Budget.

Table 6 displays the difference between the 2024-25 Governor's Budget appropriation and the revised 2023-24 expenditures and proposed 2024-25 expenditures for the CDPH/GDSP State Operations costs.

Table 6: State Operations Current Year and Budget Year Summaries Compared to 2024-25 Governor's Budget

Fund 0203 Genetic Disease Testing Fund	2023 Budget Act	FY 2023-24				FY 2024-25			
		2024-25 Governor's Budget	2024-25 May Revision	Change from Governor's Budget to May Revision	Percent Change from Governor's Budget to May Revision	2024-25 Governor's Budget	2024-25 May Revision	Change from Governor's Budget to May Revision	Percent Change from Governor's Budget to May Revision
State Operations	38,066,000	38,670,000	38,670,000	0	0.0%	38,761,000	38,761,000	0	0.0%

REVENUE PROJECTIONS

COMBINED NBS AND PNS REVENUE

For 2023-24, the CDPH/GDSP's May Revision estimates the total revenue of \$148 million, which is a decrease of \$4.2 million or 2.8 percent compared to the 2024-25 Governor's Budget amount of \$152.2 million.

For 2024-25, the CDPH/GDSP's May Revision projects the total revenue of \$175.8 million, which is a decrease of \$6.6 million or 3.6 percent compared to the 2024-25 Governor's budget amount of \$182.4 million.

The decrease in revenues for both current year and budget year is attributed to the decrease in the projection of live births in addition to a further reduced PNS Program caseload from the inclusion of additional monthly participation data in caseload projections.

REVENUE METHODOLOGY

The PNS and NBS Programs each charge a fee for screening services provided to clients. The PNS Program currently charges a fee for cfDNA screening of \$232, of which \$222 is deposited into the Genetic Disease Testing Fund (Fund 0203). Additionally, the PNS program also charges a separate fee for NTD of \$85, of which \$75 is deposited into the Genetic Disease Testing Fund (Fund 0203). The remaining \$10 of the NTD and cfDNA fees are deposited into the Birth Defects Monitoring Program Fund (BDMP Fund 3114).

The CDPH/GDSP will be increasing PNS fees by \$112 (from \$232 to \$344) beginning July 2024. This consists of the \$74 fee increase in the Prenatal Screening for adding Sex Chromosome Aneuploidies (SCA) screening and a \$38 fee increase due to the Methodology Change in Projecting Prenatal Screening Caseload.

The CDPH/GDSP invoices and collects PNS payments from individual participants, private insurers, hospital providers (e.g., Kaiser), and Medi-Cal. The CDPH/GDSP can collect approximately 99 percent of all fees owed on behalf of Medi-Cal clients and hospital providers and approximately 95 percent of the fees owed by individuals with private insurance. The CDPH/GDSP uses the following formula to estimate revenue generated from PNS fees:

Revenue Projections for PNS Patient Billing:

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

Revenue Projections for Hospital Providers/Client Billing:

$$(\text{Fee} \times \text{PNS Participants} \times \text{Hospital Participation Rate} \times \text{Hospital Collection Rate})$$

The NBS Program currently charges a fee of \$211 for newborn screening, of which the entire fee is deposited into the Genetic Disease Testing Fund (Fund 0203). Starting July 1, 2024, the CDPH/GDSP will increase NBS fees by \$15 to recover the costs of screening for two new additional conditions (MPSII and GAMT deficiency). NBS program costs are driven by per-case costs and baseline fixed costs that do not fluctuate with the number of births. Fixed costs must be supported with higher fees when the number of births drops. Unlike PNS, where CDPH/GDSP bills patients and collects fees from insurers, the CDPH/GDSP collects the bulk of NBS revenues 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. The 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)

For 2023-24, the revised NBS revenue is expected to total \$84.6 million, which is a decrease of \$861,000 or 1 percent compared to the 2024-25 Governor’s budget of \$85.4 million. For 2024-25, the GDSP projects revised NBS revenue will total \$90.1 million, which is a decrease of \$1.5 million or 1.7 percent compared to the 2024-25 Governor’s budget amount of \$91.6 million. The revenue decreases in the current year and the budget year are due to a decrease in projected caseload as a result of DRU’s updated projection of live births.

PNS REVENUE (SEE APPENDIX C2)

For 2023-24, the revised PNS revenue is expected to total \$63.4 million, which is a decrease of \$3.4 million or 5 percent compared to the 2024-25 Governor’s budget amount of \$66.7 million. For 2024-25, the CDPH/GDSP’s May Revision projects that the revised PNS revenue will total \$85.7 million, which is a decrease of \$5.1 million or 5.6 percent compared to the 2024-25 Governor’s budget amount of \$90.8 million.

The decreases in revenues for both current year and budget year are attributed to the decrease in the projection of live births in addition to a further decrease in caseload due to additional monthly participation data being included in caseload projections.

Table 7 shows the revised current year and budget year revenue compared to 2024-25 Governor’s Budget.

Table 7: Genetic Disease Screening Program Revenue Current Year and Budget Year Summaries Compared to 2024-25 Governor’s Budget

Fund 0203 Genetic Disease Testing Fund	2023 Budget Act	FY 2023-24				FY 2024-25			
		2024-25 Governor’s Budget	2024-25 May Revision	Change from Governor’s Budget to May Revision	Percent Change from Governor’s Budget to May Revision	2024-25 Governor’s Budget	2024-25 May Revision	Change from Governor’s Budget to May Revision	Percent Change from Governor’s Budget to May Revision
Total	176,165,000	152,179,000	147,966,000	-4,213,000	-2.8%	182,380,000	175,786,000	-6,594,000	-3.6%
Newborn Screening	88,908,000	85,445,000	84,584,000	-861,000	-1.0%	91,577,000	90,059,000	-1,518,000	-1.7%
Prenatal Screening	87,257,000	66,734,000	63,382,000	-3,352,000	-5.0%	90,803,000	85,727,000	-5,076,000	-5.6%

FUND CONDITION STATEMENT

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

RESOURCES	2022-23	2023-24	2024-25
BEGINNING BALANCE	\$38,414	\$33,053	\$15,962
Prior Year Adjustment	-3,878	0	0
Adjusted Beginning Balance	34,537	33,053	15,962
REVENUES			
4123400 Genetic Disease Testing Fees ^{1/}	161,683	147,966	175,786
4163000 Income from Surplus Investments	820	118	118
4171400 Escheat of Unclaimed Checks & Warrants	214	103	103
9920 Transfers and Adjustments	0	0	0
TOTALS, REVENUES	162,716	148,187	176,007
TOTAL RESOURCES	\$197,253	\$181,240	\$191,969

EXPENDITURES AND EXPENDITURE ADJUSTMENTS			
4265 Department of Public Health (State Operations)	32,519	38,670	38,761
4265 Department of Public Health (Local Assistance)	129,769	126,112	138,045
8880 Financial Information System for California (State Operations)	0	0	0
9892 Supplemental Pension Payments (State Operations)	496	496	417
9900 Statewide General Admin Exp (ProRata) (State Operations)	1,416	0	774
TOTAL EXPENDITURES AND EXPENDITURE ADJUSTMENTS	164,200	165,278	177,997

FUND BALANCE	33,053	15,962	13,972
	20%	10%	8%

REVENUE PROJECTIONS

<u>2023-24</u>					
2023-24 NBS FEES BASED ON	404,919 TESTS @ \$211.00	AND 99% Provider ^{1/}	-	\$84,584,000	
Total NBS Client Billing	404,919 TESTS @ \$211.00	AND 99% Provider ^{1/}	-	\$84,584,000	
2023-24 cfDNA FEES BASED ON	66,758 TESTS @ \$222.00	AND 99% Provider ^{2/}	-	\$14,672,000	
2023-24 NTD FEES BASED ON	73,705 TESTS @ \$75.00	AND 99% Provider ^{2/}	-	\$5,473,000	
Total PNS Client Billing	140,464		-	\$20,145,000	
2023-24 cfDNA FEES BASED ON	56,744 TESTS @ \$222.00	AND 95% Non Medi-Cal ^{3/}	-	\$11,967,000	
2023-24 cfDNA FEES BASED ON	85,117 TESTS @ \$222.00	AND 99% Medi-Cal ^{4/}	-	\$18,707,000	
Total PNS Patient Billing	141,861		-	\$30,674,000	
2023-24 NTD FEES BASED ON	68,792 TESTS @ \$75.00	AND 95% Non Medi-Cal ^{3/}	-	\$4,901,000	
2023-24 NTD FEES BASED ON	103,188 TESTS @ \$75.00	AND 99% Medi-Cal ^{4/}	-	\$7,662,000	
Total PNS Patient Billing	171,979		-	\$12,563,000	
TOTAL PNS FEES			-	\$63,382,000	
GDSP Total			-	\$147,966,000	

<u>2024-25</u>					
2024-25 NBS FEES BASED ON	402,515 TESTS @ \$226.00	AND 99% Provider ^{1/}	-	\$90,059,000	
Total NBS Client Billing	402,515 TESTS @ \$226.00	AND 99% Provider ^{1/}	-	\$90,059,000	
2024-25 cfDNA FEES BASED ON	66,346 TESTS @ \$334.00	AND 99% Provider ^{2/}	-	\$21,938,000	
2024-25 NTD FEES BASED ON	73,250 TESTS @ \$75.00	AND 99% Provider ^{2/}	-	\$5,439,000	
Total PNS Client Billing	139,596		-	\$27,377,000	
2024-25 cfDNA FEES BASED ON	56,394 TESTS @ \$334.00	AND 95% Non Medi-Cal ^{3/}	-	\$17,894,000	
2024-25 cfDNA FEES BASED ON	84,591 TESTS @ \$334.00	AND 99% Medi-Cal ^{4/}	-	\$27,971,000	
Total PNS Patient Billing	140,985		-	\$45,865,000	
2024-25 NTD FEES BASED ON	68,367 TESTS @ \$75.00	AND 95% Non Medi-Cal ^{3/}	-	\$4,871,000	
2024-25 NTD FEES BASED ON	102,550 TESTS @ \$75.00	AND 99% Medi-Cal ^{4/}	-	\$7,614,000	
Total PNS Patient Billing	170,917		-	\$12,485,000	
TOTAL PNS FEES			-	\$85,727,000	
GDSP Total			-	\$175,786,000	

1/ NBS Fees based on 99% hospital and other provider collection rate
 2/ PNS Fees based on 99% hospital provider collection rate
 3/ PNS Fees based on 95% private payer / insurance collection rate
 4/ PNS Fees based on 99% Medi-Cal collection rate

GENERAL ASSUMPTIONS

FUTURE FISCAL ISSUES

Senate Bill (SB) 1095: Newborn Screening Program

Background: Senate Bill (SB) 1095 (Chapter 393, Statutes of 2016) amended Sections 124977 and 125001 of the Health and Safety Code (H&S Code) and required the California Department of Public Health/Genetic Disease Screening Program (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), follow-up systems, and the addition of new confirmatory testing.

Discretionary?: No

Reason for Adjustment/ Change: CDPH/GDSP is statutorily required 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 \$4 million to \$7 million per year for any new disorder adopted by the RUSP. This range is only an estimate and is based on costs incurred from the last three additions to the NBS panel – spinal muscular atrophy (SMA), mucopolysaccharidosis type I (MPS I) and Pompe disease, and the upcoming additions of MPS II and GAMT deficiency. Furthermore, as additional diseases are added to the RUSP, there may be one-time resources needed to plan, prepare for, and implement the additional required screening. CDPH/GDSP will evaluate the fund reserve to assess the program's ability 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).

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

Methodology Change in Projecting Prenatal Screening Caseload

Background: Historically, Prenatal Screening (PNS) Program total caseload was determined as a percentage of the Department of Finance Demographic Research Unit (DRU)'s projected number of live births. For 2022-23 and 2023-24, GDSP used a three-year average of PNS program participation as a percentage of live births to project caseload and develop revenue and cost projections in the estimate process.

Due to a court ruling, the state regulation (17 CCR 6523(e)) that required clinical laboratories to have a contract with CDPH in order to provide prenatal birth defect screening for fetal autosomal trisomies or neural tube defects will no longer be enforced. PNS caseload has declined by approximately 20 to 21 percent since this ruling because cfDNA laboratories that were not contracted with the PNS Program are now able to screen for trisomy 13, trisomy 18, trisomy 21 and neural tube defects (NTDs) outside of the PNS Program. As a result, GDSP's previous methodology for projecting caseload is no longer applicable. Instead, GDSP will use monthly participation data since the ruling to calculate caseloads for both cfDNA and NTD screening tests.

In addition, there will be a change in estimating revenues. In the past, when the PNS Program used biochemical screening for first and second trimesters, GDSP could only bill for one test for each individual even if they had taken both tests. Under the biochemical screening, GDSP collected approximately 99 percent of all fees owed on behalf of Medi-Cal clients and approximately 95 percent of the fees owed by individuals with private insurance and these rates were used to estimate revenues. Now that GDSP has transitioned to the Prenatal Cell-Free DNA Screening, the revenue estimates will be based on the allocation of the prenatal billable cases that are billed through Patient billing and Client billing. Patient billing are cases that are billed directly through insurance companies

(MediCal and Non-MediCal), whereas Client billing are cases that are billed directly to hospital providers (ex. Kaiser Permanente).

Description of Change: Rather than projecting caseload as a percentage of the DRU's projected number of live births, GDSP is proposing to use the program's most recent participation numbers to project current year and ongoing fiscal years caseload to account for the effects of losing exclusivity. Additionally, GDSP will update its methodology to project billable caseload to better reflect the collection rate for cases that are billed directly to hospital providers.

Discretionary?: Yes

Reason for Adjustment/ Change: In the 2023-24 May Revision, GDSP introduced this assumption to align its 2022-23 budget as a temporary adjustment due to the pending litigation regarding exclusivity. Given that the court ruling is now final, GDSP is permanently aligning its 2023-24 and ongoing budget with actual/projected participation data since the loss of exclusivity. The previous methodology had estimated PNS caseload to be around 72 percent of births, whereas the new methodology estimates PNS caseload at approximately 52 percent of births. GDSP will also align the billable caseloads ratio to estimate revenues by using total Patient billing and total Client billing caseloads.

Fiscal Impact (Range) and Fund Source(s): It is estimated that this methodology change in calculating cfDNA prenatal caseload will reflect an approximate 20 and 21 percent decrease in 2023-24 and 2024-25 in prenatal participants. This will lead to a revenue decrease of approximately \$19 million in 2023-24 and \$20 million in 2024-25 and an expenditure decrease of approximately \$12 million for both 2023-24 and 2024-25.

To correct the fund's revenue and expenditure imbalance caused by this assumption, CDPH/GDSP will be implementing a PNS cfDNA fee increase of \$38 in July 2024.

The overall PNS cfDNA fee increase that CDPH/GDSP will be implementing in July 2024 will total \$112 (from \$232 to \$344). This consists of the approximate \$38 increase in this assumption and a \$74 fee increase due to the Prenatal Screening for SCAs Existing (Unchanged) Assumption. The fund source is the Genetic Disease Testing Fund (GDTF, Fund 0203).

Prenatal Screening for Sex Chromosome Aneuploidies (SCAs)

Background: The California Department of Public Health (CDPH) Genetic Disease Screening Program (GDSP) launched a redesigned Prenatal Screening (PNS) Program on September 19, 2022, by making cell-free DNA (cfDNA) screening for chromosome aneuploidies (trisomy 21, trisomy 18, and trisomy 13) available statewide based on published recommendations at the time from the American College of Obstetricians and Gynecologists (ACOG). However, on December 16, 2022, the American College of Medical Genetics and Genomics (ACMG) released an updated practice guideline that recommends offering noninvasive prenatal screening (NIPS, also known as cfDNA screening) to include screening for sex chromosome aneuploidies (SCAs) in addition to trisomies 21, 18, and 13, as well as for all single and twin pregnancies.

Description of Change: The California PNS Program is preparing for the addition of prenatal screening for SCAs using cfDNA screening beginning April 1, 2024. The additional screening will increase California PNS Program expenditures for increased cfDNA laboratory costs (to include SCA testing), increased follow-up case management services provided by Case Coordination Centers, and counseling and diagnostic services provided by Prenatal Diagnosis Centers. Planning and implementation activities will include updating forms, screening protocols and health education materials, and updating the Screening Information System to include the additional screening results.

There will be increased expenditures related to higher contract rates for screening, implementation costs associated with the computer system redesign and SIS updates, educational materials and printing, and the ongoing cost of software license and maintenance.

Discretionary?: No

Reason for Adjustment/Change: H&S 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.” In December 2022, ACMG published a “strong” recommendation to offer cfDNA SCA screening for all pregnant patients and CDPH/GDSP is anticipating making prenatal SCA screening available through the PNS Program in 2023-24.

Fiscal Impact (Range) and Fund Source(s): It is estimated that there will be a \$4 million increase in Local Assistance expenditures in 2023-24 (CDPH/GDSP will be absorbing the cost-increase in this partial year), and a \$16 million annual increase in Local Assistance expenditures in 2024-25 and ongoing.

In order to provide sufficient revenues to offset this assumption's additional expenditures, CDPH/GDSP will be implementing a fee increase of \$74 in July 2024.

The overall PNS cfDNA fee increase that CDPH/GDSP will be implementing in July 2024 will total approximately \$112 (from \$232 to \$344). This consists of the \$74 increase in this assumption and a \$38 fee increase due to the Methodology Change in Projecting Prenatal Screening Caseload Existing (Unchanged) Assumption. The fund source is the Genetic Disease Testing Fund (GDTF, Fund 0203).

2023-24 Budget Change Proposal: California Newborn Screening Program Expansion

Background: H&S Code section 125001(d) specifically requires the CDPH NBS Program to continuously expand what is included in the statewide screening of newborns. Diseases that are detectable in blood samples and have been adopted by the federal Recommended Uniform Screening Panel (RUSP) must be included in the screening within two years of adoption. On August 2, 2022, newborn screening (NBS) for mucopolysaccharidosis type II (MPS II) was added to the RUSP. On January 4, 2023, guanidinoacetate methyltransferase (GAMT) deficiency was added to the federal RUSP. The deadline for including MPS II on the California NBS panel is August 2024, and for including GAMT deficiency is January 2025.

MPS II is a genetic condition that can lead to intellectual disabilities and life-threatening cardiac and pulmonary complications due to a metabolic disorder that impairs the processing of complex sugars, causing the molecules to build up in various parts of the body. The condition can be treated by enzyme replacement through periodic intravenous infusions to help prevent storage complications, thereby improving health outcomes.

GAMT deficiency is a genetic condition that can lead to seizures, intellectual disabilities, behavioral manifestations, such as autism and movement disorders. It is possible to improve the health outcomes of this condition by treating with

supplements and dietary restrictions, helping prevent neurological complications.

Description of Change: By August 2024, CDPH will incorporate screening for MPS II and GAMT deficiency into the Newborn Screening panel.

Resources for the additional screening included \$3.5 million and 4 positions in 2023-24, \$3.3 million in 2024-25 and 2025-26, and \$2.7 million in 2026-27 and ongoing in order to cover staffing needs and increased laboratory costs. These resources were approved through a Budget Change Proposal (4265-130-BCP-2023-GB) and were included in the Budget Act of 2023. Of the \$3.5 million, approximately \$700,000 was estimated to cover increased laboratory costs that were associated with consumables, supplies, and reagents. This amount was estimated based on previous disorders added to NBS.

This amount was under-projected as recent price quotes received from vendors to purchase the consumables, supplies, and reagents of the two new disorders is \$4.4 million more than the \$700,000 amount included in the BCP.

Discretionary?: No

Reason for Adjustment/Change: Under-projection of Local Assistance costs in the BCP.

Fiscal Impact (Range) and Fund Source(s): An approximate increase in Local Assistance expenditure authority of \$4.4 million in 2024-25 and ongoing.

The costs to screen for these two additional conditions will be offset with a NBS fee increase starting July 1, 2024, of \$15. The fund source is the GDTF (Fund 0203).

DISCONTINUED ASSUMPTIONS/PREMISES

There are no Discontinued Assumptions/Premises.

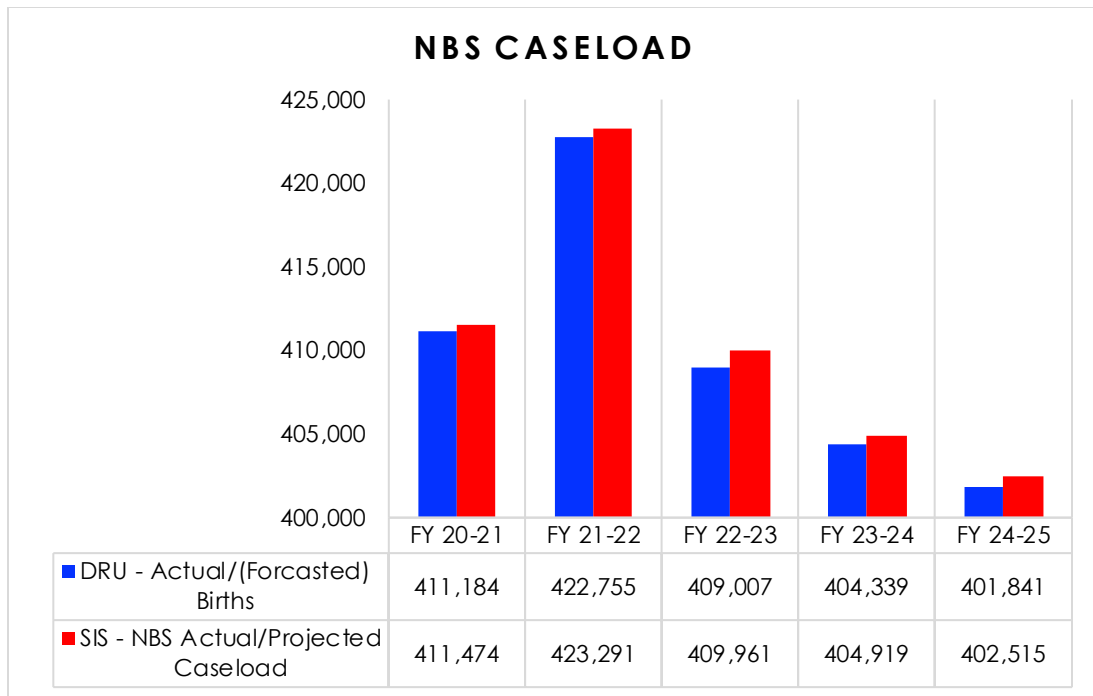
APPENDIX A: NEWBORN SCREENING PROGRAM (NBS) ASSUMPTIONS AND RATIONALE

CONTRACT LABORATORIES

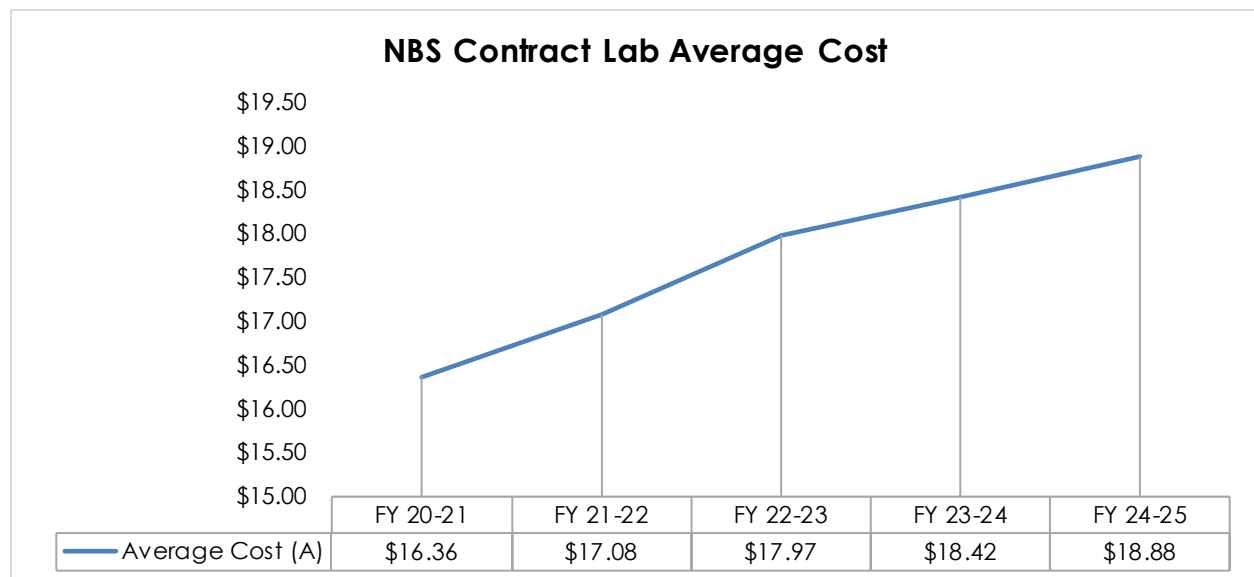
Overview: Laboratory testing of specimens is performed at regional screening laboratories contracted by the state to screen newborns for 80+ specific genetic disorders. Costs include laboratory services for processing genetic screening tests. Screening laboratories ascertain the possible presence of 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 2022-23 and 2023-24.

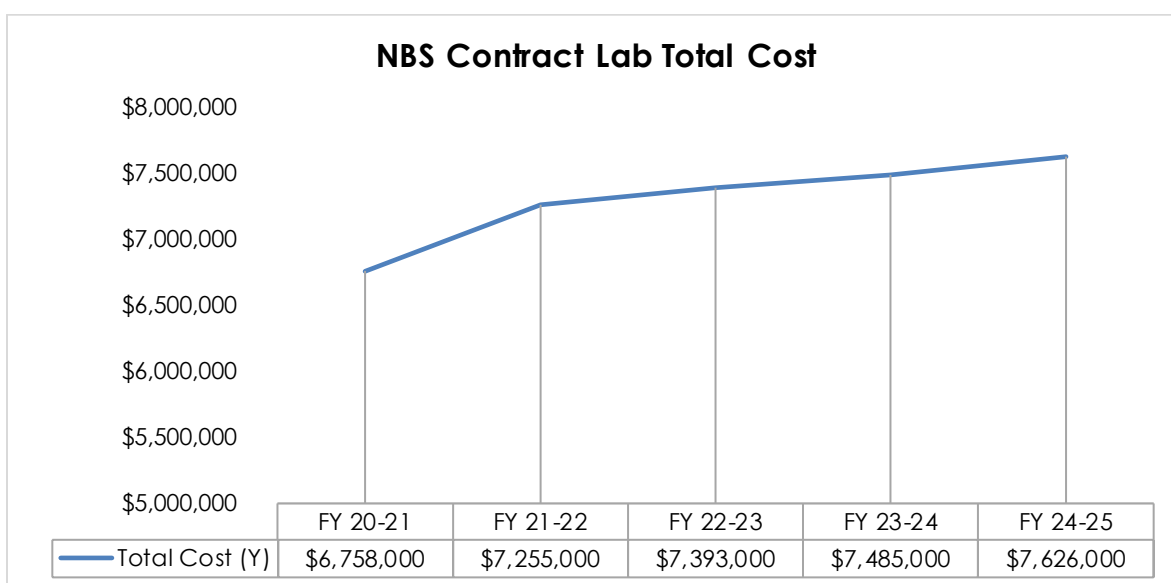
Total Caseload – The CDPH/GDSP estimates current-year caseload will total 404,919, a decrease of 5,042 or 1.2 percent compared to the 2022-23 actual total caseload of 409,961. The caseload in 2024-25 is estimated at 402,515, which is also a decrease of 2,404 or 0.6 percent compared to the current year estimate. This annual change is due to the change in DOF/DRU's projection 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.



Contract Laboratory Average Cost Projections – The CDPH/GDSP estimates current year average laboratory cost per participant will be \$18.42, which is an increase of \$0.45 or 2.5 percent compared to the 2022-23 actual average laboratory cost per participant of \$17.97. Average laboratory cost per participant in 2024-25 is estimated at \$18.88, which is an increase of \$0.46 or 2.5 percent compared to the current year estimate. The increase in average cost is due to the contract rate increases coupled with a decline in projected live births.



Contract Laboratory Total Cost Projections – The CDPH/GDSP estimates current year contract laboratory costs to total \$7.5 million, which is an increase of \$92,000 or 1.2 percent compared to 2022-23 actual contract laboratory costs of \$7.4 million. The contract laboratory costs in 2024-25 are projected to be \$7.6 million, which is an increase of \$141,000 or 1.9 percent compared to the current year.



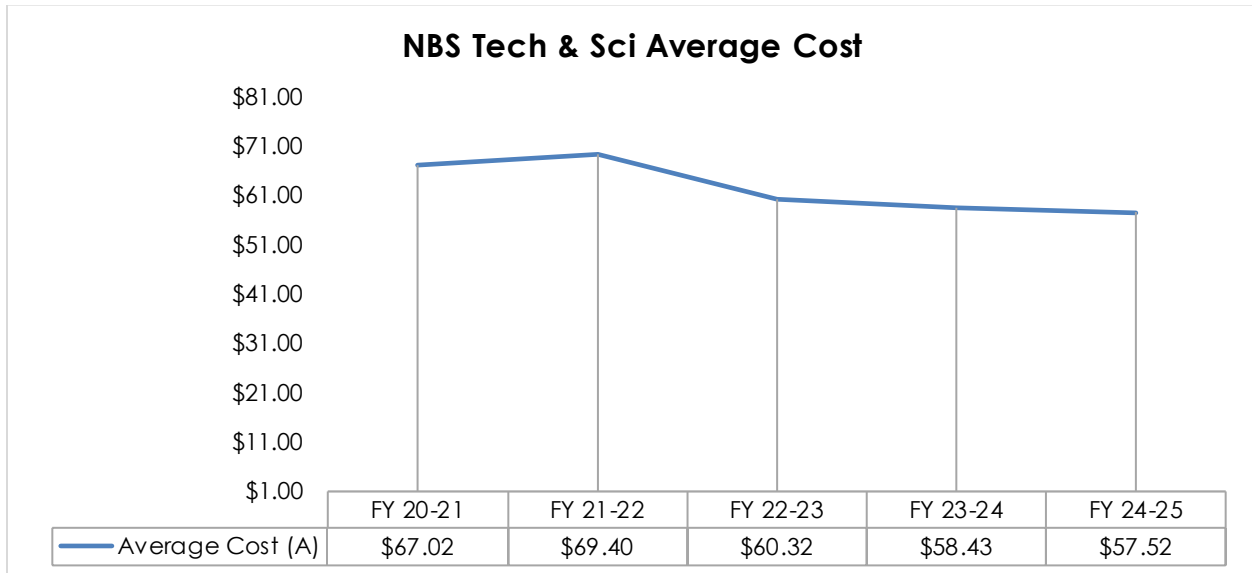
TECHNICAL AND SCIENTIFIC

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 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.

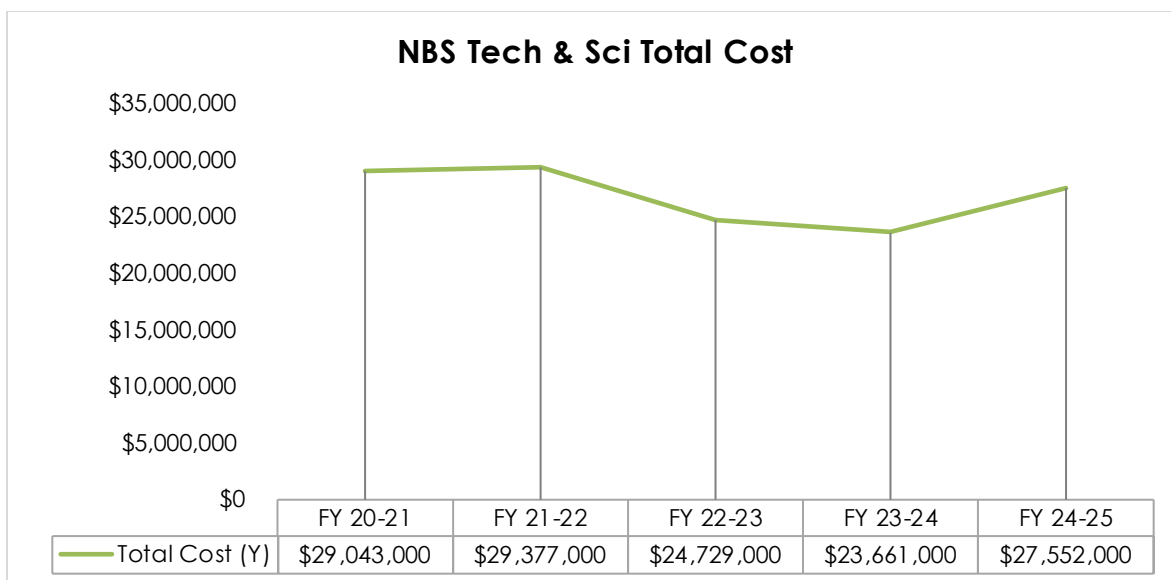
Technical and Scientific Caseload: See Appendix A 1

Technical and Scientific Average Cost – The CDPH/GDSP estimates current year average Technical and Scientific cost per participant will be \$58.43, which is a decrease of \$1.89 or 3 percent compared to 2022-23 actual average Technical and Scientific cost per participant of \$60.32. Average Technical and Scientific cost per participant in 2024-25 is estimated at \$57.52, which is a slight decrease of \$0.91 or 2 percent compared to the current year estimate. The slight

decrease in average cost is due to projected caseload decreases and its associated direct costs. Because technical and scientific costs are directly related to the number of specimen screenings conducted, the overall costs of reagent test kits, laboratory equipment and supplies, which are purchased in bulk, are reduced based on the anticipated caseload volume.



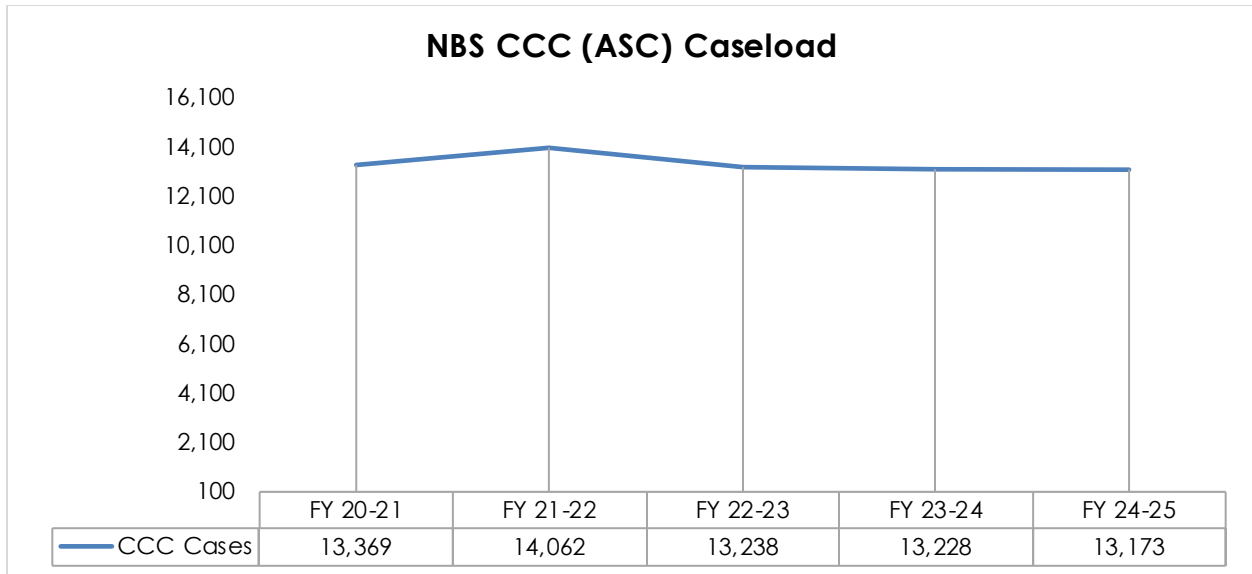
Technical and Scientific Total Cost – The CDPH/GDSP estimates current year Technical and Scientific costs to total \$23.7 million, which is a decrease of \$1.1 million or 4 percent compared to 2022-23 actual technical and scientific costs of \$24.7 million. For 2024-25, Technical and Scientific costs are estimated to be \$27.6 million, which is an increase of \$3.9 million or 16 percent compared to the current year due to the addition of MPS II and GAMT deficiency.



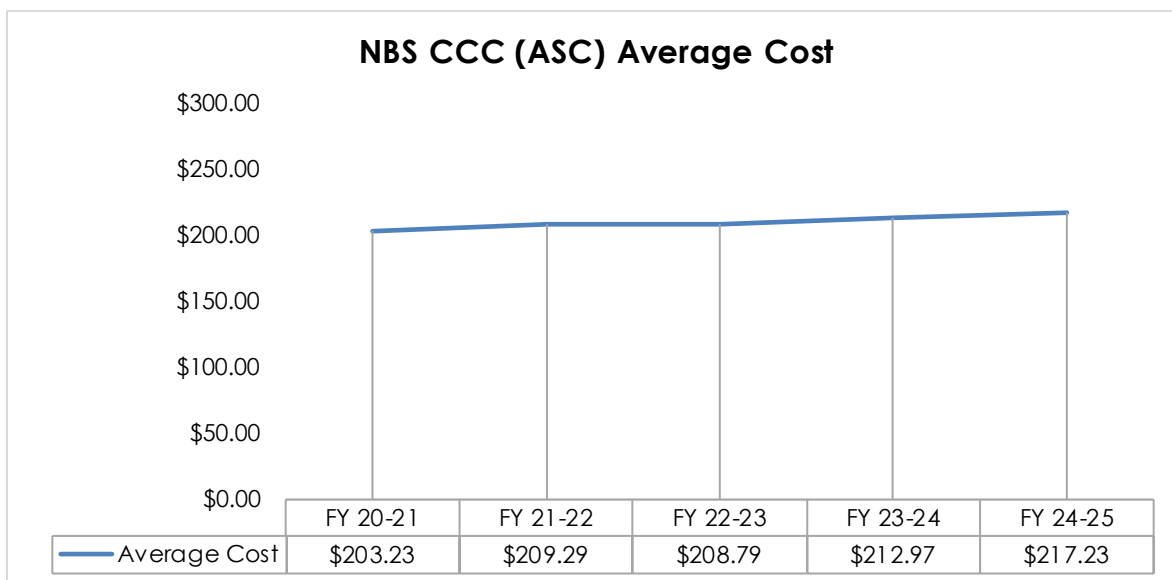
CASE MANAGEMENT AND COORDINATION SERVICES:

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 confirm that 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- The CDPH/GDSP estimates current year CMCS caseload will total 13,228, which is a slight decrease of 10 or 0.08 percent compared to 2022-23 actual CMCS caseload of 13,238. CMCS caseload in 2024-25 is estimated at 13,173, which is a slight decrease of 55 or 0.41 percent compared to the current year estimate.

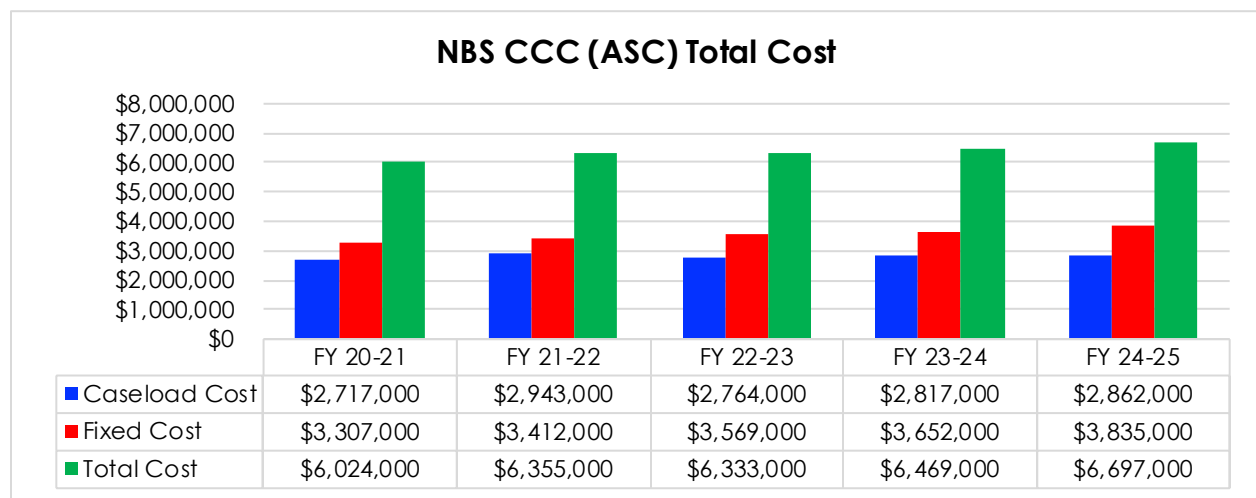


Case Management and Coordination Services (CMCS) Average Cost - CDPH/GDSP estimates current year average CMCS cost per participant will be \$212.97, which is an increase of \$4.18 or 2 percent compared to 2022-23 actual average CMCS cost per participant of \$208.79. Average CMCS cost per participant in 2024-25 is estimated at \$217.23, which is an increase of \$4.26 or 2 percent compared to the current year estimate. The increase in the average cost is tied directly to the fluctuations in caseloads and contract rate increases to the follow-up centers for the two new disorders and ongoing newborn testing.



Case Management and Coordination Services (CMCS) Total Cost – The CDPH/GDSP estimates current year CMCS costs to total \$6.5 million, which is a

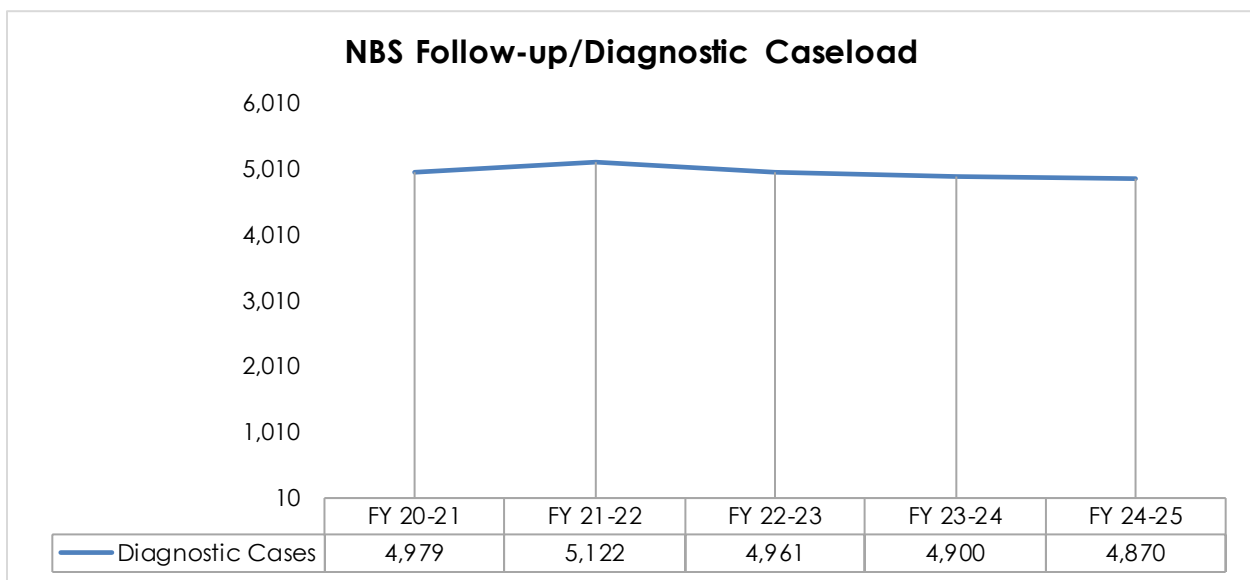
slight increase of \$136,000 or 2 percent compared to 2022-23 actual CMCS total costs of \$6.3 million. CMCS costs in 2024-25 are estimated to total \$6.7 million, which is an increase of \$228,000 or 4 percent compared to the current year estimate. The increase in current and budget year reflects the projected increases in data correction on newborn records, and an increase in ongoing expenditures in 2024-25 from the projected number of positive cases attributed to the ongoing newborn screening and the addition of the two new disorders (MPS II and GAMT deficiency). Moreover, the GDSP considered a combination of increased fixed costs, and incremental (per case) reimbursement, which includes administrative costs, rent, equipment, travel, and administrative staff.



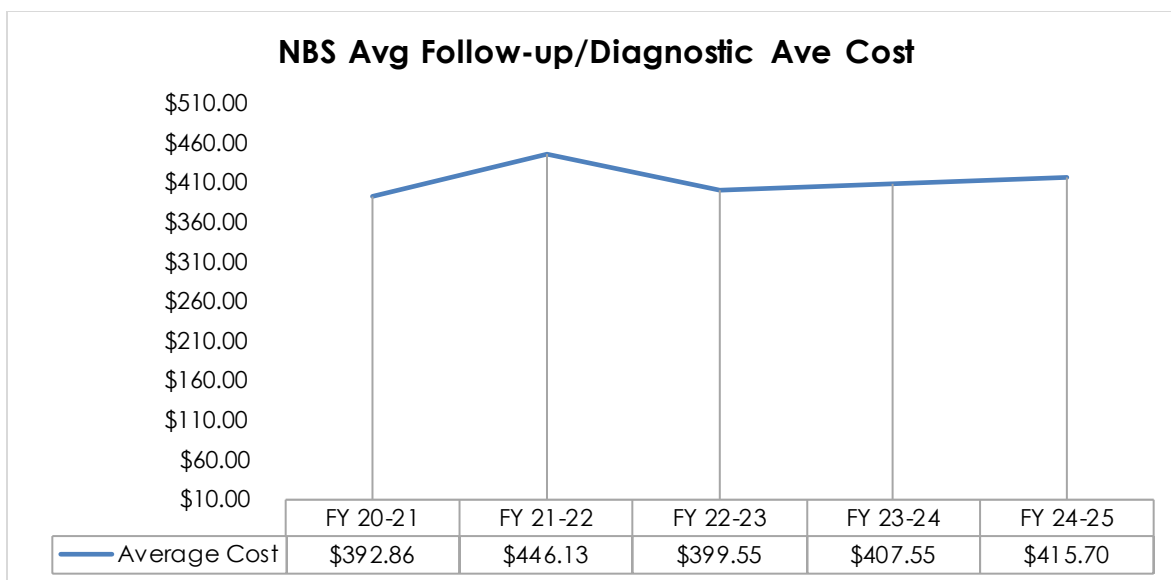
DIAGNOSTIC SERVICES

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.

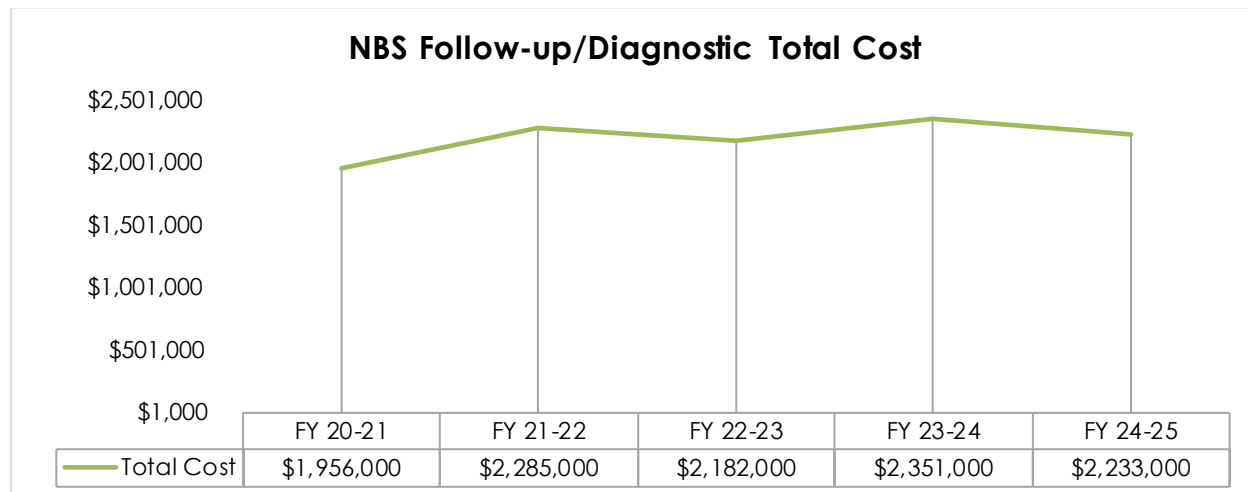
Diagnostic Services Caseload – The CDPH/GDSP estimates current year Diagnostic caseload will total 4,900, based on projected new referral cases and annual patient summary cases, which is a decrease of 61 or 1 percent compared to 2022-23 actual Diagnostic Services caseload of 4,961. Diagnostic caseload in 2024-25 is estimated at 4,870, which is a decrease of 30 or 1 percent compared to the current year estimate. The fluctuations are tied to overall DRU-based caseloads and implementation of new disorders. In addition, the GDSP 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 – The CDPH/GDSP estimates current year average Diagnostic Services cost per participant will be \$408, calculated based on projected new referral cases and annual patient summary cases, which is a slight increase of \$8 or 2 percent compared to 2022-23 actual average Diagnostic Services cost per participant of \$400. The average Diagnostic Services cost per participant in 2024-25 is estimated at \$416, which is also a slight increase of \$8 or 2 percent compared to the current year estimate. The slight increase in the current year is tied to the increasing caseload costs while projected live births decline. The increase in the budget year can be attributed to the addition of the two new disorders (MPS II and GAMT deficiency).



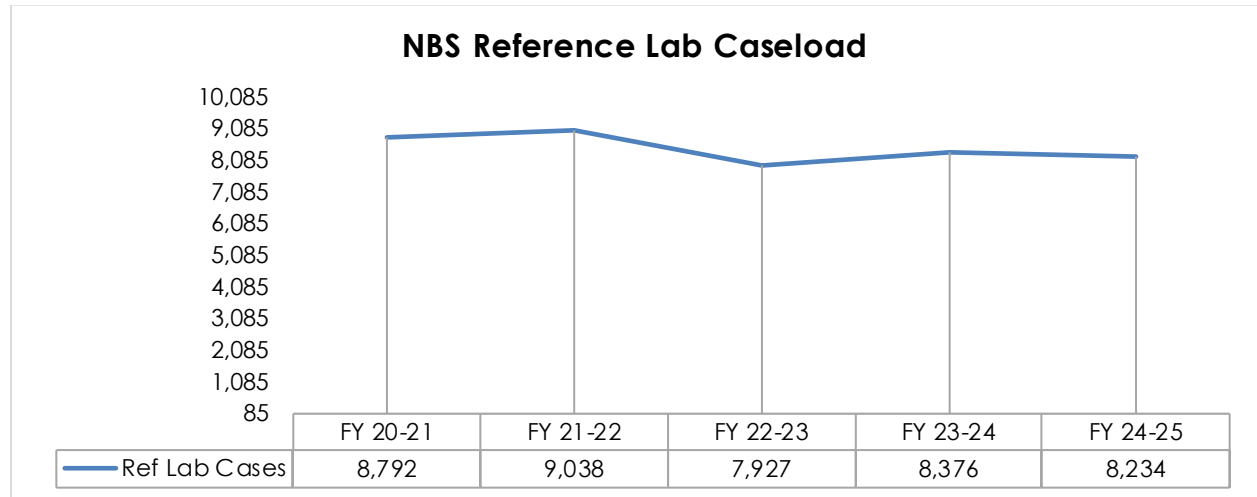
Diagnostic Services Total Cost – CDPH/GDSP estimates current year Diagnostic Services costs to total \$2.4 million, which is an increase of \$169,000 or 8 percent compared to 2022-23 actual Diagnostic Services total costs of \$2.2 million. Diagnostic Services costs in 2024-25 are estimated to total \$2.2 million, which is a decrease of \$118,000 or 5 percent compared to the current year estimate.



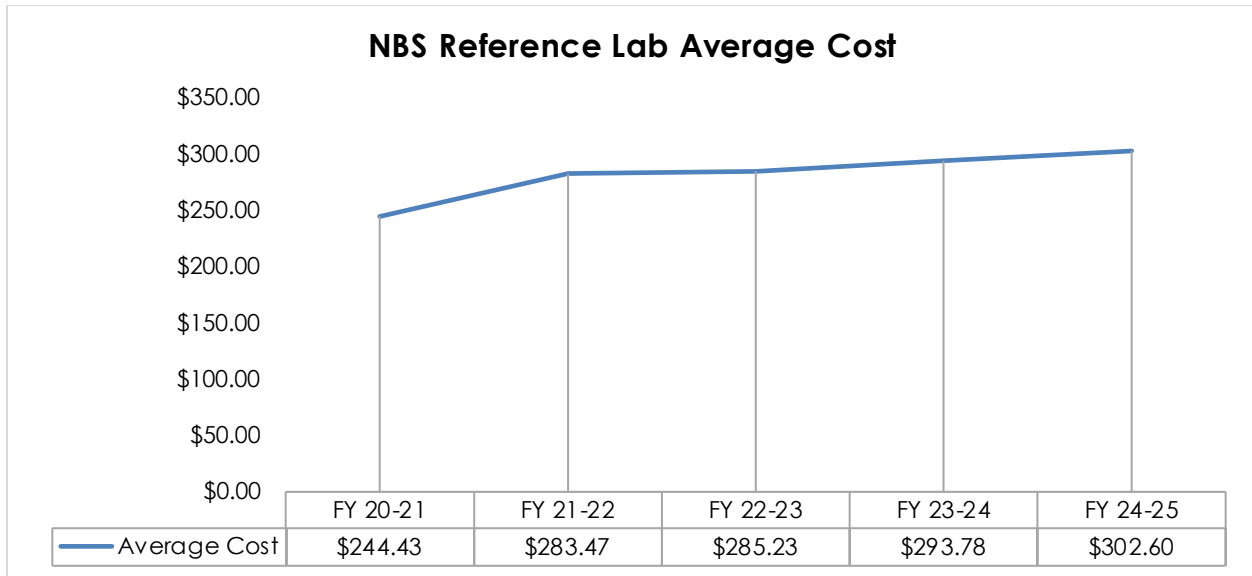
REFERENCE LABORATORIES

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.

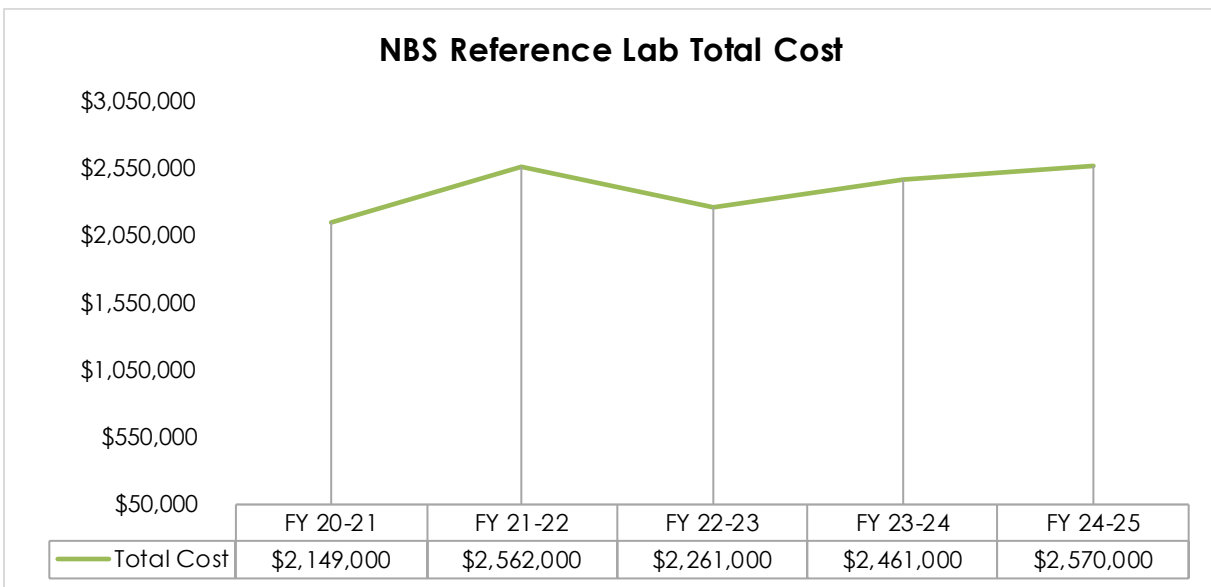
Reference Laboratory Caseload – CDPH/GDSP estimates current year Reference Laboratory caseload will total 8,376, which is an increase of 449 or 6 percent compared to 2022-23 actual Reference Laboratory caseload of 7,927. Reference Laboratory caseload in 2024-25 is estimated at 8,234, which is a decrease of 142 or 2 percent compared to the current year estimate.



Reference Laboratory Average Cost – The CDPH/GDSP estimates current year Reference Laboratory average cost per participant will be \$294, which is an increase of \$9 or 3 percent compared to 2022-23 Reference Laboratory actual average cost per participant of \$285. Reference Laboratory average cost per participant in 2024-25 is estimated at \$303, which is an increase of \$9 or 3 percent compared to the current year estimate. The fluctuation in caseload is due to the updated DRU projection of live births, and the addition of new disorders 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 200,000 or 9 percent compared to 2022-23 actual Diagnostic Services total costs of \$2.3 million. Reference Laboratory costs in 2024-25 are estimated to total \$2.6 million, which is an increase of 109,000 or 4 percent compared to the current year estimate. The cost increases from the current year to the budget year can be attributed to the fluctuations in caseloads as well as the addition of the two new disorders.



APPENDIX B: PRENATAL SCREENING PROGRAM (PNS) ASSUMPTIONS AND RATIONALE

CELL-FREE DNA (cfDNA)

Overview – “Cell-free DNA” (cfDNA) screening is a new screening methodology that involves the extraction of maternal and fetal cells from a pregnant woman’s blood sample. This new method is more efficient in terms of false positive and detection rates resulting in fewer individuals being referred for diagnostic follow-up services.

On September 19, 2022, the California Prenatal Screening Program replaced GDSP’s conventional biochemical screening with cell-free DNA (cfDNA) screening for chromosome abnormalities and a simpler biochemical screening for neural tube defects (NTD). GDSP’s screening for neural tube defects remains part of the overall screening process. The PNS Program has established contracts for new laboratories to carry out cfDNA screening; developed new structures for case management services provided by Case Coordination Centers and follow-up services provided by the Prenatal Diagnosis Centers (PDCs); and redesigned the SIS to accommodate the new screening results transmitted from the cfDNA laboratories, including redesigned test result mailers, established 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.

On December 16, 2022, the American College of Medical Genetics and Genomics (ACMG) released an updated practice guideline that recommends offering noninvasive prenatal screening (NIPS, also known as cfDNA screening) to include screening for sex chromosome aneuploidies (SCAs) in addition to trisomies 21, 18, and 13, as well as for all single and twin pregnancies. Beginning April 1, 2024, the California PNS Program is preparing for the addition of prenatal screening for SCAs using cfDNA screening. The additional screening will increase California PNS Program expenditures for increased cfDNA laboratory costs (to include SCA testing), increased follow-up case management services provided by Case Coordination Centers, and counseling and diagnostic services provided by Prenatal Diagnosis Centers. Planning and implementation activities will include updating forms, screening protocols and health education materials, and updating the Screening Information System to include the additional screening results.

Total Caseload/Specimens – The CDPH/GDSP estimates current year projected caseload for cfDNA at 216,941, which is an increase of 26,132 or 14 percent compared to the 2022-23 actual caseload of 190,809. The increase is attributed to the full-year implementation of cfDNA screening. The CDPH/GDSP estimates that the cfDNA caseload in the budget year will total 215,601, which is a decrease of 1,340 or 0.6 percent compared to the current year.

Table 1 shows the projected cfDNA cases by billable caseload, average cost, and total cost for budget year 2024-25.

TABLE 1

FY 2023-24	Forecasted Births	PNS Projected Caseload	Average Cost	Total Cost
cfDNA	404,339	216,941	\$140	\$30,371,740
FY 2024-25	Forecasted Births	PNS Projected Caseload	Average Cost	Total Cost
cfDNA + SCA	401,841	215,601	\$190	\$40,964,000

CONTRACT LABORATORIES

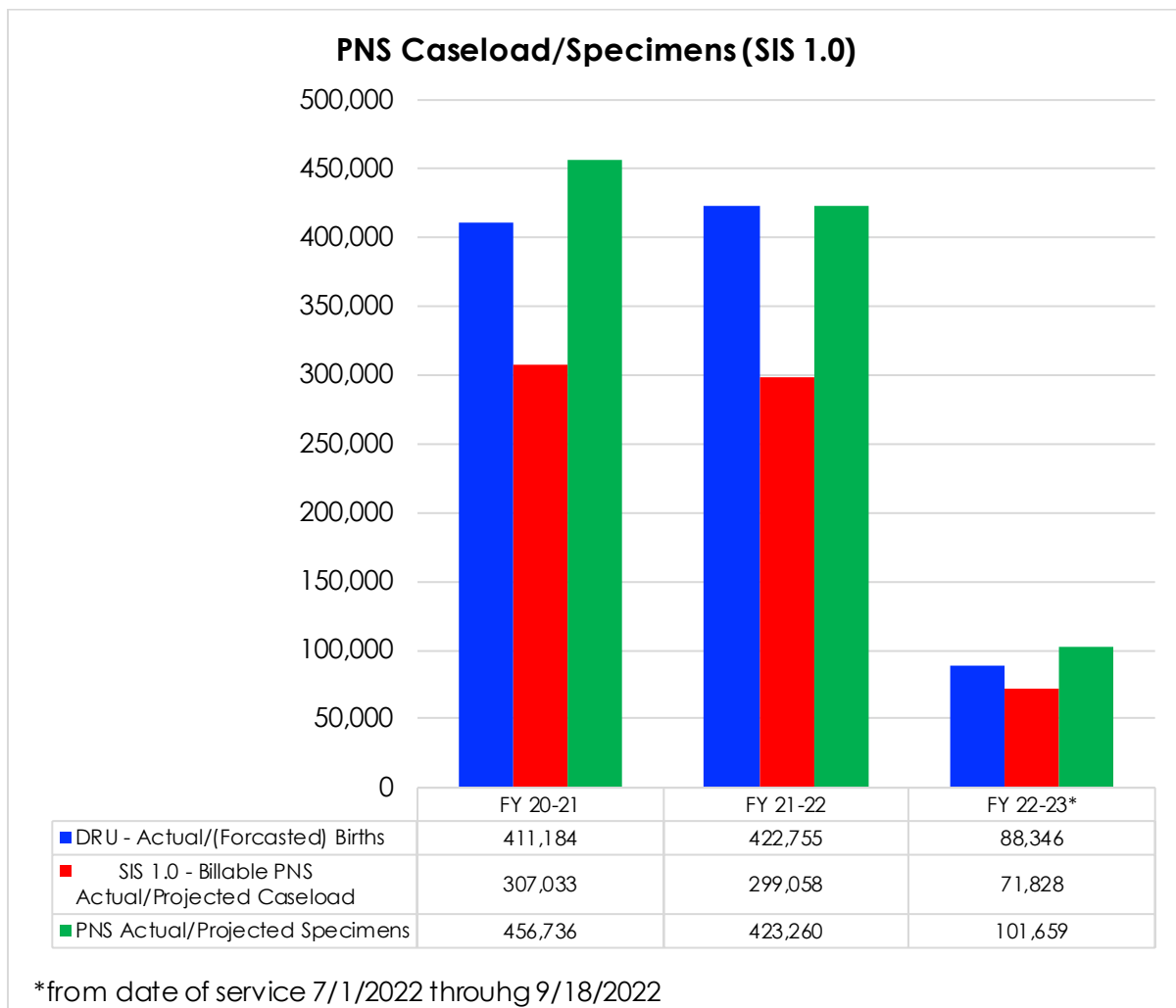
Overview – Laboratory testing to screen pregnant individuals for genetic and congenital disorders, such as trisomy 21, trisomy 18, Smith-Lemli-Opitz Syndrome (SLOS), and Neural Tube Defects. Costs include laboratory services for performing prenatal genetic screening tests. The screening test estimates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

The California Department of Public Health (CDPH) Genetic Disease Screening Program (GDSP) launched a redesigned Prenatal Screening (PNS) Program on September 19, 2022. This replaced the GDSP's conventional biochemical screening with cell-free DNA (cfDNA) screening for chromosome abnormalities and a simpler biochemical screening for neural tube defects (NTD). GDSP's screening for neural tube defects remained part of the overall screening process. Since the go live of cfDNA screening, two specimens need to be collected in the 2nd trimester with one for cfDNA screening at a cfDNA laboratory and the other one for NTD screening at a Newborn and Prenatal Screening (NAPs) laboratory.

Total Caseload/Specimens – In the beginning of 2022-23, between July 1 and September 18, 2022, one specimen collected in the 2nd trimester was used for both Trisomy 21 (T21)/ Trisomy (T18) screening and NTD screening because the serum analyte testing for both screenings was done in one NAPs laboratory processing.

The actual specimens from the old PNS Biochemical Screening test (SIS 1.0) are 101,659. The caseload in the old PNS Program is low because it is only for 2.5 months (date of service from July 1, 2022, through September 18, 2022), and cases were completed in December 2022 to allow time for individuals to take their 2nd trimester test that could be referred for follow up services, up to 24 weeks of gestational age (GA).

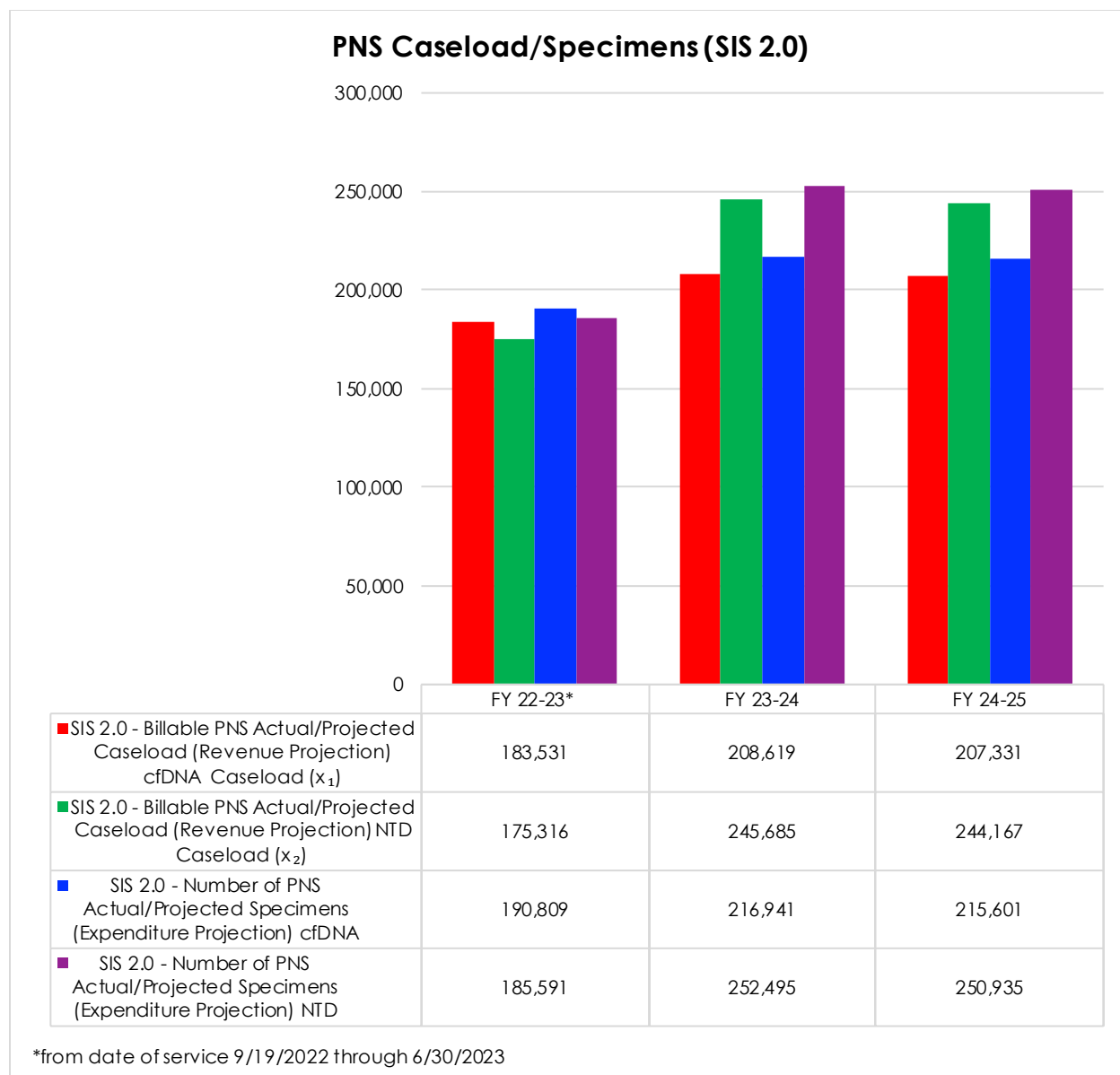
The chart below shows the actual old PNS Biochemical Screening by year, along with actual numbers from the prior year and the current year.



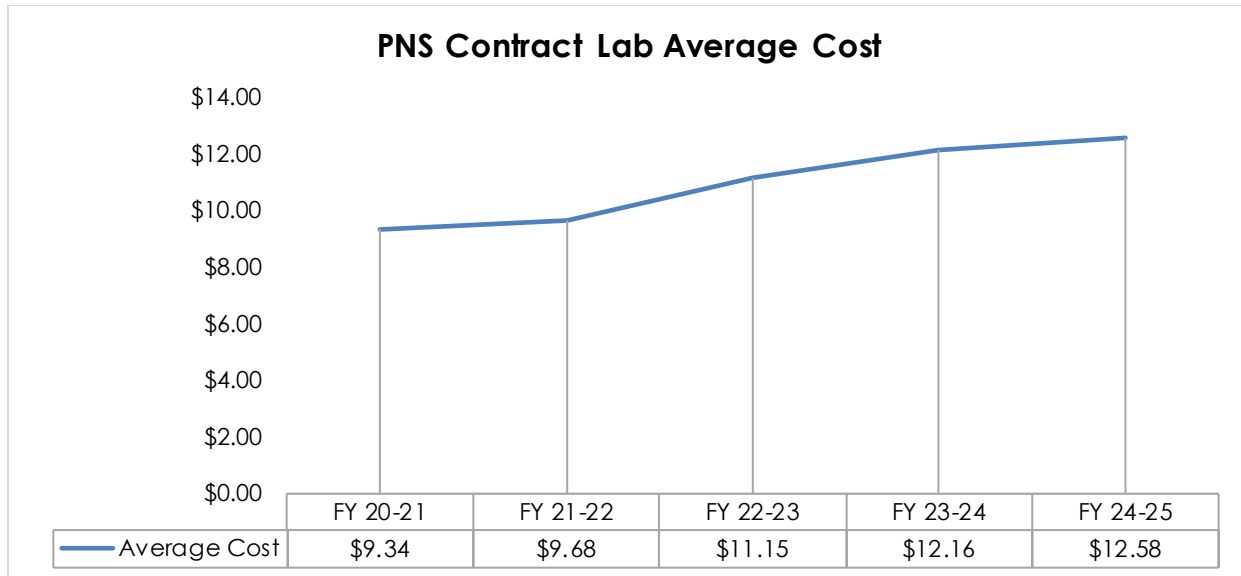
For the remainder of 2022-23 (between September 19, 2022 and June 30, 2023), two specimens were collected - one for cfDNA and the other for NTD screening. The new PNS Program specimen is estimated based on the percentage of the DOF/DRU projected number of live births, including no call low fetal fraction, and actual specimen for the date of service from September 19, 2022, through January 31, 2023. The CDPH/GDSP estimates current year specimens from the new PNS Program (SIS 2.0) will total 252,495 for NTD, which is an increase of 66,904 or 36 percent compared to 2022-23 actual NTD caseload of 185,591. The increase in the current year is due to the full-year implementation of NTD screening.

The CDPH/GDSP estimates that the budget year caseloads for NTD will total 250,935, which is a decrease of 1,560 or 0.62 percent compared to the current year. The fluctuation in the caseload is tied to the DRU's projected live births as well as the impact of exclusivity loss.

The chart below shows the actual/projected PNS cases for both cfDNA and NTD by the remainder of the current year, and the budget year.



Contract Laboratory Average Cost Projections – CDPH/GDSP estimates current year average laboratory cost per participant will be \$12.16, which is a slight increase of \$1 or 9 percent compared to 2022-23 actual average laboratory cost per participant of \$11.15. The net increase in the current year is due to an increase in contract costs and a slight decrease in projected caseload. The contract regional NAPS lab only screens pregnant individuals for neural tube defects (NTD) beginning September 19, 2022. The CDPH/GDSP estimates budget year average laboratory cost per participant will be \$12.58, which is a slight increase of 0.42 or 3 percent compared to the current year.



Contract Laboratory Total Cost Projections – The CDPH/GDSP estimates current year contract laboratory cost to total \$3.1 million, which is a decrease of \$137,000 or 4 percent compared to 2022-23 actual contract laboratory costs of \$3.2 million. The CDPH/GDSP estimates budget year contract laboratory cost to total \$3.2 million, which is an increase of \$86,000 or 3 percent compared to the current year. The fluctuation in the current and budget year is tied to the DRU's projected live births as well as the impact of exclusivity loss.

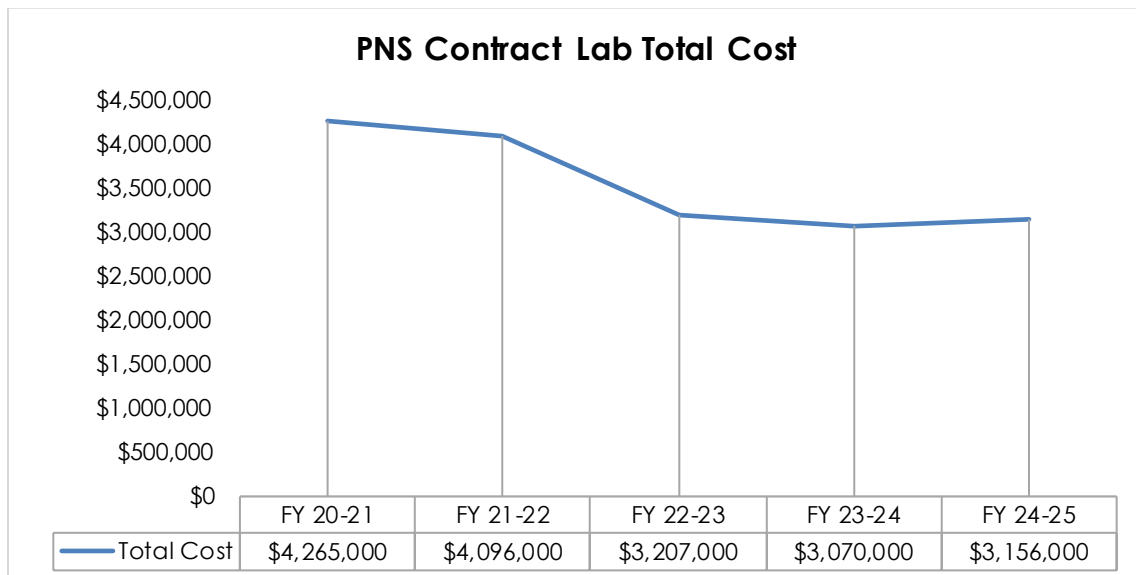


Table 2 shows the projected cases, average cost, and total cost for the cases of the neural tubes defects (NTD) test only in 2023-24 and 2024-25.

TABLE 2

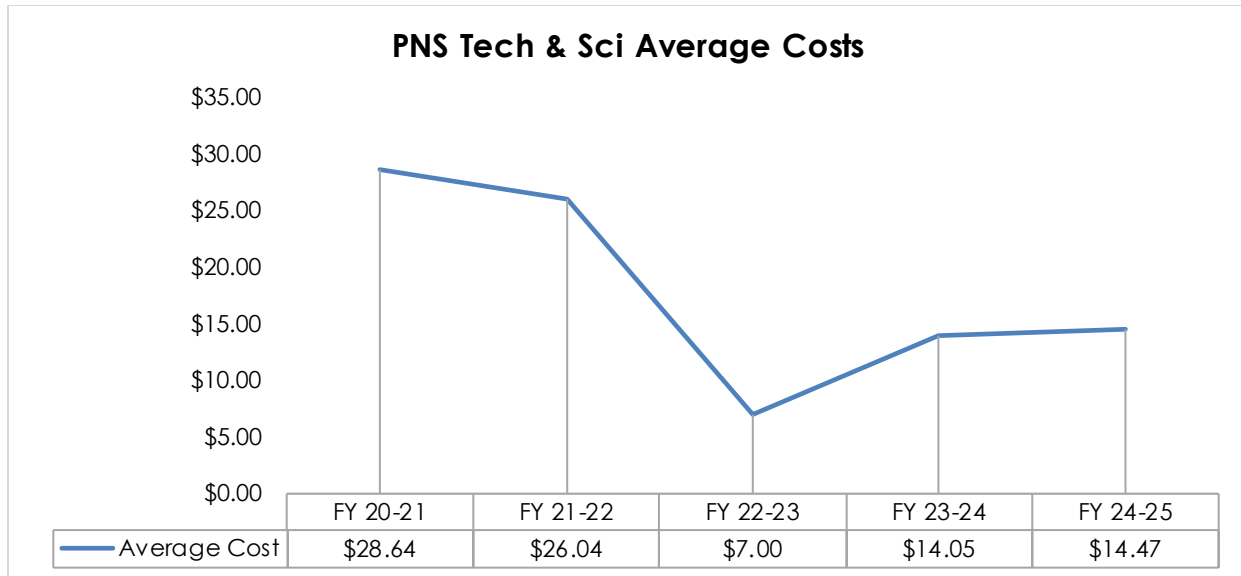
FY 2023-24	PNS Projected Caseload	Average Cost	Total Cost
NTD	252,495	\$12.16	\$3,070,000
FY 2024-25	PNS Projected Caseload	Average Cost	Total Cost
NTD	250,935	\$12.58	\$3,156,000

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 most 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 – The CDPH/GDSP estimates current year average Technical and Scientific cost per participant will be \$14.05, which is an increase of \$7.05 or 101 percent compared to 2022-23 actual average Technical and Scientific cost per specimen of \$7. The increase in the current year is attributed to inflationary contract rate increases. CDPH/GDSP estimates budget year average Technical and Scientific cost per participant will be \$14.47, which is also an increase of \$0.42 or 3 percent compared to the current year.



Technical and Scientific Total Cost – The CDPH/GDSP estimates current year Technical and Scientific costs to total \$3.5 million, which is an increase of \$2.2 million or 173 percent compared to 2022-23 actual technical and scientific costs of \$1.3 million. The increase in the current year is due to the new procurements incurred for the laboratory quality improvements. The CDPH/GDSP estimates budget year Technical and Scientific costs to total \$3.6 million, which is a slight increase of \$84,000 or 2.4 percent compared to the current year. The fluctuation in total cost is tied to the projected specimens and costs of reagents, supplies, and consumables.

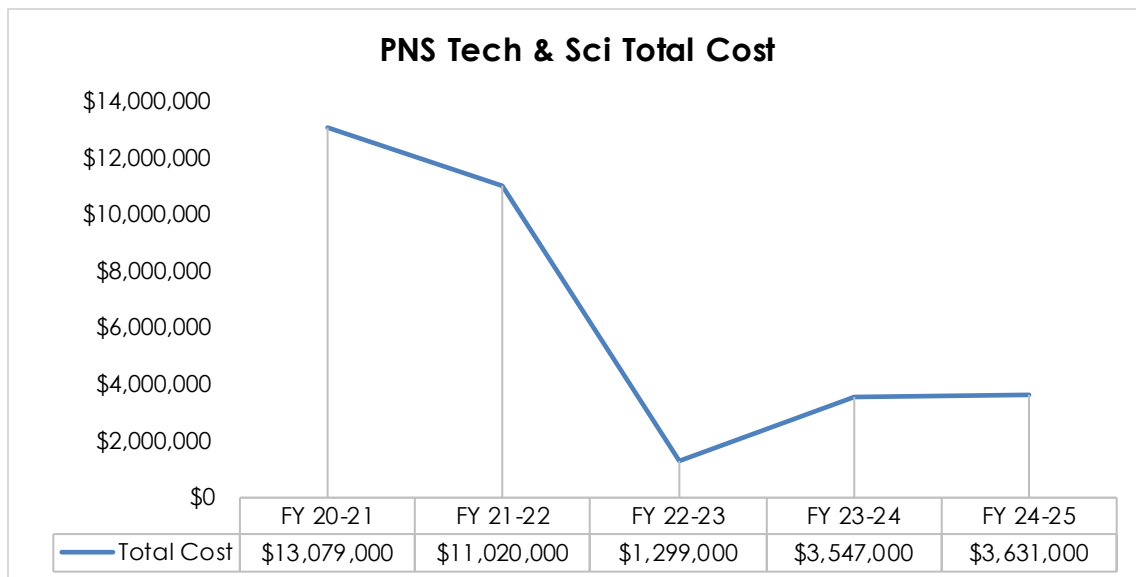


Table 3 shows the projected cases, average cost and total cost associated with technical and scientific cost for the neural tubes defects (NTD) test only in 2023-24 and 2024-25.

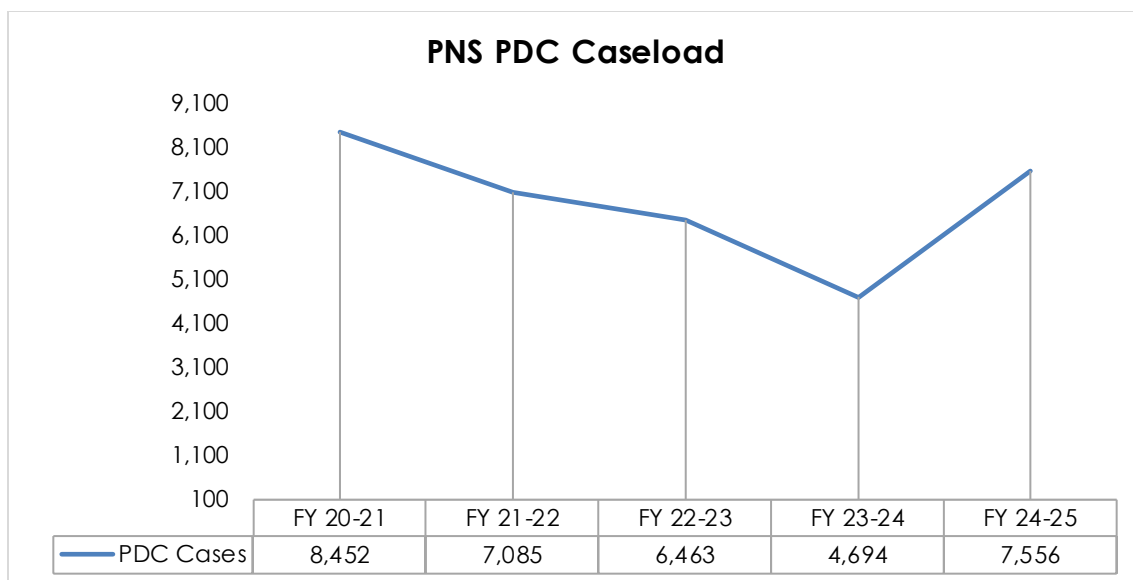
TABLE 3

FY 2023-24	Total NTD	Average Cost	Total Cost
Tech & Sci	252,495	\$14.05	\$3,547,000
FY 2024-25	Total NTD	Average Cost	Total Cost
Tech & Sci	250,935	\$14.47	\$3,631,000

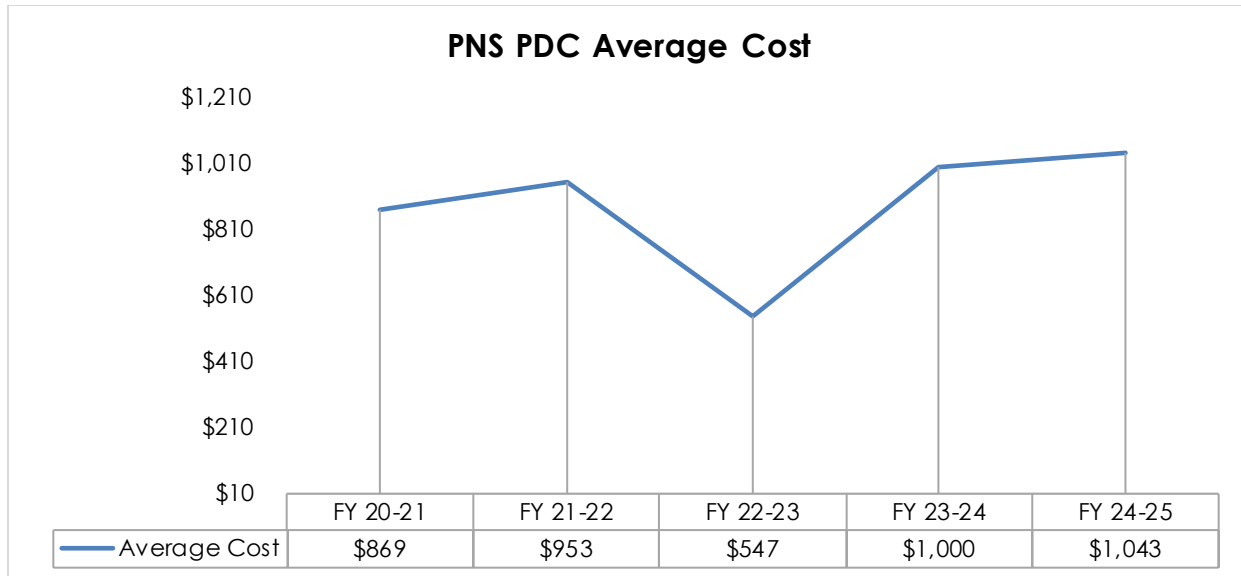
PRENATAL DIAGNOSTIC SERVICES CENTERS

Overview – Pregnant individuals 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.

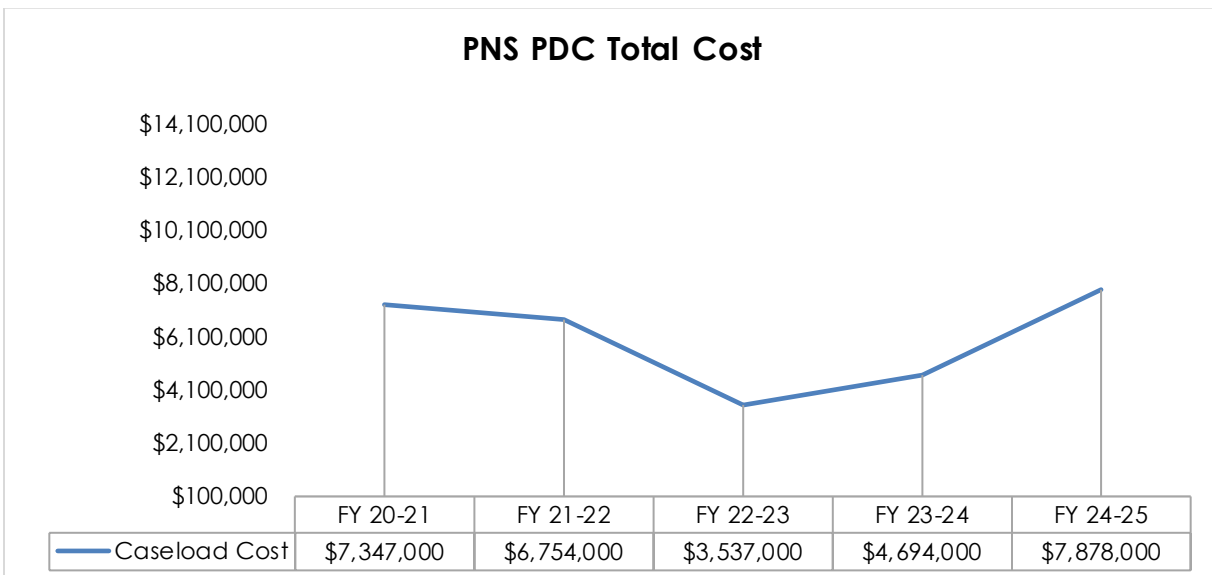
Prenatal Diagnostic Services Centers (PDC) Caseload – On September 19, 2022, cfDNA screened positive tests and with no result; and NTD screened positive tests will be referred for additional services which include confirmatory and diagnostic testing. The CDPH/GDSP estimates current year PDC caseload will total 4,694, which is a decrease of 1,769 or 27 percent compared to the 2022-23 actual PDC caseload of 6,463. The caseload decrease in the current year is due to the loss of screening exclusivity. The CDPH/GDSP estimates budget year PDC caseload will total 7,556, which is an increase of 2,862 or 61 percent compared to the current year. The increase in caseload is due to the addition of SCAs beginning April 1, 2024, in the Prenatal Screening Panel.



Prenatal Diagnostic Services Average Cost – On September 19, 2022, cfDNA tests screened positive and with no results; and NTD tests screened positive will have a separate cost analysis on diagnostic services. The CDPH/GDSP estimates current year average PDC cost per participant will be \$1,000, which is an increase of \$453 or 83 percent compared to 2022-23 actual average PDC cost per participant of \$547. The CDPH/GDSP estimates budget year average PDC cost per participant will be \$1,043, which is an increase of \$43 or 4 percent compared to the current year. The average cost increase in the current year can be attributed to the projected caseload decrease while contract costs increase due to the addition of SCAs on April 1, 2024. Additionally, increased contract costs occurred because 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 pregnant individuals in lieu of more invasive and costly procedures such as amniocentesis. Pregnant individuals who would have previously declined prenatal diagnostic services are now choosing these non-invasive procedures. The increase in average cost in the budget year can be attributed to the increasing projected caseload as a result of adding SCA into the Prenatal Screening panel and the declining birth rates.



Prenatal Diagnostic Services Total Cost – The CDPH/GDSP estimates current year PDC costs total \$4.7 million, which is an increase of \$1.2 million or 33 percent compared to 2022-23 actual PDC total costs of \$3.5 million. The CDPH/GDSP estimates budget year PDC costs to total \$7.9 million, which is an increase of \$3.2 million or 68 percent compared to the current year. The change in total expenditures is attributable mainly to fluctuations in projected PDC caseload and the addition of SCAs on April 1, 2024.

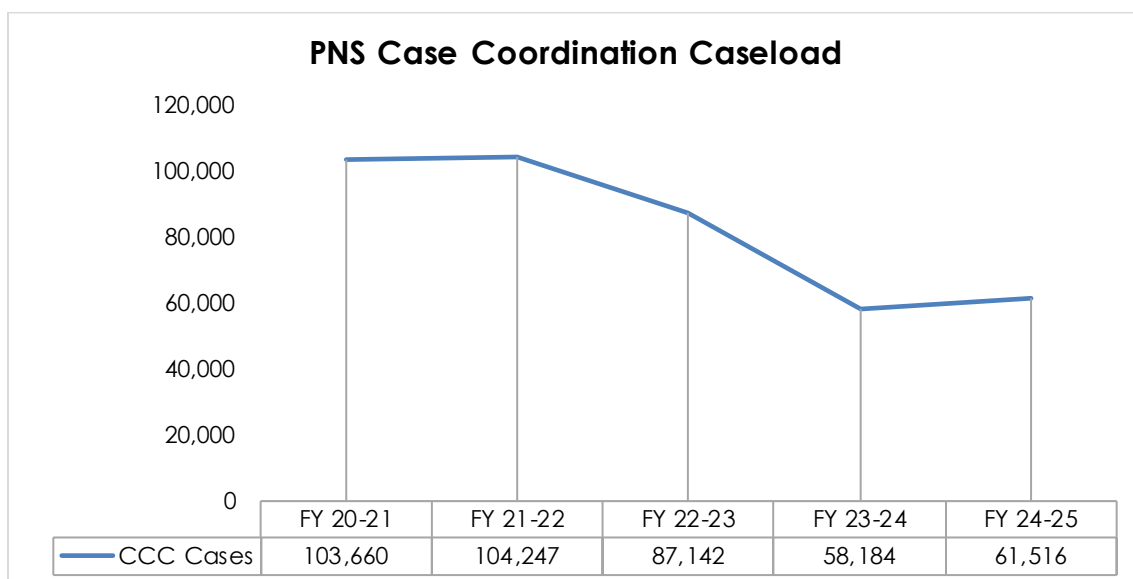


CASE MANAGEMENT AND COORDINATION SERVICES

Overview – Services provided to pregnant individuals who screen positive or have questionable results include coordination of first and second trimester

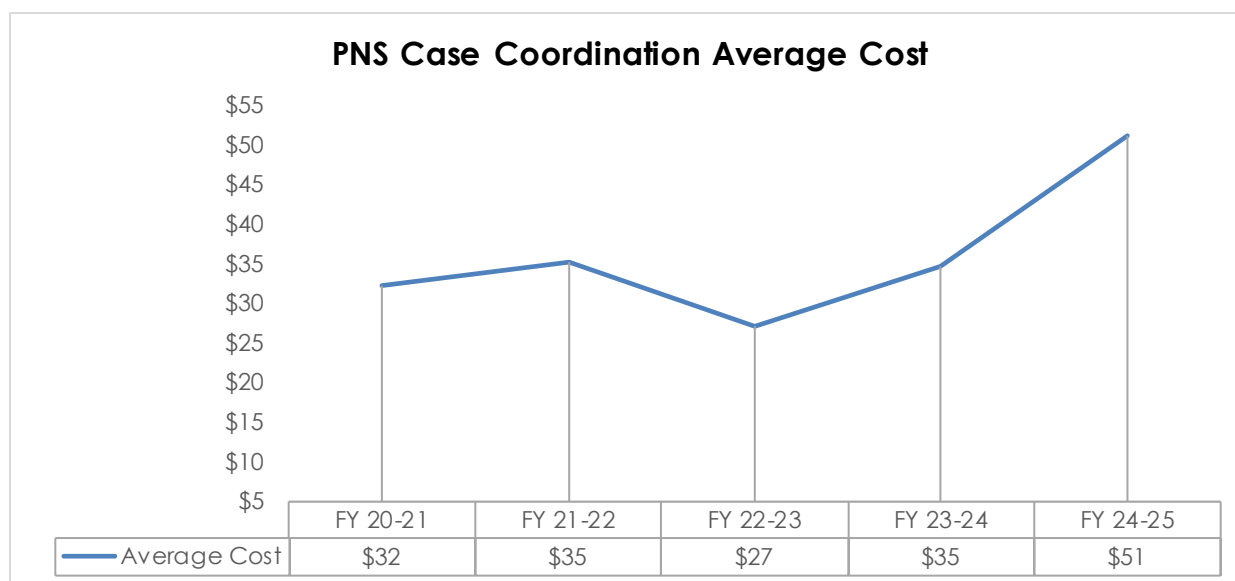
screens and ultrasounds, identifying patients whose blood specimens were drawn too early or were inadequate, requiring additional blood draws. The PNS Case Coordination Centers (CCCs) provide clinician and patient education and consultations; make referrals to Prenatal Diagnostic Centers for diagnostic and confirmatory tests, and genetic counseling; and track patients to verify that 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 depending upon the geographic location.

Case Management and Coordination Services (CMCS) Caseload – The cfDNA and NTD screened positive cases will be referred to a case coordinator for which separate services will be performed. The CDPH/GDSP estimates current year CMCS caseload will total 58,184, which is a decrease of 28,958 or 33 percent compared to 2022-23 actual CMCS caseload of 87,142. The CDPH/GDSP estimates budget year CMCS caseload to total 61,516, which is an increase of 3,332 or 6 percent compared to the current year. The caseload fluctuations are attributed to the changes in the projected live births and the addition of SCAs on April 1, 2024.

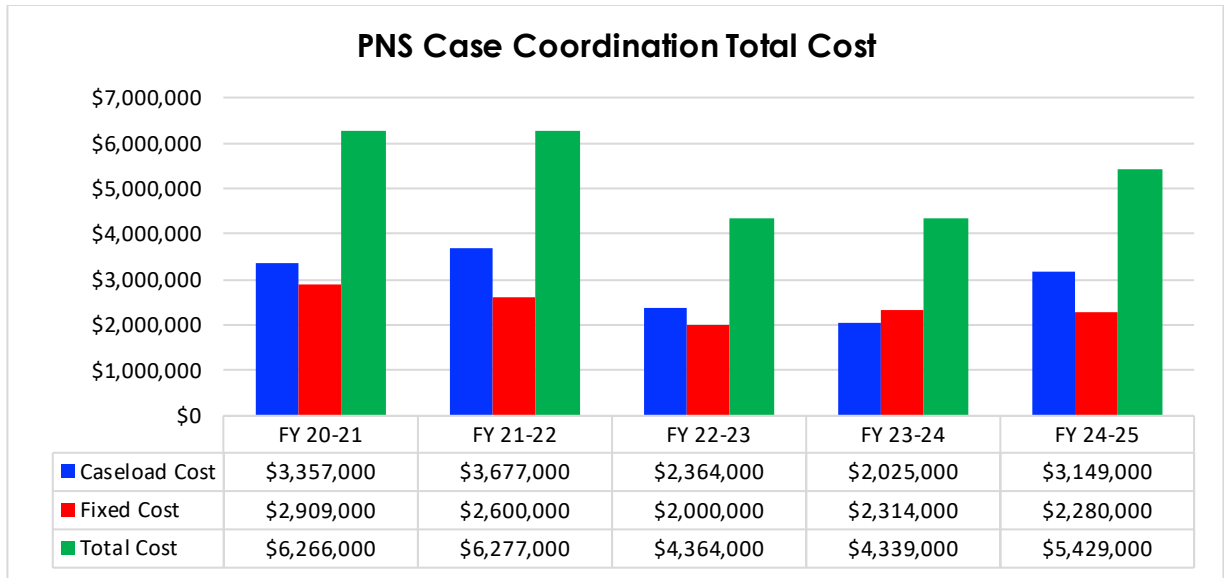


Case Management and Coordination Services Average Cost – The cfDNA and NTD positive cases will be referred to a case coordinator for which a separate cost per participant is attributed. The CDPH/GDSP estimates current year

average CMCS cost per participant will be \$34.80, which is an increase of \$7.67 or 28 percent compared to 2022-23 actual average CMCS cost per participant of \$27.13. The CDPH/GDSP estimates budget year average CMCS cost per participant will be \$51.19, which is a slight increase of \$16.39 or 47.1 percent compared to the current year. The average costs are attributable to the changes in PNS screening referrals as a result of exclusivity loss, the addition of SCAs, and changes in projected live births, but these changes are somewhat offset by an increase in contract rates and fixed costs.



Case Management and Coordination Services Total Cost – The cfDNA and NTD positive cases will be referred to a case coordinator for which contract rates are estimated on cost per test plus baseline adjustments. The CDPH/GDSP estimates current year CMCS costs to total \$4.3 million, which is a decrease of \$25,000 or 1 percent compared to 2022-23 actual CMCS total costs of \$4.4 million. The decrease in the current year is attributable to the changes in the CMCS caseload and a decrease in fixed costs. The CDPH/GDSP estimates budget year CMCS costs to total \$5.4 million, which is an increase of \$1 million or 25 percent compared to the current year. The increase in total costs is attributable to the changes in PNS screening referrals as a result of exclusivity loss, the addition of SCAs, and changes in projected live births, but these changes are somewhat offset by an increase contract rate and fixed costs.



APPENDIX C: REVENUE PROJECTIONS

NBS REVENUE

The NBS Program currently charges a fee for newborn screening of \$211. In most cases, the fee is paid directly to CDPH/GDSP by hospitals. Starting July 1, 2024, the CDPH/GDSP will be proposing a NBS fee increase of approximately \$15 to offset the costs of adding two new disorders.

For births that occur outside of the hospital, the CDPH/GDSP invoices the appropriate fee to the family of the infant or their insurance company. Since most births happen within the hospital, billing and receiving payments for NBS services are greatly streamlined and efficient. As such, the billing for NBS screening services is much more streamlined resulting in a 99 percent collection rate. The CDPH/GDSP uses the following formula to estimate revenue generated from NBS fees:

$$\# \text{ Of Projected Newborns Screened} \times \text{Fee} \times 99 \text{ percent}$$

NBS Revenue Projections

Fiscal Year	Fee (A)	Caseload (B)	Collection Rate (C)	Total Revenue (D) = (A) x (B) x (C)
FY 2023-24	\$211.00	404,919	99 percent	\$84,584,000
FY 2024-25	\$226.00	402,515	99 percent	\$90,059,000

PNS REVENUE

The Prenatal Screening Program charges a fee of \$232 on September 19, 2022, to all participating individuals. Of the total fee, \$222 is deposited into the GDTF (Fund 0203), and \$10 is deposited into the California Birth Defect Monitoring Program Fund (Fund 3114). The GDSP also added a separate fee of \$85 for neural tube defect (NTD) screening, of which \$75 is deposited into the GDTF (Fund 0203), and \$10 is deposited into the California Birth Defect Monitoring Program Fund (Fund 3114). The CDPH/GDSP will be proposing a PNS cfDNA fee increase of approximately \$112 (from \$232 to \$344). This consists of the approximate \$74 increase in the Prenatal Screening for SCAs and an approximate \$38 fee increase due to the Methodology Change in Projecting Prenatal Screening Caseload Existing (Significantly Changed) Assumption. This proposed fee is subject to change depending on the number of cfDNA participants.

Unlike NBS which collects revenues from hospitals directly, PNS invoices hospital providers and bills participants' insurance companies (analogous to the way a traditional medical provider would). This billing system, 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. The past collection rates show that PNS collects a higher percentage of anticipated revenues from Medi-Cal enrollees and hospital providers that are directly billed than those enrolled in private insurance plans, out of state plans, self-funded plan or the uninsured. GDSP proposes to estimate revenue based on the proportion of billable caseload that is billed through the patient's insurance plan, known as patient billing and the proportion billed directly to hospital providers, known as client billing.

PNS projected annual billable cfDNA caseload is 208,619 in FY 2023-24 and 207,331 in FY 2024-25, of which 32 percent are billed through Client billing. The annual neural tube defect (NTD) billable caseload is 245,685 in FY 2023-24 and 244,167 in FY 2024-25, of which 30 percent are billed through Client billing. The collection rate for claims billed directly to hospital providers is 99 percent. For Patient billing, approximately 68 percent of prenatal cases for cfDNA and 70 percent for NTD from the annual billable caseload are billed through insurance companies (Medi-Cal or Private/Commercial). The collection rate for claims submitted to Medi-Cal is 99 percent, and the collection rate for claims submitted to private insurance companies and other payers is 95 percent.

For Client Billing, PNS revenue is estimated using the following formula:

$$(\text{Fee} \times (\text{PNS Participants} \times \text{cfDNA/NTD Participation Rate})) \times \text{Collection Rate}$$

Client Billing - cfDNA

Fiscal Year	Fee	Billable Caseload	% of cfDNA	cfDNA caseload	Collection Rate	Total Revenue
(A)	(B)	(C)	(D)	(E) = (C) × (D)	(F)	(G) = (B) × (E) × (F)
FY2023-24	\$222.00	208,619	32%	66,758	99%	14,672,000
FY2024-25	\$334.00	207,331	32%	66,346	99%	21,938,000

Client Billing - NTD

Fiscal Year	Fee	Billable Caseload	% of NTD	NTD caseload	Collection Rate	Total Revenue
(A)	(B)	(C)	(D)	(E) = (C) × (D)	(F)	(G) = (B) × (E) × (F)
FY2023-24	\$75.00	245,685	30%	73,705	99%	5,473,000
FY2024-25	\$75.00	244,167	30%	73,250	99%	5,439,000

For Patient Billing, PNS revenue is estimated using the following formula:

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

Patient Billing Revenue – cfDNA

Fiscal Year	Medi-Cal Revenue	Non-Medical Revenue	Total Revenue
(A)	(B)	(C)	(D) = (B) + (C)
FY2023-24	\$18,707,000	\$11,967,000	\$30,674,000
FY2024-25	\$27,971,000	\$17,894,000	\$45,865,000

Patient Billing Revenue - NTD

Fiscal Year	Medi-Cal Revenue	Non-Medical Revenue	Total Revenue
(A)	(B)	(C)	(D) = (B) + (C)
FY2023-24	\$7,662,000	\$4,901,000	\$12,563,000
FY2024-25	\$7,614,000	\$4,871,000	\$12,485,000

Patient Billing Revenue – cfDNA – Medi-Cal

Fiscal Year	Fee	Billable Caseload	% of cfDNA from Billable Caseload	cfDNA Caseload	% of Medi-Cal from cfDNA Caseload	Medi-Cal Cases	Medi-Cal Collection Rate	Medi-Cal Revenue
(A)	(B)	(C)	(D)	(E) = (C) × (D)	(F)	(G) = (E) × (F)	(H)	(I) = (G) × (H)
FY2023-24	\$222	208,619	68%	141,861	60%	85,117	99%	\$18,707,000
FY2024-25	\$334	207,331	68%	140,985	60%	84,591	99%	\$27,971,000

Patient Billing Revenue – cfDNA – Non-Medi-Cal

Fiscal Year	Fee	Billable Caseload	% of cfDNA from Billable Caseload	cfDNA Caseload	% of Non-Medical from cfDNA Caseload	Non-Medi-Cal Caseload	Non-Medi-Cal Collection Rate	Non-Medi-Cal Revenue
(A)	(B)	(C)	(D)	(E) = (C) × (D)	(F)	(G) = (E) × (F)	(H)	(I) = (G) × (H)
FY2023-24	\$222	208,619	68%	141,861	40%	56,744	95%	\$11,967,000
FY2024-25	\$334	207,331	68%	140,985	40%	56,394	95%	\$17,894,000

Patient Billing Revenue – NTD – Medi-Cal

Fiscal Year	Fee	Billable Caseload	% of NTD from Billable Caseload	NTD Caseload	% of Medi-Cal from NTD Caseload	Medi-Cal Cases	Medi-Cal Collection Rate	Medi-Cal Revenue
(A)	(B)	(C)	(D)	(E) = (C) × (D)	(F)	(G) = (E) × (F)	(H)	(I) = (G) × (H)
FY2023-24	\$75	245,685	70%	171,979	60%	103,188	99%	\$7,662,000
FY2024-25	\$75	244,167	70%	170,917	60%	102,550	99%	\$7,614,000

Patient Billing Revenue – NTD – Non-Medi-Cal

Fiscal Year	Fee	Billable Caseload	% of NTD from Billable Caseload	NTD Caseload	% of Non-Medi-Cal from NTD Caseload	Non-Medi-Cal Caseload	Non-Medi-Cal Collection Rate	Non-Medi-Cal Revenue
(A)	(B)	(C)	(D)	(E) = (C) × (D)	(F)	(G) = (E) × (F)	(H)	(I) = (G) × (H)
FY2023-24	\$75	245,685	70%	171,979	40%	68,792	95%	\$4,901,000
FY2024-25	\$75	244,167	70%	170,917	40%	68,367	95%	\$4,871,000