Genetic Disease Screening Program

(GDSP)

Fiscal Year 2025-26

May Revision Estimates

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TABLE OF CONTENTS

ESTIMATES

PROGRAM OVERVIEW

The California Department of Public Health (CDPH), Genetic Disease Screening Program (GDSP) May Revision Estimate provides a revised projection of 2024-25 expenditures along with a revised projected 2025-26 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 and congenital diseases. Parents may opt their newborns out of the program only by claiming religious exemptions. PNS is an opt-in program for pregnant individuals who desire to participate that is made up of two separate screening programs – one screening for neural tube defects (NTD screening) and the other screening for chromosome aneuploidies (cfDNA screening). The screening tests provide 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 2025-26 Governor's Budget appropriation for 2024-25 is $175.1 million, of which $136.5 million is for Local Assistance and $38.6 million is for State Operations. The CDPH/GDSP's May Revision estimates the 2024-25 expenditure will be $173.5 million, of which $136 million is for Local Assistance and $37.5 million is for State Operations. State Operations are decreasing by $1.1 million due to Government Efficiencies Reductions in the 2024 Budget Act – Control Section 4.05 (7.95 percent state operations savings) and Control Section 4.12 (vacant position savings). Local Assistance expenditures are decreasing by $522,000, which is attributed to a lower cfDNA screening participation rate in the Prenatal Screening (PNS) Program than previously projected in the Governor's Budget.

The CDPH/GDSP's 2025-26 Governor's Budget appropriation for 2025-26 is $176.3 million, of which $138.9 million is for Local Assistance and $37.4 million is for State

Operations. The May Revision projects 2025-26 expenditures will be $174.5 million, of which $138.1 million is for Local Assistance and $36.4 million is for State Operations. State Operations expenditures are decreasing $1.1 million due to Government Efficiencies Reductions in the 2024 Budget Act. Local Assistance expenditures are decreasing by $735,000. This decrease is primarily due to $1.4 million reduction in prenatal screening costs compared to the 2025-26 Governor's Budget, driven by 0.49 percent lower participation rate in cfDNA screening. Moreover, this cost reduction is partially offset by $687,000 increase in newborn screening expenditures, attributed to a rise in projected live births. Table 1 shows the difference between the 2025-26 Governor's Budget appropriation, the revised 2024-25 expenditures and proposed 2025-26 expenditures for CDPH/GDSP.

Table 1: Genetic Disease Screen Program Current Year and Budget Year Summaries Compared to 2025-26 Governor's Budget

Fund 0203 Genetic Disease Testing Fund	2024 Budget Act	FY 2024-25				FY 2025-26			
		2025-26 Governor's Budget	2025 May Revision	Change from Governor's Budget to May Revision	Percent Change from Governor's Budget to May Revision	2025-26 Governor's Budget	2025 May Revision	Change from Governor's Budget to May Revision	Percent Change from Governor's Budget to May Revision
Total	**176,806,000**	**175,101,000**	**173,528,000**	**-1,573,000**	**-0.9%**	**176,301,000**	**174,515,000**	**-1,786,000**	**-1.0%**
State Operations	38,761,000	38,625,000	37,574,000	-1,051,000	-2.7%	37,447,000	36,396,000	-1,051,000	-2.8%
Local Assistance	138,045,000	136,476,000	135,954,000	-522,000	-0.4%	138,854,000	138,119,000	-735,000	-0.5%

LOCAL ASSISTANCE EXPENDITURE PROJECTIONS

CURRENT YEAR (2024-25)

The 2025-26 Governor's Budget appropriation for CDPH/GDSP's Local Assistance is $136.5 million in 2024-25. The CDPH/GDSP's May Revision estimates 2024-25 Local Assistance expenditures will total $136 million, which is a decrease of $522,000 or 0.4 percent compared to the 2025-26 Governor's Budget. The decrease in Local Assistance consists of a $1.5 million reduction due to a lower projected prenatal caseload, resulting from decreased participation in cfDNA screening (from 50.49 to 50.0 percent of live births) compared to the 2025-26 Governor's Budget. This decline is somewhat offset by an increase in newborn screening costs of approximately $966,000 driven by a 0.52 percent increase in the Department of Finance (Finance) Demographic Research Unit's (DRU) projected live births.

BUDGET YEAR (2025-26)

For 2025-26, the CDPH/GDSP estimates the revised Local Assistance expenditures will total $138.1 million, which is a decrease of $735,000 or 0.5 percent compared

to the 2025-26 Governor's Budget appropriation of $138.9 million. The prenatal screening cost is projected to decrease by $1.4 million compared to the 2025-26 Governor's Budget due to a lower participation rate in cfDNA screening compared to the 2025-26 Governor's Budget. This cost reduction is partially offset by an increase of $687,000 in newborn screening expenditures, driven by an increase in projected live births.

Table 2 shows the difference between the 2025-26 Governor's Budget appropriation and the revised 2024-25 and 2025-26 expenditures for CDPH/GDSP Local Assistance.

Table 2: Local Assistance Current Year and Budget Year Summaries Compared to 2025-26 Governor's Budget

Fund 0203 Genetic Disease Testing Fund	2024 Budget Act	FY 2024-25				FY 2025-26			
		2025-26 Governor's Budget	2025 May Revision	Change from Governor's Budget to May Revision	Percent Change from Governor's Budget to May Revision	2025-26 Governor's Budget	2025 May Revision	Change from Governor's Budget to May Revision	Percent Change from Governor's Budget to May Revision
Local Assistance Total	**138,045,000**	**136,476,000**	**135,954,000**	**-522,000**	**-0.4%**	**138,854,000**	**138,119,000**	**-735,000**	**-0.5%**
Newborn Screening	46,678,000	50,714,000	51,680,000	966,000	1.9%	52,737,000	53,424,000	687,000	1.3%
Prenatal Screening	61,059,000	55,454,000	53,966,000	-1,488,000	-2.7%	57,109,000	55,687,000	-1,422,000	-2.5%
Operational Support	30,308,000	30,308,000	30,308,000	0	0.0%	29,008,000	29,008,000	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 2024-25, CDPH/GDSP's May Revision estimates NBS Local Assistance expenditures will total $51.7 million, which is an increase of $966,000 or 1.9 percent compared to the 2025-26 Governor's Budget of $50.7 million. The net increase can be attributed to the caseload increases reflected in the DRU's projection of live births compared to the Governor's Budget.

For 2025-26, CDPH/GDSP's May Revision estimates NBS Local Assistance expenditures will total $53.4 million, which is an increase of $687,000 or 1.3 percent compared to the 2025-26 Governor's Budget of $52.7 million. The increase can be attributed to the caseload increases reflected in the DRU's projection of live births compared to the Governor's Budget as well as ongoing inflationary rate increases primarily observed in the NBS Technical and Scientific cost center for reagent kits, consumables, and supplies. Additionally, there have

been increases in fixed rate contract costs for regional Newborn Screening (NAPS) laboratories and Area Service Centers (ASC).

Table 3 shows the 2025-26 Governor's Budget appropriation and the revised 2024-25 and 2025-26 expenditures for the Newborn Screening Program costs by cost center type.

Table 3: Newborn Screening Current Year and Budget Year Summaries Compared to 2025-26 Governor's Budget

Fund 0203 Genetic Disease Testing Fund	2024 Budget Act	FY 2024-25				FY 2025-26			
		2025-26 Governor's Budget	2025 May Revision	Change from Governor's Budget to May Revision	Percent Change from Governor's Budget to May Revision	2025-26 Governor's Budget	2025 May Revision	Change from Governor's Budget to May Revision	Percent Change from Governor's Budget to May Revision
Total	**46,678,000**	**50,714,000**	**51,680,000**	**966,000**	**1.9%**	**52,737,000**	**53,424,000**	**687,000**	**1.3%**
Contract Lab	7,626,000	8,205,000	8,461,000	256,000	3.1%	8,575,000	8,760,000	185,000	2.2%
Tech Sci	27,552,000	31,335,000	31,311,000	-24,000	-0.1%	32,560,000	32,720,000	160,000	0.5%
Reference Lab	2,570,000	2,085,000	2,575,000	490,000	23.5%	2,178,000	2,340,000	162,000	7.4%
CMCS	6,697,000	6,859,000	7,020,000	161,000	2.3%	7,187,000	7,367,000	180,000	2.5%
Diagnostic Services	2,233,000	2,230,000	2,313,000	83,000	3.7%	2,237,000	2,237,000	0	0.0%

PNS EXPENDITURES PROJECTIONS (SEE APPENDICES B1-B4)

For 2024-25, the CDPH/GDSP's May Revision estimates PNS Local Assistance expenditures total $54 million, which is a decrease of $1.5 million or 2.7 percent compared to the 2025-26 Governor's Budget amount of $55.5 million. The decrease in the current year is attributed to a lower participation rate in cfDNA screening (50.0% of live births compared to 50.49% in the 2025-26 Governor's Budget) which has led to a reduction in caseload. This decrease is partially offset by contract cost increases in the Technical and Scientific cost center for reagent kits, consumables, and supplies, driven by 0.21 percent increase in NTD screening.

For 2025-26, the CDPH/GDSP's May Revision estimates PNS Local Assistance expenditures will total $55.7 million, which is a decrease of $1.4 million or 2.5 percent compared to the 2025-26 Governor's Budget amount of $57.1 million. The decrease in the budget year is attributed to the lower participation rate in cfDNA screening. This decrease is partially offset by contract cost increases in the Technical and Scientific cost center for reagent kits, consumables, and supplies for NTD screening as well as rising operational and fixed costs in Case Management and Coordination Center.

Table 4 displays the 2025-26 Governor's Budget appropriation, the revised 2024-25 and 2025-26 expenditures for the Prenatal Screening program costs by client type.

Table 4: Prenatal Screening Current Year and Budget Year Summaries Compared to 2025-26 Governor's Budget

Fund 0203 Genetic Disease Testing Fund	2024 Budget Act	FY 2024-25				FY 2025-26			
		2025-26 Governor's Budget	2025 May Revision	Change from Governor's Budget to May Revision	Percent Change from Governor's Budget to May Revision	2025-26 Governor's Budget	2025 May Revision	Change from Governor's Budget to May Revision	Percent Change from Governor's Budget to May Revision
Total	**61,059,000**	**55,454,000**	**53,966,000**	**-1,488,000**	**-2.7%**	**57,109,000**	**55,687,000**	**-1,422,000**	**-2.5%**
cfDNA	40,965,000	38,526,000	38,356,000	-170,000	-0.4%	39,105,000	38,173,000	-932,000	-2.4%
Contract Lab	3,156,000	3,055,000	3,055,000	0	0.0%	3,192,000	3,192,000	0	0.0%
Tech & Sci	3,631,000	3,215,000	3,243,000	28,000	0.9%	3,348,000	3,389,000	41,000	1.2%
CMCS	5,429,000	5,429,000	4,939,000	-490,000	-9.0%	5,700,000	5,726,000	26,000	0.5%
PDC	7,878,000	5,229,000	4,373,000	-856,000	-16.4%	5,764,000	5,207,000	-557,000	-9.7%

OPERATIONAL SUPPORT PROJECTIONS

For 2024-25, the CDPH/GDSP's revised Operational Support expenditures total is $30.3 million, which is no change from the 2025-26 Governor's Budget.

For 2025-26, the CDPH/GDSP projects operational support expenditures will total $29 million, which is no change from the 2025-26 Governor's Budget.

Table 5 displays the difference between the 2025-26 Governor's Budget appropriation, the revised 2024-25 and 2025-26 expenditures for Program Operational Support costs.

Table 5: Operational Support Current Year and Budget Year Summaries Compared to 2025-26 Governor's Budget

Fund 0203 Genetic Disease Testing Fund	2024 Budget Act	FY 2024-25				FY 2025-26			
		2025-26 Governor's Budget	2025 May Revision	Change from Governor's Budget to May Revision	Percent Change from Governor's Budget to May Revision	2025-26 Governor's Budget	2025 May Revision	Change from Governor's Budget to May Revision	Percent Change from Governor's Budget to May Revision
Operational Support	30,308,000	30,308,000	30,308,000	0	0.0%	29,008,000	29,008,000	0	0.0%

STATE OPERATIONS EXPENDITURE PROJECTIONS

For 2024-25, the CDPH/GDSP's May Revision estimates State Operations expenditures will total $37.6 million, which is a decrease of $1.1 million from the 2025-26 Governor's Budget due to Government Efficiencies Reductions in the 2024 Budget Act.

For 2025-26, the CDPH/GDSP's May Revision estimates State Operations expenditures will total $36.4 million, which is a decrease of $1.1 million from the 2025-26 Governor's Budget due to Government Efficiencies Reductions in the 2024 Budget Act..

Table 6 displays the difference between the 2025-26 Governor's Budget appropriation and the revised 2024-25 and 2025-26 expenditures for the CDPH/GDSP State Operations costs.

Table 6: State Operations Current Year and Budget Year Summaries Compared to 2025-26 Governor's Budget

Fund 0203 Genetic Disease Testing Fund	2024 Budget Act	FY 2024-25				FY 2025-26			
		2025-26 Governor's Budget	2025 May Revision	Change from Governor's Budget to May Revision	Percent Change from Governor's Budget to May Revision	2025-26 Governor's Budget	2025 May Revision	Change from Governor's Budget to May Revision	Percent Change from Governor's Budget to May Revision
State Operations	38,761,000	38,625,000	37,574,000	-1,051,000	-2.7%	37,447,000	36,396,000	-1,051,000	-2.8%

REVENUE PROJECTIONS

COMBINED NBS AND PNS REVENUE

For 2024-25, the CDPH/GDSP's May Revision estimates the total revenue of $174.5 million, which is an increase of $784,000 or 0.5 percent compared to the 2025-26 Governor's Budget amount of $173.7 million.

The net revenue increase of $931,000 for the current year is mainly attributed to newborn screening caseload increase, driven by the DRU's higher projection of live births. This is partially offset by prenatal screening caseload in the amount of $147,000 due to the decline in participation rates for cfDNA screening.

For 2025-26, the CDPH/GDSP's May Revision projects the total revenue of $173.7 million, which is an increase of $1.6 million or 0.9 percent compared to the 2025-26 Governor's Budget amount of $172.1 million.

The revenue increase for budget year is primarily due to the growth in newborn screening caseloads, driven by the DRU's higher projection of live births. Additionally, there is a slight caseload increase in prenatal neural tube defect (NTD) screening, despite a decline in participation rates for prenatal cfDNA screening.

REVENUE METHODOLOGY

The PNS and NBS Programs each charge a fee for screening services provided to clients. The PNS Program currently charges a fee of $334 for cfDNA screening, of which $324 is deposited into the Genetic Disease Testing Fund (Fund 0203). Additionally, the PNS program also charges a separate fee of $85 for NTD screening, of which $75 is deposited into the Genetic Disease Testing Fund (Fund

0203). The remaining $10 of the NTD and cfDNA fees is deposited into the Birth Defects Monitoring Program Fund (Fund 3114).

The CDPH/GDSP invoices and collects PNS payments from individual participants, private insurers, medical group 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 medical group providers and approximately 95 percent of the fees owed by individuals with private insurance. The CDPH/GDSP uses the following formula to estimate revenues generated from PNS fees:

Revenue Projections for PNS Patient Billing:

(A) = Medi-Cal Participation Rate x Medi-Cal Collection Rate
(B) = (1 - Medi-Cal Participation Rate) x Private Payer Collection Rate

(Fee x PNS Participants x A) + (Fee x PNS Participants x B)

Revenue Projections for Medical Group Providers/Client Billing:

(Fee x PNS Participants x Medical Group Participation Rate x Hospital Collection Rate)

The NBS Program currently charges a fee of $226 for newborn screening; the entire fee is deposited into the Genetic Disease Testing Fund (Fund 0203). NBS program costs are driven by per-case variable 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 newborn's parents or their insurance company. As a result, 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 revenues generated from NBS fees:

Fee x # of Projected Newborns screened x Collection Rate

NBS REVENUE (SEE APPENDIX C1)

For 2024-25, the revised NBS revenue is expected to total $90.4 million, which is an increase of $931,000 or 1 percent compared to the 2025-26 Governor's Budget of $89.5 million. For 2025-26, the GDSP projects revised NBS revenue will total $89.9 million, which is a further increase of $1.4 million or 1.6 percent compared to the 2025-26 Governor's Budget amount of $88.5 million. The revenue increases in the current year and the budget year are due to an increase in projected caseload as a result of DRU's updated projection of live births.

PNS REVENUE (SEE APPENDIX C2)

For 2024-25, the revised PNS revenue is expected to total $84.1 million, which is a decrease of $147,000 or 0.2 percent compared to the 2025-26 Governor's Budget amount of $84.3 million. The decrease in the current year's net revenue is attributed to lower-than-anticipated cfDNA participation rates. This decline is mitigated by increased participation rates in prenatal neural tube defect screenings.

For 2025-26, the CDPH/GDSP's May Revision projects that the revised PNS revenue will total $83.7 million, which is an increase of $186,000 or 0.2 percent compared to the 2025-26 Governor's Budget amount of $83.5 million. The revenue increase in the budget year is attributed to the higher than projected caseload increases in prenatal neural tube defect (NTD) screening, despite a decline in participation rates for prenatal cfDNA screening.

Table 7 shows the revised current year and budget year revenue compared to 2025-26 Governor's Budget.

Table 7: Genetic Disease Screening Program Revenue Current Year and Budget Year Summaries Compared to 2025-26 Governor's Budget

Fund 0203 Genetic Disease Testing Fund	2024 Budget Act	FY 2024-25				FY 2025-26			
		2025-26 Governor's Budget	2025 May Revision	Change from Governor's Budget to May Revision	Percent Change from Governor's Budget to May Revision	2025-26 Governor's Budget	2025 May Revision	Change from Governor's Budget to May Revision	Percent Change from Governor's Budget to May Revision
Total	**176,165,000**	**173,715,000**	**174,499,000**	**784,000**	**0.5%**	**172,051,000**	**173,669,000**	**1,618,000**	**0.9%**
Newborn Screening	88,908,000	89,465,000	90,396,000	931,000	1.0%	88,535,000	89,967,000	1,432,000	1.6%
Prenatal Screening	87,257,000	84,250,000	84,103,000	-147,000	-0.2%	83,516,000	83,702,000	186,000	0.2%

FUND CONDITION STATEMENT

GENETIC DISEASE TESTING FUND
FUND CONDITION REPORT
DOLLARS IN THOUSANDS

	2023-24	2024-25	2025-26
RESOURCES			
BEGINNING BALANCE	$33,053	$19,341	$19,342
Prior Year Adjustment	11,793	0	0
Adjusted Beginning Balance	44,846	19,341	19,342
REVENUES			
4123400 Genetic Disease Testing Fees [1/]	147,997	174,499	173,669
4163000 Income from Surplus Investments	1,496	118	118
4171400 Escheat of Unclaimed Checks & Warrants	313	103	103
9920 Transfers and Adjustments	0	0	0
TOTALS, REVENUES	149,806	174,720	173,890
TOTAL RESOURCES	$194,653	$194,061	$193,232
EXPENDITURES AND EXPENDITURE ADJUSTMENTS			
4265 Department of Public Health (State Operations)	33,196	37,574	36,396
4265 Department of Public Health (Local Assistance)	141,620	135,954	138,119
8880 Financial Information System for California (State Operations)	0	0	0
9892 Supplemental Pension Payments (State Operations)	496	417	417
9900 Statewide General Admin Exp (ProRata) (State Operations)	0	774	1,900
TOTAL EXPENDITURES AND EXPENDITURE ADJUSTMENTS	175,312	174,719	176,832
FUND BALANCE	19,341	19,342	16,400
	11%	11%	9%

REVENUE PROJECTIONS

2024-25

2024-25 NBS FEES BASED ON	404,023	TESTS @ $226.00	AND	99% Provider [1/]	=	$90,396,000
Total NBS Client Billing	404,023	TESTS @ $226.00	AND	99% Provider [1/]	=	**$90,396,000**
2024-25 cfDNA FEES BASED ON	64,209	TESTS @ $334.00	AND	99% Provider [2/]	=	$21,231,000
2024-25 NTD FEES BASED ON	75,540	TESTS @ $75.00	AND	99% Provider [2/]	=	$5,609,000
Total PNS Client Billing	139,749					$26,840,000
2024-25 cfDNA FEES BASED ON	54,578	TESTS @ $334.00	AND	95% Non Medi-Cal [3/]	=	$17,318,000
2024-25 cfDNA FEES BASED ON	81,867	TESTS @ $334.00	AND	99% Medi-Cal [4/]	=	$27,070,000
Total PNS Patient Billing	136,445					$44,388,000
2024-25 NTD FEES BASED ON	70,504	TESTS @ $75.00	AND	95% Non Medi-Cal [3/]	=	$5,023,000
2024-25 NTD FEES BASED ON	105,756	TESTS @ $75.00	AND	99% Medi-Cal [4/]	=	$7,852,000
Total PNS Patient Billing	176,260					$12,875,000
TOTAL PNS FEES						**$84,103,000**
GDSP Total						**$174,499,000**

2025-26

2025-26 NBS FEES BASED ON	402,104	TESTS @ $226.00	AND	99% Provider [1/]	=	$89,967,000
Total NBS Client Billing	402,104	TESTS @ $226.00	AND	99% Provider [1/]	=	**$89,967,000**
2025-26 cfDNA FEES BASED ON	63,903	TESTS @ $334.00	AND	99% Provider [2/]	=	$21,130,000
2025-26 NTD FEES BASED ON	75,179	TESTS @ $75.00	AND	99% Provider [2/]	=	$5,582,000
Total PNS Client Billing	139,082					$26,712,000
2025-26 cfDNA FEES BASED ON	54,317	TESTS @ $334.00	AND	95% Non Medi-Cal [3/]	=	$17,235,000
2025-26 cfDNA FEES BASED ON	81,476	TESTS @ $334.00	AND	99% Medi-Cal [4/]	=	$26,941,000
Total PNS Patient Billing	135,794					$44,176,000
2025-26 NTD FEES BASED ON	70,167	TESTS @ $75.00	AND	95% Non Medi-Cal [3/]	=	$4,999,000
2025-26 NTD FEES BASED ON	105,251	TESTS @ $75.00	AND	99% Medi-Cal [4/]	=	$7,815,000
Total PNS Patient Billing	175,418					$12,814,000
TOTAL PNS FEES						**$83,702,000**
GDSP Total						**$173,669,000**

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, lab consumables, lab supplies, additional personnel, changes to the Screening Information System (SIS), follow-up systems, the addition of new confirmatory testing and the educational materials and other costs associated for implementation of the new screening test.

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. On July 1, 2024, the Secretary of Health and Human Services accepted the recommendation of the Advisory Committee on Heritable Disorders in Newborns and Children to add infantile Krabbe disease (low galactocerebrosidase (GALC) and psychosine ≥ 10nM) to the Recommended Uniform Screening Panel (RUSP). CDPH/GDSP will be required to start screening by July 1, 2026.

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 estimate is based on costs incurred from the most recent additions to the NBS panel, including spinal muscular atrophy (SMA), mucopolysaccharidosis type I (MPS I), Pompe disease, MPS II, and GAMT deficiency. Additionally, as new diseases are added to the RUSP, there may be

one-time resources needed for planning, preparation, and implementation of the required screening.

CDPH/GDSP will continuously evaluate the fund reserve to assess the program's ability to absorb these increased expenditures and determine if, and when, a fee increase is needed. CDPH/GDSP believes it can still absorb the implementation costs for the upcoming screening of Krabbe disease in 2025-26. It is anticipated that an increase in Local Assistance expenditure authority will only be necessary once screening begins in 2026-27. The funding source for these expenditures 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

There are no Unchanged Assumptions/Premises.

DISCONTINUED ASSUMPTIONS/PREMISES

There are no Discontinued Assumptions/Premises.

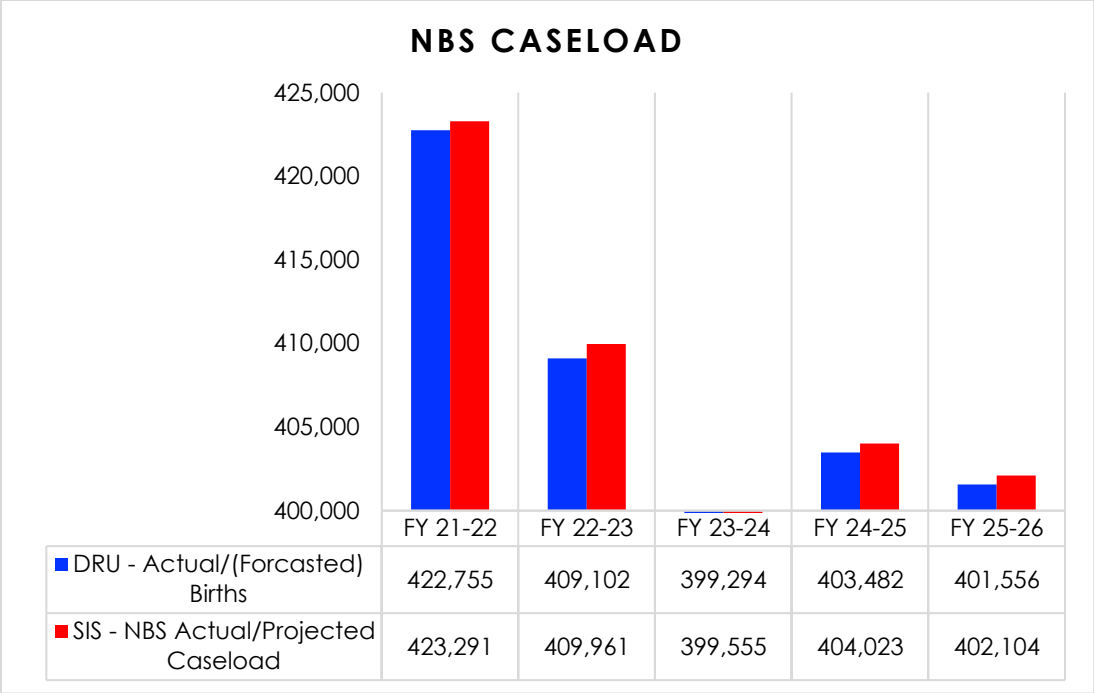
APPENDIX A: NEWBORN SCREENING PROGRAM (NBS) ASSUMPTIONS AND RATIONALE

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.

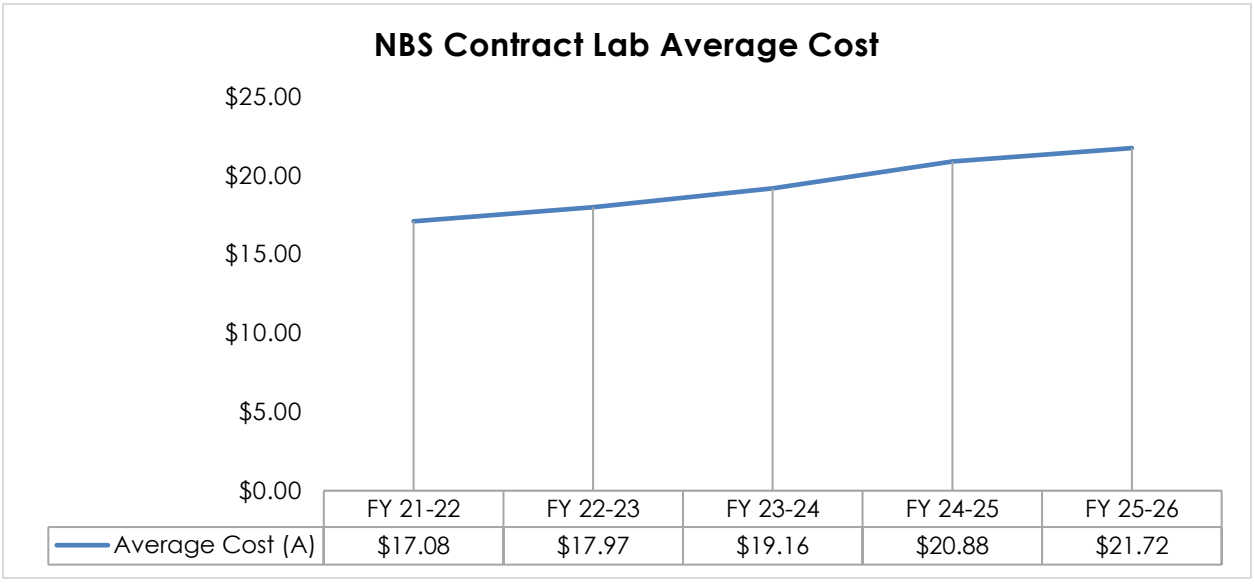
Costs associated with Contract Laboratories and Technical and Scientific supplies are driven by the total number of clients NBS serves. The total caseload is determined as a percentage of the DRU's projected number of live births. This estimate assumes that 100 percent of the DOF/DRU projected births will participate in the NBS program in 2022-23 and 2023-24.

Total Caseload – The CDPH/GDSP estimates current-year caseload will total 404,023, an increase of 4,468 or 1.1 percent compared to the 2023-24 actual total caseload of 399,555. The caseload in 2025-26 is estimated at 402,104, which is also a decrease of 1,919 or 0.5 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.



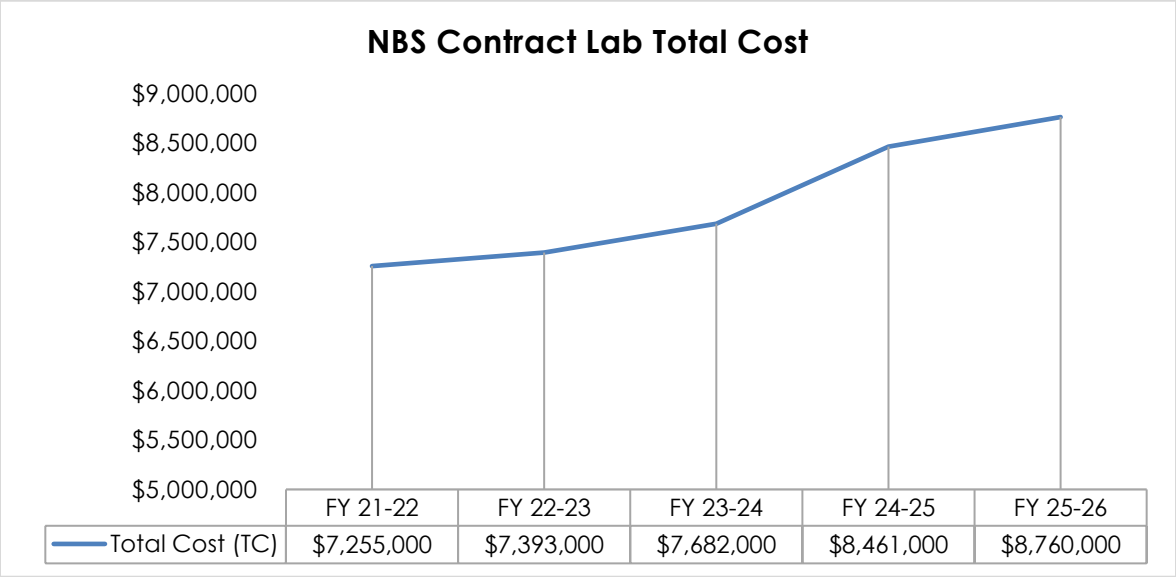
	FY 21-22	FY 22-23	FY 23-24	FY 24-25	FY 25-26
DRU - Actual/(Forcasted) Births	422,755	409,102	399,294	403,482	401,556
SIS - NBS Actual/Projected Caseload	423,291	409,961	399,555	404,023	402,104

Contract Laboratory Average Cost Projections – The CDPH/GDSP estimates current year average laboratory cost per participant will be $20.88, which is an increase of $1.72 or 9 percent compared to the 2023-24 actual average laboratory cost per participant of $19.16. Average laboratory cost per participant in 2025-26 is estimated at $21.72, which is an increase of $0.84 or 4 percent compared to the current year estimate. The increase in average cost from the current to the budget year is due to the contract rate increases, combined with a decline in projected live births.



	FY 21-22	FY 22-23	FY 23-24	FY 24-25	FY 25-26
Average Cost (A)	$17.08	$17.97	$19.16	$20.88	$21.72

Contract Laboratory Total Cost Projections – The CDPH/GDSP estimates current year contract laboratory costs to total $8.5 million, which is an increase of $779,000 or 10 percent compared to 2023-24 actual contract laboratory costs of $7.7 million. The contract laboratory costs in 2025-26 are projected to be $8.8 million, which is an increase of $299,000 or 3.5 percent compared to the current year.



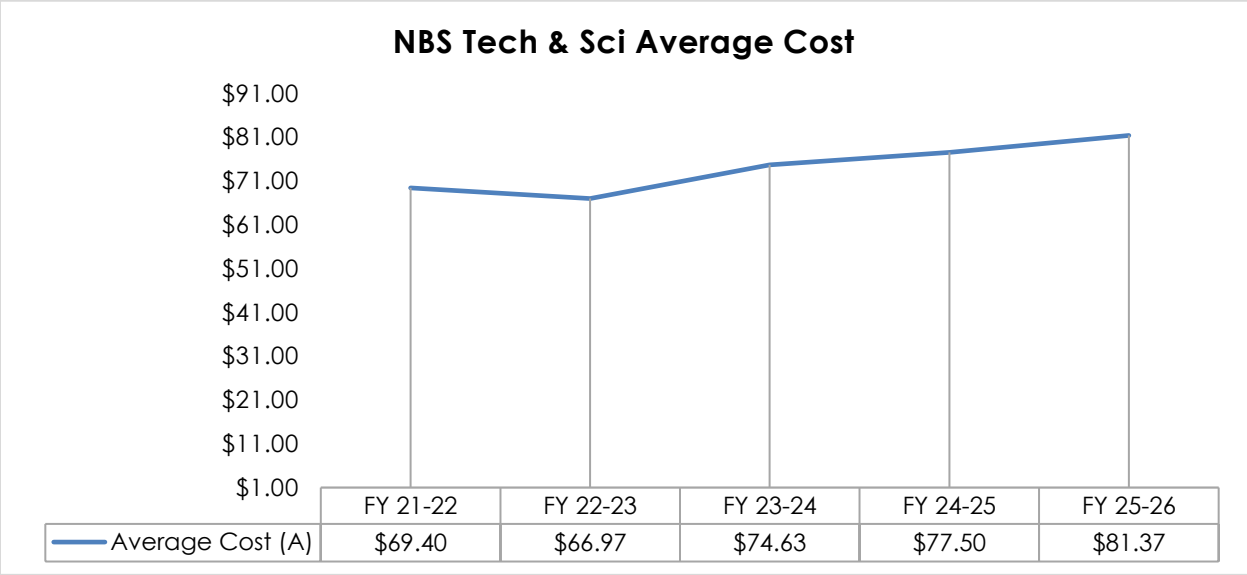
TECHNICAL AND SCIENTIFIC

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.

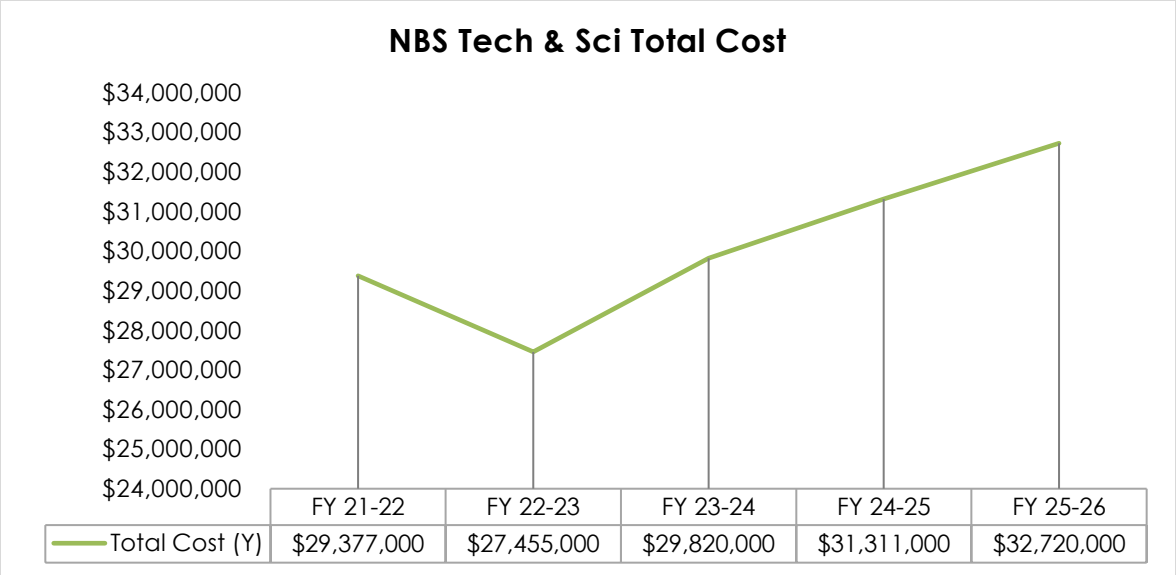
Technical and Scientific Caseload – See Appendix A 1

Technical and Scientific Average Cost – The CDPH/GDSP estimates current year average Technical and Scientific cost per participant will be $77.50, which is an increase of $2.87 or 4 percent compared to 2023-24 actual average Technical and Scientific cost per participant of $74.63. Average Technical and Scientific cost per participant in 2025-26 is estimated at $81.37, which is an increase of $3.87 or 5 percent compared to the current year estimate. The increase in

average cost is due to the inflationary cost increases. The fluctuation of caseload is small compared to the magnitude of the caseload cost increases due to inflation. 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.



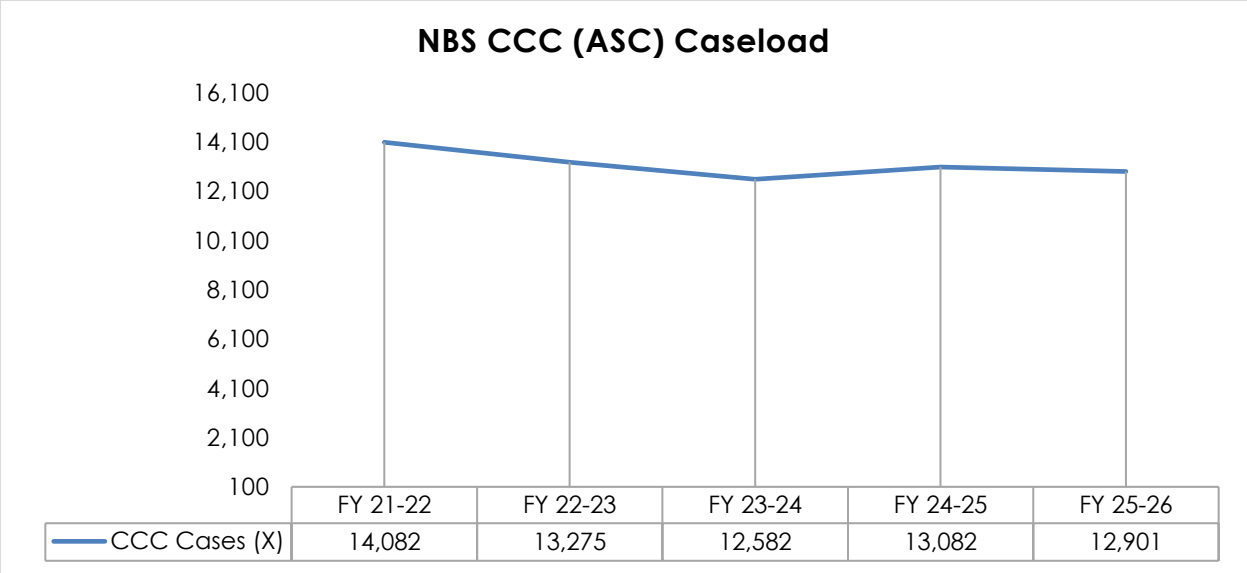
Technical and Scientific Total Cost – The CDPH/GDSP estimates current year Technical and Scientific costs to total $31.3 million, which is an increase of $1.5 million or 5 percent compared to 2023-24 actual technical and scientific costs of $30 million. For 2025-26, Technical and Scientific costs are estimated to be $32.7 million, which is an increase of $1.4 million or 5 percent compared to the current year. The cost increases in current and budget years are attributed to increased cost of reagent kits and consumables, as well as general inflation seen in all lab spending.



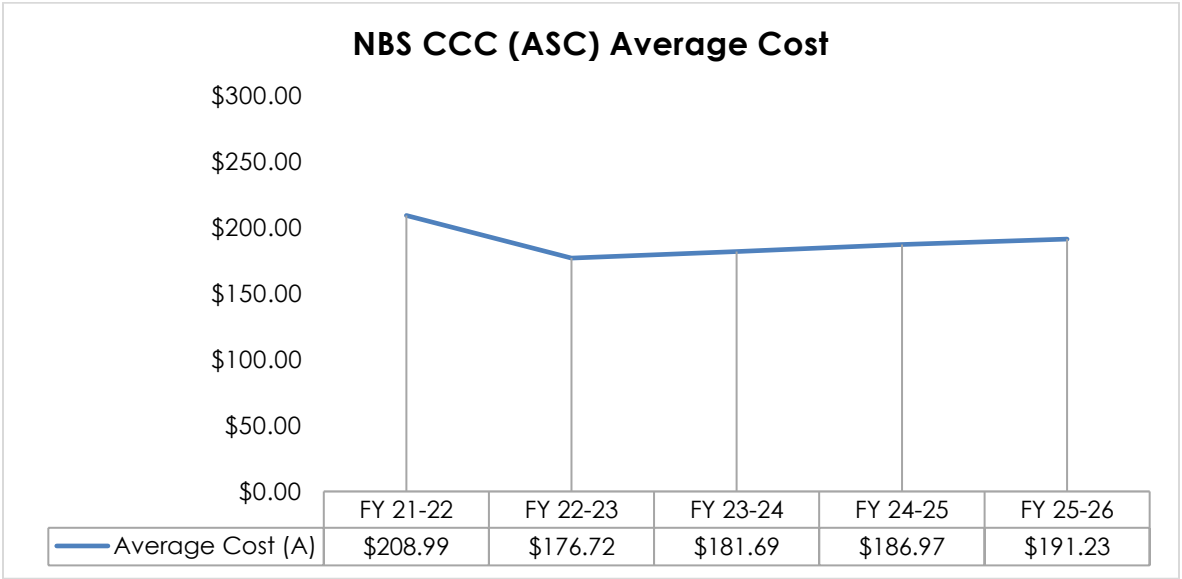
CASE MANAGEMENT AND COORDINATION SERVICES:

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 13,082, which is an increase of 500 or 4 percent compared to 2023-24 actual CMCS caseload of 12,582. CMCS caseload in 2025-26 is estimated at 12,901, which is a decrease of 181 or 1 percent compared to the current year estimate.

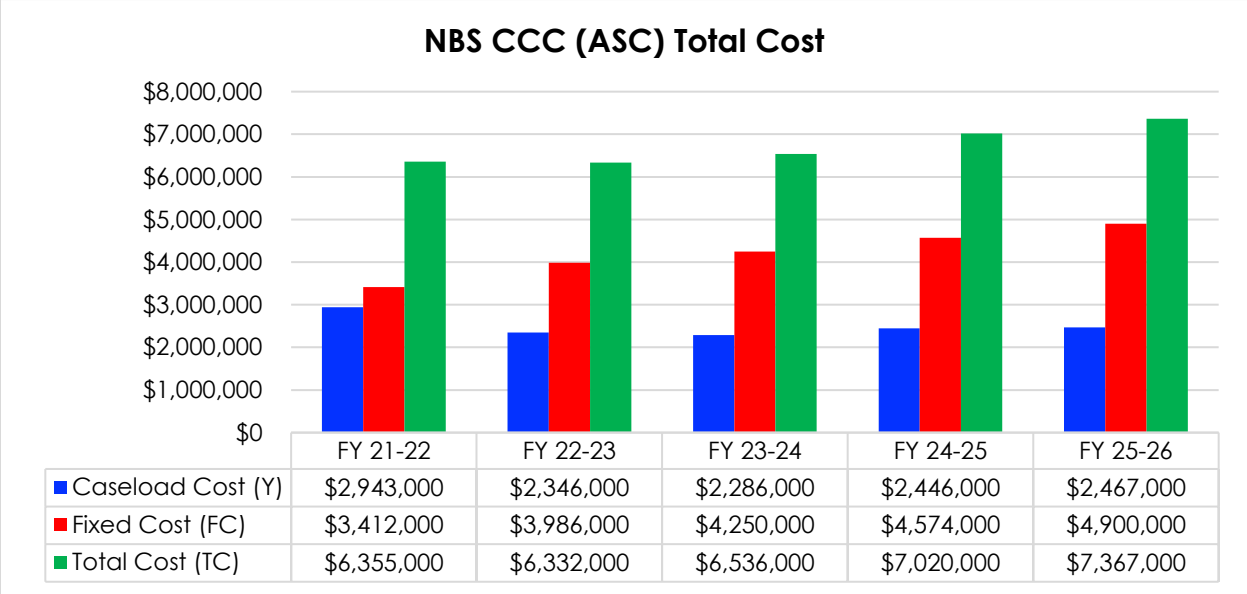


Case Management and Coordination Services (CMCS) Average Cost - CDPH/GDSP estimates current year average CMCS cost per participant will be $186.97, which is an increase of $5.28 or 3 percent compared to 2023-24 actual average CMCS cost per participant of $181.69. Average CMCS cost per participant in 2025-26 is estimated at $191.23, which is an increase of $4.26 or 2 percent compared to the current year estimate. The fluctuation in the average cost is tied directly to the caseloads and its associated direct costs.



Case Management and Coordination Services (CMCS) Total Cost – The CDPH/GDSP estimates current year CMCS costs to total $7 million, which is an increase of $484,000 or 7 percent compared to 2023-24 actual CMCS total costs

of $6.5 million. CMCS costs in 2025-26 are estimated to total $7.4 million, which is an increase of $347,000 or 5 percent compared to the current year estimate. The increase in current and budget year reflects the projected increases in ongoing data corrections on newborn records, and an increase in ongoing expenditures in 2025-26 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.

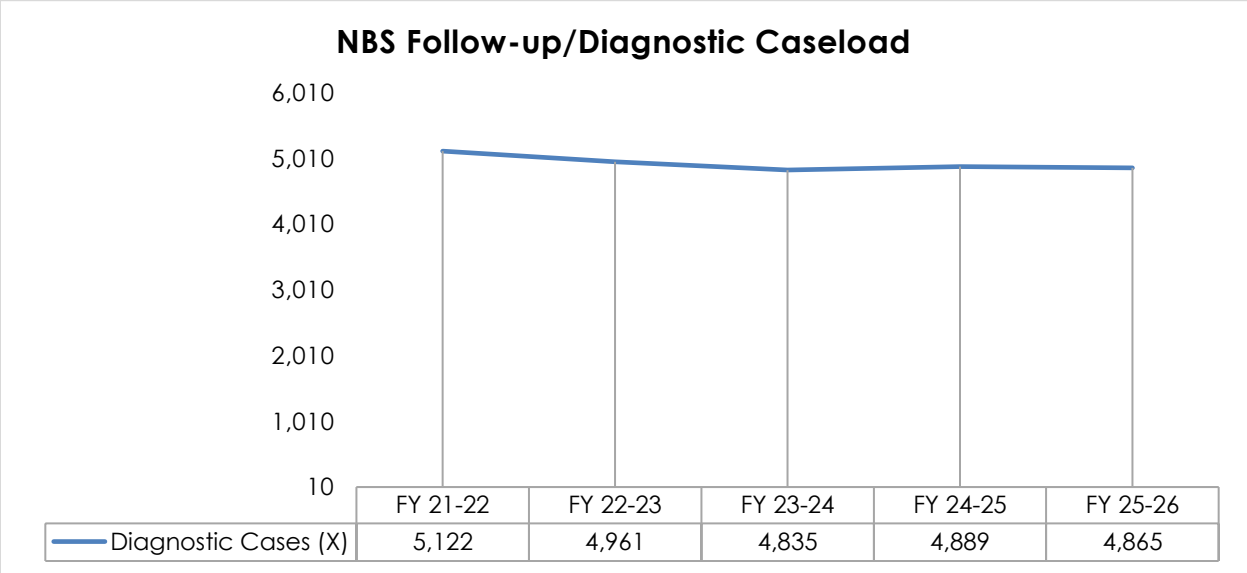


	FY 21-22	FY 22-23	FY 23-24	FY 24-25	FY 25-26
Caseload Cost (Y)	$2,943,000	$2,346,000	$2,286,000	$2,446,000	$2,467,000
Fixed Cost (FC)	$3,412,000	$3,986,000	$4,250,000	$4,574,000	$4,900,000
Total Cost (TC)	$6,355,000	$6,332,000	$6,536,000	$7,020,000	$7,367,000

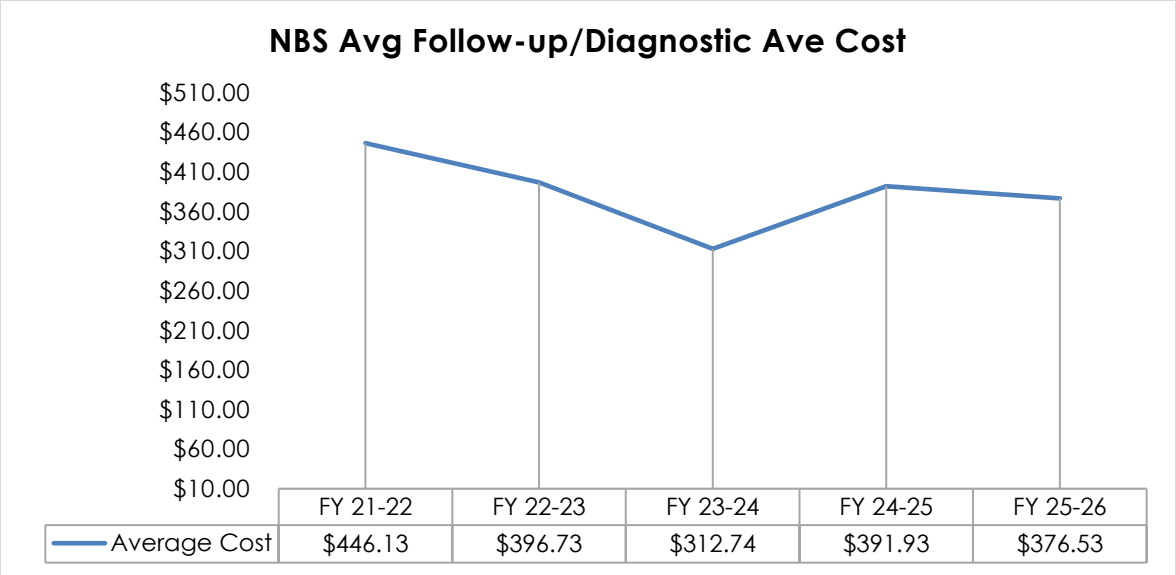
DIAGNOSTIC SERVICES

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.

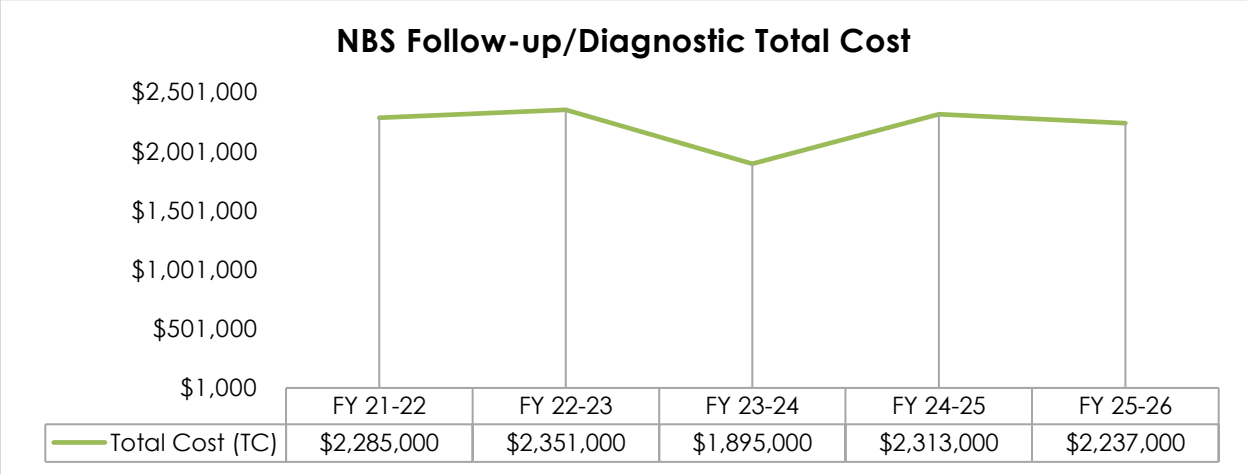
Diagnostic Services Caseload – The CDPH/GDSP estimates current year Diagnostic caseload will total 4,889, based on projected new referral cases and annual patient summary cases, which is an increase of 54 or 1 percent compared to 2023-24 actual Diagnostic Services caseload of 4,835. Diagnostic caseload in 2025-26 is estimated at 4,865, which is a decrease of 24 or 0.5 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 $392, calculated based on projected new referral cases and annual patient summary cases, which is an increase of $79 or 25 percent compared to 2023-24 actual average Diagnostic Services cost per participant of $313. The average Diagnostic Services cost per participant in 2025-26 is estimated at $377, which is a decrease of $15 or 4 percent compared to the current year estimate. The fluctuation of the cost per case in the current and budget years is tied directly to the change in caseloads and its associated direct costs.



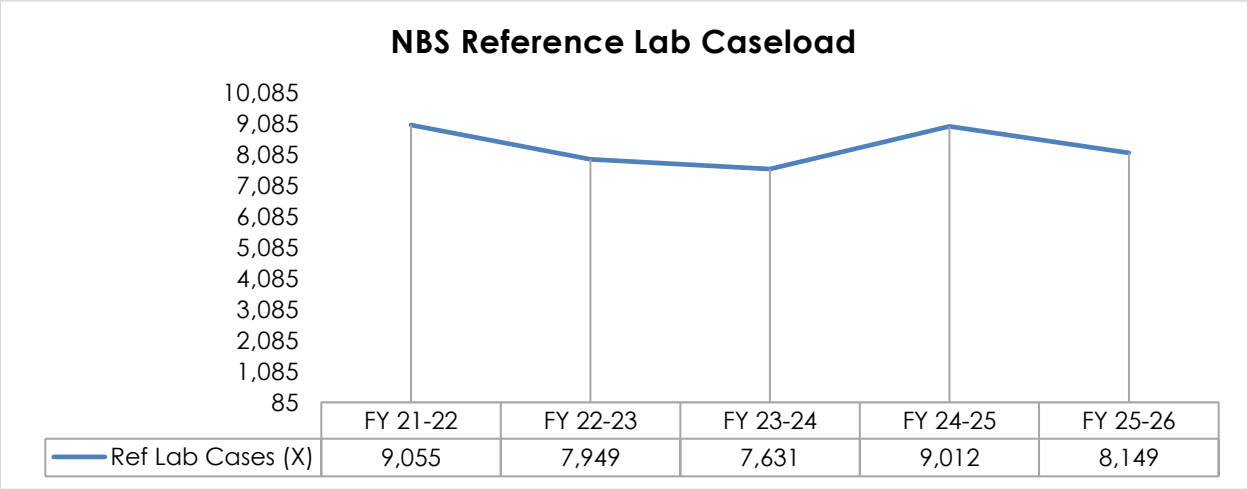
Diagnostic Services Total Cost – CDPH/GDSP estimates current year Diagnostic Services costs to total $2.3 million, which is an increase of $418,000 or 22 percent compared to 2023-24 actual Diagnostic Services total costs of $2 million. Diagnostic Services costs in 2025-26 are estimated to total $2.2 million, which is a decrease of $76,000 or 3 percent compared to the current year estimate.



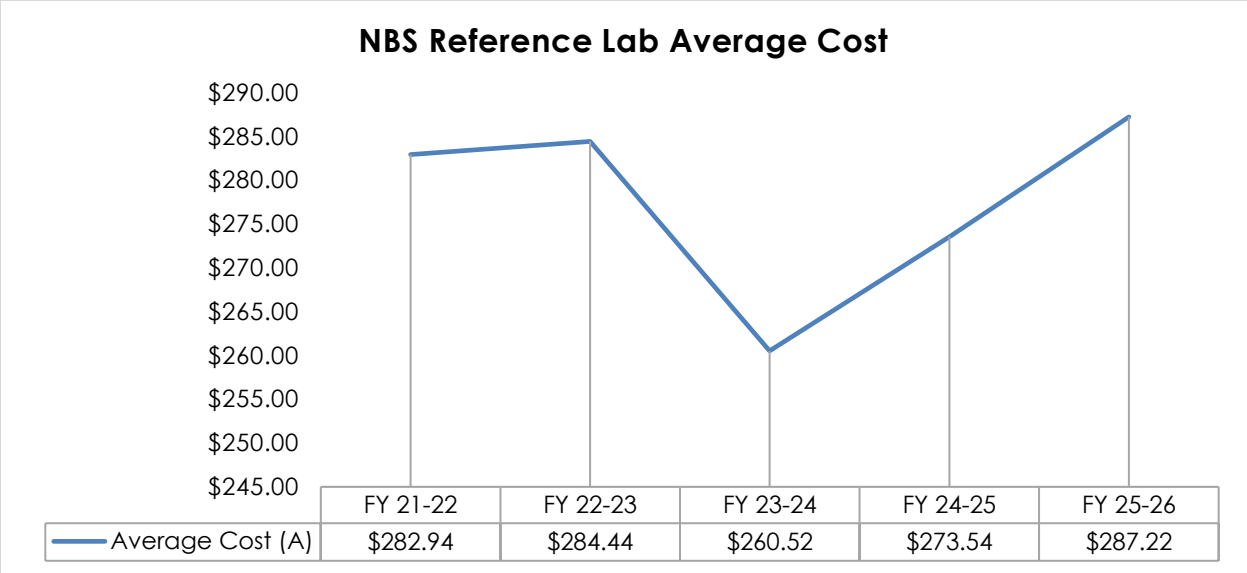
REFERENCE LABORATORIES

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.

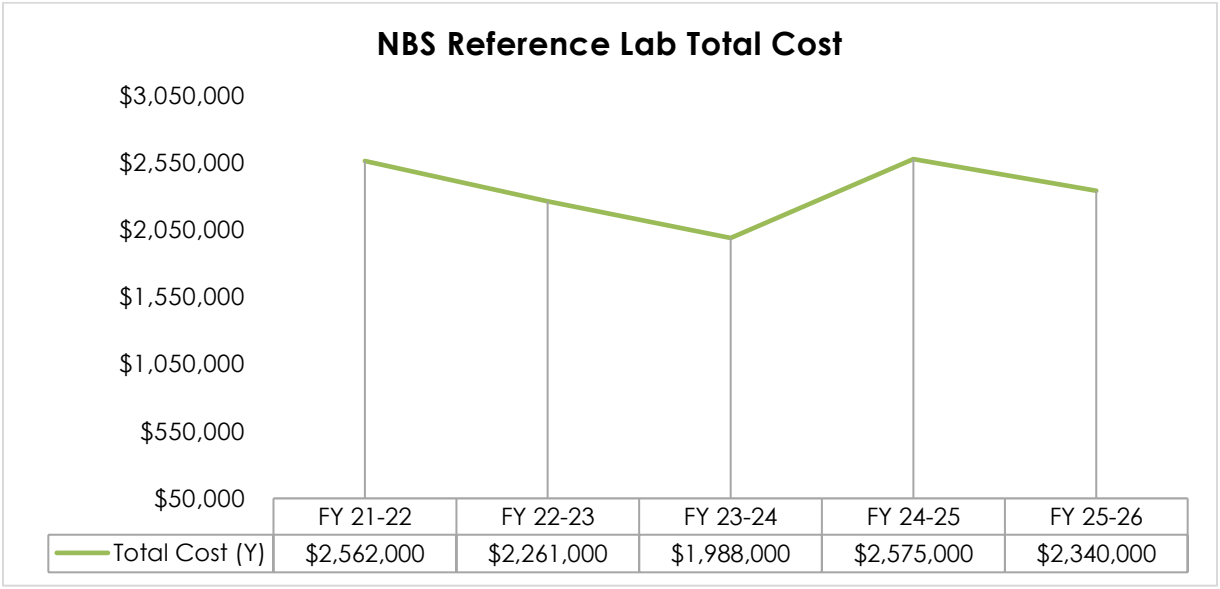
Reference Laboratory Caseload – CDPH/GDSP estimates current year Reference Laboratory caseload will total 9,012, which is an increase of 1,381 or 18 percent compared to 2023-24 actual Reference Laboratory caseload of 7,631. Reference Laboratory caseload in 2025-26 is estimated at 8,149, which is a decrease of 863 or 10 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 $274, which is an increase of $13 or 5 percent compared to 2023-24 Reference Laboratory actual average cost per participant of $261. Reference Laboratory average cost per participant in 2025-26 is estimated at $287, which is a slight increase of $14 or 5 percent compared to the current year estimate. The average cost increases from the current to the budget year can be attributed to the increasing costs despite caseload reductions.



Reference Laboratory Total Cost – CDPH/GDSP estimates current year Reference Laboratory costs to total $2.6 million, which is an increase of 587,000 or 30 percent compared to 2023-24 actual Diagnostic Services total costs of $2 million. Reference Laboratory costs in 2025-26 are estimated to total $2.3 million, which is a decrease of 235,000 or 9 percent compared to the current year estimate. The cost decreases from the current year to the budget year can be attributed to the fluctuations in caseloads.



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 individual'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 additional screening results.

Total Caseload/Specimens – The CDPH/GDSP estimates current year projected caseload for cfDNA at 201,875, which is a decrease of 598 or 0.3 percent compared to the 2023-24 actual caseload of 202,473. The CDPH/GDSP estimates that the cfDNA caseload in the budget year will total 200,911, which is a further decrease of 964 or 0.5 percent compared to the current year. The caseload decreases from the current to the budget year can be attributed to the cfDNA participation declines.

Table 1 shows the projected cfDNA cases by billable caseload, average cost, and total cost for budget year 2025-26.

TABLE 1: cfDNA + SCA

Fiscal Year	Forecasted Births	PNS Projected Caseload	Average Cost	Total Cost
2024-25	403,482	201,875	$190	$38,356,000
2025-26	401,556	200,911	$190	$38,173,000

CONTRACT LABORATORIES

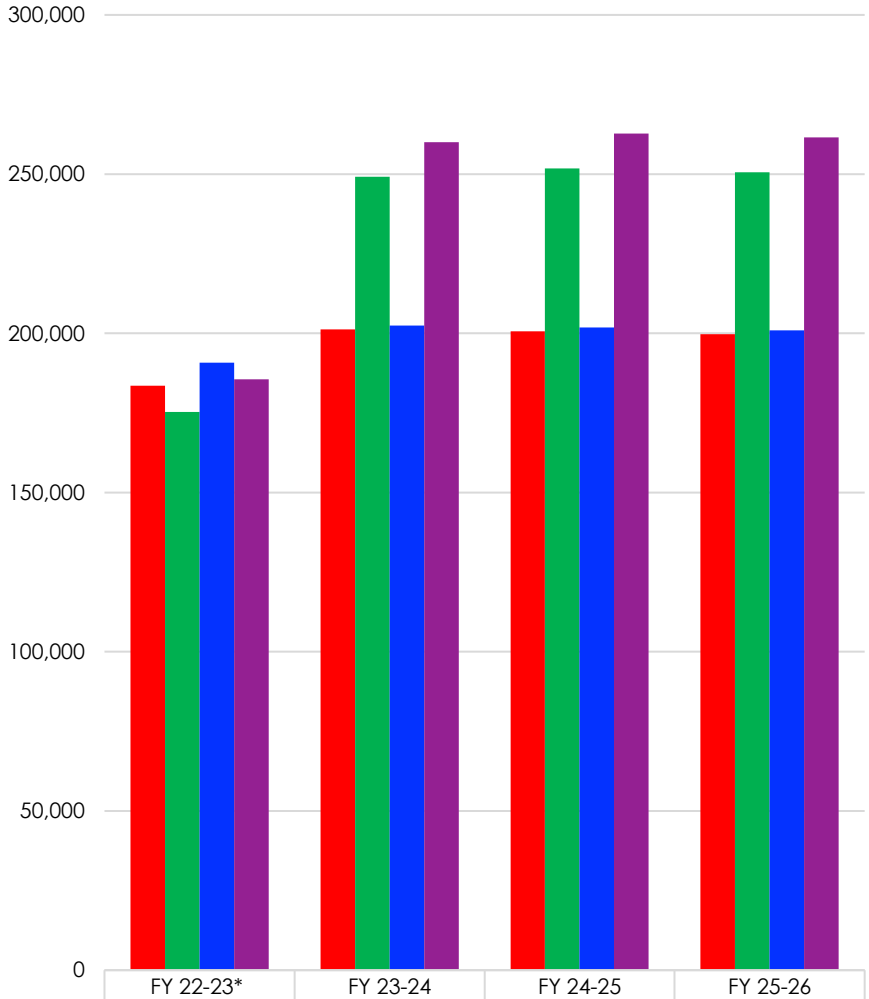
Overview – Laboratory testing to screen pregnant individuals for genetic and congenital disorders, such as trisomy 21, trisomy 18, Smith-Lemli-Opitz Syndrome (SLOS), and Neural Tube Defects. Costs include laboratory services for performing prenatal genetic screening tests. The screening test estimates the chance or risk that the fetus has a certain birth defect; the screening provides a risk assessment but not a diagnosis. The state is 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: The CDPH/GDSP estimates that the NTD caseload in the current year will total 262,783, which is an increase of 2,728 or 1.5 percent compared to 2023-24 NTD caseload of 260,055. The NTD caseload in the

budget year is estimated at 261,529, which is a decrease of 1,254 or 0.5 percent compared to the current year. The caseload fluctuation is tied to the DRU's projected live births.

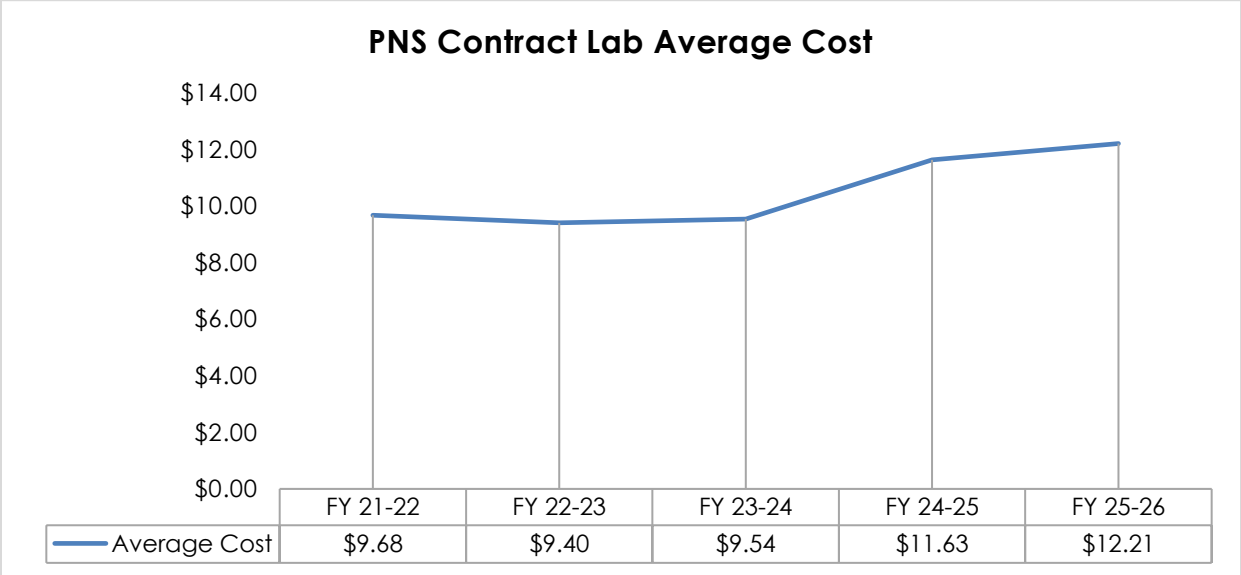
PNS Caseload/Specimens (SIS 2.0)



	FY 22-23*	FY 23-24	FY 24-25	FY 25-26
SIS 2.0 - Billable PNS Actual/Projected Caseload (Revenue Projection) cfDNA Caseload (x_1)	183,531	201,249	200,654	199,696
SIS 2.0 - Billable PNS Actual/Projected Caseload (Revenue Projection) NTD Caseload (x_2)	175,316	249,186	251,800	250,598
SIS 2.0 - Number of PNS Actual/Projected Specimens (Expenditure Projection) cfDNA	190,809	202,473	201,875	200,911
SIS 2.0 - Number of PNS Actual/Projected Specimens (Expenditure Projection) NTD	185,591	260,055	262,783	261,529

*from date of service 9/19/2022 through 6/30/2023

Contract Laboratory Average Cost Projections – CDPH/GDSP estimates current year average laboratory cost per participant will be $11.63, which is a slight increase of $2 or 22 percent compared to 2023-24 actual average laboratory cost per participant of $9.54. The CDPH/GDSP estimates budget year average laboratory cost per participant will be $12.21, which is a slight increase of 0.58 or 5 percent compared to the current year. The increases in the current and the budget year are due to the magnitude of contract cost increases outpacing the projected caseload increase as a result of inflation. Moreover, the contract regional NAPS lab has only screened pregnant individuals for neural tube defects (NTD) since September 19, 2022.



Contract Laboratory Total Cost Projections – The CDPH/GDSP estimates current year contract laboratory cost to total $3.1 million, which is an increase of $575,000 or 21 percent compared to 2023-24 actual contract laboratory costs of $2.5 million. The CDPH/GDSP estimates budget year contract laboratory cost to total $3.2 million, which is an increase of $137,000 or 4 percent compared to the current year.

The cost fluctuation is tied to the DRU's projected live births. Despite the loss of cfDNA screening exclusivity, there has been an increase of NTD screening participation. The pregnant individuals who did not elect the cfDNA screening with the GDSP elected the NTD screening in addition to the ones who had participated throughout the entire prenatal screening process.

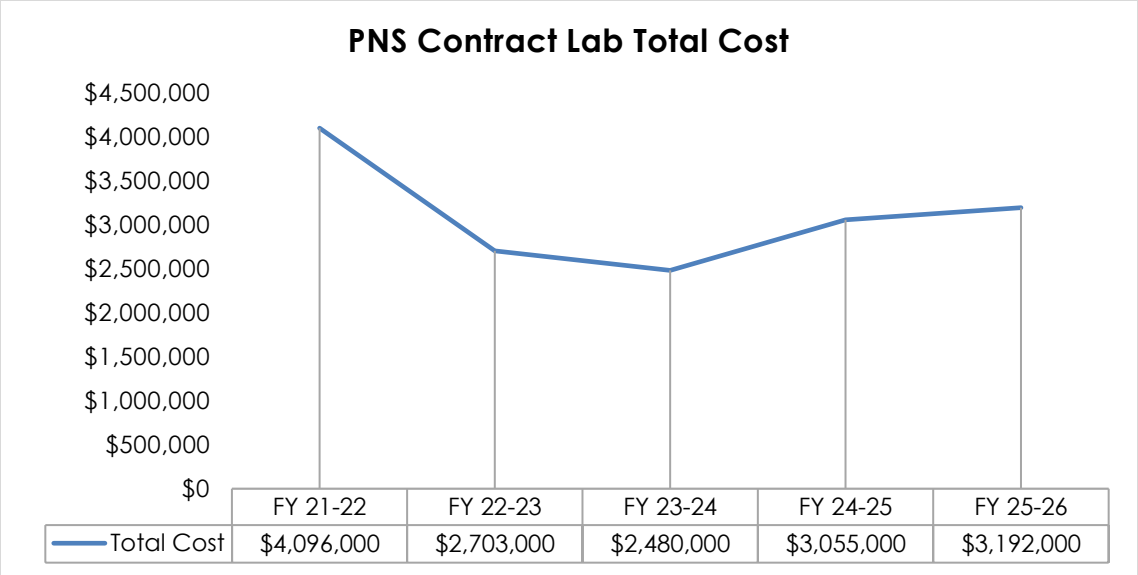


Table 2 shows the projected cases, average cost, and total cost for the cases of the neural tubes defects (NTD) test only in 2024-25 and 2025-26.

TABLE 2: NTD

Fiscal Year	PNS Projected Caseload	Average Cost	Total Cost
2024-25	262,783	$11.63	$3,055,000
2025-26	261,529	$12.21	$3,192,000

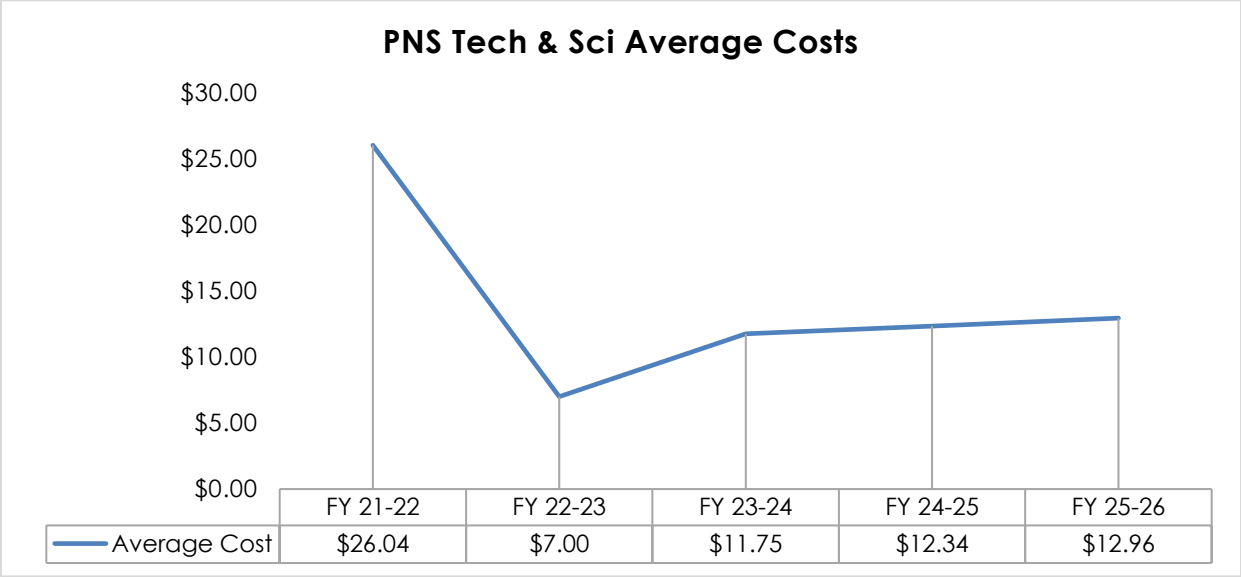
TECHNICAL AND SCIENTIFIC

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 $12.34, which is an increase of $0.59 or 8 percent compared to 2023-24 actual average Technical and Scientific cost per specimen of $11.75. 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 $12.96, which is also an increase of $0.62 or 5 percent compared to the current year.



Technical and Scientific Total Cost – The CDPH/GDSP estimates current year Technical and Scientific costs to total $3.2 million, which is an increase of $188,000 or 14 percent compared to 2023-24 actual technical and scientific costs of $3.1 million. The CDPH/GDSP estimates budget year Technical and Scientific costs to total $3.4 million, which is a slight increase of $146,000 or 4.5 percent compared to the current year. The fluctuation in total cost is tied to the projected specimens and costs of reagents, supplies, and consumables.

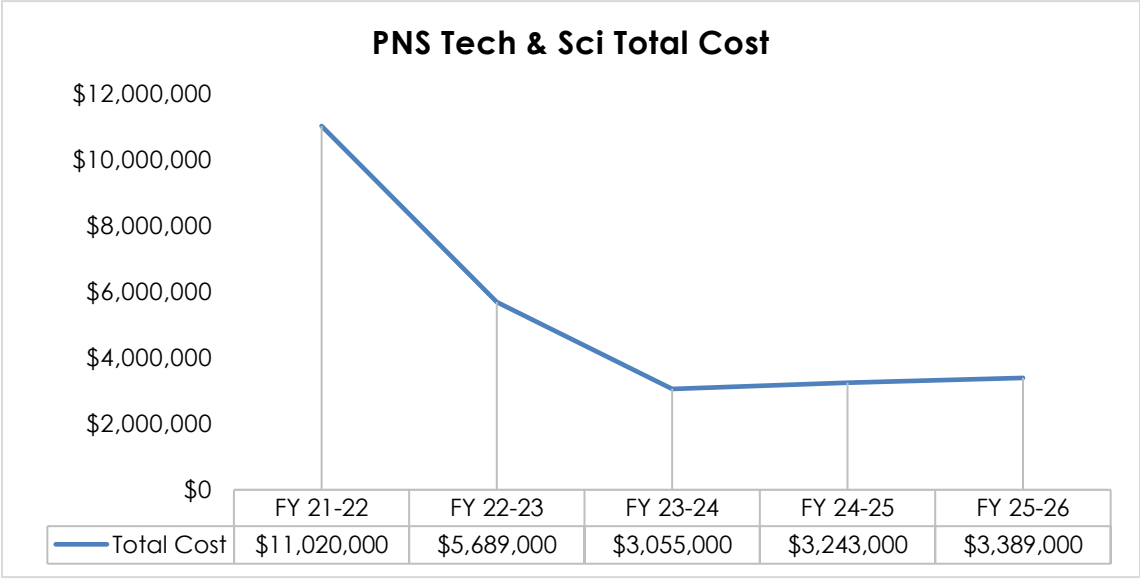


Table 3 shows the projected cases, average cost, and total cost associated with technical and scientific cost for the neural tubes defects (NTD) test only in 2024-25 and 2025-26.

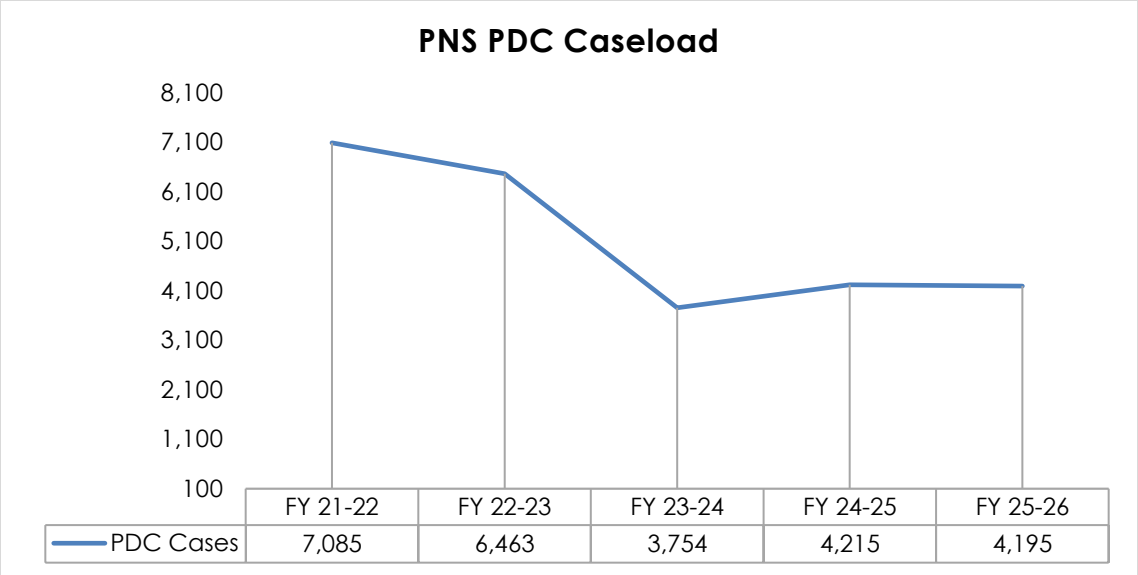
TABLE 3: Tech & Sci

Fiscal Year	Total NTD	Average Cost	Total Cost
2024-25	262,783	$12.34	$3,243,000
2025-26	261,529	$12.96	$3,389,000

PRENATAL DIAGNOSTIC SERVICES CENTERS

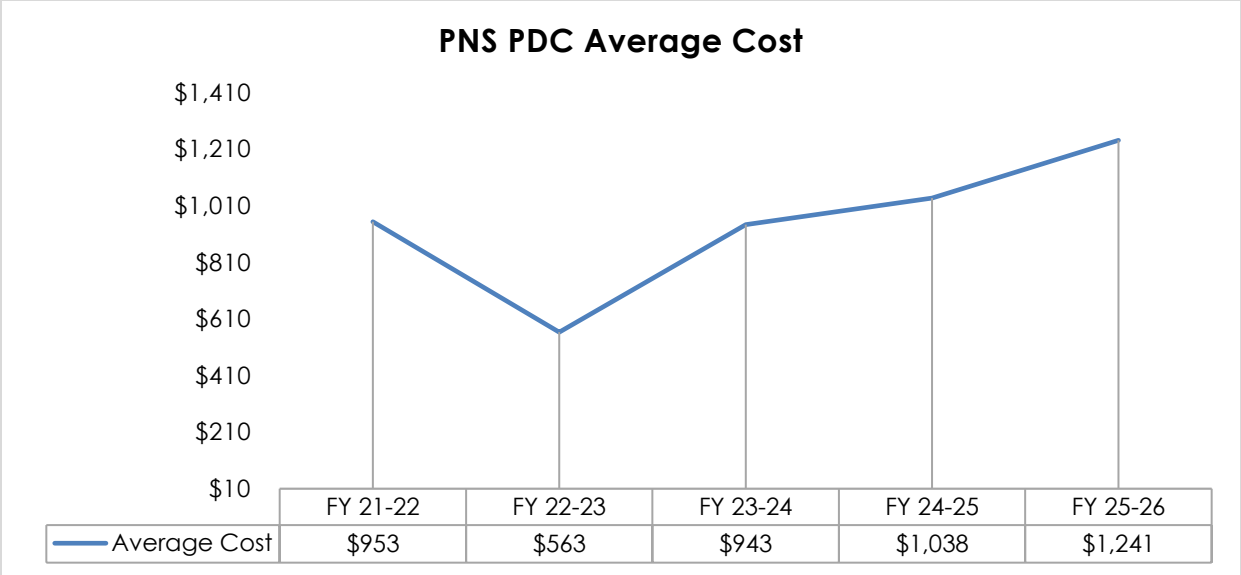
Overview – Pregnant individuals with positive results are provided additional services, which include confirmatory and diagnostic prenatal testing, genetic counseling, education, coordinated medical care referrals, and coordination and consultation with patient's physician, and specialty care providers.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

Prenatal Diagnostic Services Centers (PDC) Caseload – Since September 19, 2022, cfDNA screened positive tests, those with no results, and NTD screened positive tests have been referred for additional services which include confirmatory and diagnostic testing. The CDPH/GDSP estimates the current year PDC caseload at 4,215, which is an increase of 461 or 7 percent compared to the 2023-24 actual PDC caseload of 3,754. The caseload increase in the current year is due to the addition of SCA on April 1, 2024. The CDPH/GDSP estimates the budget year PDC caseload at 4,195, which is a slight decrease of 20 or 0.5 percent compared to the current year. The decrease is caused by a projected decline in pregnant individuals choosing to further pursue diagnostic care.

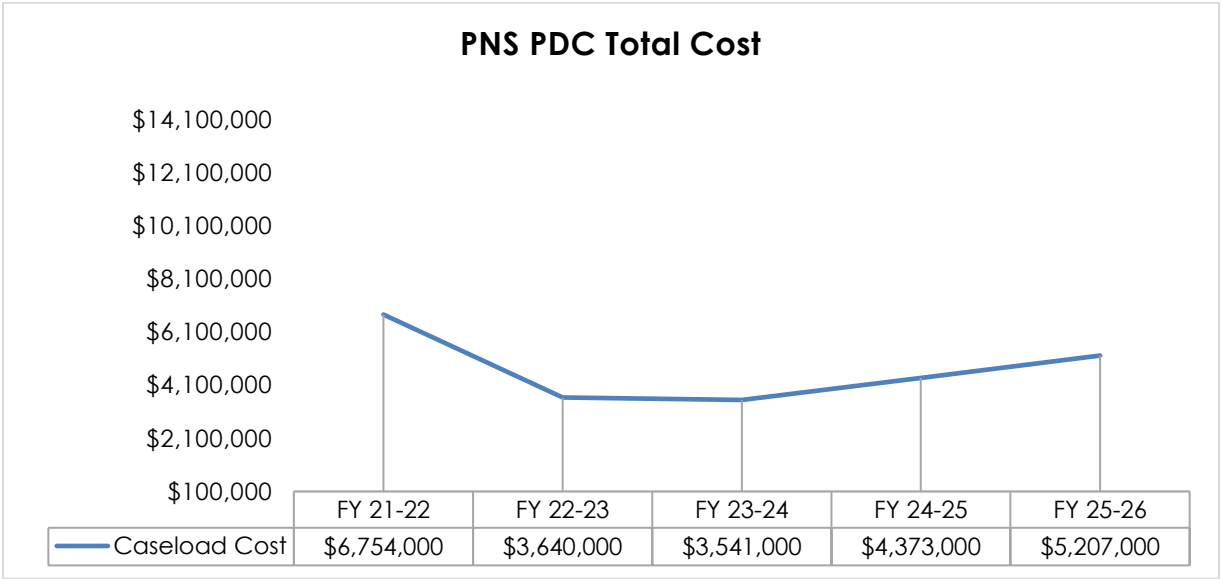


Prenatal Diagnostic Services Average Cost – Since September 19, 2022, cfDNA tests screened positive, those with no results, and NTD tests screened positive will have a separate cost analysis on diagnostic services. The CDPH/GDSP estimates the current year average PDC cost per participant at $1,038, which is an increase of $94 or 17 percent compared to 2023-24 actual average PDC cost per participant of $943. The CDPH/GDSP estimates the budget year average PDC cost per participant will be $1,241, which is an increase of $203 or 10 percent compared to the current year.

The average cost increase in the current and budget year can be attributed to the contract rate increases as a result of adding SCAs into the Prenatal Screening panel since April 1, 2024. In addition, the changes in the types of procedures used to diagnose genetic diseases have also contributed to the cost increases.



Prenatal Diagnostic Services Total Cost – The CDPH/GDSP estimates current year PDC costs total $4.4 million, which is an increase of $832,000 or 23 percent compared to 2023-24 actual PDC total costs of $3.5 million. The CDPH/GDSP estimates budget year PDC costs to total $5.2 million, which is an increase of $834,000 or 19 percent compared to the current year. The change in total expenditure is attributable mainly to fluctuations in projected PDC caseload and the addition of SCAs since April 1, 2024.

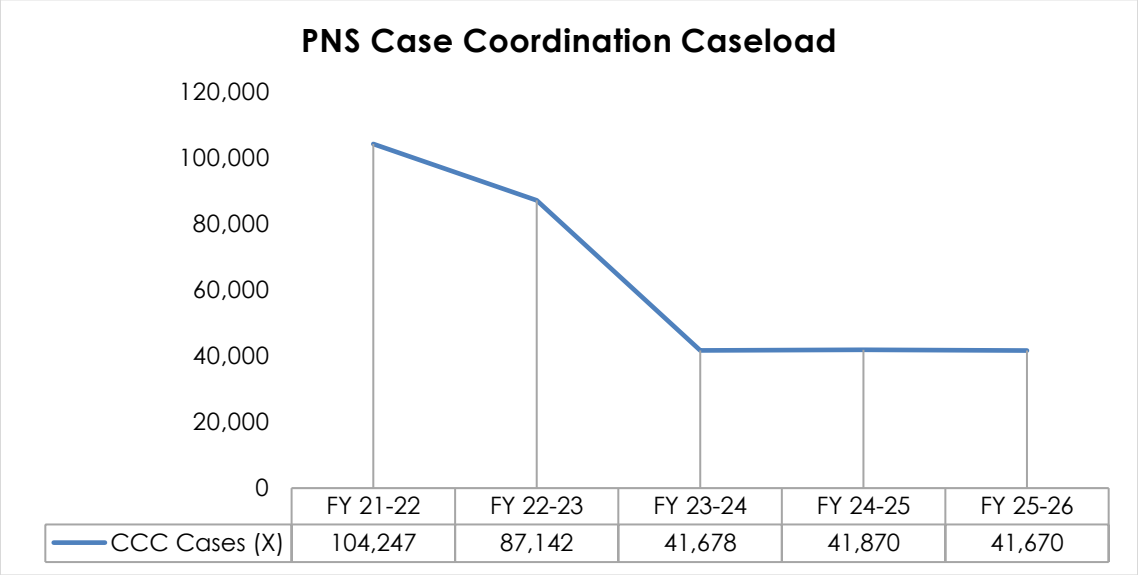


CASE MANAGEMENT AND COORDINATION SERVICES

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

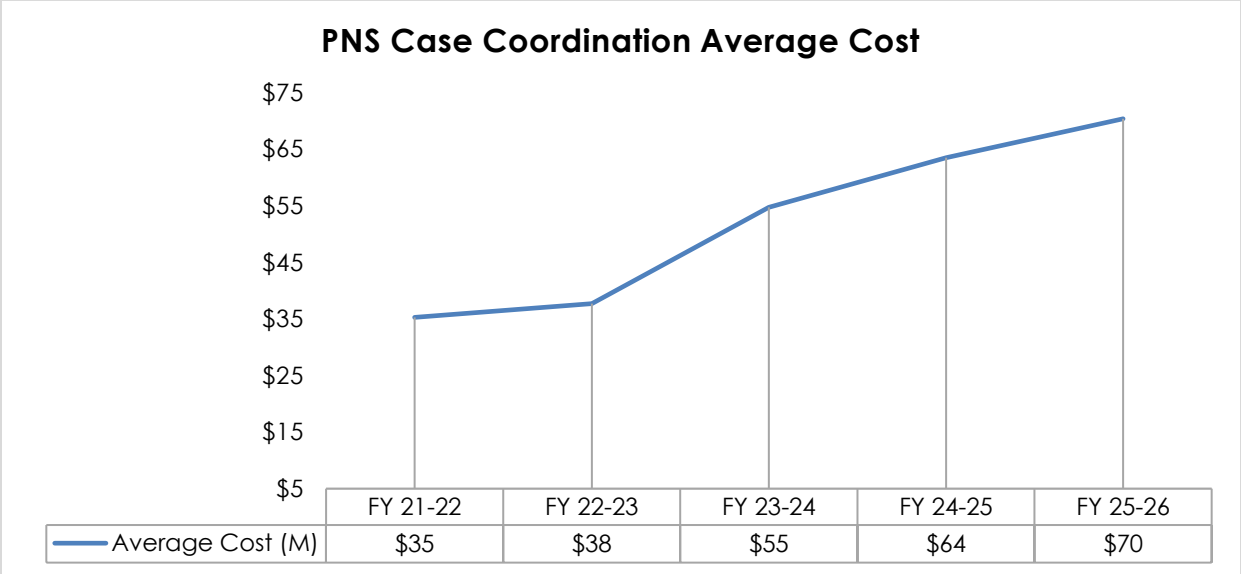
screens and ultrasounds, identifying patients whose blood specimens were drawn too early or were inadequate, requiring additional blood draws. The PNS Case Coordination Centers (CCCs) provide clinician and patient education and consultations; make referrals to Prenatal Diagnostic Centers for diagnostic 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 are referred to a case coordinator for which separate services are performed. The CDPH/GDSP estimates the current year CMCS caseload at 41,870, which is a slight increase of 192 or 0.2 percent compared to 2023-24 actual CMCS caseload of 41,678. The CDPH/GDSP estimates the budget year CMCS caseload at 41,670, which is a slight decrease of 200 or 0.5 percent compared to the current year. The caseload fluctuations are attributed to the projected specimens and the impact of the decline in cfDNA and SCA participation in PNS program.

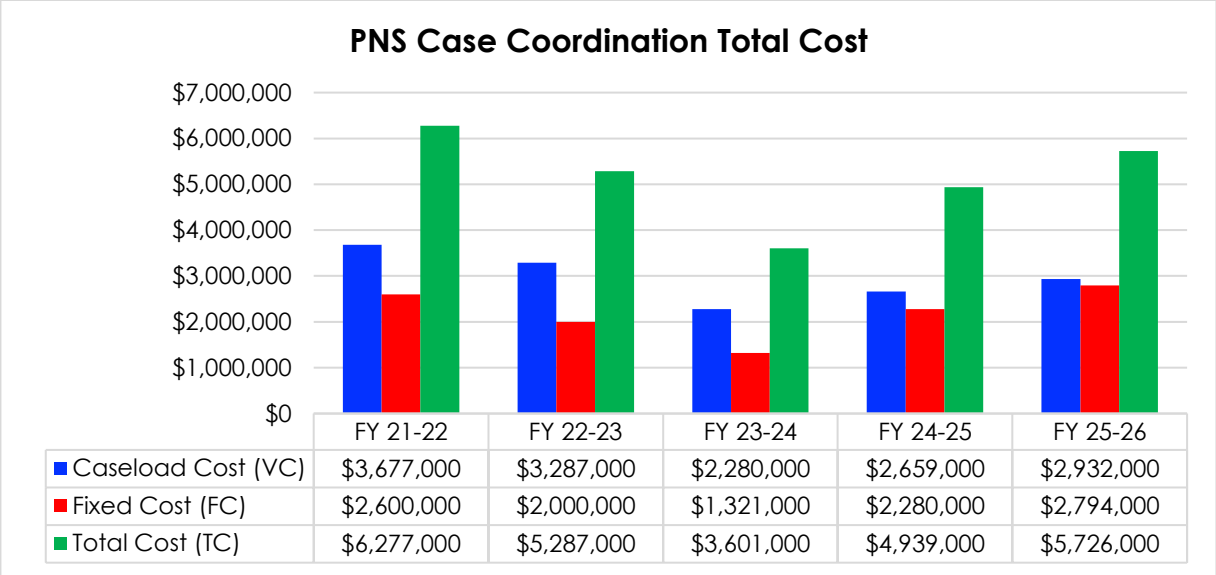


Case Management and Coordination Services Average Cost – The cfDNA and NTD positive cases are referred to a case coordinator for which a separate cost per participant is attributed. The CDPH/GDSP estimates the current year

average CMCS cost per participant at $63.51, which is an increase of $8.80 or 23 percent compared to 2023-24 actual average CMCS cost per participant of $54.71. The CDPH/GDSP estimates the budget year average CMCS cost per participant will be $70.36, which is a slight increase of $6.86 or 11 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 operational 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 is attributed on cost per test plus a base allocation. The CDPH/GDSP estimates the current year CMCS costs at $5 million, which is an increase of $1 million or 25 percent compared to 2023-24 actual CMCS total costs of $4 million. The increase in the current year is attributable to the changes in the CMCS caseload and a slight increase in fixed costs. The CDPH/GDSP estimates the budget year CMCS costs at $5.7 million, which is an increase of $787,000 or 16 percent compared to the current year. The increase is mainly due to the increase in the operational and fixed costs.



	FY 21-22	FY 22-23	FY 23-24	FY 24-25	FY 25-26
Caseload Cost (VC)	$3,677,000	$3,287,000	$2,280,000	$2,659,000	$2,932,000
Fixed Cost (FC)	$2,600,000	$2,000,000	$1,321,000	$2,280,000	$2,794,000
Total Cost (TC)	$6,277,000	$5,287,000	$3,601,000	$4,939,000	$5,726,000

APPENDIX C: REVENUE PROJECTIONS

NBS REVENUE

The NBS Program currently charges a fee of $226 for newborn screening, this reflects an addition of $15 added to the fee on July 1, 2024, to offset the costs of adding two new disorders (MPS II and GAMT deficiency) to the screening panel. In most cases, the fee is paid directly to CDPH/GDSP by hospitals.

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, resulting in a 99 percent collection rate. The CDPH/GDSP uses the following formula to estimate revenue generated from NBS fees:

Of Projected Newborns Screened × Fee × 99 percent

NBS Revenue Projections

Fiscal Year	Fee (A)	Caseload (B)	Collection Rate (C)	Total Revenue (D) = (A) x (B) x (C)
FY 2024-25	$226.00	404,023	99 percent	**$90,396,000**
FY 2025-26	$226.00	402,104	99 percent	**$89,967,000**

PNS REVENUE

The Prenatal Screening Program charges a fee of $334 to all individuals participating in cfDNA screening program. Of the total fee, $324 is deposited into the GDTF (Fund 0203), and $10 is deposited into the California Birth Defect Monitoring Program Fund (Fund 3114). The GDSP charges a separate fee of $85 for those individuals who participate in 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).

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. Past collection rates show that PNS collects a higher percentage of anticipated revenues from Medi-

Cal enrollees and hospital providers that are directly billed as opposed to those enrolled in private insurance plans, out of state plans, self-funded plans, or the uninsured. The CDPH/GDSP estimates revenues 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 medical group providers, known as client billing.

PNS projected annual billable cfDNA caseload of 200,654 in Fiscal Year 2024-25 and 199,696 in 2025-26, and NTD caseload of 251,800 in 2024-25 and 250,598 in 2025-26. Out of these billable caseloads, approximately 32 percent of cfDNA and 30 percent of neural tube defect (NTD) are billed through client billing. The collection rate for claims billed directly to medical group 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 precent, 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:

(Fee × (PNS Participants × cfDNA/NTD Participation Rate) × 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)**
FY 2024-25	$334.00	200,654	32%	64,209	99%	**$21,231,000**
FY 2025-26	$334.00	199,696	32%	63,903	99%	**$21,130,000**

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)**
FY 2024-25	$75.00	251,800	30%	75,540	99%	**$5,609,000**
FY 2025-26	$75.00	250,598	30%	75,179	99%	**$5,582,000**

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

(Fee × cfDNA/NTD Participants × Medi-Cal Participation Rate × Medi-Cal Collection Rate) + (Fee × PNS Participants × Private Payer Rate × Private Payer Collection Rate)

Patient Billing Revenue – cfDNA

Fiscal Year	Medi-Cal Revenue	Non-Medical Revenue	Total Revenue
(A)	(B)	(C)	(D) = (B) + (C)
FY 2024-25	$27,070,000	$17,318,000	**$44,388,000**
FY 2025-26	$26,941,000	$17,235,000	**$44,176,000**

Patient Billing Revenue - NTD

Fiscal Year	Medi-Cal Revenue	Non-Medical Revenue	Total Revenue
(A)	(B)	(C)	(D) = (B) + (C)
FY 2024-25	$7,852,000	$5,023,000	**$12,875,000**
FY 2025-26	$7,815,000	$4,999,000	**$12,814,000**

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) × (B)
FY 2024-25	$334	200,654	68%	136,445	60%	81,867	99%	**$27,070,000**
FY 2025-26	$334	199,696	68%	135,794	60%	81,476	99%	**$26,941,000**

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) × (B)**
FY 2024-25	$334	200,654	68%	136,445	40%	54,578	95%	**$17,318,000**
FY 2025-26	$334	199,696	68%	135,794	40%	54,317	95%	**$17,235,000**

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)**
FY 2024-25	$75	251,800	70%	176,260	60%	105,756	99%	**$7,852,000**
FY 2025-26	$75	250,598	70%	175,418	60%	105,251	99%	**$7,815,000**

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) × (B)**
FY 2024-25	$75	251,800	70%	176,260	40%	70,504	95%	**$5,023,000**
FY 2025-26	$75	250,598	70%	175,418	40%	70,167	95%	**$4,999,000**