

Genetic Disease Screening Program

(GDSP)

2025-26 November Estimate



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ESTIMATES

PROGRAM OVERVIEW

The California Department of Public Health (CDPH), Genetic Disease Screening Program (GDSP) November Estimate provides a revised projection of 2024-25 expenditures along with a 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 diseases. Parents may opt their newborns out of the program by claiming religious exemptions. PNS is an opt-in program for women who desire to participate. The screening test provides the pregnant 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 Budget Act appropriation is \$176.8 million, of which \$138 million is for Local Assistance and \$38.8 million is for State Operations. The CDPH/GDSP estimates 2024-25 expenditures of \$175.1 million, which is a decrease of \$1.7 million or 1 percent compared to the 2024 Budget Act. Much of the decrease is attributed to lower Prenatal Screening (PNS) Program participation than previously projected cost in the May Revision Estimates, which is offset by the cost increase in Newborn Screening (NBS) Program.

The combined State Operations and Local Assistance budget expenditures for 2025-26 total \$176.3 million, which is a decrease of \$505,000 or 0.3 percent compared to the 2024 Budget Act. The \$505,000 decrease consists of a \$809,000 increase in Local Assistance and a \$1.3 million decrease in State Operations. The increase in Local Assistance expenditures is attributed to an increase in the participation of neural tube defect (NTD) screening and the addition of sex chromosome aneuploidies (SCA) to the prenatal screening panel. The decrease in State Operations is due to baseline adjustments.

Table 1 shows the difference between the 2024 Budget Act appropriation and the revised 2024-25 expenditures and proposed 2025-26 expenditures for CDPH/GDSP.

Table 1: Genetic Disease Screening Program: Current Year and Budget Year Budget Summaries Compared to 2024 Budget Act

| Fund 0203 Genetic Disease Testing Fund | 2024 Budget Act | November Estimate | Change from Budget Act | Percent Change from Budget Act |
|---|----------------------------|------------------------------|-----------------------------------|---|
| Fiscal Year 2024-2025 Total | \$176,806,000 | \$175,101,000 | (\$1,705,000) | -1.0% |
| Fiscal Year 2024-2025 State Operations | \$38,761,000 | \$38,625,000 | (\$136,000) | -0.4% |
| Fiscal Year 2024-2025 Local Assistance | \$138,045,000 | \$136,476,000 | (\$1,569,000) | -1.1% |
| Fiscal Year 2025-2026 Total | \$176,806,000 | \$176,301,000 | (\$505,000) | -0.3% |
| Fiscal Year 2025-2026 State Operations | \$38,761,000 | \$37,447,000 | (\$1,314,000) | -3.4% |
| Fiscal Year 2025-2026 Local Assistance | \$138,045,000 | \$138,854,000 | \$809,000 | 0.6% |

LOCAL ASSISTANCE EXPENDITURE PROJECTIONS

CURRENT YEAR (2024-25)

The 2024 Budget Act appropriation for CDPH/GDSP’s Local Assistance is \$138 million in 2024-25. The CDPH/GDSP estimates 2024-25 Local Assistance expenditures will total \$136.4 million, which is a decrease of \$1.6 million or 1.1 percent compared to the 2024 Budget Act. The decrease in Local Assistance consists of a \$5.6 million decrease from lower projected prenatal caseload due to lower participation in Cell-Free DNA (cfDNA) Screening (from 52 to 50 percent) compared to the 2024 Budget Act. This decline is somewhat offset by newborn screening contract rate increases of approximately \$4 million.

BUDGET YEAR (2025-26)

For 2025-26, the CDPH/GDSP estimates Local Assistance expenditures will total \$138.8 million, which is a net increase of \$809,000 or 0.6 percent compared to the 2024 Budget Act amount of \$138 million. The net increase in Local Assistance is attributed to the laboratory supplies and services and case management and coordination services (CMCS) contract rate increases. These increases are somewhat offset by lower participation in Prenatal cfDNA Screening (52 to 50 percent) and an overall decrease in

both NBS and PNS caseload because of the Department of Finance (Finance) Demographic Research Units (DRU) declining projection of live births compared to the projections used in the 2024 Budget Act.

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

Table 2: Local Assistance Total: Current Year and Budget Year Budget Summaries Compared to 2024 Budget Act

| Fund 0203 Genetic Disease Testing Fund | 2024 Budget Act | November Estimate | Change from Budget Act | Percent Change from Budget Act |
|---|----------------------------|------------------------------|-----------------------------------|---|
| Fiscal Year 2024-2025 Local Assistance Total | \$138,045,000 | \$136,476,000 | (\$1,569,000) | -1.1% |
| Fiscal Year 2024-2025 Newborn Screening | \$46,678,000 | \$50,714,000 | \$4,036,000 | 8.6% |
| Fiscal Year 2024-2025 Prenatal Screening | \$61,059,000 | \$55,454,000 | (\$5,605,000) | -9.2% |
| Fiscal Year 2024-2025 Operational Support | \$30,308,000 | \$30,308,000 | \$0 | 0.0% |
| Fiscal Year 2025-2026 Local Assistance Total | \$138,045,000 | \$138,854,000 | \$809,000 | 0.6% |
| Fiscal Year 2025-2026 Newborn Screening | \$46,678,000 | \$52,737,000 | \$6,059,000 | 13.0% |
| Fiscal Year 2025-2026 Prenatal Screening | \$61,059,000 | \$57,109,000 | (\$3,950,000) | -6.5% |
| Fiscal Year 2025-2026 Operational Support | \$30,308,000 | \$29,008,000 | (\$1,300,000) | -4.3% |

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 is presented in the appendices.

NBS EXPENDITURE PROJECTIONS (SEE APPENDICES A1-A5)

For 2024-25, CDPH/GDSP estimates NBS Local Assistance expenditures will total \$50.7 million, which is a net increase of \$4 million or 8.6 percent compared to the 2024

Budget Act amount of \$47 million. The net increase is attributed to contract rate increases and the increased costs of reagent kits, consumables, and supplies.

For 2025-26, CDPH/GDSP estimates that NBS Local Assistance expenditures will total \$52.7 million, which is an increase of \$6 million or 13 percent compared to the 2024 Budget Act amount of \$47 million. The increase is attributed to the continuing inflationary rate increases mainly seen in NBS Technical and Scientific cost center for reagent kits, consumables, and supplies. There have also been increases in contracted regional Newborn and Prenatal Screening (NAPS) costs and Area Service Center (ASC) contract fixed costs. These increases are offset by the decreases for Reference Laboratories as a result of canceled confirmatory services contracts and the continually declining birth rate.

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

Table 3: Newborn Screening: Current Year and Budget Year Budget Summaries Compared to 2024 Budget Act

| Fund 0203 Genetic Disease Testing Fund | 2024 Budget Act | November Estimate | Change from Budget Act | Percent Change from Budget Act |
|---|------------------------|--------------------------|-------------------------------|---------------------------------------|
| Fiscal Year 2024-2025 Total | \$46,678,000 | \$50,714,000 | \$4,036,000 | 8.6% |
| Fiscal Year 2024-2025 Contract Lab | \$7,626,000 | \$8,205,000 | \$579,000 | 7.6% |
| Fiscal Year 2024-2025 Tech Sci | \$27,552,000 | \$31,335,000 | \$3,783,000 | 13.7% |
| Fiscal Year 2024-2025 Reference Lab | \$2,570,000 | \$2,085,000 | (\$485,000) | -18.9% |
| Fiscal Year 2024-2025 CMCS | \$6,697,000 | \$6,859,000 | \$162,000 | 2.4% |
| Fiscal Year 2024-2025 Diagnostic Services | \$2,233,000 | \$2,230,000 | (\$3,000) | -0.1% |
| Fiscal Year 2025-2026 Total | \$46,678,000 | \$52,737,000 | \$6,059,000 | 13.0% |
| Fiscal Year 2025-2026 Contract Lab | \$7,626,000 | \$8,575,000 | \$949,000 | 12.4% |
| Fiscal Year 2025-2026 Tech Sci | \$27,552,000 | \$32,560,000 | \$5,008,000 | 18.2% |
| Fiscal Year 2025-2026 Reference Lab | \$2,570,000 | \$2,178,000 | (\$392,000) | -15.3% |

| Fund 0203 Genetic Disease Testing Fund | 2024 Budget Act | November Estimate | Change from Budget Act | Percent Change from Budget Act |
|---|------------------------|--------------------------|-------------------------------|---------------------------------------|
| Fiscal Year 2025-2026 CMCS | \$6,697,000 | \$7,187,000 | \$490,000 | 7.3% |
| Fiscal Year 2025-2026 Diagnostic Services | \$2,233,000 | \$2,237,000 | \$4,000 | 0.2% |

PNS EXPENDITURES PROJECTIONS (SEE APPENDICES B1-B4)

For 2024-25, the CDPH/GDSP estimates PNS Local Assistance expenditures to total \$55.5 million, which is a decrease of \$5.6 million or 9.2 percent compared to the 2024 Budget Act amount of \$61.1 million. The decrease in the current year is attributed to the decrease in caseloads due to lower participation rate in cfDNA screening and DRU’s lower than previously projected live births.

For 2025-26, the CDPH/GDSP estimates that PNS Local Assistance expenditures will total \$57 million, which is a net decrease of \$4 million or 6.5 percent compared to the 2024 Budget Act. The net decrease is attributed to the cost reductions in cfDNA screening, the Technical & Scientific cost center, and Prenatal Diagnosis Centers (PDC) referrals due to a lower cfDNA participation rate and lower than previously projected birth rates from the DRU in May Revision. These decreases are slightly offset by the increases in Contract Lab and CMCS categories due to the increasing participation for NTD screening.

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

Table 4: Prenatal Screening: Current Year and Budget Year Budget Summaries Compared to 2024 Budget Act

| Fund 0203 Genetic Disease Testing Fund | 2024 Budget Act | November Estimate | Change from Budget Act | Percent Change from Budget Act |
|---|------------------------|--------------------------|-------------------------------|---------------------------------------|
| Fiscal Year 2024-2025 Total | \$61,059,000 | \$55,454,000 | (\$5,605,000) | -9.2% |
| Fiscal Year 2024-2025 cfDNA | \$40,965,000 | \$38,526,000 | (\$2,439,000) | -6.0% |
| Fiscal Year 2024-2025 Contract Lab | \$3,156,000 | \$3,055,000 | (\$101,000) | -3.2% |
| Fiscal Year 2024-2025 Tech & Sci | \$3,631,000 | \$3,215,000 | (\$416,000) | -11.5% |

| Fund 0203 Genetic Disease Testing Fund | 2024 Budget Act | November Estimate | Change from Budget Act | Percent Change from Budget Act |
|---|------------------------|--------------------------|-------------------------------|---------------------------------------|
| Fiscal Year 2024-2025 CMCS | \$5,429,000 | \$5,429,000 | \$0 | 0.0% |
| Fiscal Year 2024-2025 PDC | \$7,878,000 | \$5,229,000 | (\$2,649,000) | -33.6% |
| Fiscal Year 2025-2026 Total | \$61,059,000 | \$57,109,000 | (\$3,950,000) | -6.5% |
| Fiscal Year 2025-2026 cfDNA | \$40,965,000 | \$39,105,000 | (\$1,860,000) | -4.5% |
| Fiscal Year 2025-2026 Contract Lab | \$3,156,000 | \$3,192,000 | \$36,000 | 1.1% |
| Fiscal Year 2025-2026 Tech & Sci | \$3,631,000 | \$3,348,000 | (\$283,000) | -7.8% |
| Fiscal Year 2025-2026 CMCS | \$5,429,000 | \$5,700,000 | \$271,000 | 5.0% |
| Fiscal Year 2025-2026 PDC | \$7,878,000 | \$5,764,000 | (\$2,114,000) | -26.8% |

OPERATIONAL SUPPORT PROJECTIONS

For 2024-25, the CDPH/GDSP Operational Support expenditures total is \$30 million, which is no change from the 2024 Budget Act.

For 2025-26, the CDPH/GDSP projects operational support expenditures will total \$29 million, which is a decrease of \$1.3 million or 4.3 percent compared to the 2024 Budget Act. The cost reduction is due to the completion of Microsoft Dynamics migration for cfDNA implementation.

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

Table 5: Operational Support: Current Year and Budget Year Budget Summaries Compared to 2024 Budget Act

| Fund 0203 Genetic Disease Testing Fund | 2024 Budget Act | November Estimate | Change from Budget Act | Percent Change from Budget Act |
|---|------------------------|--------------------------|-------------------------------|---------------------------------------|
| Fiscal Year 2024-2025 Operational Support | \$30,308,000 | \$30,308,000 | \$0 | 0.0% |
| Fiscal Year 2025-2026 Operational Support | \$30,308,000 | \$29,008,000 | (\$1,300,000) | -4.3% |

STATE OPERATIONS EXPENDITURE PROJECTIONS

The 2024 Budget Act appropriation for CDPH/GDSP's State Operations is \$38.8 million. For 2024-25, the CDPH/GDSP estimates State Operations expenditures will total \$38.6 million, which is a decrease of \$136,000 or 0.4 percent compared to the 2024 Budget Act. For 2025-26, the CDPH/GDSP estimates State Operations expenditures will total \$37.4 million, which is a decrease of \$1.3 million or 3.4 percent compared to the 2024 Budget Act. The reduction in both current and budget year from the 2024 Budget Act is attributed to baseline adjustments.

Table 6 displays the 2024-25 and 2025-26 expenditures for the CDPH/GDSP State Operations costs.

Table 6: State Operations: Current Year and Budget Year Budget Summaries Compared to 2024 Budget Act

| Fund 0203 Genetic Disease Testing Fund | 2024 Budget Act | November Estimate | Change from Budget Act | Percent Change from Budget Act |
|---|------------------------|--------------------------|-------------------------------|---------------------------------------|
| Fiscal Year 2024-2025 State Operations | \$38,761,000 | \$38,625,000 | (\$136,000) | -0.4% |
| Fiscal Year 2025-2026 State Operations | \$38,761,000 | \$37,447,000 | (\$1,314,000) | -3.4% |

REVENUE PROJECTIONS**COMBINED NBS AND PNS REVENUE**

For 2024-25, the CDPH/GDSP estimates the total revenue of \$173.7 million, which is a decrease of \$2.1 million or 1.2 percent compared to the 2024 Budget Act amount of \$175.8 million.

For 2025-26, the CDPH/GDSP estimates the total revenue of \$172.1 million, which is a decrease of \$3.7 million or 2.1 percent compared to the 2024 Budget Act.

The revenue decreases in the current and budget year are attributed to the continuing decline in the birth rate in addition to the decrease in cfDNA screening participation.

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 NBS revenue is projected at \$89.5 million, which is a decrease of \$594,000 or 0.7 percent compared to the 2024 Budget Act amount of \$90.1 million. For 2025-26, the CDPH/GDSP projects that the NBS revenue would total \$88.5 million, which is a decrease of 1.7 percent compared to the 2024 Budget Act amount. The

revenue decreases in the current and budget year are due to decreases in projected caseloads as a result of DRU's projection of declining live births.

PNS REVENUE (SEE APPENDIX C2)

For 2024-25, the PNS revenue is projected at \$84.2 million, which is a decrease of \$1.5 million or 1.7 percent compared to the 2024 Budget Act amount of \$85.7 million. For 2025-26, the CDPH/GDSP projects that the PNS revenue would total \$83.5 million, which is a decrease of \$2.2 million or 2.6 percent compared to the 2024 Budget Act.

The revenue decreases in the current and budget year are attributed to lower cfDNA screening participation and DRU birth rate declines.

Table 7 shows the current year and budget year revenues compared to the 2024 Budget Act.

Table 7: Genetic Disease Screening Program Revenue: Current Year and Budget Year Revenue Summaries Compared to 2024 Budget Act

| Fund 0203 Genetic Disease Testing Fund | 2024 Budget Act | November Estimate | Change from Budget Act | Percent Change from Budget Act |
|---|------------------------|--------------------------|-------------------------------|---------------------------------------|
| Fiscal Year 2024-2025 Total | \$175,786,000 | \$173,715,000 | (\$2,071,000) | -1.2% |
| Fiscal Year 2024-2025 Newborn Screening | \$90,059,000 | \$89,465,000 | (\$594,000) | -0.7% |
| Fiscal Year 2024-2025 Prenatal Screening | \$85,727,000 | \$84,250,000 | (\$1,477,000) | -1.7% |
| Fiscal Year 2025-2026 Total | \$175,786,000 | \$172,051,000 | (\$3,735,000) | -2.1% |
| Fiscal Year 2025-2026 Newborn Screening | \$90,059,000 | \$88,535,000 | (\$1,524,000) | -1.7% |
| Fiscal Year 2025-2026 Prenatal Screening | \$85,727,000 | \$83,516,000 | (\$2,211,000) | -2.6% |

FUND CONDITION STATEMENT

This Fund Condition Report lists both actual and projected revenues, expenditures, and expenditure adjustments for current and future fiscal years under Genetic Disease Testing Fund. All dollar figures are expressed in thousands of dollars.

Table 8. RESOURCES

| RESOURCES | 2023-24 | 2024-25 | 2025-26 |
|----------------------------|----------------|----------------|----------------|
| BEGINNING BALANCE | \$33,053 | \$19,341 | \$16,985 |
| Prior Year Adjustment | \$11,793 | \$0 | \$0 |
| Adjusted Beginning Balance | \$44,846 | \$19,341 | \$16,985 |

Table 9. REVENUES

| REVENUES | 2023-24 | 2024-25 | 2025-26 |
|--|----------------|----------------|----------------|
| 4123400 Genetic Disease Testing Fees | \$147,997 | \$173,715 | \$172,051 |
| 4163000 Income from Surplus Investments | \$1,496 | \$118 | \$118 |
| 4171400 Escheat of Unclaimed Checks & Warrants | \$313 | \$103 | \$103 |
| Total Revenues | \$149,806 | \$173,936 | \$172,272 |

Table 10. TOTAL RESOURCES

| TOTAL RESOURCES | 2023-24 | 2024-25 | 2025-26 |
|----------------------------|----------------|----------------|----------------|
| Adjusted Beginning Balance | \$44,846 | \$19,341 | \$16,985 |
| Total Revenues | \$149,806 | \$173,936 | \$172,272 |
| Total Resources | \$194,653 | \$193,277 | \$189,257 |

Table 11. EXPENDITURES AND EXPENDITURE ADJUSTMENTS

| EXPENDITURES AND EXPENDITURE ADJUSTMENTS | 2023-24 | 2024-25 | 2025-26 |
|---|----------------|----------------|----------------|
| 4265 Department of Public Health (State Operations) | \$33,196 | \$38,625 | \$37,447 |
| 4265 Department of Public Health (Local Assistance) | \$141,620 | \$136,476 | \$138,854 |
| 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 | \$176,292 | \$178,618 |

Table 12. FUND BALANCE

| FUND BALANCE | 2023-24 | 2024-25 | 2025-26 |
|--|----------------|----------------|----------------|
| Total Resources | \$194,653 | \$193,277 | \$189,257 |
| Total Expenditures and Expenditure Adjustments | \$175,312 | \$176,292 | \$178,618 |
| Fund Balance | \$19,341 | \$16,985 | \$10,639 |
| Fund Balance as a Percentage of Total Expenditures and Expenditure Adjustments | 11% | 10% | 6% |

Table 13. GDSP REVENUE PROJECTION 2024-2025 OF \$173,715,000

| Billing Types | Number of Tests | Cost | Collection Rate | Revenue |
|----------------------|------------------------|-------------|------------------------|----------------|
| NBS Client Billing | 399,861 NBS | \$226.00 | Provider: 99% | \$89,465,000 |
| PNS Client Billing | 64,503 cfDNA | \$334.00 | Provider: 99% | \$21,329,000 |
| PNS Client Billing | 74,910 NTD | \$75.00 | Provider: 99% | \$5,562,000 |
| PNS Patient Billing | 54,828 cfDNA | \$334.00 | Non-Medi-Cal: 95% | \$17,397,000 |
| PNS Patient Billing | 82,242 cfDNA | \$334.00 | Medi-Cal: 99% | \$27,194,000 |
| PNS Patient Billing | 69,916 NTD | \$75.00 | Non-Medi-Cal: 95% | \$4,981,000 |
| PNS Patient Billing | 104,874 NTD | \$75.00 | Medi-Cal: 99% | \$7,787,000 |

Table 14. GDSP REVENUE PROJECTION 2025-2026 OF \$172,051,000

| Billing Types | Number of Tests | Cost | Collection Rate | Revenue |
|----------------------|------------------------|-------------|------------------------|----------------|
| NBS Client Billing | 395,705 NBS | \$226.00 | Provider: 99% | \$88,535,000 |
| PNS Client Billing | 63,941 cfDNA | \$334.00 | Provider: 99% | \$21,143,000 |
| PNS Client Billing | 74,257 NTD | \$75.00 | Provider: 99% | \$5,514,000 |
| PNS Patient Billing | 54,350 cfDNA | \$334.00 | Non-Medi-Cal: 95% | \$17,245,000 |
| PNS Patient Billing | 81,525 cfDNA | \$334.00 | Medi-Cal: 99% | \$26,957,000 |
| PNS Patient Billing | 69,306 NTD | \$75.00 | Non-Medi-Cal: 95% | \$4,938,000 |
| PNS Patient Billing | 103,960 NTD | \$75.00 | Medi-Cal: 99% | \$7,719,000 |

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. The Federal Advisory Committee voted on July 1, 2024 to add the infantile Krabbe disease (low galactocerebrosidase [GALC] and psychosine $\geq 10\text{nM}$) 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 range is only an estimate and is based on costs incurred from the last additions to the NBS panel – spinal muscular atrophy (SMA), mucopolysaccharidosis type I (MPS I) and Pompe disease, and 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 continually 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. At this time, CDPH/GDSP believes it can absorb implementation costs in 2025-26 associated with the upcoming screening of Krabbe disease and should only need to request an increase in Local Assistance expenditure authority once screening begins in 2026-27. 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

There are no Unchanged Assumptions/Premises.

DISCONTINUED ASSUMPTIONS/PREMISES

There are no Discontinued Assumptions/Premises.

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

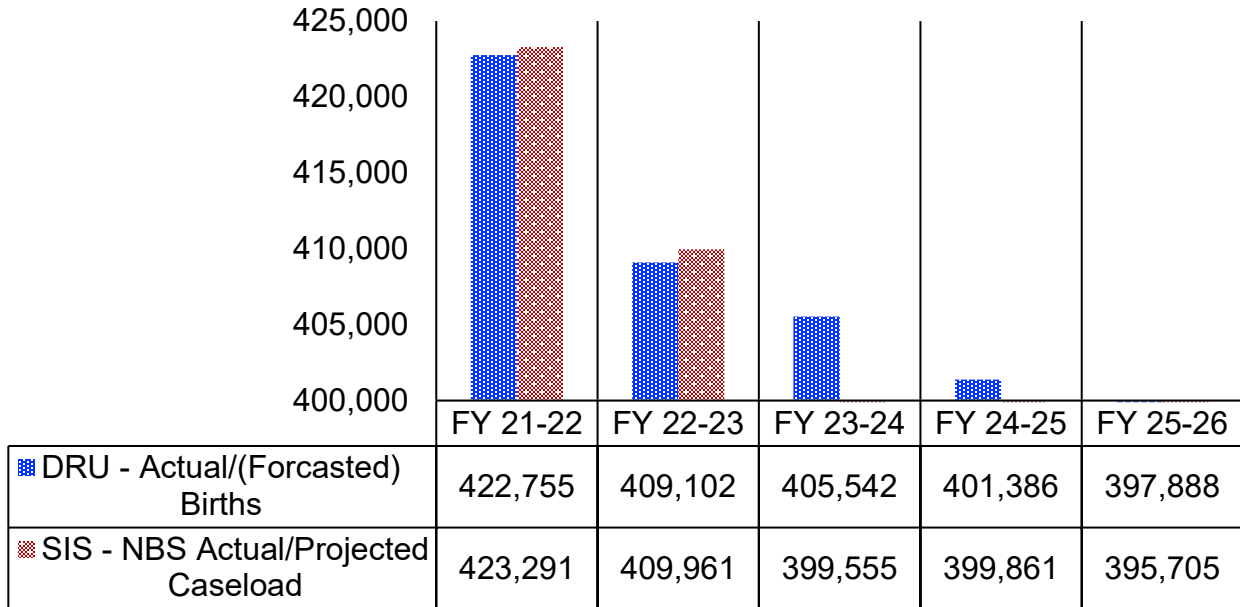
CONTRACT LABORATORIES

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 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 Finance/DRU projected births will participate in the NBS program in 2023-24 and 2024-25.

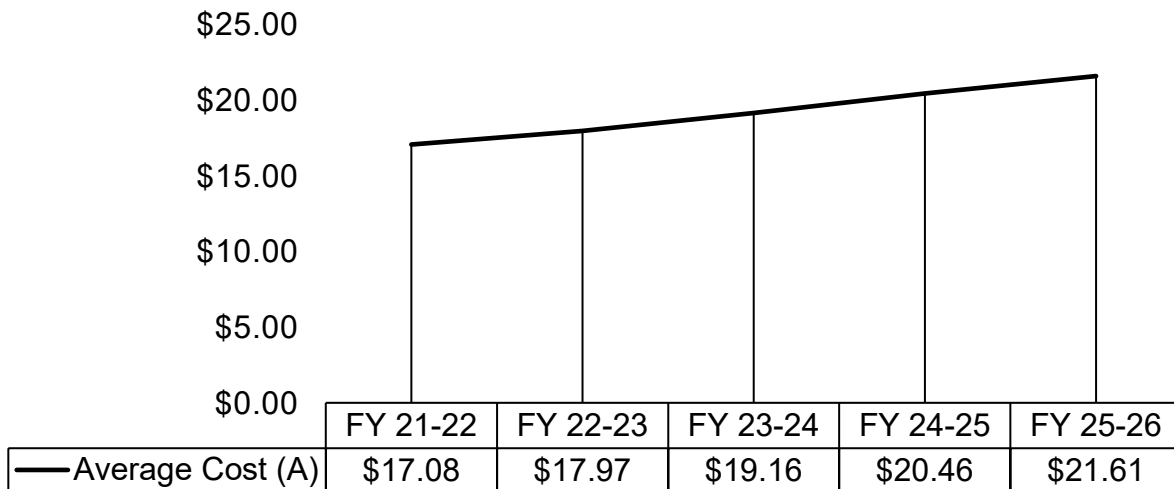
Total Caseload – The CDPH/GDSP estimates current-year caseload will total 399,861, a decrease of 306 or 0.1 percent compared to the 2023-24 actual total caseload of 399,555. The caseload in 2025-26 is estimated at 395,705, which is another decrease of 4,156 or 1 percent compared to the current year estimate. This annual change is due to the change in Finance/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.

NBS CASELOAD



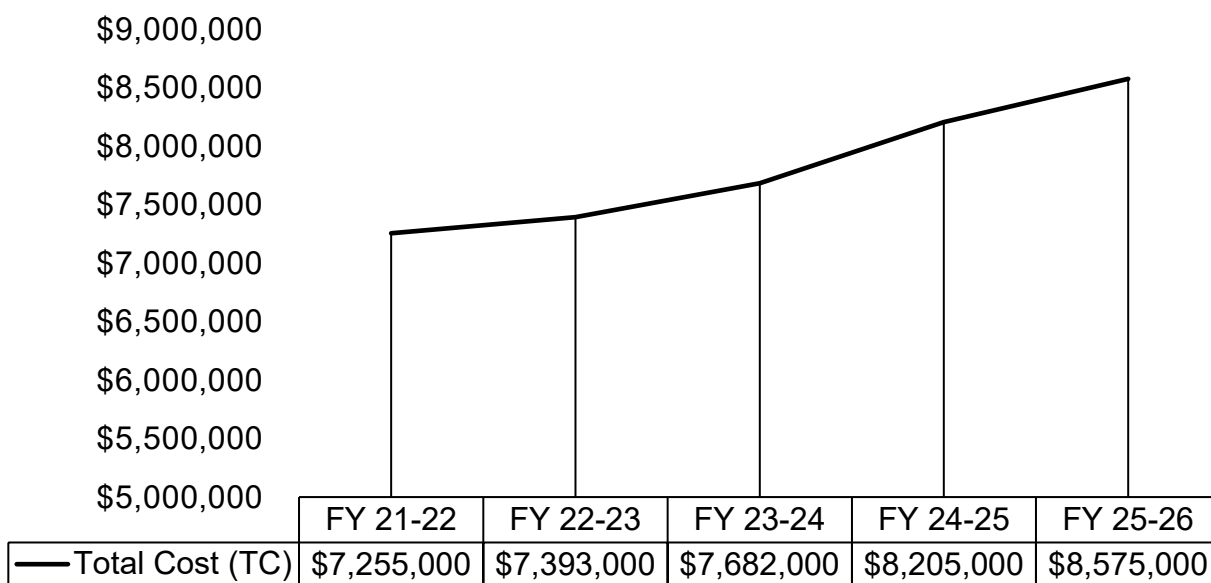
Contract Laboratory Average Cost Projections – The CDPH/GDSP estimates current year average laboratory cost per participant will be \$20.46, which is an increase of \$1.30 or 6.8 percent compared to the 2023-24 actual average laboratory cost per participant of \$19.16. Average laboratory cost per participant in 2025-26 is estimated at \$21.61, which is an increase of \$1.15 or 5.6 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.

NBS Contract Lab Average Cost



Contract Laboratory Total Cost Projections – The CDPH/GDSP estimates current year contract laboratory costs to total \$8.2 million, which is an increase of \$523,000 or 6.8 percent compared to 2023-24 actual contract laboratory costs of \$7.7 million. The contract laboratory costs in 2025-26 are projected to be \$8.6 million, which is an increase of \$370,000 or 4.5 percent compared to the current year.

NBS Contract Lab Total Cost



TECHNICAL AND SCIENTIFIC

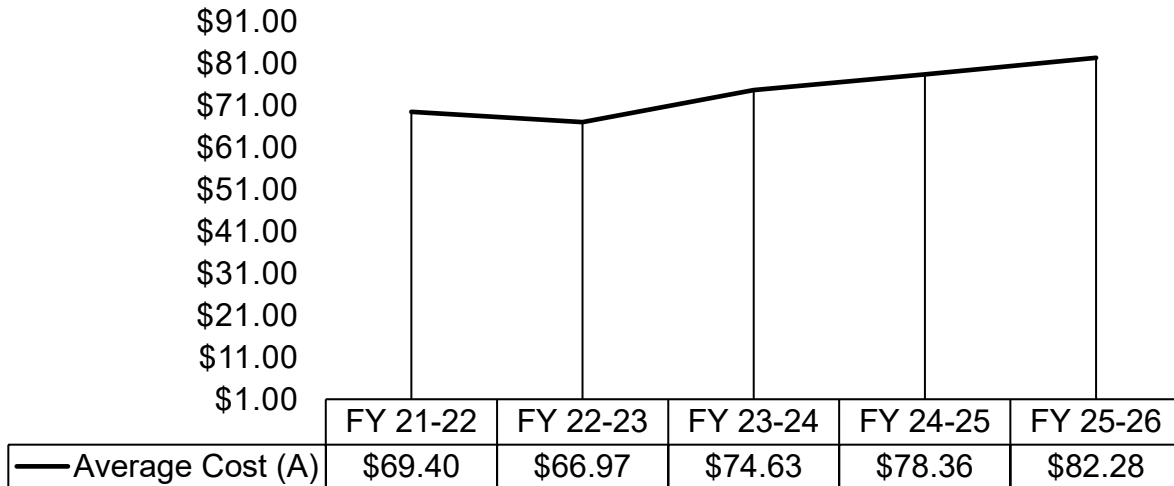
Overview: Costs associated with specimen screening include reagents kits, supplies, processing, and limited maintenance and support of laboratory equipment. In addition, there are minimal fixed costs associated with specimen screening including: laboratory supplies, blood specimen filter paper, blood 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 \$78.36, which is an increase of \$3.73 or 5 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 \$82.28, which is an increase of \$3.92 or 5 percent

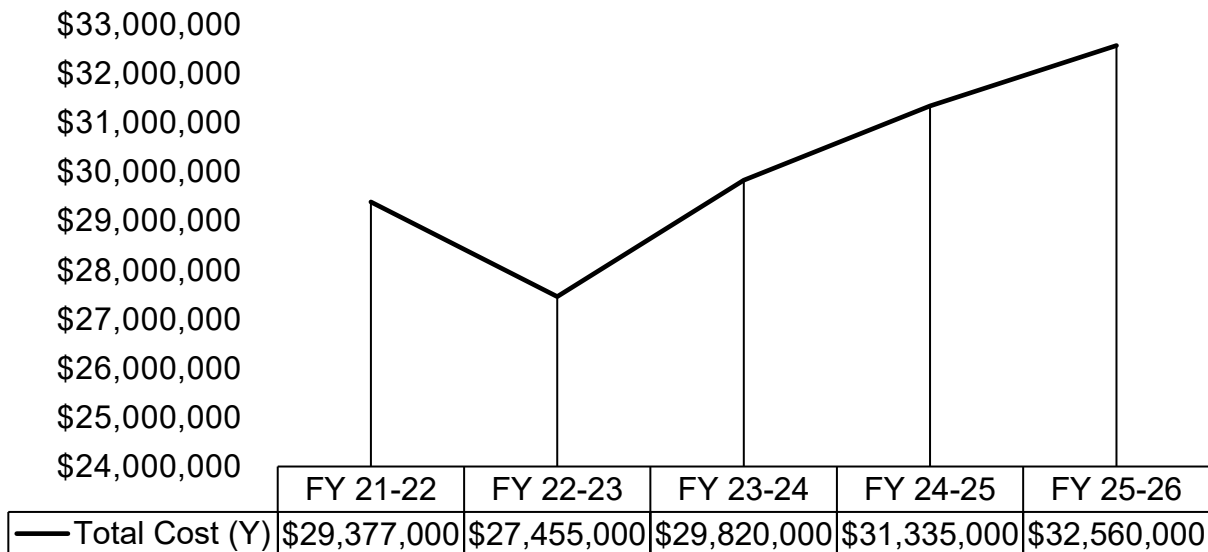
compared to the current year estimate. The increase in average cost is due to the increasing marginal costs due to inflation.

NBS Tech & Sci Average Cost



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, the Technical and Scientific costs is estimated at \$32.6 million, which is an increase of \$1.2 million or 4 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.

NBS Tech & Sci Total Cost

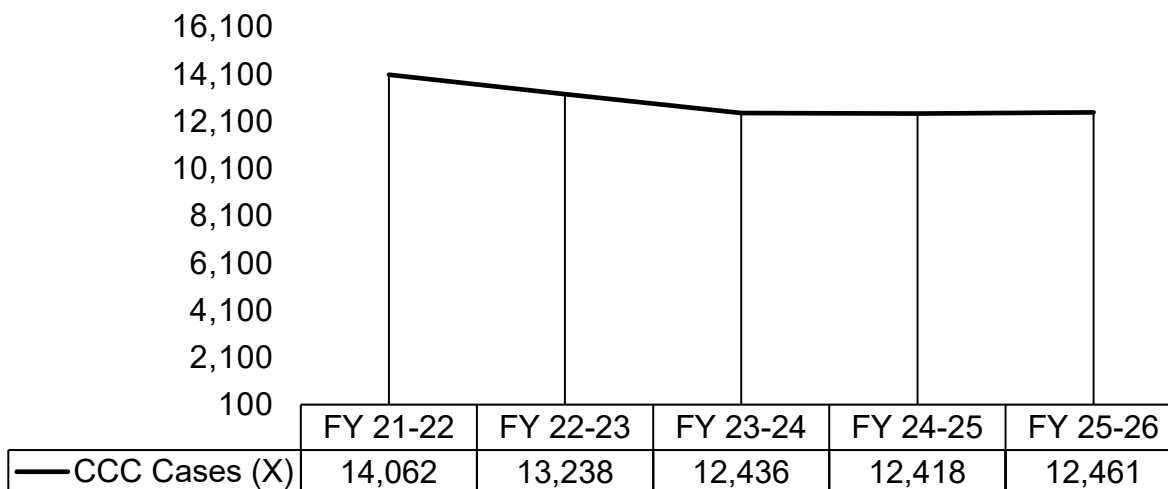


CASE MANAGEMENT AND COORDINATION SERVICES:

Overview – Services provided to infants who screen initial positive or have questionable screening test results for the 80+ 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. Base allocation costs vary by ASC and are dependent upon the geographical location.

Case Management and Coordination Services (CMCS) Caseload – The CDPH/GDSP estimates current year CMCS caseload will total 12,418, which is a decrease of 18 or 0.1 percent compared to 2023-24 actual CMCS caseload of 12,436. CMCS caseload in 2025-26 is estimated at 12,461, which is a slight increase of 43 or 0.3 percent compared to the current year estimate. Despite birth declines, the projected caseload increases are due to ongoing data corrections on newborn records.

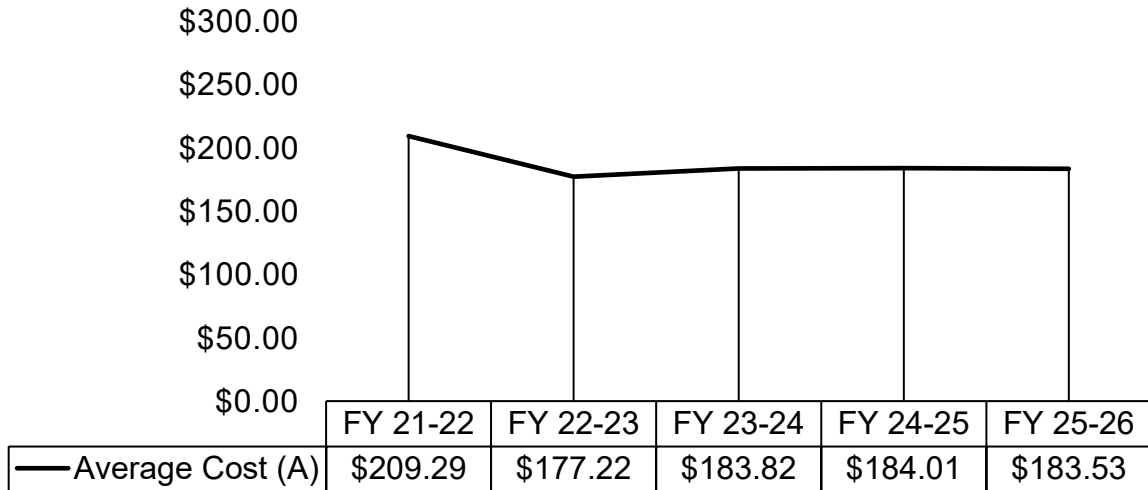
NBS CCC (ASC) Caseload



Case Management and Coordination Services (CMCS) Average Cost - CDPH/GDSP estimates current year average CMCS cost per participant will be \$184, which is a slight increase of \$0.19 or 0.1 percent compared to 2023-24 actual average CMCS cost per participant of \$183.8. Average CMCS cost per participant in 2025-26 is estimated at \$183.5, which is a slight decrease of \$0.48 or 0.26 percent compared to the current

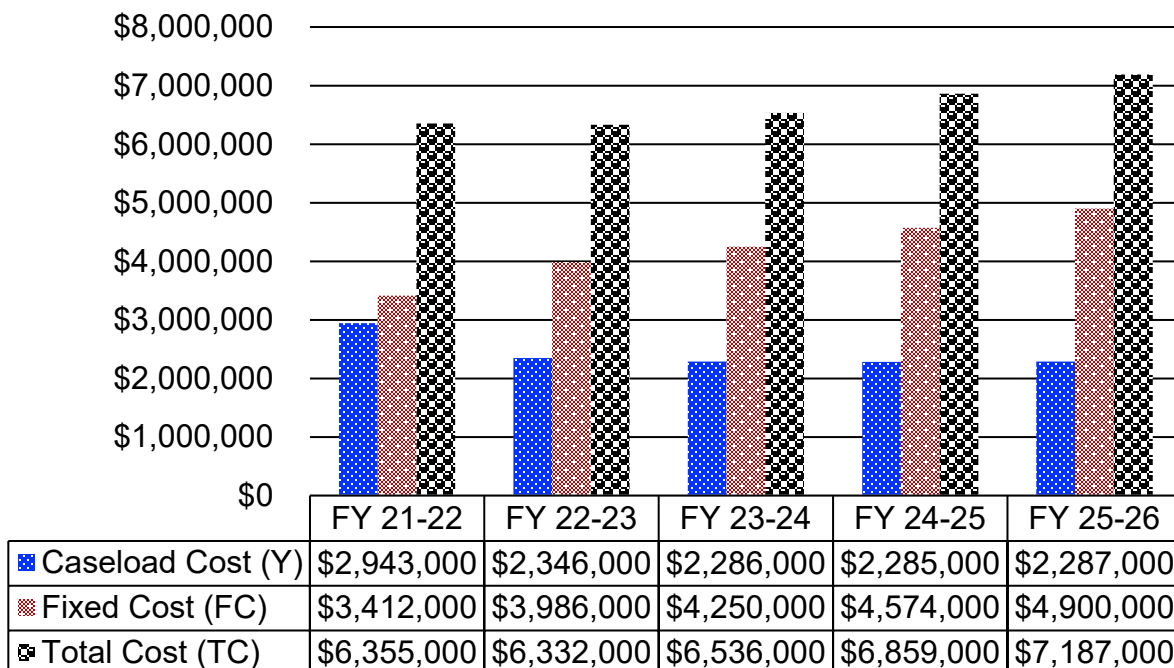
year estimate. The fluctuation in the average cost is tied directly to the caseloads and its associated direct costs.

NBS CCC (ASC) Average Cost



Case Management and Coordination Services (CMCS) Total Cost – The CDPH/GDSP estimates current year CMCS costs to total \$6.9 million, which is an increase of \$323,000 or 5 percent compared to 2023-24 actual CMCS total costs of \$6.5 million. CMCS costs in 2025-26 are estimated to total \$7.2 million, which is an increase of \$328,000 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.

NBS CCC (ASC) Total Cost

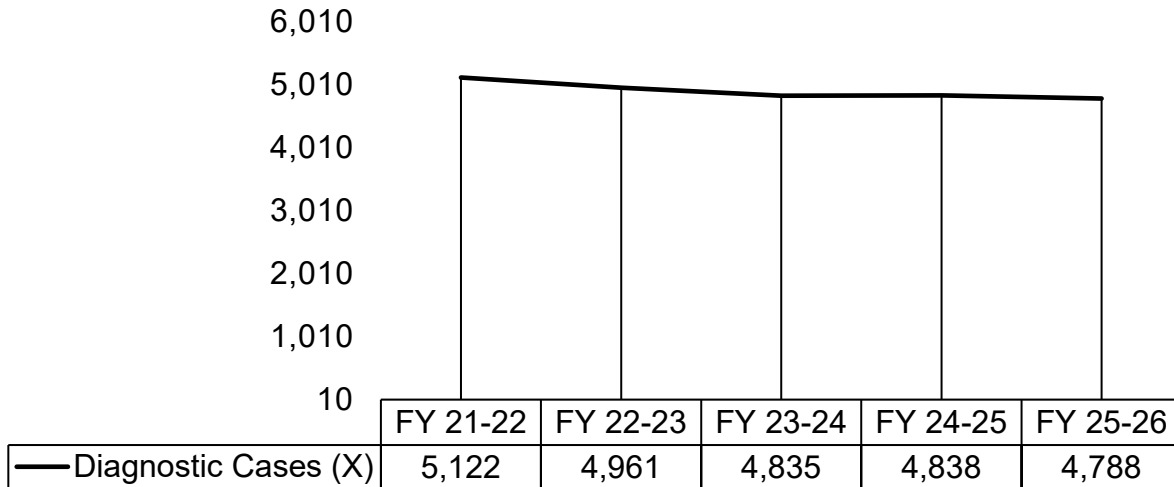


DIAGNOSTIC SERVICES

Overview – Diagnostic Services are for infants with positive screening results who require confirmatory testing and diagnosis. Clinical outcome data is collected on infants once diagnosis is made or ruled out as a means of tracking, confirming, evaluating, and refining program standards. Services include coordination with the ASC and Public Health/GDSP to report on 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.

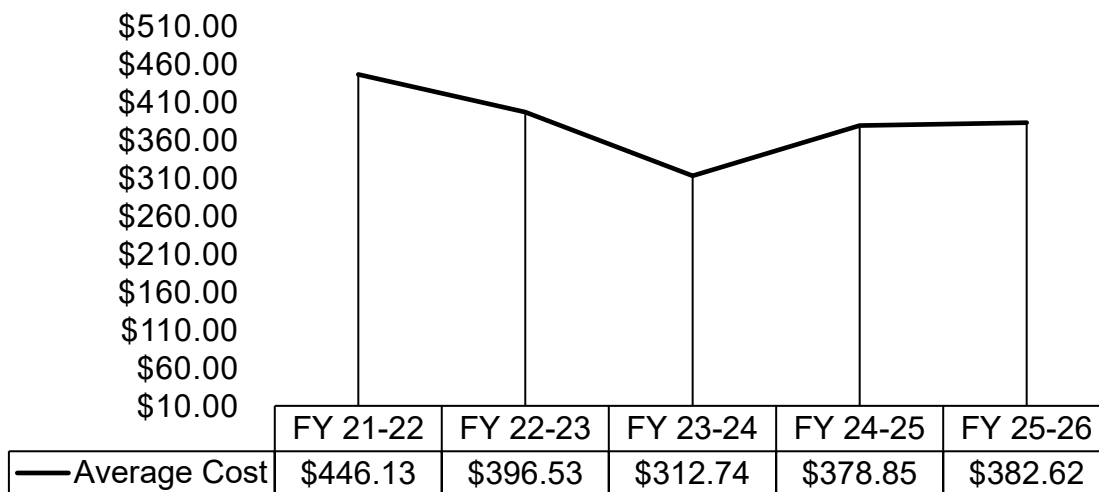
Diagnostic Services Caseload – The CDPH/GDSP estimates current year Diagnostic caseload will total 4,838, based on projected new referral cases and annual patient summary cases, which is an increase of 3 or 0.1 percent compared to 2023-24 actual Diagnostic Services caseload of 4,835. Diagnostic caseload in 2025-26 is estimated at 4,788, which is a decrease of 50 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.

NBS Follow-up/Diagnostic Caseload



Diagnostic Services Average Cost – The CDPH/GDSP estimates current year average Diagnostic Services cost per participant will be \$379, calculated based on projected new referral cases and annual patient summary cases, which is a slight increase of \$66 or 21 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 \$383, which is also a slight increase of \$4 or 1 percent compared to the current year estimate. The slight increase in the current year is attributed to the addition of the two new disorders (MPS II and GAMT deficiency). The increase in the budget year is tied to the increasing fixed costs that do not fluctuate with the caseloads.

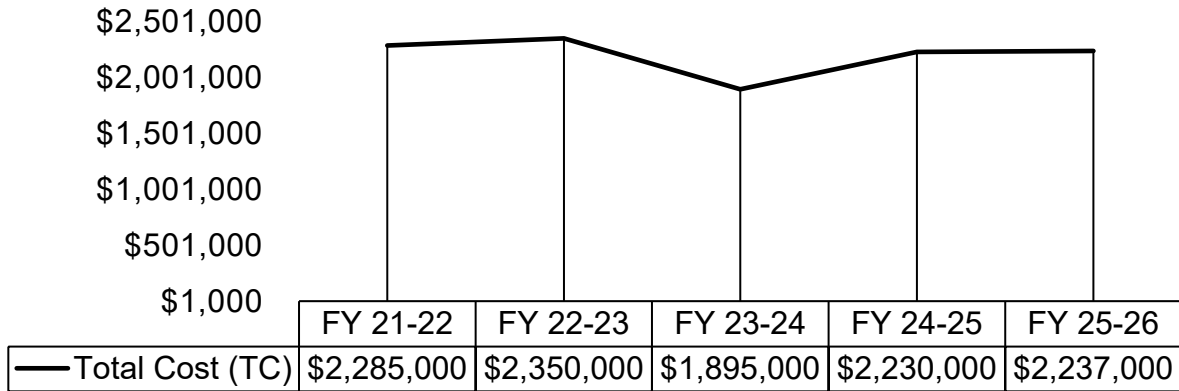
NBS Avg Follow-up/Diagnostic Ave Cost



Diagnostic Services Total Cost – The CDPH/GDSP estimates current year Diagnostic Services costs at \$2 million, which is an increase of \$335,000 or 18 percent compared

to 2023-24 actual Diagnostic Services total costs of \$1.9 million. Diagnostic Services costs in 2025-26 are estimated at \$2 million, which is a slight increase of \$7,000 or 0.3 percent compared to the current year estimate.

NBS Follow-up/Diagnostic Total Cost

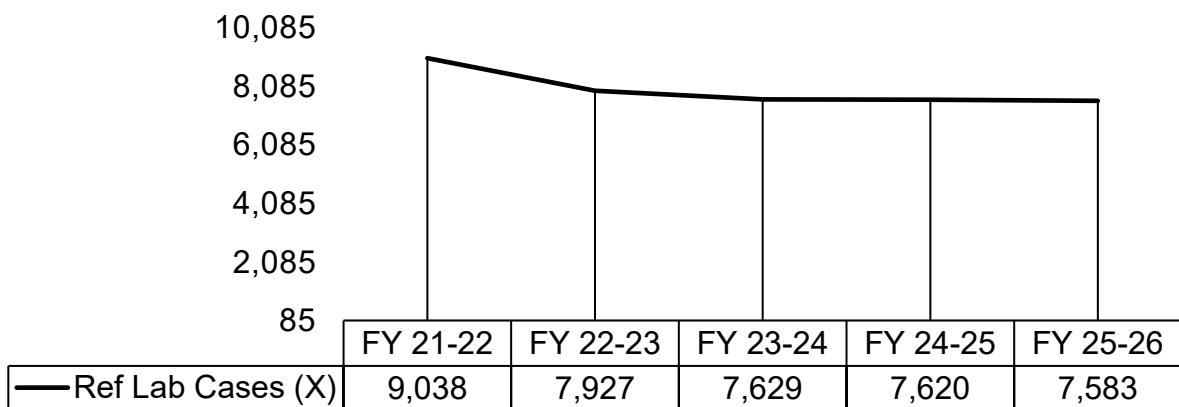


REFERENCE LABORATORIES

Overview – Cases that result in a positive screening test are referred for diagnostic testing at various confirmatory reference 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.

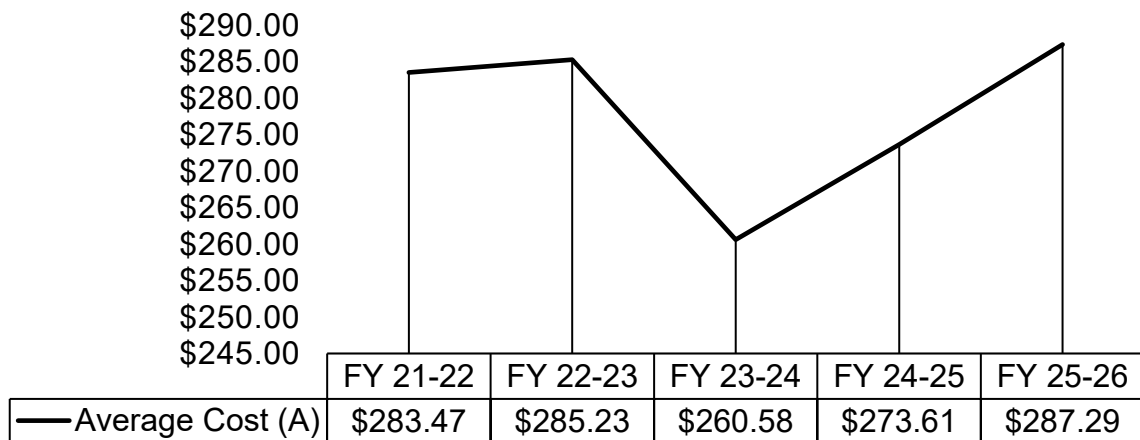
Reference Laboratory Caseload – CDPH/GDSP estimates current year Reference Laboratory caseload will total 7,620, which is a slight decrease of 9 or 0.1 percent compared to 2023-24 actual Reference Laboratory caseload of 7,629. Reference Laboratory caseload in 2025-26 is estimated at 7,583, which is a decrease of 37 or 0.5 percent compared to the current year estimate.

NBS Reference Lab Caseload



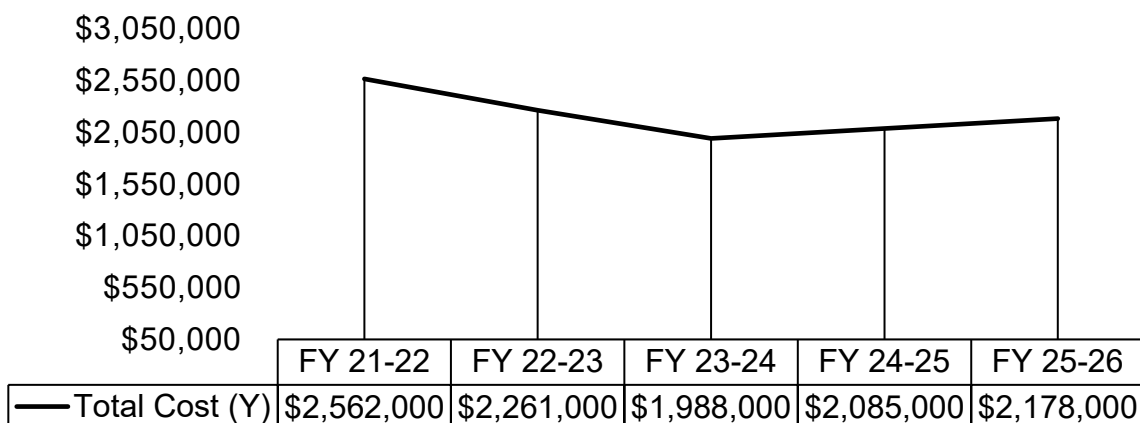
Reference Laboratory Average Cost – The CDPH/GDSP estimates current year Reference Laboratory average cost per participant at \$274, which is an increase of \$13 or 5 percent compared to 2023-24 Reference Laboratory actual average cost per participant of \$261. Reference Laboratory average cost per participant in 2025-26 is estimated at \$287, which is an 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.

NBS Reference Lab Average Cost



Reference Laboratory Total Cost – The CDPH/GDSP estimates current year Reference Laboratory costs at \$2.1 million, which is an increase of \$97,000 or 5 percent compared to 2023-24 actual Diagnostic Services total costs of \$2 million. Reference Laboratory costs in 2025-26 are estimated at \$2.2 million, which is an increase of \$93,000 or 4 percent compared to the current year estimate. The cost increases from the current to the budget year can be attributed to the addition of new disorders since July 1, 2024, as well as inflation.

NBS Reference Lab Total Cost



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 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. It has developed new structures for Case Coordination Centers (CCC) to provide case management services and for Prenatal Diagnosis Centers (PDCs) to provide follow-up services. It has 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. Since April 1, 2024, the California PNS Program has gone live in the addition of prenatal screening for SCAs using cfDNA screening. Since then, the PNS program has updated forms, screening protocols and health education materials, and updated the Screening Information System to include the additional screening results. The addition of SCAs has increased cfDNA laboratory, increased follow-up case management services provided by the CCCs, and counseling and diagnostic services provided by the PDCs.

Total Caseload/Specimens – The CDPH/GDSP estimates current year projected caseload for cfDNA at 202,771, which is an increase of 331 or 0.2 percent compared to the 2023-24 actual caseload of 202,440. The increase can be attributed to the full-year implementation of cfDNA screening. The CDPH/GDSP estimates that the cfDNA caseload in the budget year at 205,817, which is a slight increase of 3,046 or 1.5

percent compared to the current year. With the addition of SCA, the CDPH/GDSP estimates the number of specimens would also increase in the budget year.

Table 15 shows the projected cfDNA cases by billable caseload, average cost, and total cost for budget year 2025-26.

Table 15. cfDNA Projected Caseload and Costs

| Fiscal Year | Forecasted Births | PNS Projected Caseload | Average Cost | Total Cost |
|--------------------|--------------------------|-------------------------------|---------------------|-------------------|
| 2024-2025 | 401,386 | 202,771 | \$190 | \$38,526,000 |
| 2025-2026 | 397,888 | 205,817 | \$190 | \$39,105,000 |

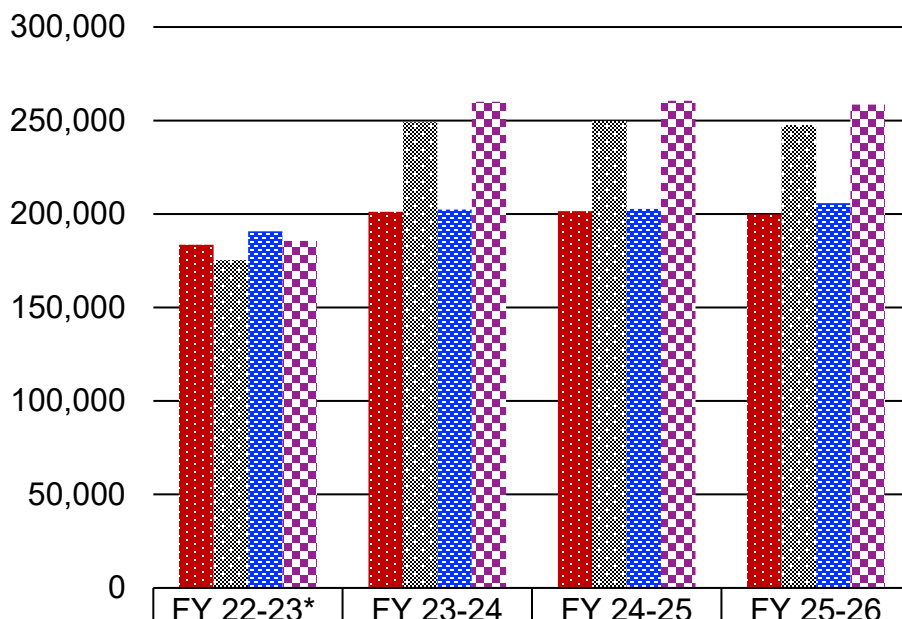
CONTRACT LABORATORIES

Overview – Laboratory testing to screen pregnant individuals for genetic and congenital disorders, such as specific chromosome abnormalities, 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 contracts with five regional contract laboratories for NTD screening and four laboratories for cfDNA screening that are paid on a per-specimen basis.

The Genetic Disease Screening Program launched a redesigned PNS Program on September 19, 2022. This replaced the GDSP’s conventional biochemical screening with cfDNA screening for chromosome abnormalities. GDSP’s biochemical screening for neural tube defects remained part of the overall screening process. Since cfDNA screening went live, two specimens need to be collected: one for cfDNA screening and the other one for NTD screening.

Total Caseload/Specimens – The CDPH/GDSP estimates that the NTD caseload in the current year will total 260,591, which is an increase of 551 or 0.3 percent compared to 2023-24 NTD caseload of 260,040. The NTD caseload in the budget year is estimated at 258,490, which is a decrease of 2,101 or 0.8 percent compared to the current year. The caseload fluctuation is tied to the DRU’s projected live births.

PNS Caseload/Specimens (SIS 2.0)



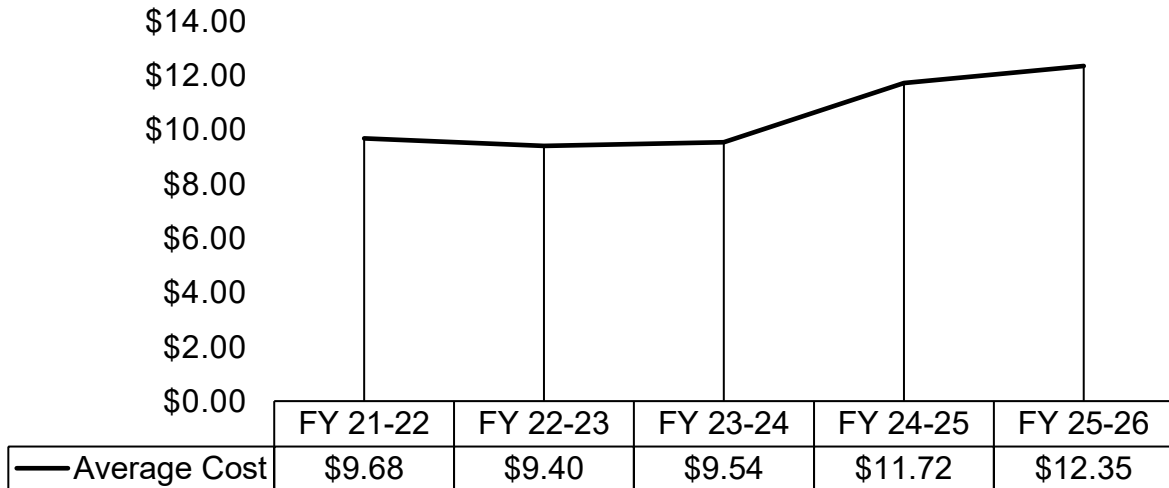
| | FY 22-23* | FY 23-24 | FY 24-25 | FY 25-26 |
|--|-----------|----------|----------|----------|
| ■ SIS 2.0 - Billable PNS Actual/Projected Caseload (Revenue Projection) cfDNA Caseload (x ₁) | 183,531 | 201,244 | 201,573 | 199,816 |
| ▒ SIS 2.0 - Billable PNS Actual/Projected Caseload (Revenue Projection) NTD Caseload (x ₂) | 175,316 | 249,177 | 249,699 | 247,523 |
| ■ SIS 2.0 - Number of PNS Actual/Projected Specimens (Expenditure Projection) cfDNA | 190,809 | 202,440 | 202,771 | 205,817 |
| ■ SIS 2.0 - Number of PNS Actual/Projected Specimens (Expenditure Projection) NTD | 185,591 | 260,040 | 260,591 | 258,490 |

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

Contract Laboratory Average Cost Projections – The CDPH/GDSP estimates the current year average laboratory cost per participant will be \$11.72, which is an increase of \$2 or 23 percent compared to 2023-24 actual average laboratory cost per participant of \$9.54. The increase in the current year is due to the magnitude of contract cost increases outpacing the projected caseload increase as a result of inflation. The contract regional NAPS lab has only screened pregnant individuals for neural tube defects (NTD) since September 19, 2022. The CDPH/GDSP estimates the budget year

average laboratory cost per participant will be \$12.35, which is a slight increase of \$0.63 or 5 percent compared to the current year.

PNS Contract Lab Average Cost



Contract Laboratory Total Cost Projections – Since September 19, 2022, the contract regional NAPS lab has only screened pregnant individuals for neural tube defects (NTD). The CDPH/GDSP estimates the current year contract laboratory cost at \$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 the budget year contract laboratory cost at \$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.

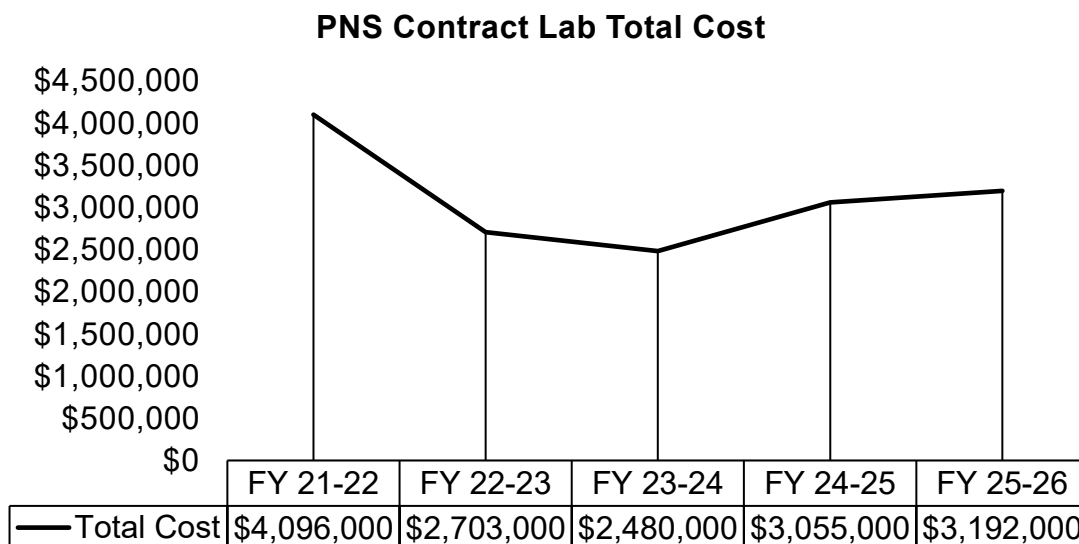


Table 16 shows the projected cases, average cost, and total cost for the cases of the neural tubes defects (NTD) test only in 2024-25 and 2025-26.

Table 16. Contract Laboratory Total and Average Costs

| Fiscal Year | PNS Projected Caseload | Average Cost | Total Cost |
|-------------|------------------------|--------------|-------------|
| 2024-2025 | 260,591 | \$11.72 | \$3,055,000 |
| 2025-2026 | 258,490 | \$12.35 | \$3,192,000 |

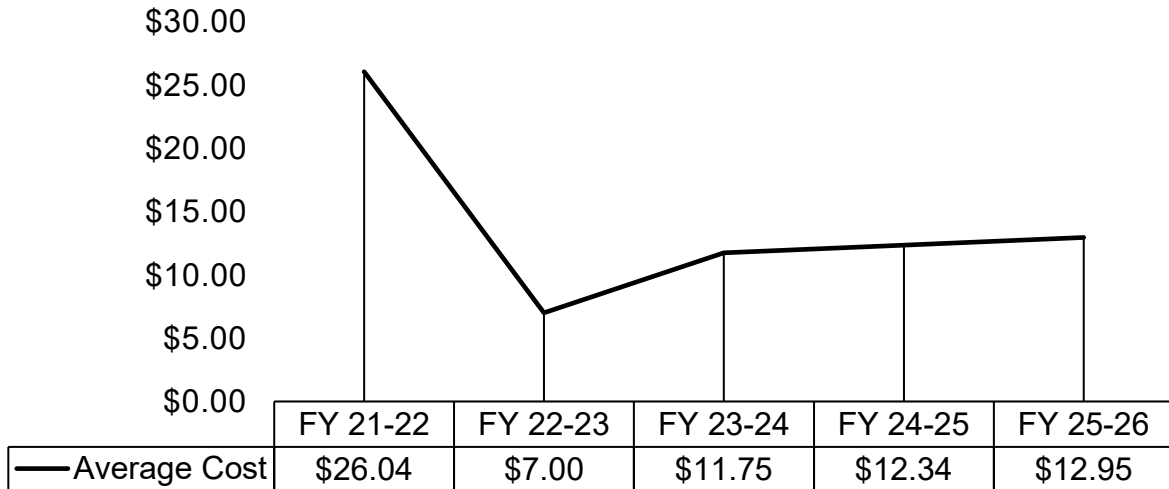
TECHNICAL AND SCIENTIFIC

Overview – Costs associated with screening services provided at the laboratory include reagent kits, maintenance and support 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 majority of the Technology and Scientific costs, are purchased in lots based on anticipated specimens.

Technical and Scientific Caseload: See appendix B 1

Technical and Scientific Average Cost – Since September 19, 2022, the NTD screening has been using only AFP kits. The CDPH/GDSP estimates the current year average Technical and Scientific cost per participant at \$12.34, which is a slight 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 the inflationary contract rate increase. The CDPH/GDSP estimates the budget year average Technical and Scientific cost per participant will be \$12.95, which is a slight increase of \$0.61 or 5 percent compared to the current year.

PNS Tech & Sci Average Costs



Technical and Scientific Total Cost – Since September 19, 2022, a simpler biochemical screening has been used for neural tube defects (NTD). The CDPH/GDSP estimates the current year Technical and Scientific costs at \$3.2 million, which is an increase of \$160,000 or 12 percent compared to 2023-24 actual technical and scientific costs of \$3.1 million. The CDPH/GDSP estimates the budget year Technical and Scientific costs at \$3.3 million, which is an additional increase of \$133,000 or 4 percent compared to the current year. The cost increases are due to contract rate increases as a result of inflation.

PNS Tech & Sci Total Cost

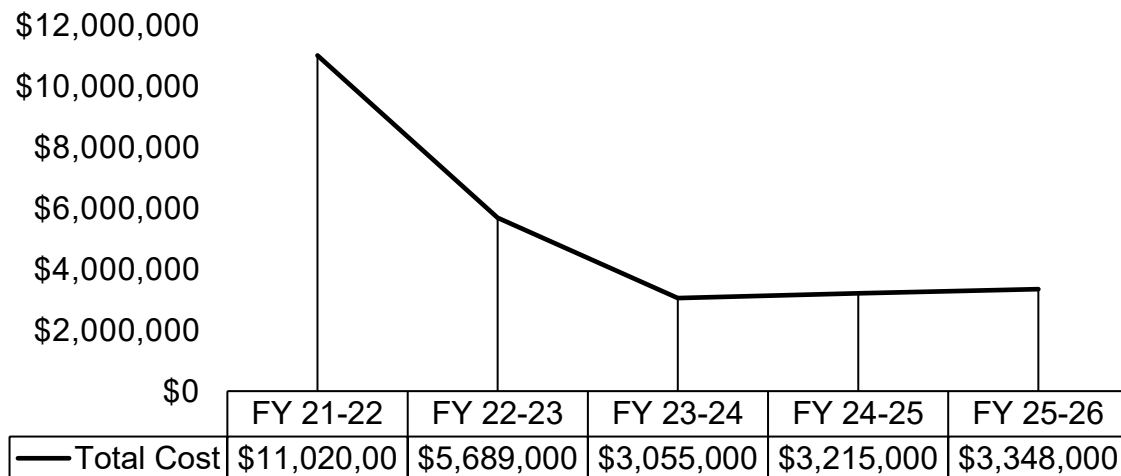


Table 17 shows the projected cases, average cost, and total cost associated with technical and scientific cost for the neural tubes defects (NTD) test only in 2024-25 and 2025-26.

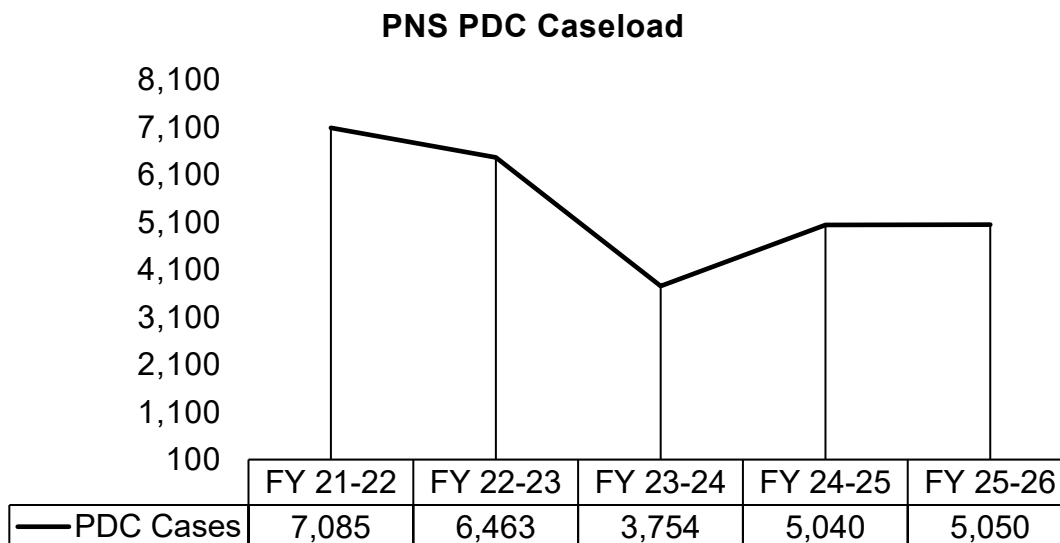
Table 17. Technical and Scientific Average and Total Costs

| Fiscal Year | Total NTD | Average Cost | Total Cost |
|-------------|-----------|--------------|-------------|
| 2024-2025 | 260,591 | \$12.34 | \$3,215,000 |
| 2025-2026 | 258,490 | \$12.95 | \$3,348,000 |

PRENATAL DIAGNOSTIC SERVICES CENTERS

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

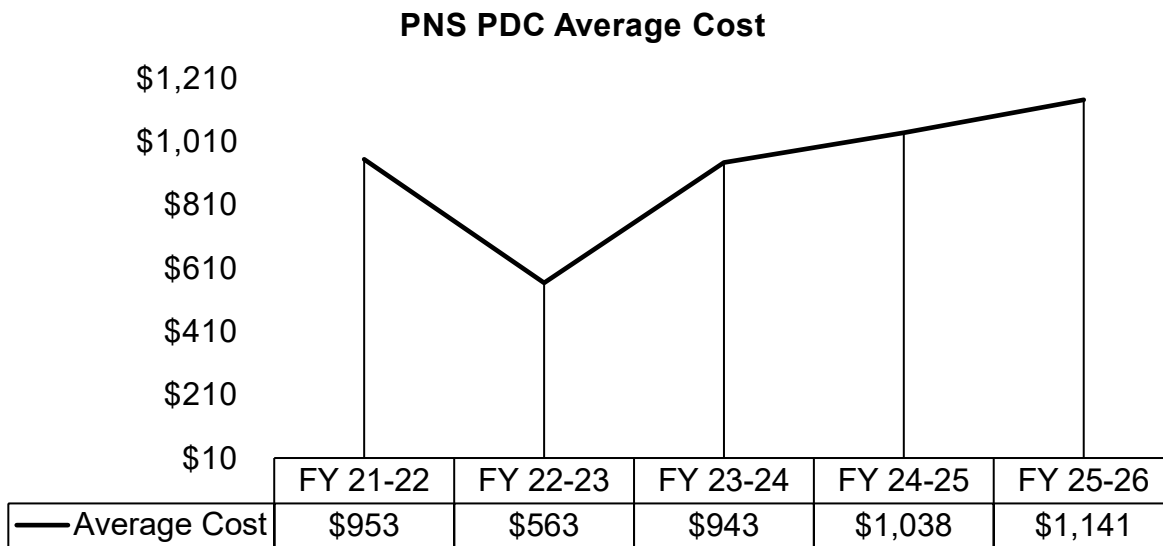
Prenatal Diagnostic Services Centers (PDC) Caseload – Since September 19, 2022, cfDNA screened positive tests, those with no results and NTD screened positive tests, have been referred for additional services which include confirmatory and diagnostic testing. The CDPH/GDSP estimates the current year PDC caseload at 5,040, which is an increase of 1,286 or 20 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 5,050, which is a slight increase of 10 or 0.2 percent compared to the current year. The increase is caused by a projected increase 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

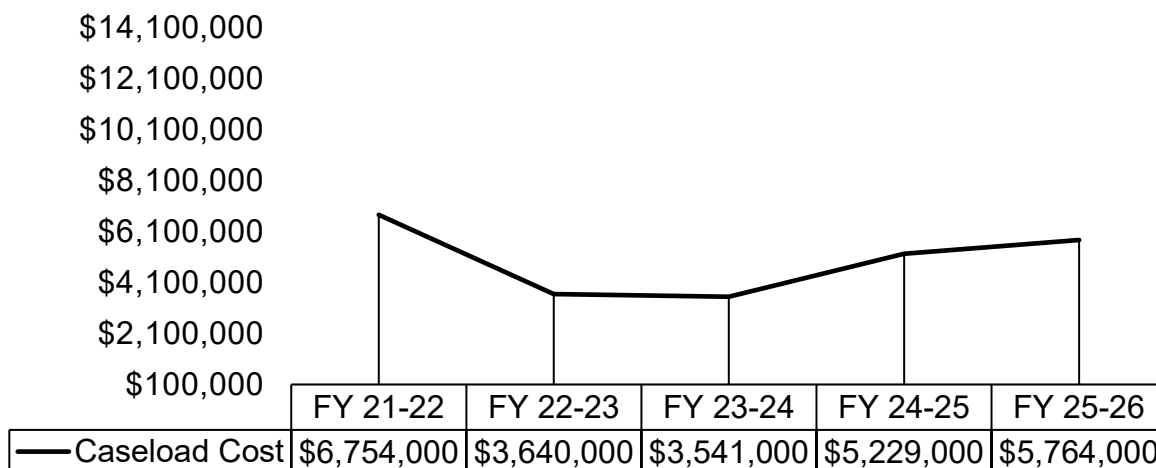
year average PDC cost per participant at \$1,038, which is an increase of \$95 or 10 percent compared to 2023-24 actual average PDC cost per participant of \$943. The CDPH/GDSP estimates the budget year average PDC cost per participant will be \$1,141, which is an increase of \$103 or 10 percent compared 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 the current year PDC costs at \$5.2 million, which is an increase of \$1.7 million or 46 percent compared to 2023-24 actual PDC total costs of \$3.5 million. The CDPH/GDSP estimates the budget year PDC costs at \$5.8 million, which is an increase of \$535,000 or 10 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 since April 1, 2024.

PNS PDC Total Cost

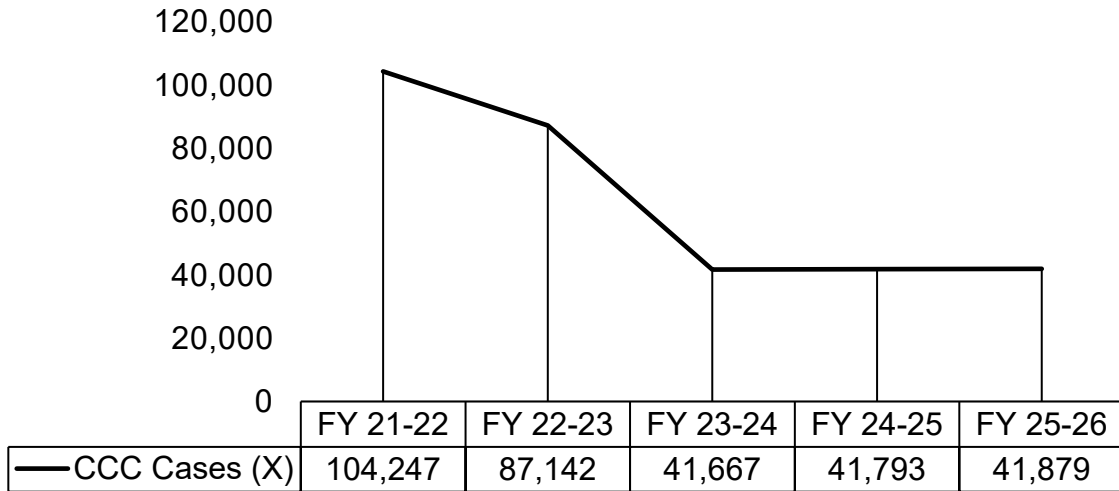


CASE MANAGEMENT AND COORDINATION SERVICES

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 PDCs 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 PDCs. The CCCs are reimbursed based on caseload and the type of service performed along with a monthly base allocation. Base allocation costs vary by CCC dependent upon the geographic location.

Case Management and Coordination Services (CMCS) Caseload – 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 41,793, which is an increase of 126 or 0.15 percent compared to 2023-24 actual CMCS caseload of 41,667. The CDPH/GDSP estimates the budget year CMCS caseload at 41,879, which is an increase of 86 or 0.2 percent compared to the current year. The caseload fluctuations are attributed to the projected specimens and the addition of SCAs since April 1, 2024.

PNS Case Coordination Caseload



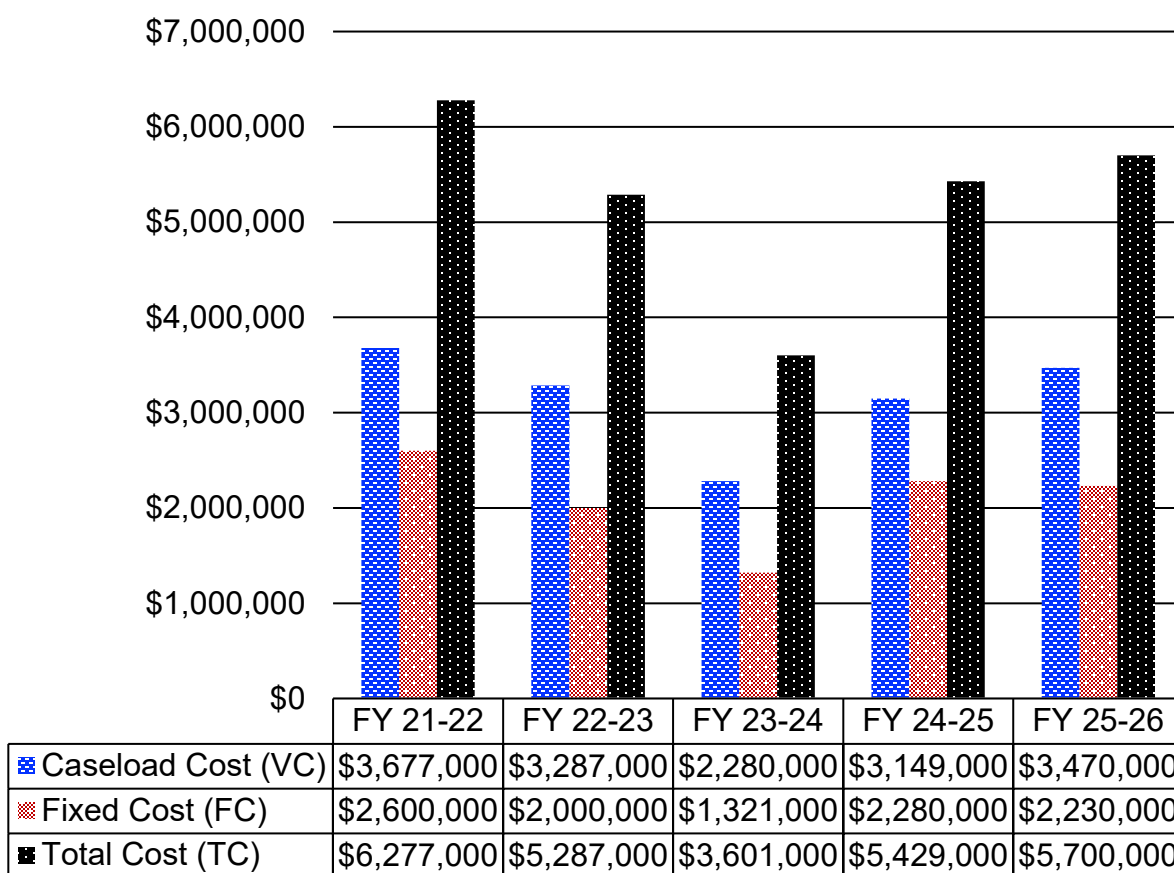
Case Management and Coordination Services Average Cost – The cfDNA and NTD positive cases are referred to a case coordinator for which a separate cost per participant is attributed. The CDPH/GDSP estimates the current year average CMCS cost per participant at \$75.35, which is an increase of \$21 or 55 percent compared to 2023-24 actual average CMCS cost per participant of \$54.72. The CDPH/GDSP estimates the budget year average CMCS cost per participant will be \$82.86, which is a slight increase of \$7.51 or 10 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 fixed costs.

PNS Case Coordination Average Cost



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 \$5.4 million, which is an increase of \$1.8 million or 35 percent compared to 2023-24 actual CMCS total costs of \$3.6 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 \$271,000 or 5 percent compared to the current year. The increase is due to the increase in the projected caseloads and an increase in the fixed costs.

PNS Case Coordination Total Cost



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:

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

Table 18. NBS Revenue Projections

| Fiscal Year | Fee (A) | Caseload (B) | Collection Rate (C) | Total Revenue (D) = (A) x (B) x (C) |
|--------------------|----------------|---------------------|----------------------------|--|
| 2024-2025 | \$226.00 | 399,861 | 99 percent | \$89,465,000 |
| 2025-2026 | \$226.00 | 395,705 | 99 percent | \$88,535,000 |

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 201,573 in Fiscal Year 2024-25 and 199,816 in 2025-26, and NTD caseload of 249,699 in 2024-25 and 247,523 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 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:

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

Table 19. 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) |
| 2024-2025 | \$334.00 | 201,573 | 32% | 64,503 | 99% | \$21,329,000 |
| 2025-2026 | \$334.00 | 199,816 | 32% | 63,941 | 99% | \$21,143,000 |

Table 20. Client Billing – NTD

| 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) |
| 2024-2025 | \$75.00 | 245,685 | 30% | 73,705 | 99% | 5,473,000 |
| 2025-2026 | \$75.00 | 244,167 | 30% | 73,250 | 99% | 5,439,000 |

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

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

Table 21. Patient Billing Revenue – cfDNA

| Fiscal Year | Medi-Cal Revenue | Non-Medical Revenue | Total Revenue |
|-------------|------------------|---------------------|-----------------|
| (A) | (B) | (C) | (D) = (B) + (C) |
| 2024-2025 | \$27,194,000 | \$17,397,000 | \$44,591,000 |
| 2025-2026 | \$26,957,000 | \$17,245,000 | \$44,202,000 |

Table 22. Patient Billing Revenue - NTD

| Fiscal Year | Medi-Cal Revenue | Non-Medical Revenue | Total Revenue |
|-------------|------------------|---------------------|-----------------|
| (A) | (B) | (C) | (D) = (B) + (C) |
| 2024-2025 | \$7,787,000 | \$4,981,000 | \$12,768,000 |
| 2025-2026 | \$7,719,000 | \$4,938,000 | \$12,657,000 |

Table 23. 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) |
| 2024-2025 | \$334 | 201,573 | 68% | 137,070 | 60% | 82,242 | 99% | \$27,194,000 |
| 2025-2026 | \$334 | 199,816 | 68% | 135,875 | 60% | 81,525 | 99% | \$26,957,000 |

Table 24. 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) |
| 2024-2025 | \$334 | 201,573 | 68% | 137,070 | 40% | 54,828 | 95% | \$17,397,000 |
| 2025-2026 | \$334 | 199,816 | 68% | 135,875 | 40% | 54,350 | 95% | \$17,245,000 |

Table 25. 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) |
| 2024-2025 | \$75 | 249,699 | 70% | 174,789 | 60% | 104,874 | 99% | \$7,787,000 |
| 2025-2026 | \$75 | 247,523 | 70% | 173,266 | 60% | 103,960 | 99% | \$7,719,000 |

Table 26. 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) |
| 2024-2025 | \$75 | 249,699 | 70% | 174,789 | 40% | 69,916 | 95% | \$4,981,000 |
| 2025-2026 | \$75 | 247,523 | 70% | 173,266 | 40% | 69,306 | 95% | \$4,938,000 |