

GENETIC DISEASE SCREENING PROGRAM (GDSP)

**FISCAL YEAR 2022-2023
NOVEMBER ESTIMATE**



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ESTIMATES

PROGRAM OVERVIEW

The California Department of Public Health (CDPH), Genetic Disease Screening Program (GDSP) Estimate provides a revised projection of 2021-22 expenditures along with projected costs for 2022-23 Local Assistance and State Operations budget for CDPH/GDSP.

The CDPH/GDSP Local Assistance budget funds two distinct programs: The Newborn Screening Program (NBS) and the Prenatal Screening Program (PNS). NBS is a mandatory program that screens all infants born in California for genetic diseases. Parents may opt their newborns out of the program by claiming religious exemptions. PNS is an opt-in program for women who desire to participate. The screening test provides the pregnant woman with a risk profile. Screenings that meet or exceed a specified risk threshold are identified and further testing and genetic counseling/diagnostic services are offered at no additional expense to the participant.

EXPENDITURE OVERVIEW

The CDPH/GDSP 2021 Budget Act appropriation is \$145.7 million, of which \$112.4 million is for Local Assistance and \$33.3 million is for State Operations. The CDPH/GDSP estimates 2021-22 expenditures of \$145.9 million, which is a slight increase of \$229,000 or 0.2 percent compared to the 2021 Budget Act. The combined State Operations and Local Assistance budget expenditures for 2022-23 total \$175 million, which is an increase of \$29.3 million or 20.1 percent compared to the 2021 Budget Act. In current year, there is a decrease of \$961,000 in Local Assistance due to the declining caseloads resulting from the Department of Finance Demographic Research Unit's (DRU) projection of live births combined with the inclusion of some State Operations baseline adjustments made in the prior 2020-21. An increase of \$28.1 million in Local Assistance for 2022-23 is due to the implementation of Cell-free Deoxyribonucleic Acid (cfDNA) screening and increased contract rates.

Table 1 shows the difference between the 2021 Budget Act appropriation and the revised 2021-22 expenditures and proposed 2022-23 expenditures for CDPH/GDSP.

Table 1. GDSP: Current Year and Budget Year Budget Summaries Compared to 2021 Budget Act

| Fund 0203 Genetic Disease Testing Fund | 2021 Budget Act | November Estimate | Change from Budget Act | Percent Change from Budget Act |
|---|----------------------------|------------------------------|-----------------------------------|---|
| Fiscal Year 2021-2022 Total | \$145,655,000 | \$145,884,000 | \$229,000 | 0.2% |
| FY2021-22 State Operations | \$33,322,000 | \$34,512,000 | \$1,190,000 | 3.6% |
| FY2021-22 Local Assistance | \$112,333,000 | \$111,372,000 | -\$961,000 | -0.9% |
| Fiscal Year 2022-2023 Total | \$145,655,000 | \$174,986,000 | \$29,331,000 | 20.1% |
| FY2022-23 State Operations | \$33,322,000 | \$34,512,000 | \$1,190,000 | 3.6% |
| FY2022-23 Local Assistance | \$112,333,000 | \$140,474,000 | \$28,141,000 | 25.1% |

LOCAL ASSISTANCE EXPENDITURE PROJECTIONS

CURRENT YEAR (2021-22)

The 2021 Budget Act appropriation for CDPH/GDSP's Local Assistance is \$112 million in 2021-22. The CDPH/GDSP estimates 2021-22 Local Assistance expenditures will total \$111 million, which is a decrease of \$961,000 or 0.9 percent compared to the 2021 Budget Act. The decrease in Local Assistance is attributed to an overall decrease in the DRU's projection of live births.

BUDGET YEAR (2022-23)

For 2022-23, CDPH/GDSP estimates Local Assistance expenditures will total \$140 million, which is an increase of \$28 million or 25.1 percent compared to the 2021 Budget Act amount of \$112 million. The increase in Local Assistance is attributed to cfDNA screening implementation, and system redesign of Prenatal Screening Program and Screening Information System (SIS) Migration to the new Cloud platform for both newborn and prenatal screening programs.

Table 2 shows the difference between the 2021 Budget Act appropriation and the revised 2021-22 expenditures and proposed 2022-23 expenditures for CDPH/GDSP Local Assistance.

Table 2. Local Assistance Total: Current Year and Budget Year Budget Summaries Compared to 2021 Budget Act

| Fund 0203 Genetic Disease Testing Fund | 2021 Budget Act | November Estimate | Change from Budget Act | Percent Change from Budget Act |
|---|----------------------------|------------------------------|-----------------------------------|---|
| Fiscal Year 2021-2022 Local Assistance Total | \$112,333,000 | \$111,372,000 | -\$961,000 | -0.9% |
| FY2021-22 NBS | \$47,233,000 | \$48,720,000 | \$1,487,000 | 3.1% |
| FY2021-22 PNS | \$33,776,000 | \$31,328,000 | -\$2,448,000 | -7.2% |
| FY2021-22 Operational Support | \$31,324,000 | \$31,324,000 | \$0 | 0.0% |
| Fiscal Year 2022-2023 Local Assistance Total | \$112,333,000 | 140,474,000 | 28,141,000 | 25.1% |
| FY2022-23 NBS | \$47,233,000 | 47,355,000 | 122,000 | 0.3% |
| FY2022-23 PNS | \$33,776,000 | 57,666,000 | 23,890,000 | 70.7% |
| FY2022-23 Operational Support | \$31,324,000 | 35,453,000 | 4,129,000 | 13.2% |

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 2021-22, CDPH/GDSP estimates NBS Local Assistance expenditures will total \$49 million, which is an overall net increase of \$1.5 million or 3 percent compared to the 2021 Budget Act of \$47 million. Although caseload decreased from the 2021 Budget

Act, there is an increase in the Technical and Scientific category of \$3.6 million due to higher contract rates and higher cost for the new reagent kits that are necessary for more efficient lab instrument implementation. The net decrease of \$2.1 million from the other cost centers is due to a decline in caseload results based on Department of Finance's Demographic Research Unit's (DRU) projection of live births.

For 2022-23, CDPH/GDSP estimates that NBS Local Assistance expenditures will total \$47 million, which is an overall net increase of \$122,000 or 0.3 percent compared to the 2021 Budget Act of \$47 million. The net increase of \$687,000 is attributed to contract rate increases in the Contract Laboratory, Technical and Scientific, and Case Coordination categories. The net decrease of \$565,000 in Reference Laboratory and Diagnostic Services is due to cost savings by combining special care centers into one contract. Its rate cost is tied to fluctuations in caseloads and baseline adjustments.

Table 3 shows the 2021 Budget Act appropriation and the revised 2021-22 expenditures and proposed 2022-23 expenditures for the Newborn Screening Program costs by cost center type.

Table 3. NBS: Current Year and Budget Year Budget Summaries Compared to 2021 Budget Act

| Fund 0203 Genetic Disease Testing Fund | 2021 Budget Act | November Estimate | Change from Budget Act | Percent Change from Budget Act |
|---|----------------------------|------------------------------|-----------------------------------|---|
| Fiscal Year 2021-2022 Total | \$47,233,000 | \$48,720,000 | \$1,487,000 | 3.1% |
| FY2021-22 Contract Lab | \$7,386,000 | \$6,666,000 | -\$720,000 | -9.7% |
| FY2021-22 Tech Sci | \$28,478,000 | \$32,064,000 | \$3,586,000 | 12.6% |
| FY2021-22 Reference Lab | \$2,469,000 | \$2,075,000 | -\$394,000 | -16.0% |
| FY2021-22 CMCS | \$6,174,000 | \$5,808,000 | -\$366,000 | -5.9% |
| FY2021-22 Diagnostic Services | \$2,726,000 | \$2,107,000 | -\$619,000 | -22.7% |
| Fiscal Year 2022-2023 Total | \$47,233,000 | \$47,355,000 | \$122,000 | 0.3% |
| FY2022-23 Contract Lab | \$7,386,000 | \$7,392,000 | \$6,000 | 0.1% |
| FY2022-23 Tech Sci | \$28,478,000 | \$29,001,000 | \$523,000 | 1.8% |
| FY2022-23 Reference Lab | \$2,469,000 | \$2,330,000 | -\$139,000 | -5.6% |
| FY2022-23 CMCS | \$6,174,000 | \$6,332,000 | \$158,000 | 2.6% |
| FY2022-23 Diagnostic Services | \$2,726,000 | \$2,300,000 | -\$426,000 | -15.6% |

PNS EXPENDITURES PROJECTIONS (SEE APPENDICES B1-B4)

For 2021-22, CDPH/GDSP estimates PNS Local Assistance expenditures to total \$31 million, which is a decrease of \$2.4 million or 7.2 percent compared to the 2021 Budget Act. For 2022-23, CDPH/GDSP estimates that PNS Local Assistance expenditures will total \$58 million which is an increase of \$23.9 million or 70.7 percent compared to the 2021 Budget Act.

The decrease in the current year is attributed to fewer cases being referred to Prenatal Diagnostic Centers as well as the drop in the birthrate. The increase in the budget year can be attributed to the implementation of cell-free DNA (cfDNA) screening.

Table 4 displays the 2021 Budget Act appropriation, the revised 2021-22 expenditures and proposed 2022-23 expenditures for the Prenatal Screening program costs by client type.

Table 4. PNS: Current Year and Budget Year Budget Summaries Compared to 2021 Budget Act

| Fund 0203 Genetic Disease Testing Fund | 2021 Budget Act | November Estimate | Change from Budget Act | Percent Change from Budget Act |
|---|----------------------------|------------------------------|-----------------------------------|---|
| Fiscal Year 2021-2022 Total | \$33,776,000 | \$31,328,000 | -\$2,448,000 | -7.2% |
| FY2021-22 cfDNA | \$0 | \$0 | \$0 | 0.0% |
| FY2021-22 Contract Lab | \$4,556,000 | \$4,253,000 | -\$303,000 | -6.7% |
| FY2021- 22Tech & Sci | \$12,944,000 | \$12,870,000 | -\$74,000 | -0.6% |
| FY2021-22 CMCS | \$6,633,000 | \$6,204,000 | -\$429,000 | -6.5% |
| FY2021-22 PDC | \$9,643,000 | \$8,001,000 | -\$1,642,000 | -17.0% |
| Fiscal Year 2022-2023 Total | \$33,776,000 | \$57,666,000 | \$23,890,000 | 70.7% |
| FY2022-23 cfDNA | \$0 | \$42,688,000 | \$42,688,000 | 0.0% |
| FY2022-23 Contract Lab | \$4,556,000 | \$2,845,000 | -\$1,711,000 | -37.6% |
| FY2022- 23Tech & Sci | \$12,944,000 | \$2,012,000 | -\$10,932,000 | -84.5% |
| FY2022-23 CMCS | \$6,633,000 | \$2,468,000 | -\$4,165,000 | -62.8% |
| FY2022-23 PDC | \$9,643,000 | \$7,653,000 | -\$1,990,000 | -20.6% |

OPERATIONAL SUPPORT PROJECTIONS

For 2021-22, the CDPH/GDSP Operational Support expenditures total is \$31.3 million, which is unchanged from the 2021 Budget Act.

For 2022-23, CDPH/GDSP projects operational support expenditures will total \$35.5 million, which is an overall net increase of \$4 million or 13 percent compared to the 2021 Budget Act. \$8 million will be spent to migrate the Screening Information System (SIS), which is used by both the NBS and PNS programs, to a Cloud platform. This is offset by a decrease of \$3.9 million due to the one-time cost request in the FY2021-22 Budget Change Proposal for the screening launch preparation activities of cfDNA.

Table 5 displays the difference between the 2021 Budget Act appropriation, the revised 2021-22 expenditures and proposed 2022-23 expenditures for Program Operational Support costs.

Table 5. Operational Support: Current Year and Budget Year Budget Summaries Compared to 2021 Budget Act

| Fund 0203 Genetic Disease Testing Fund | 2021 Budget Act | November Estimate | Change from Budget Act | Percent Change from Budget Act |
|---|------------------------|--------------------------|-------------------------------|---------------------------------------|
| Fiscal Year 2021-2022 Operational Support | \$31,324,000 | \$31,324,000 | \$0 | 0.0% |
| Fiscal Year 2022-2023 Operational Support | \$31,324,000 | \$35,453,000 | \$4,129,000 | 13.2% |

STATE OPERATIONS EXPENDITURE PROJECTIONS

For both 2021-22 and 2022-23 CDPH/GDSP estimates State Operations expenditures will total \$34.5 million, which is an increase of \$1.2 million compared to the 2021 Budget Act. The increases in both current and budget year are due to baseline adjustments that occurred in the prior 2020-21 fiscal year.

Table 6 displays the difference between the 2021 Budget Act appropriation and the revised 2021-22 expenditures and proposed 2022-23 expenditures for the CDPH/GDSP State Operations costs.

Table 6. State Operations: Current Year and Budget Year Budget Summaries
Compared to 2021 Budget Act

| Fund 0203 Genetic Disease Testing Fund | 2021 Budget Act | November Estimate | Change from Budget Act | Percent Change from Budget Act |
|---|------------------------|--------------------------|-------------------------------|---------------------------------------|
| Fiscal Year 2021-2022 State Operations | \$33,322,000 | \$34,512,000 | \$1,190,000 | 3.57% |
| Fiscal Year 2022-2023 State Operations | \$33,322,000 | \$34,512,000 | \$1,190,000 | 3.6% |

REVENUE PROJECTIONS

COMBINED NBS AND PNS REVENUE

CDPH/GDSP has revenue estimates for 2021-22 totaling \$129 million, which is a decrease of \$11.9 million or 8.5 percent compared to the 2021 Budget Act amount of \$141 million. The decrease in revenue for the current year is attributed to the decline in the birthrate. For 2022-23, CDPH/GDSP projects revenue will total \$177 million, which is an increase of \$36 million or 25.8 percent compared to the 2021 Budget Act amount of \$141 million and is attributed an increased birthrate projected by the DRU and additional revenue generated by the new fee structure of the PNS Program (separate neural tube defects fee of \$75) and further increases to the cfDNA and NBS fees.

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 \$221.60, of which \$211.60 is deposited into the Genetic Disease Testing Fund (Fund 0203). The remaining \$10 is deposited into the Birth Defects Monitoring Program Fund (Fund 3114). Beginning July 1, 2022, GDSP will add an additional amount of \$85 to the PNS fee for neural tube defects (NTD) and increase the current PNS program fee by \$10.40 from \$221.60 to \$232 for the new cfDNA testing fee. Similar to the current structure, \$10 out of the NTD and cfDNA fees will be deposited into the Birth Defects Monitoring Program Fund (BDMP Fund 3114). The Genetic Disease Testing Fund (Fund 0203) will deposit \$222 out of the \$232 cfDNA testing fee and \$75 out of the \$85 NTD testing fee.

GDSP invoices and collects PNS payments from individual participants, private insurers and Medi-Cal. GDSP is able to collect approximately 98 percent of all fees owed on behalf of Medi-Cal clients (which is approximately 55 percent of the total caseload) and

approximately 94 percent of the fees owed by individuals with private insurances. In the future years, GDSP expects to increase the collection rate to 99 percent for Medi-Cal insurers and 95 percent to non-Medi-Cal insurers. CDPH/GDSP uses the following formula to estimate revenue generated from PNS fees:

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

Beginning July 1, 2022, GDSP will increase NBS fee by \$33.75 from the current rate of \$177.25 to \$211.00 to offset per case increases due to the declining birth rate. While portions of the NBS program are driven by per case costs, there are baseline costs that do not fluctuate with the birthrate and those costs must be supported with higher fees when the birthrate drops. Unlike PNS, where CDPH/GDSP bills patients and collects fees from insurers, CDPH/GDSP collects the bulk of NBS revenue directly from hospitals. Only home births, where specimens are collected outside of the hospital, are billed to the newborns' parents or their insurance company. As such, the billing for NBS screening services is much more streamlined resulting in a 99 percent collection rate. CDPH/GDSP uses the following formula to estimate revenue generated from NBS fees:

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

NBS REVENUE (SEE APPENDIX C1)

In 2021-22, NBS revenue is expected to total \$69 million, which is a decrease of \$9 million or 11 percent compared to the 2021 Budget Act of \$77 million. The decrease in revenue for the current year is due to the decrease in projected caseload resulting from the DRU's projection of live births declining birth rate.

In 2022-23, GDSP projects NBS revenue will total \$89.4 million, which is an increase of \$12 million or 15.6 percent compared to the 2021 Budget Act of \$77 million. The increase in revenue for the budget year is due to the increase in newborn fee from \$177.25 to \$211.00 as well as an increase in the DRU projection of births.

PNS REVENUE (SEE APPENDIX C2)

In 2021-22, PNS revenue is expected to total \$60 million, which is a decrease of \$3.3 million or 5.3 percent compared to the 2021 Budget Act amount of \$63 million. In 2022-23, CDPH/GDSP projects PNS revenue will total \$87.6 million, which is an increase of \$24.2 million or 38.2 percent compared to the 2021 Budget Act of \$63 million.

The decrease in the current year is due to the decrease in the DRU projected caseload. The increase in the budget year is due to the new separate fee of \$75 for NTD and

increase PNS program fee from \$211.60 to \$222 due to cfDNA testing as well as an increase in the DRU's projected births. A change in collection rate from 94 percent to 95 percent for individuals with private insurance and from 98 percent to 99 percent for Medi-Cal insurers also helped increase revenue for PNS to support the increasing cost of the program. Despite a decrease in projected births from the 2021 Budget Act, there is a very slight increasing trend in the utilization of the PNS program, and the demand is anticipated to increase after cfDNA screening is fully implemented in the future years.

Table 7 shows the revised current year and budget year revenue compared to 2021 Budget Act.

Table 7. GDSP Revenue: Current Year and Budget Year Revenue Summaries Compared to 2021 Budget Act

| Fund 0203 Genetic Disease Testing Fund | 2021 Budget Act | November Estimate | Change from Budget Act | Percent Change from Budget Act |
|---|------------------------|--------------------------|-------------------------------|---------------------------------------|
| Fiscal Year 2021-2022 Total | \$140,781,000 | \$128,863,000 | -\$11,918,000 | -8.5% |
| FY2021-22 NBS | \$77,370,000 | \$68,795,000 | -\$8,575,000 | -11.1% |
| FY2021-22 PNS | \$63,411,000 | \$60,068,000 | -\$3,343,000 | -5.3% |
| Fiscal Year 2022-2023 Total | \$140,781,000 | \$177,052,000 | \$36,271,000 | 25.8% |
| FY2022-23 NBS | \$77,370,000 | \$89,419,000 | \$12,049,000 | 15.6% |
| FY2022-23 PNS | \$63,411,000 | \$87,633,000 | \$24,222,000 | 38.2% |

FUND CONDITION STATEMENT

GENETIC DISEASE TESTING FUND FUND CONDITION REPORT

This Fund Condition Report lists both actual and projected revenues, expenditures, and expenditure adjustments for current and future fiscal years.

DOLLARS IN THOUSANDS

Table 8. RESOURCES

| RESOURCES | 2020-2021 | 2021-2022 | 2022-2023 |
|----------------------------|------------------|------------------|------------------|
| BEGINNING BALANCE | \$21,133 | \$18,130 | \$1,029 |
| Prior Year Adjustment | -654 | 0 | 0 |
| Adjusted Beginning Balance | 20,479 | 18,130 | 1,029 |

Table 9. REVENUES

| REVENUES | 2020-2021 | 2021-2022 | 2022-2023 |
|---|------------------|------------------|------------------|
| 121100 Genetic Disease Testing Fees | 135,766 | 128,863 | 177,053 |
| 150300 Income from Surplus Investments | 121 | 370 | 370 |
| 161000 Escheat of Unclaimed Checks & Warrants | 50 | 1 | 1 |
| TOTAL REVENUES | 135,937 | 129,234 | 177,424 |

Table 10. TOTAL RESOURCES

| TOTAL RESOURCES | 2020-2021 | 2021-2022 | 2022-2023 |
|----------------------------|------------------|------------------|------------------|
| Adjusted Beginning Balance | 20,479 | 18,130 | 1,029 |
| TOTAL REVENUES | 135,937 | 129,234 | 177,424 |
| TOTAL RESOURCES | \$156,416 | \$147,364 | \$178,453 |

Table 11. EXPENDITURES AND EXPENDITURE ADJUSTMENTS

| EXPENDITURES AND EXPENDITURE ADJUSTMENTS | 2020-2021 | 2021-2022 | 2022-2023 |
|--|------------------|------------------|------------------|
| 4265 Department of Public Health (State Operations) | 31,424 | 34,512 | 34,512 |
| 4265 Department of Public Health (Local Assistance) | 105,098 | 111,372 | 140,475 |
| 8880 Financial Information System for California (State Operations) | 0 | 0 | 0 |
| 9800 Employee Compensation (State Operations) | 0 | 1,244 | 1,293 |
| Control Section 3.60 Retirement | 0 | -30 | -30 |
| Lease Revenue Debt Service Adjustment | 0 | 4 | 5 |
| 9892 Supplemental Pension Payments (State Operations) | 496 | 496 | 496 |
| 9900 Statewide General Admin Exp (ProRata) (State Operations) | 1,268 | 1,737 | 1,416 |
| 9920 Loan Transfer to Other Funds | 0 | -3,000 | 0 |
| TOTAL EXPENDITURES AND EXPENDITURE ADJUSTMENTS | 138,286 | 146,335 | 178,167 |
| FUND BALANCE | 18,130 | 1,029 | 286 |
| Fund Balance as a percentage of Total Expenditures and Expenditure Adjustments | 13% | 1% | 0% |

Table 12. GDSP REVENUE PROJECTION 2021-2022 of \$128,863,000

| Number of Tests | Cost | Collection Rate | Revenue |
|------------------------|-------------|------------------------|----------------|
| 392,044 NBS | \$177.25 | Provider: 99% | \$68,795,000 |
| 131,423 PNS | \$211.60 | Non Medi-Cal: 95% | \$26,419,000 |
| 160,628 PNS | \$211.60 | Medi-Cal: 99% | \$33,649,000 |

Table 13. GDSP REVENUE PROJECTION 2022-2023 of \$177,053,000

| Number of Tests | Cost | Collection Rate | Revenue |
|------------------------|-------------|------------------------|----------------|
| 428,070 NBS | \$211.00 | Provider: 99% | \$89,419,000 |
| 139,061 PNS | \$222.00 | Non Medi-Cal: 95% | \$29,328,000 |
| 169,964 PNS | \$222.00 | Medi-Cal: 99% | \$37,355,000 |
| 129,327 NTD | \$75.00 | Non Medi-Cal: 95% | \$9,215,000 |
| 158,066 NTD | \$75.00 | Medi-Cal: 99% | \$11,736,000 |

GENERAL ASSUMPTIONS

FUTURE FISCAL ISSUES

Senate Bill (SB) 1095: Newborn Screening Program

Background:

Senate Bill (SB) 1095 (Chapter 393, Statutes of 2016) amends Sections 124977 and 125001 of the Health and Safety Code (H&S Code) and requires the California Department of Public Health/Genetic Disease Screening Program (CDPH/GDSP) to expand statewide screening of newborns to include screening for any disease that is detectable in blood samples within two years of the disease being adopted by the federal Recommended Uniform Screening Panel (RUSP).

Description of Change:

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

Discretionary?: No

Reason for Adjustment/ Change:

Passage of SB 1095 requires CDPH/GDSP to expand statewide screening of newborns to include screening for any disease that is detectable in blood samples within two years of the disease being adopted by the federal RUSP. Mucopolysaccharidosis Type II and Guanidinoacetate Methyltransferase Deficiency are two Newborn Screening Program (NBS) conditions that are currently in the federal evidence review process. A vote by the Federal Advisory Committee is expected to take place sometime in 2022 to determine whether to add these conditions to the federal RUSP. If they are voted in, deadlines for including in the NBS panel would be mandated sometime in 2024. CDPH/GDSP is closely monitoring the federal approval status of both conditions. At this time, CDPH/GDSP is not expecting an impact in 2021-22 or 2022-23.

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

Expenditures may increase by approximately \$2 million to \$4 million per year for any new disorder adopted by the RUSP. This range is only an estimate and is based on costs from the last three additions to the Newborn Screening panel – Spinal Muscular Atrophy (SMA), Mucopolysaccharidosis Type 1 (MPS-I) and Pompe disease. Furthermore, as additional diseases are added to the RUSP, there may one-time

resources needed to plan, prepare for, and implement the additional required screening. Public Health/GDSP will assess the fund reserve to ensure the program is able to absorb the increase in expenditures and determine if, and when, a fee increase is needed. The fund source is the Genetic Disease Testing Fund (GDTF) (Fund 0203).

NEW ASSUMPTIONS/ PREMISES

Revised Cost of Cell-free DNA (cfDNA) Screening

Background:

See Unchanged Assumption – 2021-22 Budget Change Proposal: Improving the California Prenatal Screening Program.

Description of Change:

The cfDNA laboratory screening process that will be contracted out to private laboratories beginning July 2022 will now require \$23.9 million in Local Assistance expenditure authority in 2022-23 and ongoing. This is an increase of \$3.7 million on top of the expected \$20.2 million increase.

Discretionary? Yes

Reason for Adjustment/ Change:

The \$3.7 million increase is attributed to increasing contract rates and higher expenditures from additional reagent kits and diagnostic follow-up services for inconclusive cfDNA results. The GDSP did not account for additional costs associated with inconclusive results in the Improving the California Prenatal Screening Program Budget Change Proposal (4265-080-2021-BCP-GB) and 2021-22 May Revision Estimate.

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

An additional \$3.7 million increase in Local Assistance expenditures in 2022-23 and ongoing on top of the expected \$20.2 million increase referenced in the Unchanged Assumption – 2021-22 Budget Change Proposal: Improving the California Prenatal Screening Program.

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

Prenatal Screening and Newborn Screening Fee IncreaseBackground:

HSC sections 124977(a) and (b), 124996, and 125000(b) require the Department to charge a fee for any tests or activities performed under the program; mandate that the program be fully supported from fees collected; and state that the amount of the fee shall be established by regulation and periodically adjusted by the Director. HSC section 124996 also specifies that the Genetic Disease Testing Fund (GDTF) is a special fund in the State Treasury and is continuously appropriated to the Department to carry out the purposes of the Hereditary Disorders Act. The fees collected from the institution of birth and fees collected from pregnant woman's health insurance policy, a health care service plan, or by Medi-Cal for beneficiaries are deposited in a special fund called the Genetic Disease Testing Fund (GDTF). The majority of funds are deposited in the Genetic Disease Testing Fund (GDTF), with \$10 from each prenatal screening test deposited in the California Birth Defects Monitoring Program Fund, as mandated by HSC section 124977(b). GDSP is not funded by the State's General Fund. The GDTF is used to pay expenses of program operations including costs of supplies, forms, educational materials and contracts with private vendors for laboratory analysis, tracking and follow-up of positive test results, data processing and fee collection.

The Legislature has found that timely implementation of changes in genetic screening programs and continuous maintenance of quality statewide services requires expeditious regulatory action and administrative procedures (HSC § 124977(c) (1)).

Description of Change:

Through the rulemaking process, CDPH/GDSP will propose a fee increase of \$33.75 (from \$177.25 to \$211.00) for NBS and increases to the PNS fee structure identified in the 2021 Budget Act. Previously, CDPH/GDSP had identified fees of \$221.60 for the cfDNA test and \$75 for the NTD test. CDPH/GDSP is now proposing additional fee increases of \$10.40 (\$221.60 to \$232.00) for the cfDNA test and \$10 (\$75 to \$85) for the NTD test beginning July 1, 2022. These fee changes are needed to support the loss of revenue due to the decrease in projected caseload resulting from the DRU's projection of live births; increased expenditures related to higher contract rates for screening; higher costs associated with the computer system redesign and SIS migration to the new Cloud platform; the ongoing cost of software license and maintenance; and to support the pregnancy blood sample, storage, testing, and research activities of the California Birth Defects Monitoring Program.

Discretionary: No

Reason for Adjustment/ Change:

A considerable decrease in the birth rate had a significant unplanned impact to the program which resulted in loss of revenue of \$11.9 million in the current year and negative fund balance in the budget year. The larger than expected decrease in projected caseload may have occurred for a variety of reasons including the social and economic impacts of the COVID-19 pandemic. The GDTF pays for program personnel and operations including costs of supplies, forms, educational materials and contracts with private vendors for laboratory analysis, tracking and follow-up of positive test results, data processing and fee collection.

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

An increase in annual revenue of approximately \$38 million annually beginning 2022-23 due to a \$33.75 NBS fee increase and a \$10.40 PNS fee increase for cfDNA testing, fee (See Unchanged Assumption – 2021-22 Budget Change Proposal: Improving the California Prenatal Screening Program). The fund source is the GDTF (Fund 0203).

An increase in annual revenues of \$2.8 million from the \$10 PNS fee increase for NTD testing from \$75 to \$85. The fund source is the BDMP (Fund 3114).

All fee increases will be approved through the rulemaking process.

Accounts Receivables (AR) Collection Rate Change for PNS Patient billingBackground:

In 2016-17, CDPH contracted with Sutherland Healthcare Solutions (SHS) due to its powerful billing system, customer care expertise, extensive knowledge of healthcare policy and programs and state of the art technology. The goal was to accelerate revenue collection, reduce the overall risk and cost to collect and reduce uncollectable accounts. GDSP fully transitioned its in-house patient billing process to SHS. Prior to that, with the in-house process using state staff, GDSP had an approximate 83 percent collection rate within two years collection time. Over the past four fiscal years, the patient billing has continued to progress under this outsourced AR system, the collection rate for non-Medi-Cal insurers for PNS increased from 94 percent to now 95 percent collection rate, while Medi-Cal insurers for PNS has a collection rate increased from 98 percent to 99 percent. This new rate will be used for GDSP's 2021-22 estimates for revenue projections. The increase in collection rate is driven by the increase in electronic claims submission versus paper claims which reduced the timeline of collecting revenue from 12 months to 6 months; the increase in answered calls and decrease in abandoned calls; and increased use of GDSP's payment portal

where patients provide updates to their demographic and insurance information and pay online.

Description of Change:

Since GDSP contracted with Sutherland for PNS billing and collection, the collection rate for PNS non-Medi-Cal participants has improved from 94 percent to 95 percent. The collection rate for PNS Medi-Cal participants has improved from 98 percent to 99 percent.

Discretionary: Yes

Reason for Adjustment/ Change:

The rate of collection for PNS non-Medi-Cal participants and Medi-Cal participants needs to be updated to reflect accurate revenue figures.

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

An annual increase for PNS non-Medi-Cal participants in projected revenues is approximately \$400,000. The annual increase for PNS Medi-Cal in projected revenues is approximately \$500,000. The fund source is the GDTF (Fund 0203).

EXISTING (SIGNIFICANTLY CHANGED) ASSUMPTIONS/PREMISES

There are no Existing (Significantly Changed) Assumptions.

UNCHANGED ASSUMPTIONS/PREMISES

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

Background:

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

Health and Safety Code section 125055 (g)(1) states that Public Health “shall expand prenatal screening to include all tests that meet or exceed the current standard of care as recommended by nationally recognized medical or genetic organizations.” A position statement from the ACMGG indicated that cfDNA has been rapidly integrated into prenatal care and new evidence strongly suggests that it “can replace conventional screening for Patau (trisomy 13), Edwards, and Down syndromes across the maternal age spectrum.” This new technology may be the standard of care and should be offered to all women in California, regardless of income, education, or ability to pay.

Description of Change:

The California PNS Program plans to replace GDSP’s current conventional biochemical screening for chromosome abnormalities with cfDNA screening. GDSP’s screening for neural tube defects will remain part of the overall screening process. The proposed changes would require the California PNS Program to initiate the following activities in preparation for the new screening launch: redesign the Test Request Forms for providers to order prenatal screening; redesign numerous screening protocols to administer the new test to all California individuals who seek prenatal screening; develop new health education materials; establish a contract for new laboratories to carry out cfDNA screening; develop new fee structures for case management services provided by Case Coordination Centers and follow-up services provided by the Prenatal Diagnosis Centers (PDCs); and redesign the SIS to accommodate the new screening results transmitted from the cfDNA laboratories, including redesign of test result mailers, new algorithms to designate a case as screen-positive and the subsequent referral mechanisms to refer high risk cases to the PDCs for follow-up services. These screening launch preparation activities are estimated to be a one-time Local Assistance cost of \$3.9 million in 2021-22

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

The actual laboratory screening replacement is expected to commence in July 2022 and will be contracted out to private laboratories. The new laboratory screening process will require a \$20.2 million annual increase in Local Assistance expenditure authority in 2022-23 and ongoing. This factors in expected annual savings of approximately \$6 million due to decreases in Case Coordination Center and Prenatal Diagnosis Center referrals that will reduce chromosomal abnormality follow-up services by 91 percent.

Discretionary?: Yes

Reason for Adjustment/ Change:

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

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

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

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

A \$449,000 increase in State Operations expenditures in 2021-22 and ongoing and a one-time Local Assistance expenditure increase of \$3.9 million in 2021-22 have already been included in the Budget Act of 2021. However, this unchanged assumption will increase Local Assistance expenditures by \$20.2 million in 2022-23 and ongoing. An additional \$3.7 million expenditure increase in Local Assistance on top of the \$20.2 million is being requested in 2022-23 and ongoing through the New Assumption – Revised Cost of cfDNA Screening.

As part of the plans to improve the PNS program and ensure appropriate fees are charged to support the program and its new screening activities, a change in the fee structure will be necessary beginning 2022-23 (current revenue levels are sufficient to offset expenditure increases only through the end of 2021-22). Beginning July 2022, CDPH will charge a fee of \$232 for cfDNA, which is slightly higher than the \$221.60 rate that is charged for the current PNS biochemical screening. When the BCP was included in the 2021 Budget Act, CDPH/GDSP initially forecasted that it would charge the same \$221.60 amount for cfDNA, however higher than expected contract costs and caseload decreases are the reason for the \$232 fee. Additionally, the NTD screening test in the second trimester, which is currently included in the PNS biochemical screening fees, will now require a new separate fee of \$85 instead of \$75, which is an increase of \$10 from the fees identified in the 2021 Budget Act. All the proposed fee increases will be established through the rulemaking process. These fee structure

changes will generate sufficient ongoing revenue to offset the additional laboratory screening costs.

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

DISCONTINUED ASSUMPTIONS/PREMISES

There are no Discontinued Assumptions.

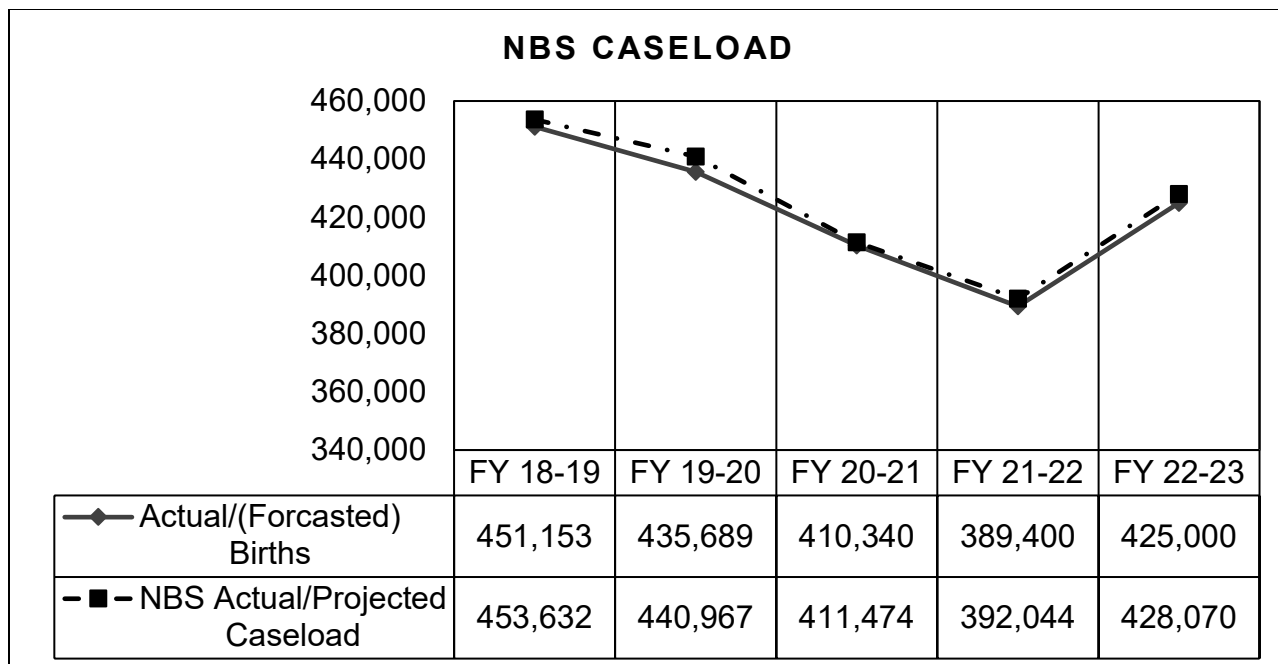
APPENDIX A: NEWBORN SCREENING PROGRAM (NBS) ASSUMPTIONS AND RATIONALE

CONTRACT LABORATORIES

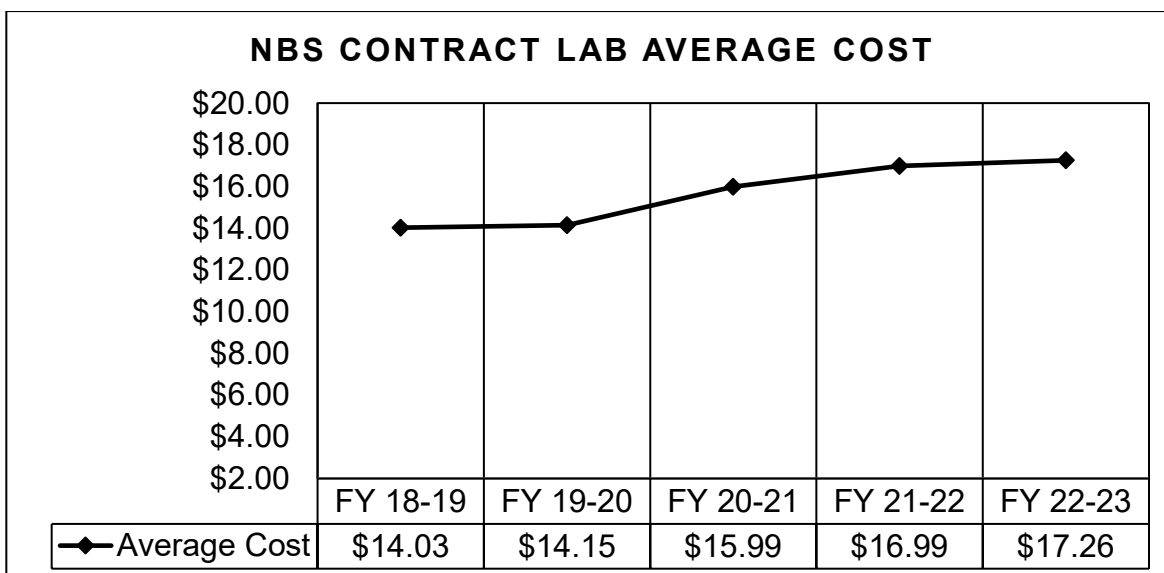
Overview: Laboratory testing of specimens is performed at regional screening laboratories contracted by the state to screen newborns for 75+ specific genetic disorders. Costs include laboratory services for processing genetic screening tests. Screening laboratories ascertain the possible presence of a birth defect or a congenital disorder; a screening test is not diagnostic, and additional follow-up is likely to be required for a case that has an initial positive or questionable screening test result. The state contracts with several regional contract laboratories that are paid on a per specimen basis.

Costs associated with Contract Laboratories and Technical and Scientific supplies are both driven by the total number of clients NBS serves. The total caseload is determined as a percentage of the DRU's projected number of live births. This estimate assumes that 100 percent of the DOF/DRU projected births will participate in the NBS program in 2020-21 and 2021-22.

Total Caseload –CDPH/GDSP estimates current year caseload will total 392,044, a decrease of 19,430 or 4.7 percent compared to the 2020-21 actual total caseload of 411,474. Caseload in 2022-23 is estimated at 428,070, which is an increase of 36,026 or 9.2 percent compared to the current year estimate. This year over year change is due to the DOF/DRU's projected number of live births. The following chart shows the actual NBS cases by fiscal year, along with our projected numbers for the remainder of the current year and budget year.

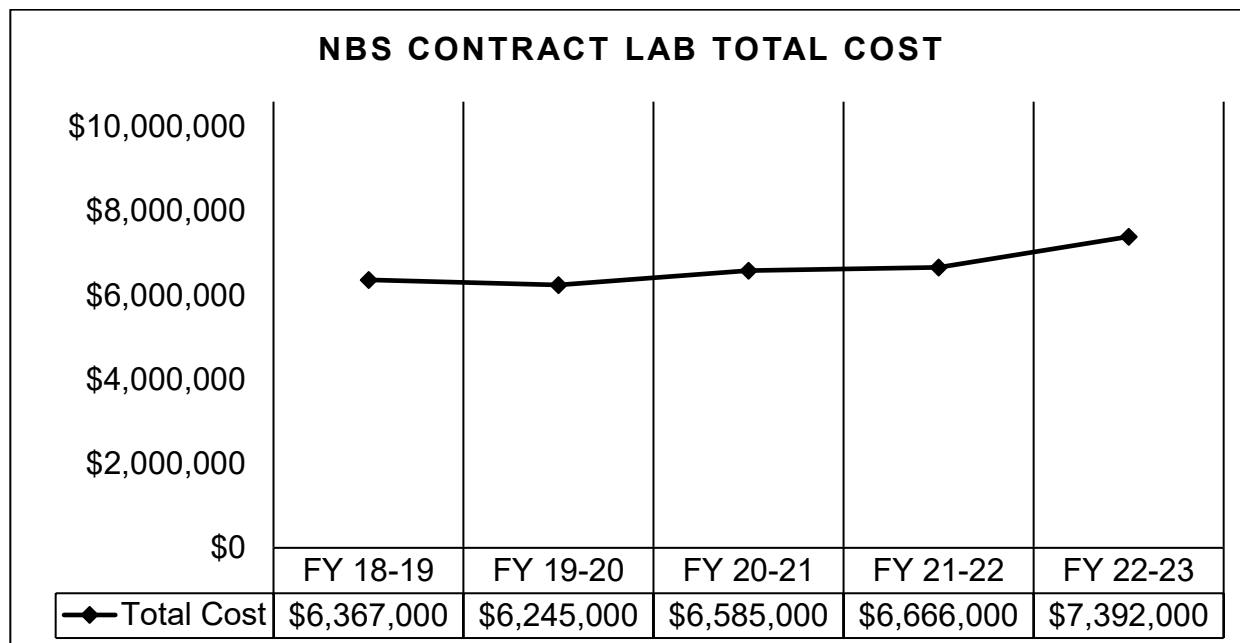


Contract Laboratory Average Cost Projections – CDPH/GDSP estimates current year average laboratory cost per participant will be \$16.99, which is an increase of \$1 or 6.2 percent compared to the 2020-21 actual average laboratory cost per participant of \$15.99. Average laboratory cost per participant in 2022-23 is estimated at \$17.26, which is an increase of \$0.27 or 1.6 percent compared to the current year estimate. The increase is due to the increased cost rate of the laboratory contracts.



Contract Laboratory Total Cost Projections – CDPH/GDSP estimates current year contract laboratory costs to total \$6.7 million, which is an increase of \$81,000 or 1.2 percent compared to 2020-21 actual contract laboratory costs of \$6.6 million. 2022-23

contract laboratory costs are projected to be \$7.4 million, which is an increase of \$726,000 or 11 percent compared to the current year.

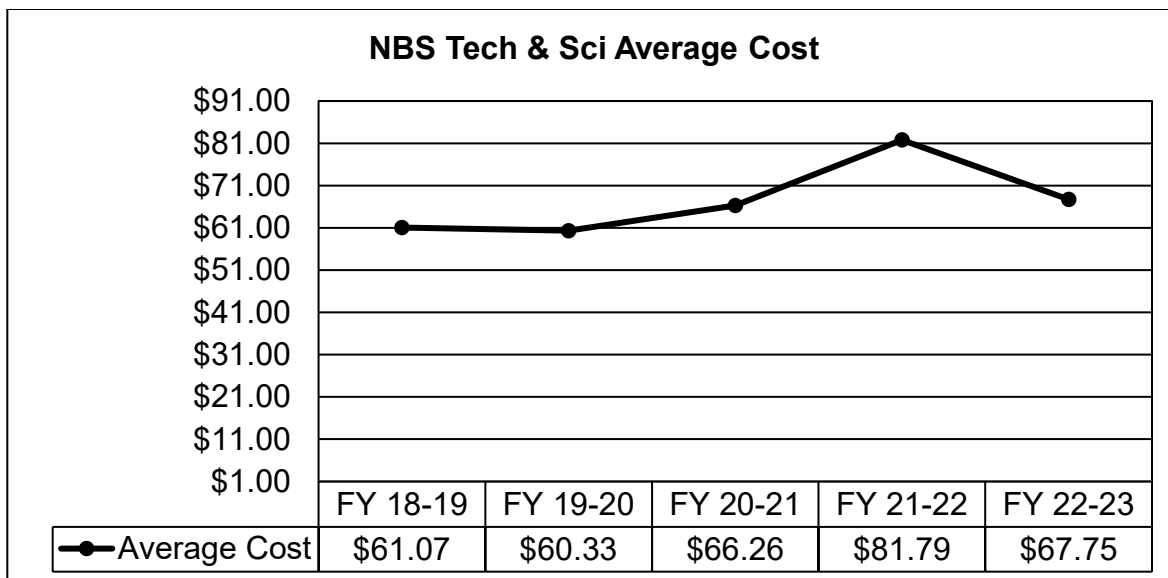


TECHNICAL AND SCIENTIFIC

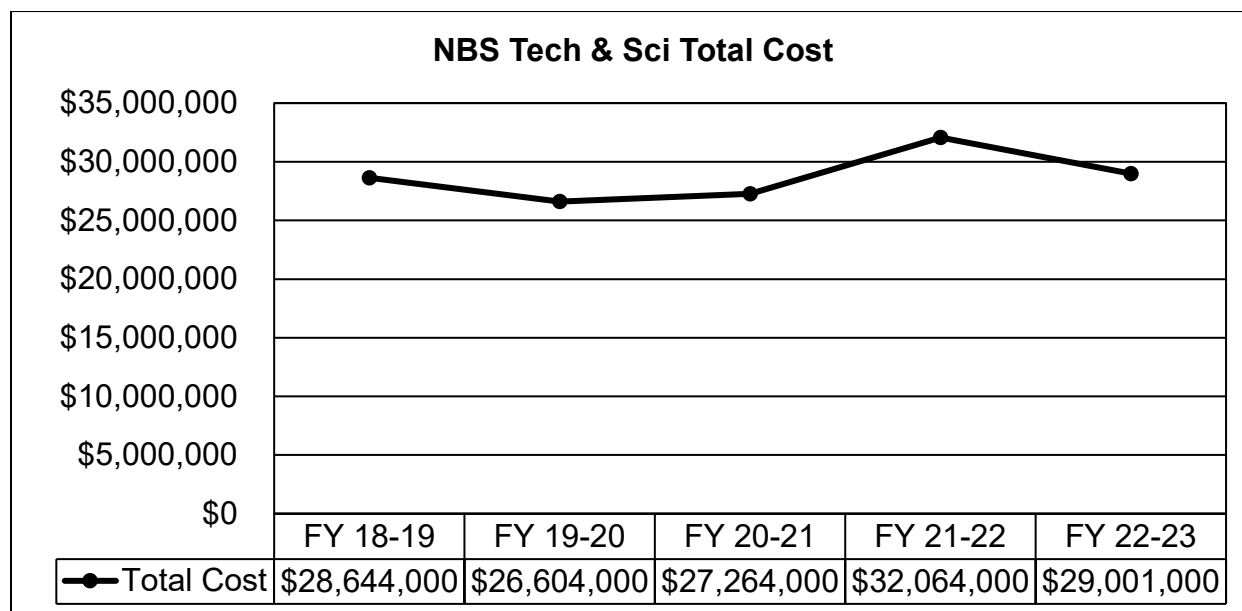
Overview: Costs associated with specimen screening include reagents kits, supplies, processing, and limited maintenance and support of laboratory equipment. In addition, there are minimal fixed costs associated with specimen screening including: laboratory supplies, blood specimen filter paper, blood specimen storage, and costs for special packaging for blood specimen transport, etc. Reagent test kits, which make up the majority of the Technology and Scientific costs, are purchased in lots based on anticipated caseload volume. Reagents vary in cost depending upon the type of screening performed.

Technical and Scientific Caseload: See Appendix A 1

Technical and Scientific Average Cost – CDPH/GDSP estimates current year average Technical and Scientific cost per participant will be \$81.79, which is an increase of \$15.53 or 23 percent compared to 2020-21 actual average Technical and Scientific cost per participant of \$66.26. Average Technical and Scientific cost per participant in 2022-23 is estimated at \$67.75, which is a decrease of \$14.04 or 17 percent compared to the current year estimate.



Technical and Scientific Total Cost – CDPH/GDSP estimates current year Technical and Scientific costs to total \$32.1 million, which is an increase of \$4.8 million or 18 percent compared to 2020-21 actual technical and scientific costs of \$27.3 million. For 2022-23, the Technical and Scientific costs is estimated to be \$29 million, which is a decrease of \$3.1 million or 9.6 percent compared to the current year. The change in cost is tied to the fluctuations of caseload.

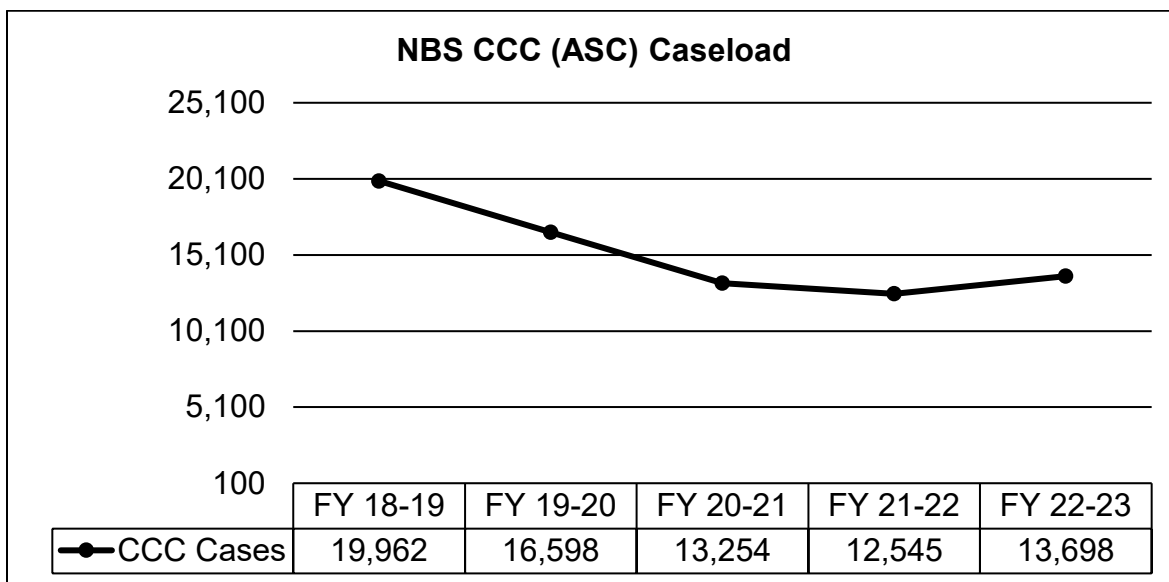


CASE MANAGEMENT AND COORDINATION SERVICES:

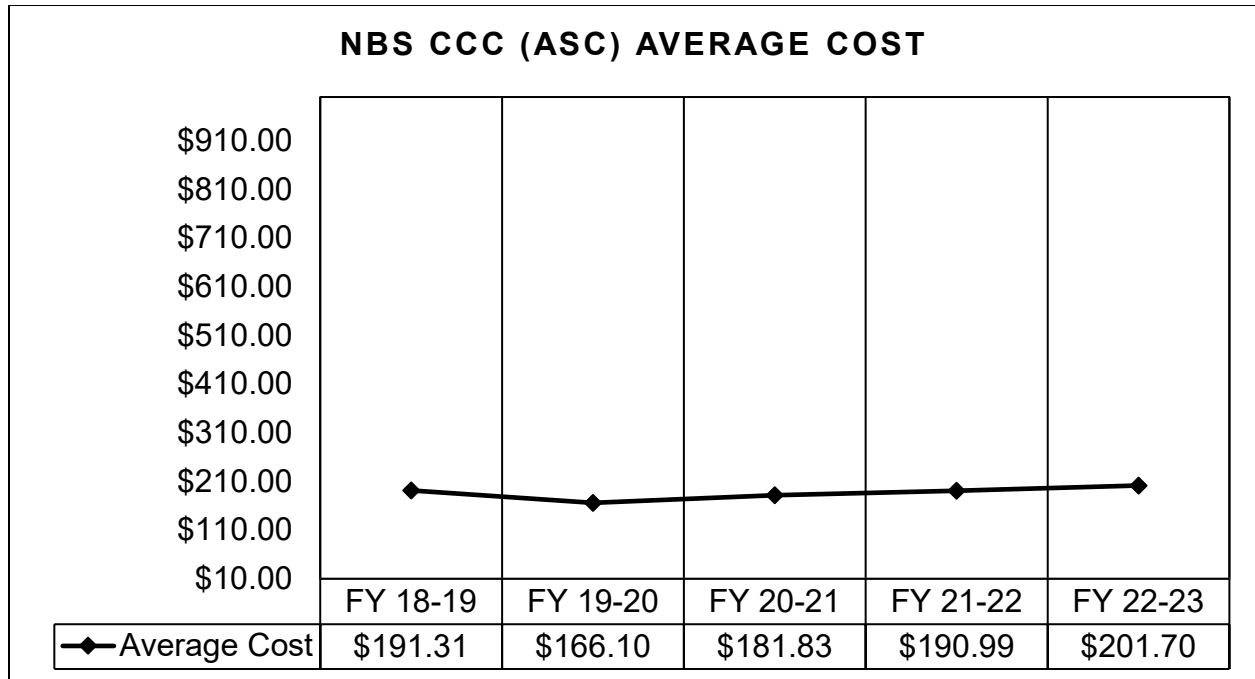
Overview- Services provided to infants who screen initial positive or have questionable screening test results for the 75+ genetic disorders screened. These services include

time-sensitive coordination for specific confirmatory testing, family consultation – including consultation with the infant’s pediatrician, genetic disease counseling, family educational services, and coordinated care referrals to specialized medical institutions. The NBS Area Service Centers (ASC) provide critical coordination and tracking services to ensure appropriate diagnostic measures are completed, and that affected infants are provided with appropriate medical care and receive treatment within a critical timeframe. The ASCs are reimbursed based on caseload and the type of service performed along with a monthly base allocation; this funding supports a required core team of clinical professionals. Costs vary by ASC, dependent upon the geographical location as well as the volume of caseload served.

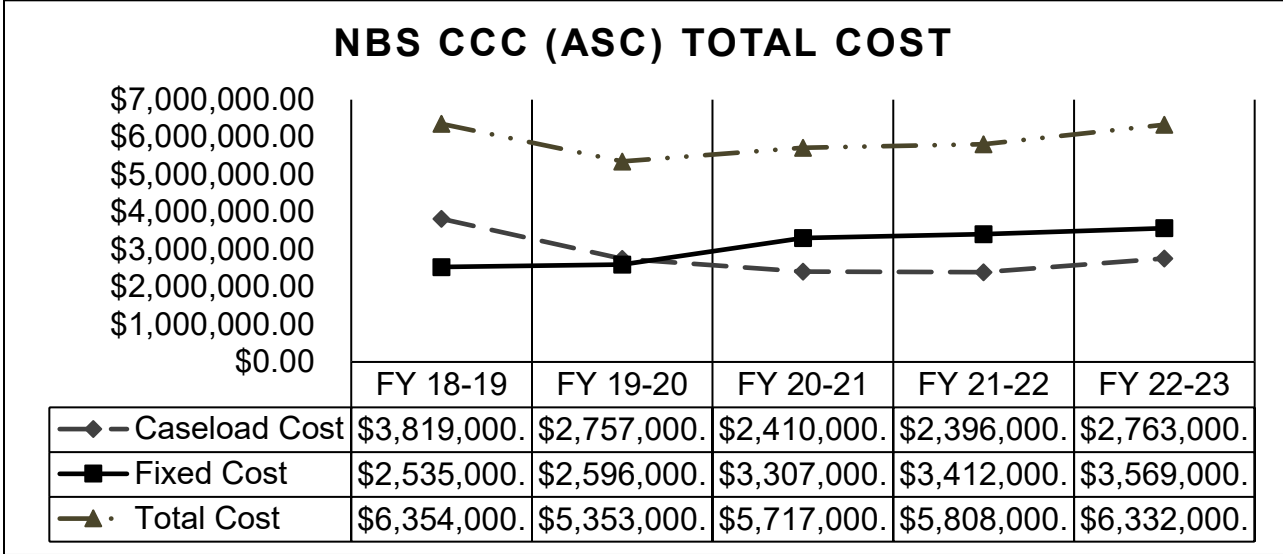
Case Management and Coordination Services (CMCS) Caseload – CDPH/GDSP estimates current year CMCS caseload will total 12,545, which is a decrease of 709 or 5 percent compared to 2020-21 actual CMCS caseload of 13,254. CMCS caseload in 2022-23 is estimated at 13,698, which is an increase of 1,153 or 9 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 \$191, which is an increase of \$9 or 5 percent compared to 2020-21 actual average CMCS cost per participant of \$182. Average CMCS cost per participant in 2022-23 is estimated at \$202, which is an increase of \$11 or 6 percent compared to the current year estimate. The increase in the average cost is tied directly to the fluctuations in the total cost and additional specialized follow-up centers for the ongoing newborn testing.



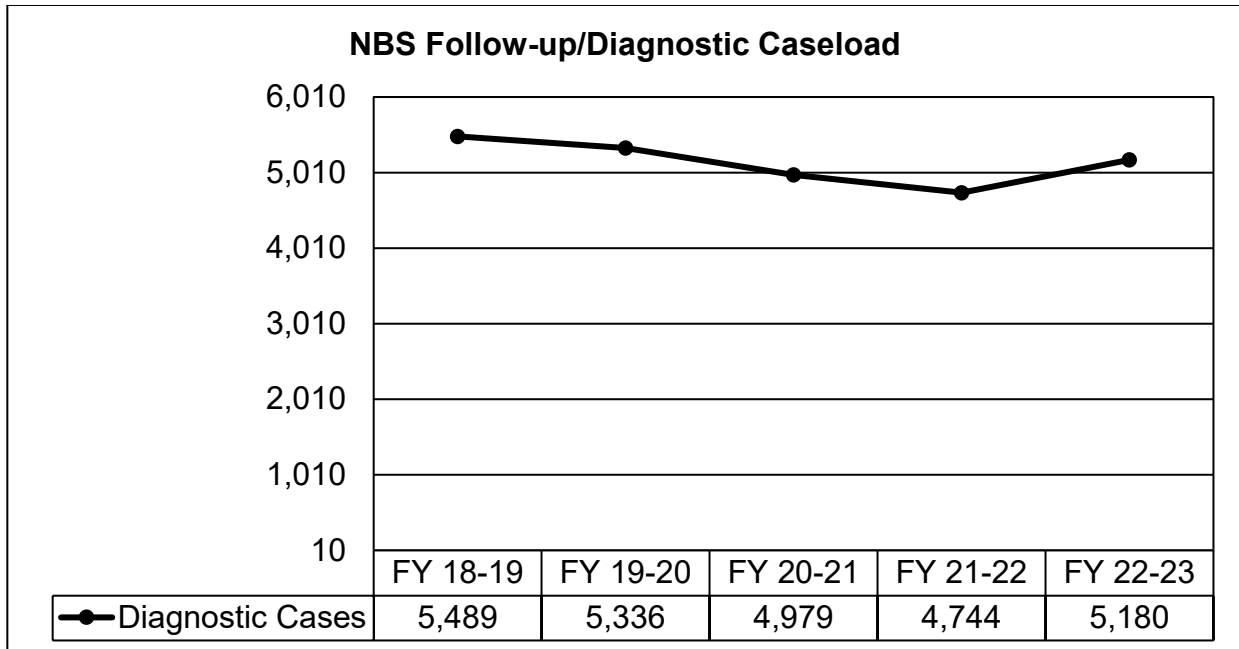
Case Management and Coordination Services (CMCS) Total Cost - CDPH/GDSP estimates current year CMCS costs to total \$5.8 million, which is an increase of \$91,000 or 2 percent compared to 2020-21 actual CMCS total costs of \$5.7 million. CMCS costs in 2022-23 are estimated to total \$6.3 million, which is an increase of \$524,000 or 9 percent compared to the current year estimate. The increase in current year reflects the projected increase in data correction on newborn records, and an increase in ongoing expenditures in 2022-23 due to the projected number of positive cases attributed to the implemented screening for SMA. In addition, we considered a combination of increased fixed costs, and incremental (per case) reimbursement, which includes administrative costs, rent, equipment, travel and administrative staff.



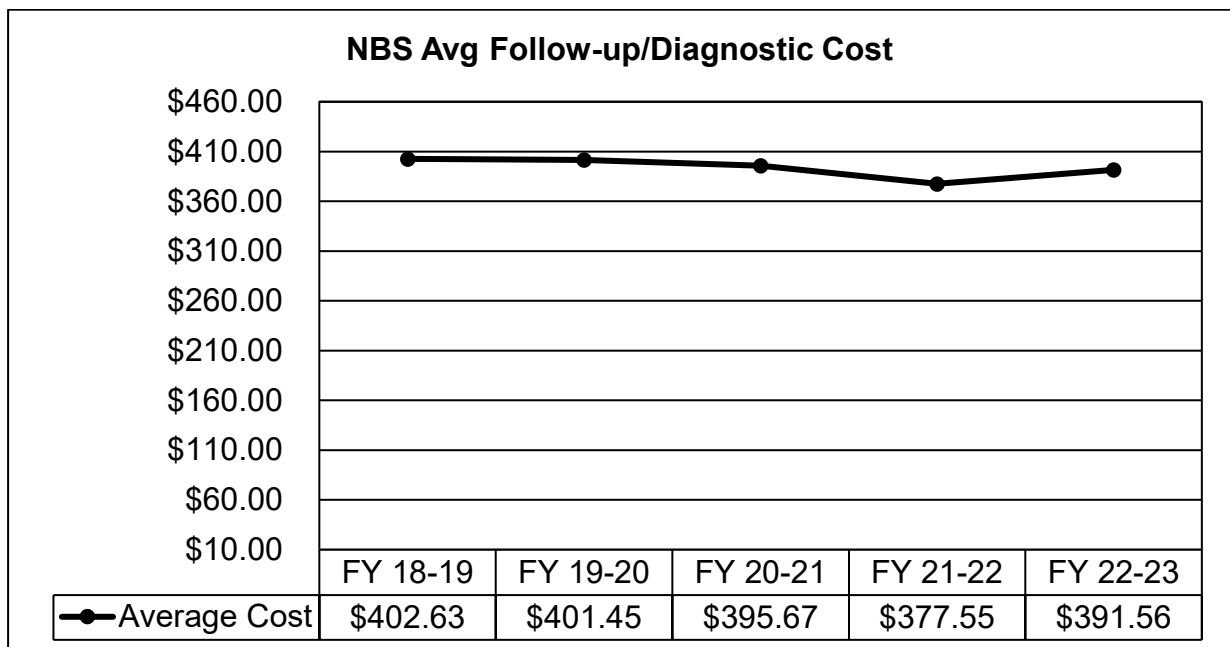
DIAGNOSTIC SERVICES

Overview- Diagnostic Services are for infants who require extended monitoring while undergoing confirmatory testing and diagnosis. Clinical outcome data is collected on infants once diagnosis is made as a means of tracking, confirming, evaluating, and refining program standards. Services include: coordination with the NBS, ASC and Public Health/GDSP for ongoing medical care, ensuring the establishment of infant treatment plans through specialty care hospitals and university medical centers specializing in the genetic disorders such as sickle cell anemia, cystic fibrosis, PKU, beta thalassemia, alpha thalassemia, and various neurologic, metabolic, and endocrine disorders, etc. Services are provided through Special Care Centers, which are composed of highly specialized medical teams; cost is based on per case reimbursement and a small base allocation.

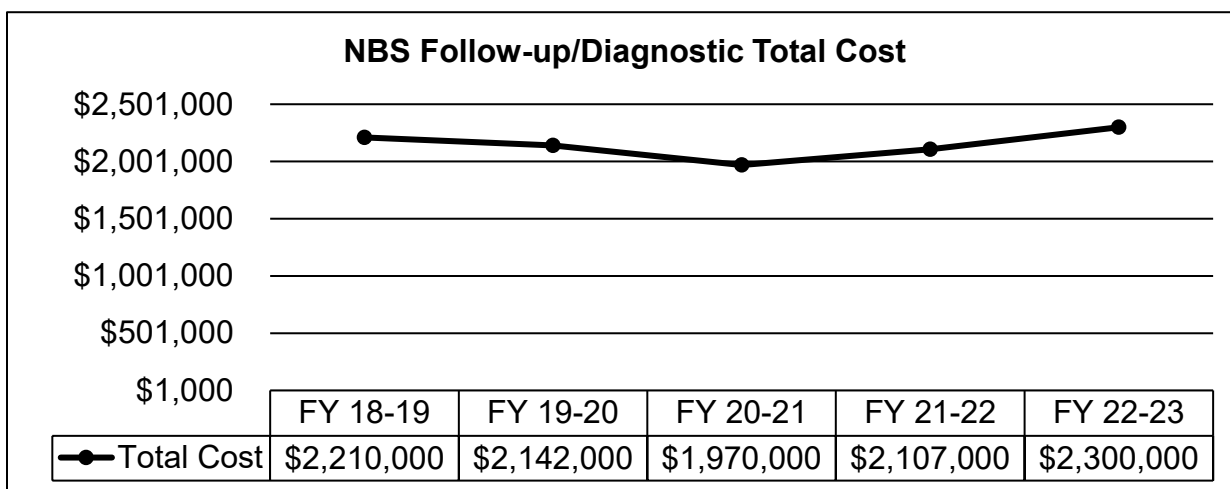
Diagnostic Services Caseload – CDPH/GDSP estimates current year Diagnostic caseload will total 4,744, based on projected new referral cases and annual patient summary cases, which is a decrease of 235 or 5 percent compared to 2020-21 actual Diagnostic Services caseload of 4,979. Diagnostic caseload in 2022-23 is estimated at 5,180, which is an increase of 436 or 9 percent compared to the current year estimate. Fluctuations are tied to overall DRU-based caseload. In addition, we considered a combination of increased fixed costs, and incremental (per case) reimbursement, which includes administrative costs, rent, equipment, travel, and administrative staff.



Diagnostic Services Average Cost - CDPH/GDSP estimates current year average Diagnostic Services cost per participant will be \$378, calculated based on projected new referral cases and annual patient summary cases, which is a decrease of \$18 or 5 percent compared to 2020-21 actual average Diagnostic Services cost per participant of \$396. The Average Diagnostic Services cost per participant in 2022-23 are estimated at \$392, which is an increase of \$14 or 4 percent compared to the current year average cost. The decrease in the current year is tied to the caseload decreases while the costs are anticipated to increase for the budget year.



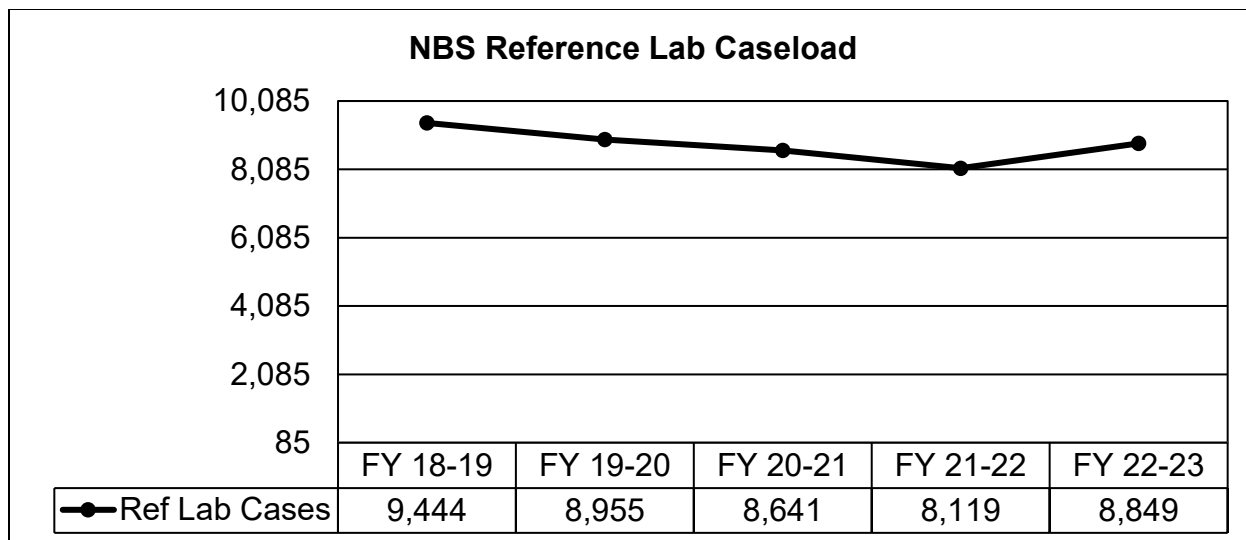
Diagnostic Services Total Cost - CDPH/GDSP estimates current year Diagnostic Services costs to total \$2 million, which is no change compared to 2020-21 actual Diagnostic Services total costs. Diagnostic Services costs in 2022-23 are estimated to total \$2 million, which remains unchanged compared to the current year estimate. The slight increases in total costs from the current to the budget year can be attributed to the slight caseload increases.



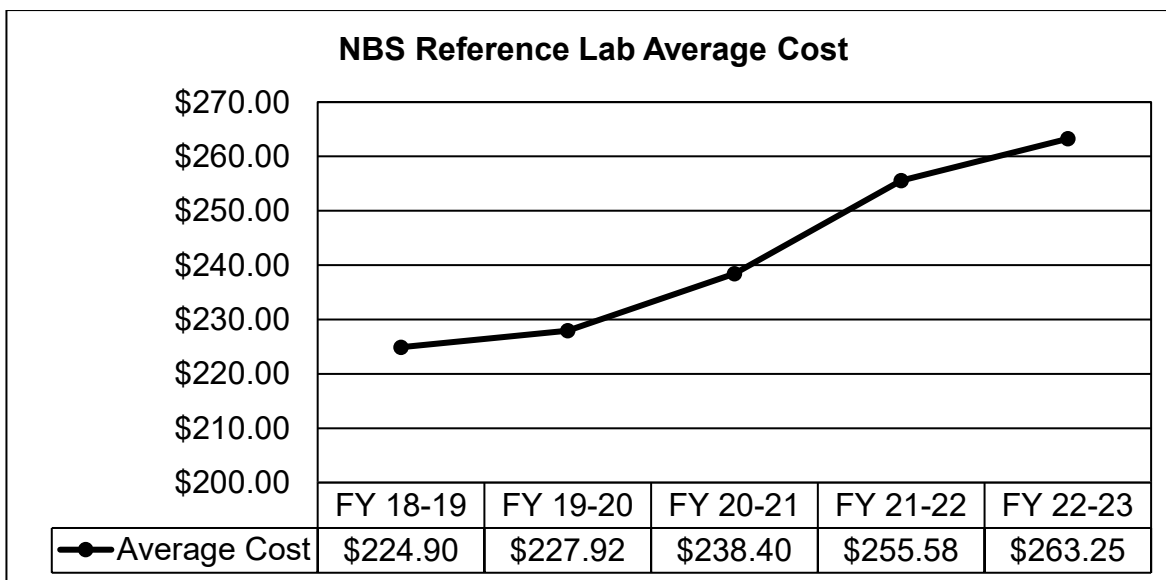
REFERENCE LABORATORIES

Overview- Cases that result in a positive screening test are referred for diagnostic testing at various confirmatory laboratories. Costs include medical and confirmatory diagnostic tests, as well as fixed costs for lab technical support, and expert medical consultation services for rare genetic abnormalities. Reference Laboratories are reimbursed on a cost per test basis.

Reference Laboratory Caseload – CDPH/GDSP estimates current year Reference Laboratory caseload will total 8,119, which is a decrease of 522 or 6 percent compared to 2020-21 actual Reference Laboratory caseload of 8,641. Reference Laboratory caseload in 2022-23 is estimated at 8,849, which is an increase of 730 or 9 percent compared to the current year estimate.

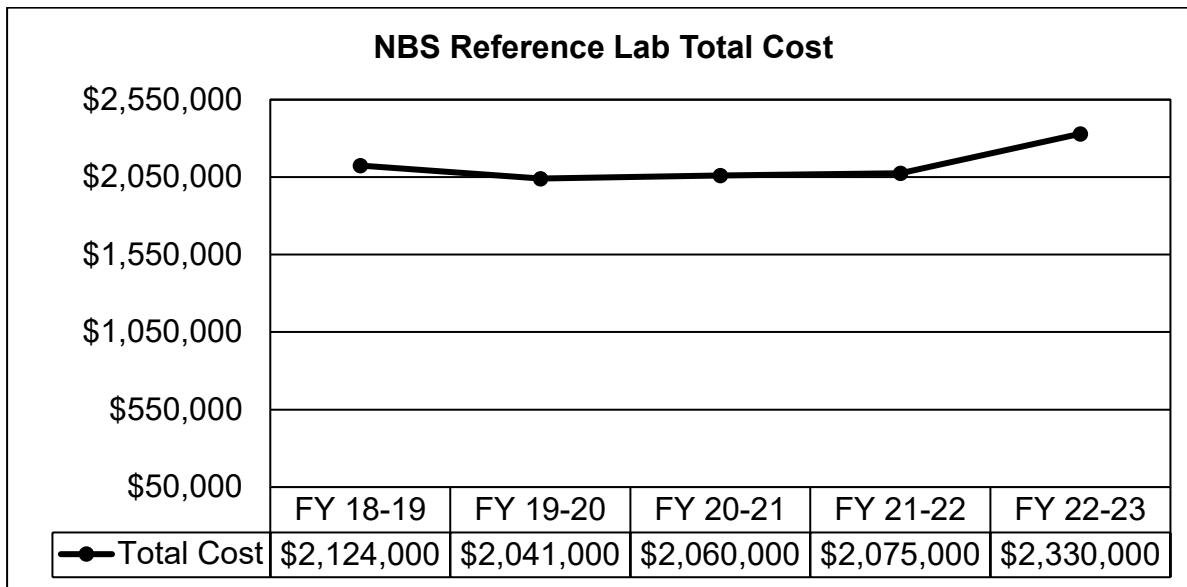


Reference Laboratory Average Cost – CDPH/GDSP estimates current year Reference Laboratory average cost per participant will be \$255.58, which is an increase of \$17.18 or 7 percent compared to 2020-21 Reference Laboratory actual average cost per participant of \$238.40. Reference Laboratory average cost per participant in 2022-23 is estimated at \$263.25, which is an increase of \$7.67 or 3 percent compared to the current year estimate. The fluctuation in caseload is tied to the total costs.



Reference Laboratory Total Cost – CDPH/GDSP estimates current year Reference Laboratory costs to total \$2 million, which is virtually no change compared to 2020-21 actual Diagnostic Services total costs. Reference Laboratory costs in 2022-23 are estimated to total \$2 million, which remains unchanged compared to the current year estimate. The slight cost increases from the current year to the budget year can be attributed to the additional cost for adding confirmatory DNA sequencing for new

disorders and contract increases for sickle cell trait follow-up, and fluctuations in caseloads.



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

CELL-FREE DNA (CFDNA)

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

Beginning July 1, 2022, the California Prenatal Screening Program will replace 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 will remain part of the overall screening process. The changes would require the California PNS Program to establish a contract for new laboratories to carry out cfDNA screening; develop new structures for case management services provided by Case Coordination Centers and follow-up services provided by the Prenatal Diagnosis Centers (PDCs); and redesign the SIS to accommodate the new screening results transmitted from the cfDNA laboratories, including redesign of test result mailers, new algorithms to designate a case as screen-positive and the subsequent referral mechanisms to refer high risk cases to the PDCs for follow-up services.

Total Caseload/Specimens – CDPH/GDSP estimates budget year projected caseload for cfDNA at 309,025, which is 73 percent of the projected births from DOF/DRU birth rates. Only 304,913, which is 98.7 percent of that will be referred and the cfDNA company may not charge specimens without results after one redraw and no charge on pregnancies with 2nd failure of cfDNA testing. There will be redraws, but the cfDNA company will invoice GDSP only once per pregnancy.

Table 14 shows the projected cfDNA cases by billable caseload, average cost and total cost for budget year 2022-23.

Table 14. cfDNA Projected Caseload and Costs

| FY 2022-23 | Forecasted Births | Billable PNS Projected Caseload | PNS Projected Specimens | Average Cost | Total Cost |
|-------------------|--------------------------|--|--------------------------------|---------------------|-------------------|
| cfDNA | 425,000 | 304,913 | 596,419 | \$140 | \$42,688,000 |

CONTRACT LABORATORIES

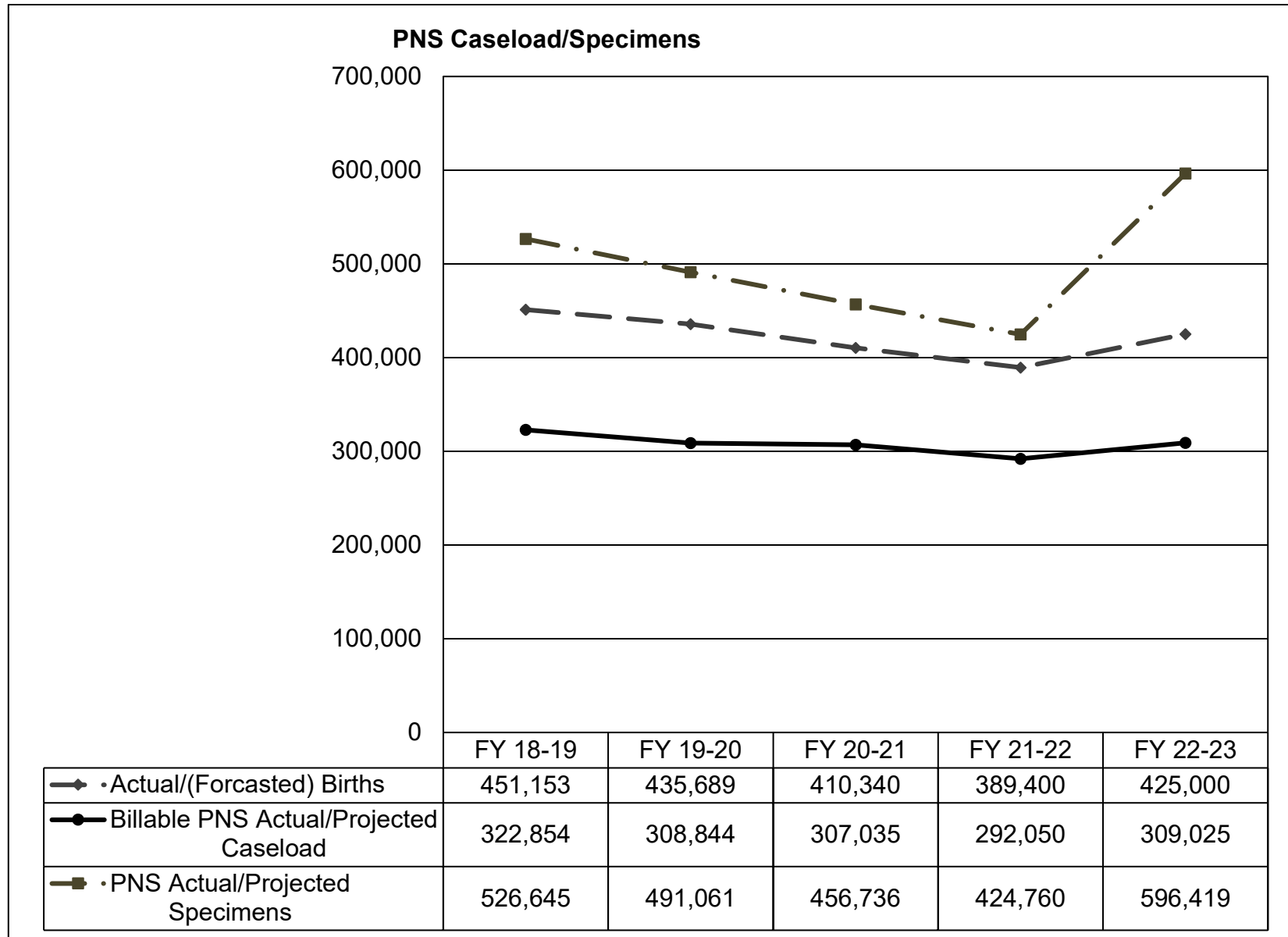
Overview - Laboratory testing to screen pregnant women for genetic and congenital disorders, such as trisomy 21, trisomy 18, Smith-Lemli-Opitz Syndrome (SLOS), and Neural Tube Defects. Costs include laboratory services for performing prenatal genetic screening tests. The screening test estimates the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

In the past CDPH/GDSP estimated the number of 1st trimester and 2nd trimester screens performed separately in the estimate. This is because the average cost of the 1st trimester screen was substantially less than the cost of the 2nd trimester screens. Currently, the regional laboratory cost of each test is the same, as such GDSP will estimate the average cost to provide both screens without differentiating between the two tests a participant may receive. Beginning 2022-23, 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 NAPs laboratory for which a separate fiscal analysis will be performed.

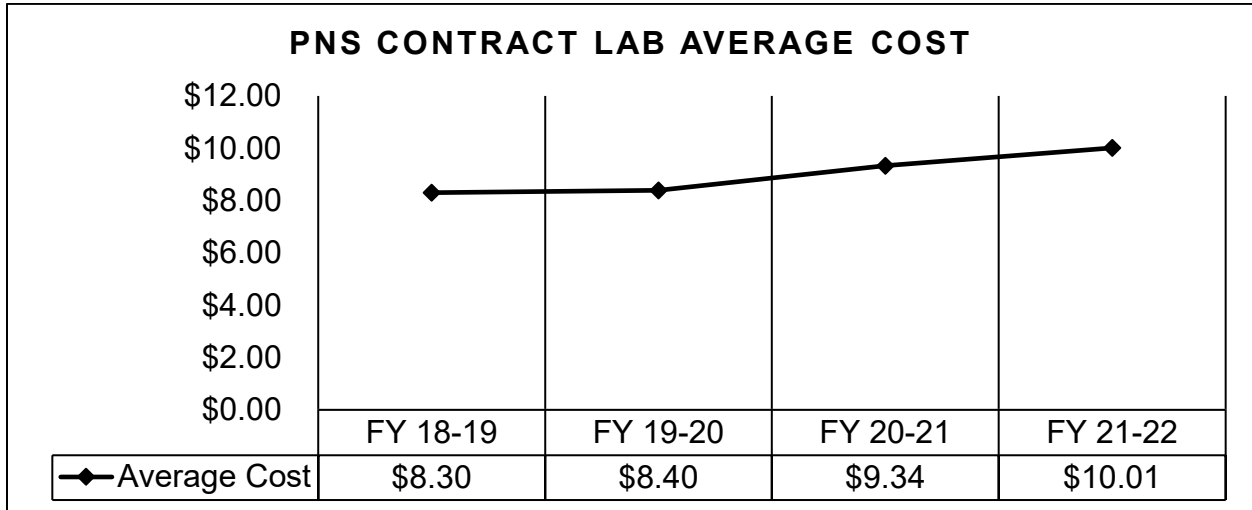
Total Caseload/Specimens – CDPH/GDSP estimates current year specimens will total 424,760, which is a decrease of 31,976 or 7 percent compared to 2020-21, actual total specimens of 456,736. The PNS program participation is estimated as a percentage of the DOF/DRU projected number of live births. In 2021-22, one specimen collected in the 2nd trimester is used for both Trisomy 21 (T21)/ Trisomy (T18) screening and NTD screening because the serum analyte testing for both screenings are done in one NAPs laboratory processing. But in 2022-23, 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 NAPs laboratory.

CDPH/GDSP estimates that 75 percent (based from a three-year actual average) of the projected births will participate in the PNS program in 2021-22, and that the number of participants will decrease to 73% in 2022-23. The 2021-22 projections do not increase

with DOF/DRU birth rates because PNS participation has not remained constant as a percent of DRU birth projections due to women choosing other types of prenatal testing offered outside of the State program. The following chart shows the actual PNS cases by year, along with our projected numbers for the remainder of the current year and budget year.



Contract Laboratory Average Cost Projections – CDPH/GDSP estimates current year average laboratory cost per participant will be \$10, which is an increase of \$1 or 7 percent compared to 2020-21 actual average laboratory cost per participant of \$9. The increase in the current year is due to an increase in contract rates. Beginning 2022-23, The contract regional NAPS lab will only screen pregnant women for neural tube defects (NTD), for which a separate fiscal analysis will be performed.



Contract Laboratory Total Cost Projections – CDPH/GDSP estimates current year contract laboratory cost to total \$4 million, which is virtually no change compared to 2020-21 actual contract laboratory costs of \$4 million. Beginning 2022-23, the contract regional NAPS lab will only screen pregnant women for neural tube defects (NTD), for which a separate fiscal analysis will be performed.

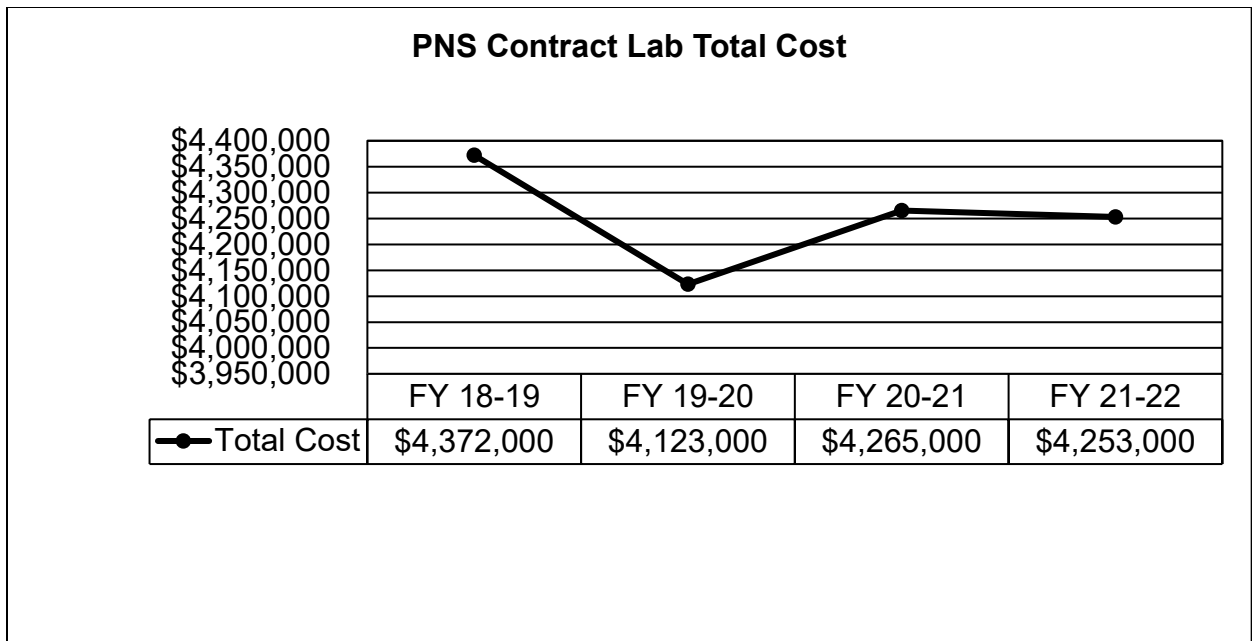


Table 15 shows the projected cases, average cost, and total cost for neural tubes defects in budget year 2022-23.

Table 15. Contract Laboratory Total and Average Costs

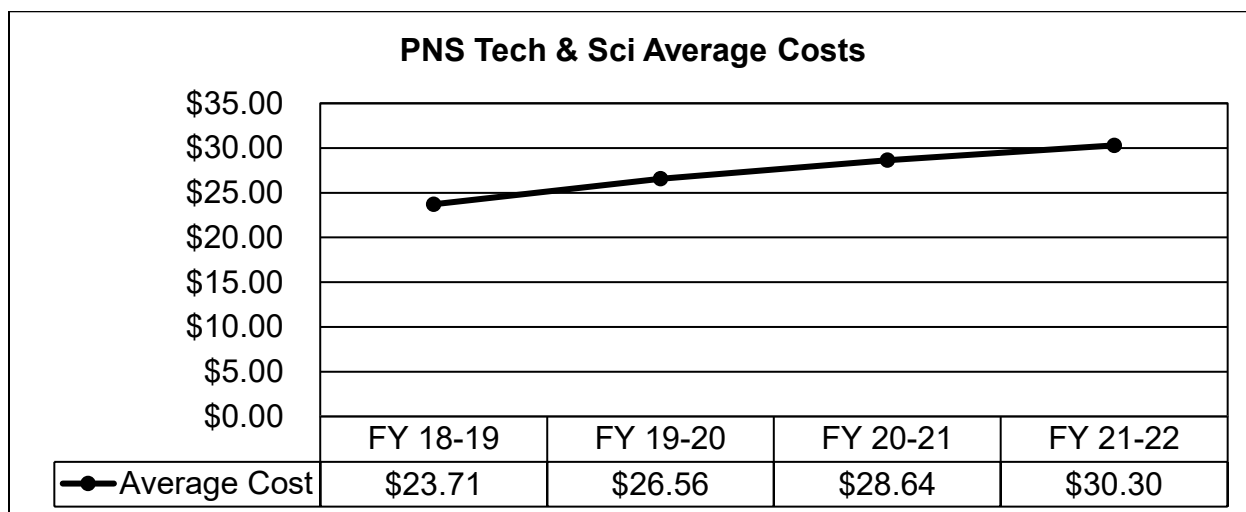
| FY 2022-23 | Total NTD | Average Cost | Total Cost |
|-----------------------|-----------|--------------|-------------|
| Contract Laboratories | 287,393 | \$9.90 | \$2,845,000 |

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 the majority of the Technology and Scientific costs, are purchased in lots based on anticipated specimens. Reagents vary in cost depending upon the type of screening performed.

Technical and Scientific Caseload: See appendix B 1

Technical and Scientific Average Cost – CDPH/GDSP estimates current year average Technical and Scientific cost per participant will be \$30.3, which is an increase of \$2 or 6 percent compared to 2020-21 actual average Technical and Scientific cost per specimen of \$28.6. The increase in the current year is attributed to the increase in total cost and is tied to the total projected specimens tested. Beginning 2022-23, NTD screen will use AFP kit lot for AFP testing only for which a separate fiscal analysis will be performed.



Technical and Scientific Total Cost – CDPH/GDSP estimates current year Technical and Scientific costs to total \$12.9 million, which is a slightly decrease of \$209,000 or 2 percent compared to 2020-21 actual technical and scientific costs of \$13 million. Fluctuation in total cost is tied to the projected specimens and decrease in costs of reagents, supplies, and consumables. Beginning 2022-23, a simpler biochemical screening will be used for neural tube defects (NTD), for which a separate fiscal analysis will be performed.

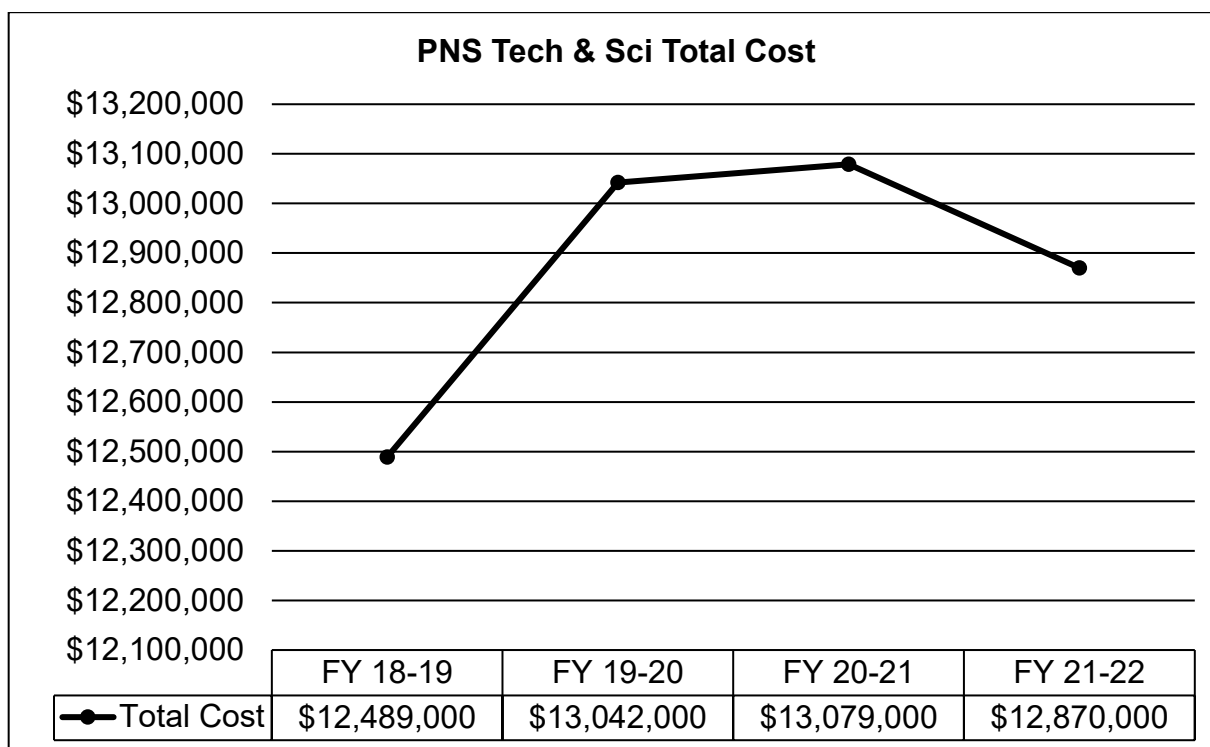


Table 16 shows the projected cases, average cost and total cost associated with technical and scientific cost per neural tubes defects testing in budget year 2022-23.

Table 16. Technical and Scientific Costs

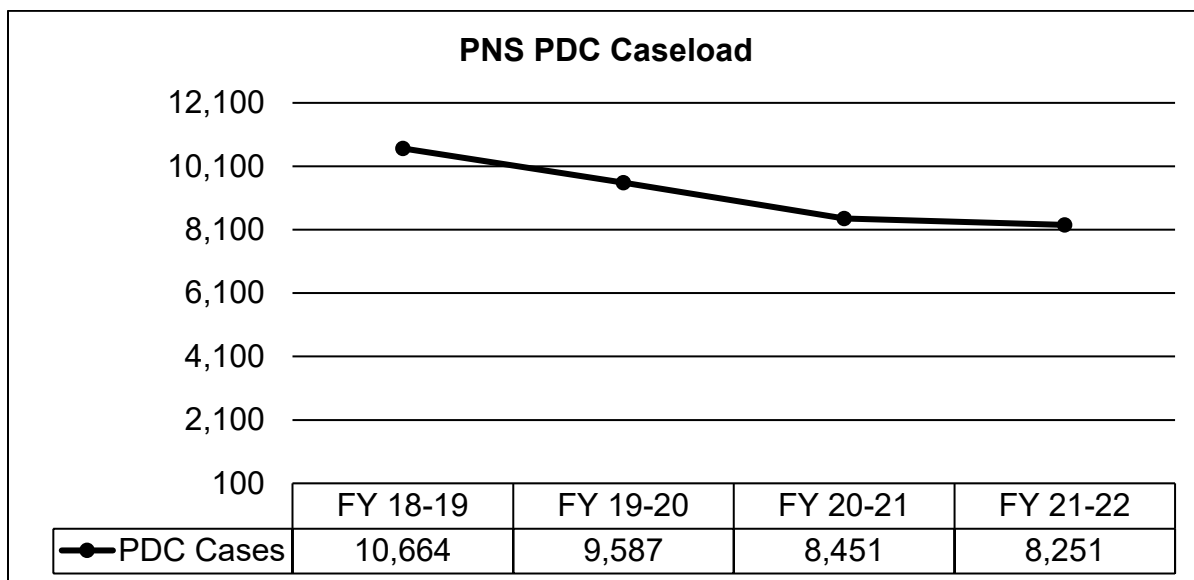
| FY 2022-23 | Total NTD | Average Cost | Total Cost |
|------------|-----------|--------------|-------------|
| Tech & Sci | 294,033 | \$7.00 | \$2,058,000 |

PRENATAL DIAGNOSTIC SERVICES CENTERS

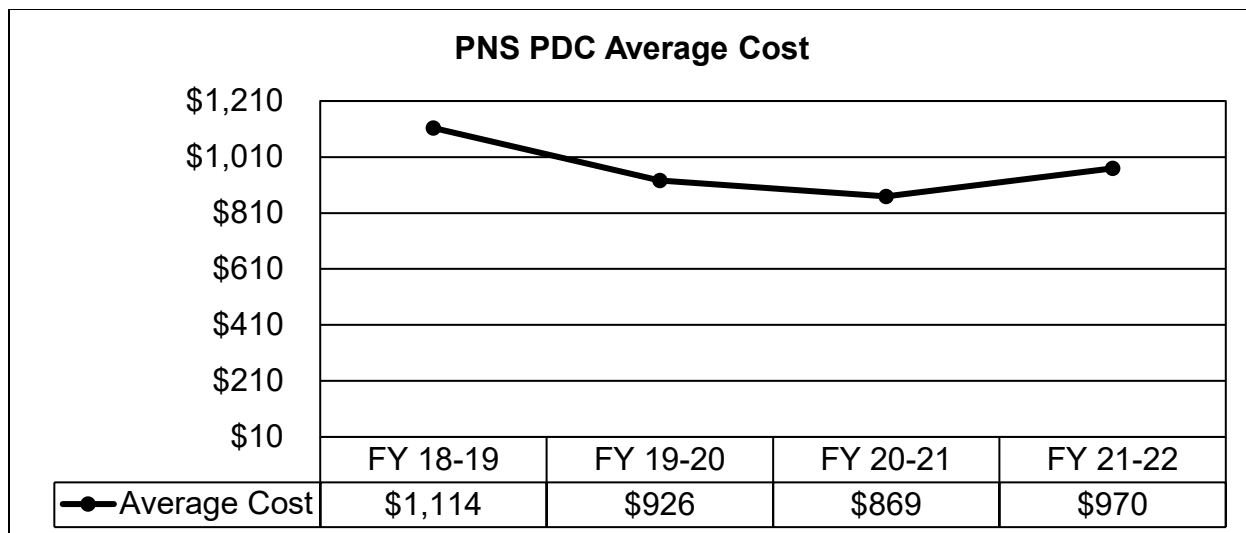
Overview - Women with positive results are provided additional services, which include: confirmatory and diagnostic prenatal testing, genetic counseling, education, coordinated medical care referrals, and coordination and consultation with patient’s physician, and

specialty care providers. Services are provided through Prenatal Diagnostic Services Centers and are reimbursed per service type.

Prenatal Diagnostic Services Centers (PDC) Caseload – CDPH/GDSP estimates current year PDC caseload will total 8,251, which is a decrease of 200 or 2 percent compared to the 2020-21 actual PDC caseload of 8,451. The decrease is caused by a projected decline in women choosing to further pursue diagnostic care. Beginning 2022-23, cfDNA screened positive and with no result; and NTD screened positive will be referred for additional services which include confirmatory and diagnostic testing for which a separate fiscal analysis will be performed.



Prenatal Diagnostic Services Average Cost – CDPH/GDSP estimates current year average PDC cost per participant will be \$969.65, which is an increase of \$100 or 12 percent compared to 2020-21 actual average PDC cost per participant of \$869.36. The increase in average cost in the current year is due to the fluctuations in the projected caseloads derived from the projected participations and referrals. Additionally, increased contract costs as a result of changes in the types of procedures used to diagnose genetic diseases. Procedures like Non-Invasive Prenatal Testing and Micro Array can be offered to women in lieu of more invasive and costly procedures such as amniocentesis. Women who would previously have declined prenatal diagnostic services are now choosing these non-invasive procedures. Beginning 2022-23, cfDNA screened positive and with no results; and NTD screened positive will have a separate cost analysis on diagnostic services.



Prenatal Diagnostic Services Total Cost – CDPH/GDSP estimates current year PDC costs to total \$8 million, which is an increase of \$654,000 or 9 percent compared to 2020-21 actual PDC total costs of \$7 million. The change in total expenditures is attributable mainly to fluctuating projected PDC caseload. Beginning 2022-23, cfDNA screening (all positive and no results) will be used for chromosome abnormalities and NTD for biochemical screening, for which a separate fiscal analysis will be performed.

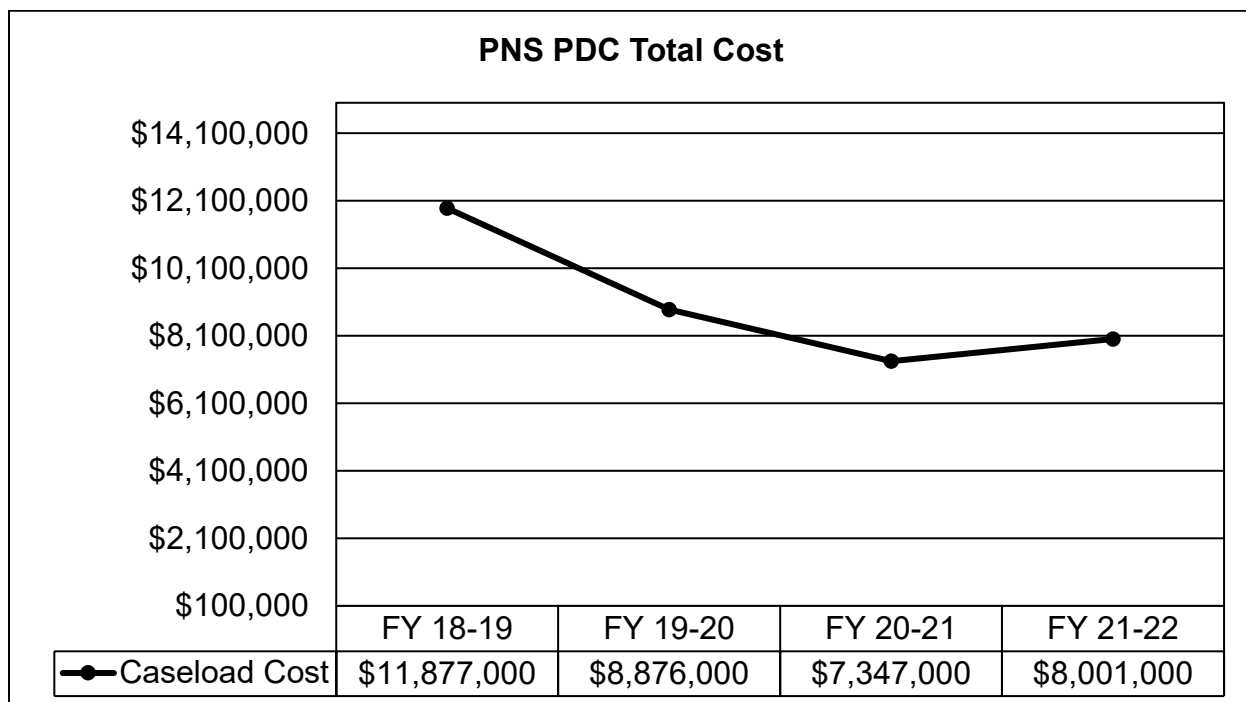


Table 17 shows the projected PDC cases, average cost and total cost associated for diagnostic follow up services per cfDNA (screened positive and with no results) and per screened positive neural tubes defects in budget year 2022-23.

Table 17. Projected Prenatal Diagnostic Center Costs

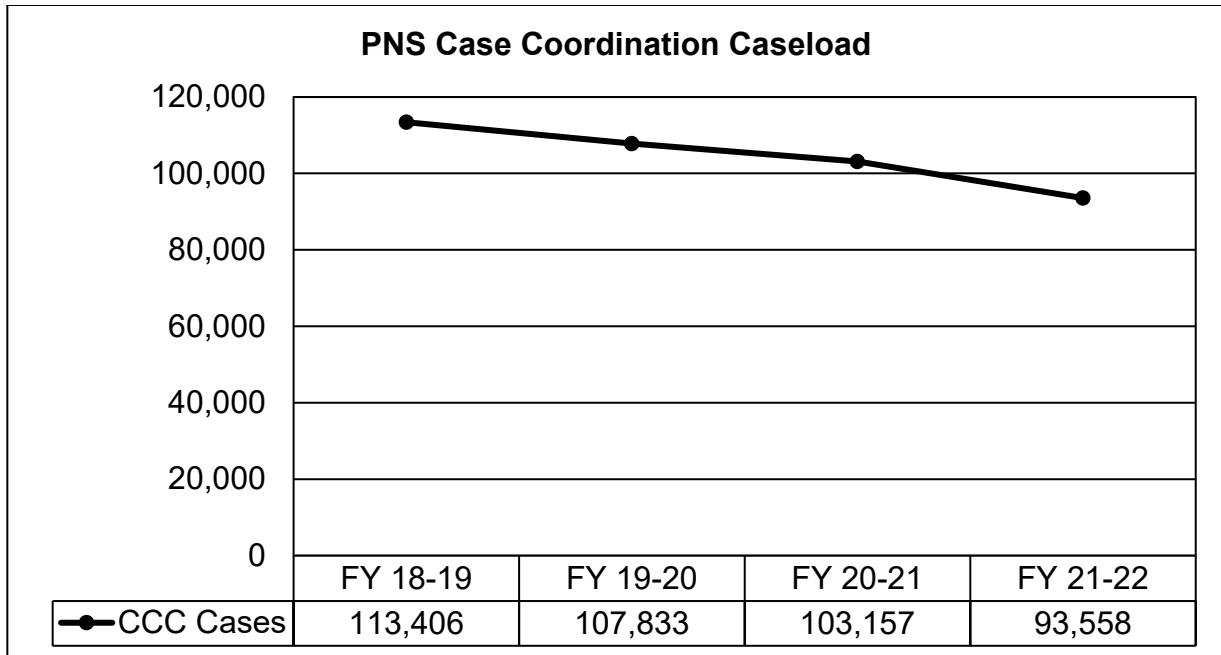
| FY2022-23 | Total Specimens /Billable | PDC Cases | Caseload Cost | Average Cost | PDC as % of Total |
|-----------------------------|----------------------------------|------------------|----------------------|---------------------|--------------------------|
| Prenatal Diagnostic Centers | 596,419 | 7,958 | \$7,653,000 | \$962 | 1.3% |

CASE MANAGEMENT AND COORDINATION SERVICES

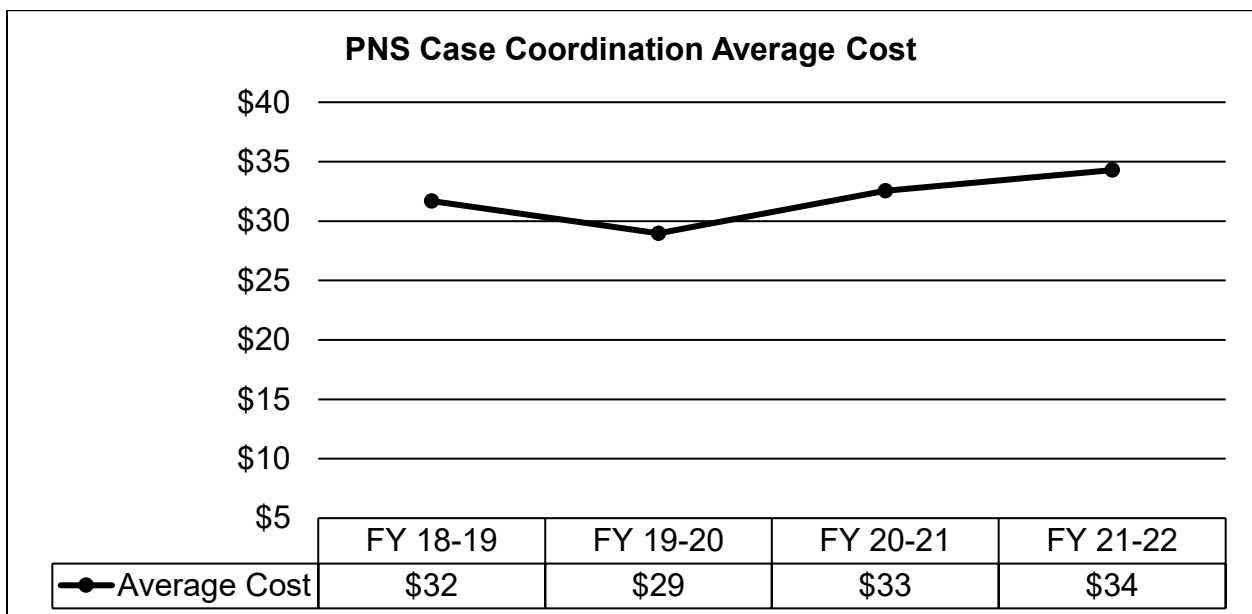
Overview - Services provided to pregnant women who screen positive or have questionable results include coordination of first and second trimester screens and ultrasounds, identifying patients whose blood specimens were drawn too early or were inadequate, requiring additional blood draws. The PNS Case Coordination Centers (CCCs) provide clinician and patient education and consultations; make referrals to Prenatal Diagnostic Centers for diagnostic and confirmatory tests, and genetic counseling; and track patients to ensure appointments are kept and patients seen within prescribed timeframes. Coordinators confirm and verify specific patient information as needed with the treating physician offices, and the Prenatal Diagnostic Centers. The CCCs are reimbursed based on caseload and the type of service performed along with a monthly base allocation. Base allocation costs vary by CCC dependent upon the geographic location.

Case Management and Coordination Services (CMCS) Caseload - CDPH/GDSP estimates current year CMCS caseload will total 93,558, which is a decrease of 9,599 or 9 percent compared to 2020-21 actual CMCS caseload of 103,157. This is due largely to changes in the DRU-based caseload. Beginning 2022-23, cfDNA and NTD screened positive cases will be referred to a case coordinator for which separate services will be performed.

The following chart shows the actual CMCS cases by month, along with projected numbers for the remainder of the current year and budget year.



Case Management and Coordination Services Average Cost - CDPH/GDSP estimates current year average CMCS cost per participant will be \$34.29, which is an increase of \$2 or 5 percent compared to 2020-21 actual average CMCS cost per participant of \$32.54. The increase in the current year is attributable to the decrease in caseloads while the fixed costs increase. Beginning 2022-23, cfDNA and NTD screened positives will be referred to a case coordinator for which a separate cost per participant is attributed.



Case Management and Coordination Services Total Cost - CDPH/GDSP estimates current year CMCS costs to total \$6.2 million, which is a decrease of \$62,000 or 1 percent compared to 2020-21 actual CMCS total costs of \$6.3 million. The decrease in the current year is attributable to the decrease in contract rates causing a decrease in the total cost despite slight increases in fixed costs. Beginning 2022-23, cfDNA and NTD screened positives will be referred to a case coordinator for which contract rates is attributed on cost per test plus baseline adjustments.

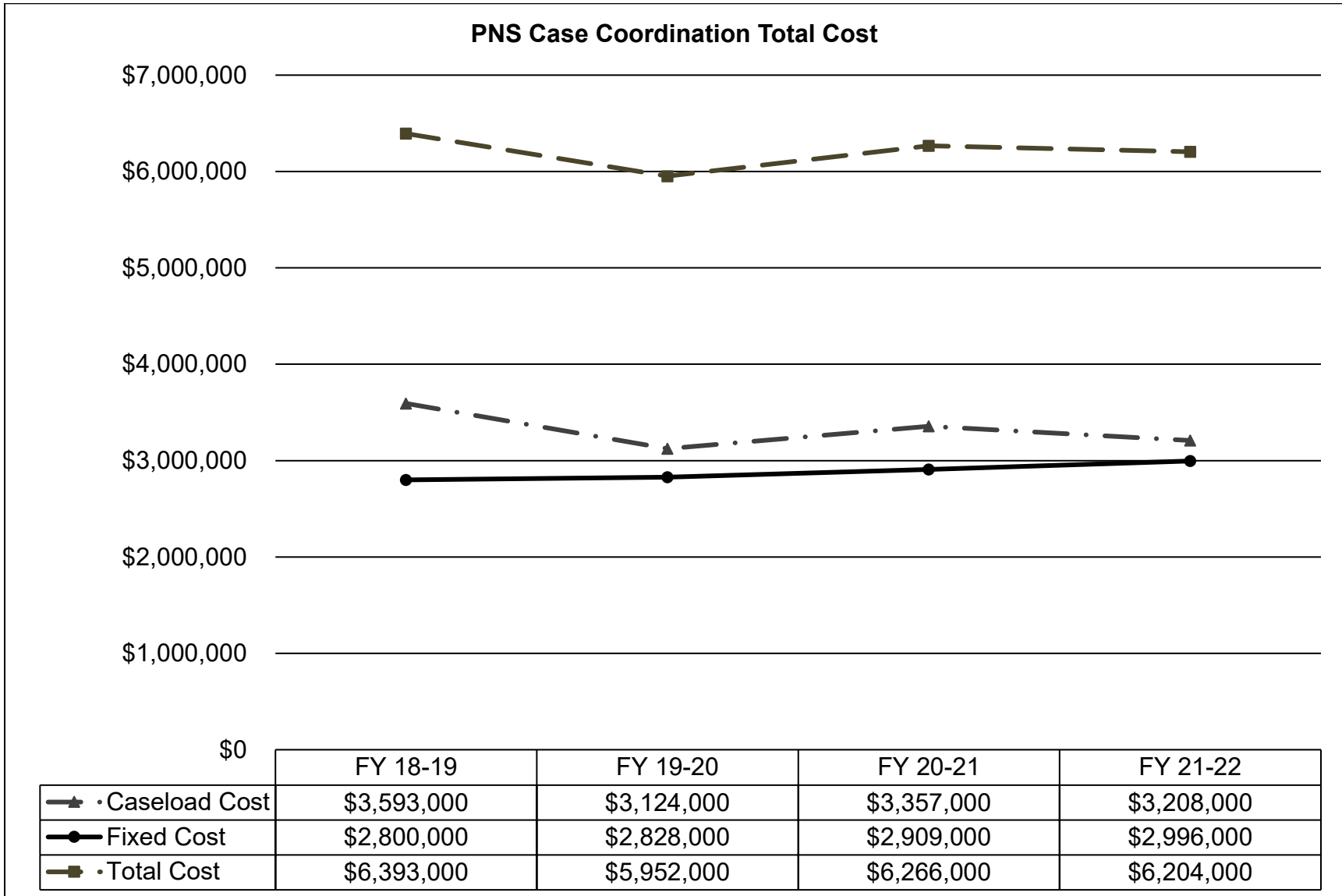


Table 18 shows the projected CCC cases, average cost, fixed cost, and total cost associated for clinician and patient consultation on referred positive cases per cfDNA and per neural tubes defects testing in budget year 2022-23.

Table 18. Projected Case Coordination Costs

| FY 2022-23 | Total Specim ens/Bill able | CCC Cases | Avera ge Cost | Caseload Cost | Fixed Cost | Total Cost | CCC as % of Tot |
|--------------------------|---|----------------------|------------------------------|--------------------------|-----------------------|-------------------|------------------------------------|
| Case Coordin ation | 596,419 | 50,496 | \$28 | \$1,407,000 | \$1,061,000 | \$2,468,000 | 8% |

APPENDIX C: REVENUE PROJECTIONS**NBS REVENUE**

Newborn Screening Program charges a fee of \$177.25. Beginning July 1, 2022, GDSP will assess an additional amount of \$33.75 to \$211 for NBS fees. In most cases, the fee is paid to directly to CDPH/GDSP by hospitals. For births that occur outside of a hospital, CDPH/GDSP invoice the appropriate fee to the family of the infant or their insurance company. Since the majority of births happen within a hospital, billing and receiving payment for NBS services is greatly streamlined and efficient. Past actual collection amounts indicate that CDPH/GDSP collects approximately 98 percent of all revenue related to providing NBS services. Since last year, the collection rate has increased to 99 percent. As such, NBS revenue is estimated using the following formula:

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

Table 19. NBS Revenue Projections

| Fiscal Year | Fee (A) | Caseload (B) | Collection Rate (C) | Total Revenue (D) = (A) x (B) x (C) |
|--------------------|----------------|---------------------|----------------------------|--|
| FY 2021-22 | \$177.25 | 392,044 | 99% | \$68,795,000 |
| FY 2022-23 | \$211.00 | 428,070 | 99% | \$89,419,000 |

PNS REVENUE

The Prenatal Screening Program charges a fee of \$221.60 to all participating women. Of the total fee, \$211.60 is deposited into the GDTF (Fund 0203), and \$10 is deposited into the California Birth Defect Monitoring Program Fund (Fund 3114). Beginning July 1, 2022, GDSP will add \$75 for neural tube defect (NTD) screening and \$10.40 for the new cfDNA testing to the PNS fees. Unlike NBS which collects revenue from hospitals directly, PNS invoices participants and bills insurance companies (analogous to the way a traditional medical provider would). This system of billing which shares cost between the participant and one or more third party payers makes full, or close to full collection of revenue a challenge for the program. Past collection rates have revealed that PNS collects a higher percentage of anticipated revenue from Medi-Cal enrollees than those enrolled in private insurance plans or the uninsured. PNS receives approximately 98 percent of all claims submitted to Medi-Cal, and approximately 94 percent of all claims submitted to private insurance companies and other payers. In the future years, GDSP expects to increase the collection rate to 99 percent for Medi-Cal insurers and 95% to non-Medi-Cal insurers. Approximately 55 percent of all PNS participants are enrolled in Medi-Cal. PNS revenue is estimated using the following formula:

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

Table 20. PNS Revenue Projections

| Fiscal Year | Fee (A) = \$221.60 - \$10 | Caseload (B) | % Medi-Cal (C) | % Non-Medical (D) = 1 - (C) | Medi-Cal Collection Rate (E) | Private Insurance Collection Rate (F) | Medi-Cal Cases (G) = (B) x (C) | Non Medi-Cal Cases (H) = (B) x (D) | Total Revenue (I) = (G x A x E) + (H x A x F) |
|-------------|------------------------------|--------------|----------------|-----------------------------|------------------------------|---------------------------------------|--------------------------------|------------------------------------|---|
| FY 2021-22 | \$211.60 | 292,050 | 55% | 45% | 99% | 95% | 160,628 | 131,423 | \$60,068,000 |
| FY 2022-23 | \$222.00 | 309,025 | 55% | 45% | 99% | 95% | 169,964 | 139,061 | \$66,682,000 |

Table 21. NTD Revenue Projections

| Fiscal Year | Fee | Caseload | % Medi-Cal | % Non-Medical | Medi-Cal Collection Rate | Private Insurance Collection Rate | Medi-Cal Cases | Non Medi-Cal Cases | Total Revenue |
|-------------|---------|----------|------------|---------------|--------------------------|-----------------------------------|----------------|--------------------|---------------|
| FY 2022-23 | \$75.00 | 287,393 | 55% | 45% | 99% | 95% | 158,066 | 129,327 | \$20,950,978 |