

**Genetic Disease Screening Program
(GDSP)**

Fiscal Year 2023-24

November Estimate



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

California Department of Public Health

TABLE OF CONTENTS

- I. ESTIMATES..... 1**
 - A. PROGRAM OVERVIEW 1
 - B. EXPENDITURE OVERVIEW 1
 - C. LOCAL ASSISTANCE EXPENDITURE PROJECTIONS..... 2
 - CURRENT YEAR (2022-23) 2
 - BUDGET YEAR (2023-24) 2
 - EXPENDITURE METHODOLOGY (KEY DRIVERS OF COST) 3
 - NBS EXPENDITURE PROJECTIONS (SEE APPENDICES A1-A5) 4
 - PNS EXPENDITURES PROJECTIONS (SEE APPENDICES B1-B4) 6
 - OPERATIONAL SUPPORT PROJECTIONS..... 7
 - D. STATE OPERATIONS EXPENDITURE PROJECTIONS 8
 - E. REVENUE PROJECTIONS 8
 - COMBINED NBS AND PNS REVENUE 8
 - REVENUE METHODOLOGY 9
 - NBS REVENUE (SEE APPENDIX C1) 9
 - PNS REVENUE (SEE APPENDIX C2) 10
- II. FUND CONDITION STATEMENT 12**
- III. GENERAL ASSUMPTIONS 14**
 - FUTURE FISCAL ISSUES 14
 - NEW ASSUMPTIONS/ PREMISES 15
 - EXISTING (SIGNIFICANTLY CHANGED) ASSUMPTIONS/PREMISES..... 18
 - UNCHANGED ASSUMPTIONS/PREMISES 18
 - DISCONTINUED ASSUMPTIONS/PREMISES..... 18
- IV. APPENDIX A: NEWBORN SCREENING PROGRAM (NBS) ASSUMPTIONS AND RATIONALE..... 19**
 - CONTRACT LABORATORIES 19
 - TECHNICAL AND SCIENTIFIC 21
 - CASE MANAGEMENT AND COORDINATION SERVICES: 22
 - DIAGNOSTIC SERVICES 25
 - REFERENCE LABORATORIES 27
- V. APPENDIX B: PRENATAL SCREENING PROGRAM (PNS) ASSUMPTIONS AND RATIONALE..... 29**
 - CELL-FREE DNA (CFDNA)..... 29
 - CONTRACT LABORATORIES 30
 - TECHNICAL AND SCIENTIFIC 33
 - PRENATAL DIAGNOSTIC SERVICES CENTERS 35
 - CASE MANAGEMENT AND COORDINATION SERVICES 37
- VI. APPENDIX C: REVENUE PROJECTIONS 41**
 - NBS REVENUE 41
 - PNS REVENUE 41

ESTIMATES

PROGRAM OVERVIEW

The California Department of Public Health (CDPH), Genetic Disease Screening Program (GDSP) November Estimate provides a revised projection of 2022-23 expenditures along with a projected 2023-24 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 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 2022 Budget Act appropriation is \$173 million, of which \$137.3 million is for Local Assistance and \$35.8 million is for State Operations. The CDPH/GDSP estimates 2022-23 expenditures of \$173.9 million, which is an increase of 894,000 or 0.5 percent compared to the 2022 Budget Act. This net increase consists of a \$1.1 million increase in State Operations from baseline adjustments (increased employee compensation and pension contribution adjustments) and a \$177,000 Local Assistance decrease due to declining caseload based on the Department of Finance Demographic Research Unit's (DRU) projection of live births.

The combined State Operations and Local Assistance budget expenditures for 2023-24 total \$ 184.4 million, which is an increase of \$11.4million or 6.6 percent compared to the 2022 Budget Act. This increase consists of State Operations adjustments that include \$1.1 million for baseline adjustments (increased employee compensation and pension contribution adjustments) and \$1.2 million for adding 4 permanent positions and funding for temporary positions per the New Assumption - 2023-24 Budget Change Proposal: California Newborn Screening Program Expansion. There is also a \$9 million increase in Local Assistance (a one-time increase of \$2.2 million per the New Assumption - 2023-24 Budget Change Proposal: California Newborn Screening Program Expansion for database and software system updates, \$6.8 million due to a full year of cfDNA screening, and slight increases in contract rates and projected caseload).

Table 1 shows the difference between the 2022 Budget Act appropriation and the revised 2022-23 expenditures and proposed 2023-24 expenditures for CDPH/GDSP.

Table 1. Genetic Disease Screening Program: Current Year and Budget Year Budget Summaries Compared to 2022 Budget Act

Fund 0203 Genetic Disease Testing Fund	2022 Budget Act	November Estimate	Change from Budget Act	Percent Change from Budget Act
Fiscal Year 2022-2023 Total	\$173,046,000	\$173,940,000	\$894,000	0.5%
Fiscal Year 2022-2023 State Operations	\$35,780,000	\$36,851,000	\$1,071,000	3.0%
Fiscal Year 2022-2023 Local Assistance	\$137,266,000	\$137,089,000	\$(177,000)	-0.1%
Fiscal Year 2023-2024 Total	\$173,046,000	\$184,388,000	\$11,342,000	6.6%
Fiscal Year 2023-2024 State Operations	\$35,780,000	\$38,066,000	\$2,286,000	6.4%
Fiscal Year 2023-2024 Local Assistance	\$137,266,000	\$146,322,000	\$9,056,000	6.6%

LOCAL ASSISTANCE EXPENDITURE PROJECTIONS

CURRENT YEAR (2022-23)

The 2022 Budget Act appropriation for CDPH/GDSP’s Local Assistance is \$137.3 million in 2022-23. The CDPH/GDSP estimates 2022-23 Local Assistance expenditures will total \$137 million, which is a slight decrease of \$177,000 or 0.1 percent compared to the 2022 Budget Act. The decrease in Local Assistance is attributed to an overall decrease in the DRU’s projection of live births compared to the 2022 Budget Act.

BUDGET YEAR (2023-24)

For 2023-24, CDPH/GDSP estimates Local Assistance expenditures will total \$146 million, which is an increase of \$9.1 million or 6.6 percent compared to the 2022 Budget Act amount of \$137.3 million. The net increase in Local Assistance can be attributed to the New Assumption - 2023-24 Budget Change Proposal: California Newborn Screening Program Expansion that adds MPS II and GAMT deficiency to its screening

panel, a full fiscal year of cfDNA screening (cfDNA screening started September 19, 2022), and inflationary contract rates increases.

Table 2 shows the difference between the 2022 Budget Act appropriation and the revised 2022-23 expenditures and proposed 2023-24 expenditures for CDPH/GDSP Local Assistance.

Table 2. Local Assistance Total: Current Year and Budget Year Budget Summaries Compared to 2022 Budget Act

Fund 0203 Genetic Disease Testing Fund	2022 Budget Act	November Estimate	Change from Budget Act	Percent Change from Budget Act
Fiscal Year 2022-2023 Local Assistance Total	\$137,266,000	\$137,089,000	\$(177,000)	-0.1%
Fiscal Year 2022-2023 Newborn Screening	\$47,914,000	\$47,930,000	\$16,000	0.0%
Fiscal Year 2022-2023 Prenatal Screening	\$53,899,000	\$53,706,000	\$(193,000)	-0.4%
Fiscal Year 2022-2023 Operational Support	\$35,453,000	\$35,453,000	\$0	0.0%
Fiscal Year 2023-2024 Local Assistance Total	\$137,266,000	\$146,322,000	\$9,056,000	6.6%
Fiscal Year 2023-2024 Newborn Screening	\$47,914,000	\$49,252,000	\$1,338,000	2.8%
Fiscal Year 2023-2024 Prenatal Screening	\$53,899,000	\$59,407,000	\$5,508,000	10.2%
Fiscal Year 2023-2024 Operational Support	\$35,453,000	\$37,663,000	\$2,210,000	6.2%

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 2022-23, CDPH/GDSP estimates NBS Local Assistance expenditures will total \$47.9 million, which is a slight increase of \$16,000 or 0.03 percent compared to the 2022 Budget Act of \$47.9 million. The net increase of \$16,000 is attributed to a slight

increase in the Case Coordination, Reference Laboratory Services and Follow-up Diagnostic Services cost center categories due to contract rate increases.

For 2023-24, CDPH/GDSP estimates that NBS Local Assistance expenditures will total \$49.3 million, which is an overall increase of \$1.3 million or 2.8 percent compared to the 2022 Budget Act of \$47.9 million. The net increase in all NBS cost center categories is due to inflationary contract rates increases and slight increase in projected caseload.

Table 3 shows the 2022 Budget Act appropriation and the revised 2022-23 expenditures and proposed 2023-24 expenditures for the Newborn Screening Program costs by cost center type.

Table 3. Newborn Screening: Current Year and Budget Year Budget Summaries Compared to 2022 Budget Act

Fund 0203 Genetic Disease Testing Fund	2022 Budget Act	November Estimate	Change from Budget Act	Percent Change from Budget Act
Fiscal Year 2022-2023 Total	\$47,914,000	\$47,930,000	\$16,000	0.0%
Fiscal Year 2022-2023 Contract Lab	\$7,506,000	\$7,397,000	\$(109,000)	-1.5%
Fiscal Year 2022-2023 Tech Sci	\$29,464,000	\$29,288,000	\$(176,000)	-0.6%
Fiscal Year 2022-2023 Reference Lab	\$2,263,000	\$2,494,000	\$231,000	10.2%
Fiscal Year 2022-2023 CMCS	\$6,358,000	\$6,410,000	\$52,000	0.8%
Fiscal Year 2022-2023 Diagnostic Services	\$2,323,000	\$2,341,000	\$18,000	0.8%
Fiscal Year 2023-2024 Total	\$47,914,000	\$49,252,000	\$1,338,000	2.8%
Fiscal Year 2023-2024 Contract Lab	\$7,506,000	\$7,582,000	\$76,000	1.0%
Fiscal Year 2023-2024 Tech Sci	\$29,464,000	\$30,185,000	\$721,000	2.4%
Fiscal Year 2023-2024 Reference Lab	\$2,263,000	\$2,574,000	\$311,000	13.7%
Fiscal Year 2023-2024 CMCS	\$6,358,000	\$6,551,000	\$193,000	3.0%
Fiscal Year 2023-2024 Diagnostic Services	\$2,323,000	\$2,360,000	\$37,000	1.6%

PNS EXPENDITURES PROJECTIONS (SEE APPENDICES B1-B4)

For 2022-23, CDPH/GDSP estimates PNS Local Assistance expenditures to total \$53.7 million, which is a slight decrease of \$193,000 or 0.4 percent compared to the 2022 Budget Act amount of \$53.9 million. 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.

For 2023-24, CDPH/GDSP estimates that PNS Local Assistance expenditures will total \$59 million, which is an increase of \$5.5 million or 10.2 percent compared to the 2022 Budget Act. The net increase in the budget year is attributed to the increase cost of cell-free DNA (cfDNA) screening laboratories as it is the first full fiscal year of the new Prenatal Screening Program rather than nine and half months since the new program was implemented on September 19, 2022. Additional factors include decreases in costs in Contract Laboratories and Technical & Scientific categories due to less caseload in these areas from caused by the change in prenatal screening program from first and second trimester test to neural tube defects (NTD) screening test only and higher contract costs in Case Coordination Centers (CCC) due to the increase assignment of regional areas when 7 centers are consolidated into 4 centers.

Table 4 displays the 2022 Budget Act appropriation, the revised 2022-23 expenditures and proposed 2023-24 expenditures for the Prenatal Screening program costs by client type.

Table 4. Prenatal Screening: Current Year and Budget Year Budget Summaries Compared to 2022 Budget Act

Fund 0203 Genetic Disease Testing Fund	2022 Budget Act	November Estimate	Change from Budget Act	Percent Change from Budget Act
Fiscal Year 2022-2023 Total	\$53,899,000	\$53,706,000	\$(193,000)	-0.4%
Fiscal Year 2022-2023 cfDNA	\$36,159,000	\$35,711,000	\$(448,000)	-1.2%
Fiscal Year 2022-2023 Contract Lab	\$3,180,000	\$3,145,000	\$(35,000)	-1.1%
Fiscal Year 2022-2023 Tech & Sci	\$4,591,000	\$4,220,000	\$(371,000)	-8.1%
Fiscal Year 2022-2023 CMCS	\$2,495,000	\$2,977,000	\$482,000	19.3%
Fiscal Year 2022-2023 PDC	\$7,474,000	\$7,653,000	\$179,000	2.4%

Fund 0203 Genetic Disease Testing Fund	2022 Budget Act	November Estimate	Change from Budget Act	Percent Change from Budget Act
Fiscal Year 2023-2024 Total	\$53,899,000	\$59,407,000	\$5,508,000	10.2%
Fiscal Year 2023-2024 cfDNA	\$36,159,000	\$43,227,000	\$7,068,000	19.5%
Fiscal Year 2023-2024 Contract Lab	\$3,180,000	\$2,968,000	\$(212,000)	-6.7%
Fiscal Year 2023-2024 Tech & Sci	\$4,591,000	\$2,098,000	\$(2,493,000)	-54.3%
Fiscal Year 2023-2024 CMCS	\$2,495,000	\$3,047,000	\$552,000	22.1%
Fiscal Year 2023-2024 PDC	\$7,474,000	\$8,067,000	\$593,000	7.9%

OPERATIONAL SUPPORT PROJECTIONS

For 2022-23, the CDPH/GDSP Operational Support expenditures total is \$35.5 million, which is unchanged from the 2022 Budget Act.

For 2023-24, the CDPH/GDSP projects operational support expenditures will total \$37.7 million, which is an increase of \$2.2 million or 6.2 percent compared to the 2022 Budget Act. The \$2.2 million net increase is attributed to the New Assumption - 2023-24 Budget Change Proposal: California Newborn Screening Program Expansion. The additional authority will allow CDPH/GDSP to configure and update the Screening Information System (SIS) and Specimen Gate Laboratory Management Information System due to the additional two new disorders.

Table 5 displays the difference between the 2022 Budget Act appropriation, the revised 2022-23 expenditures and proposed 2023-24 expenditures for Program Operational Support costs.

Table 5. Operational Support: Current Year and Budget Year Budget Summaries Compared to 2022 Budget Act

Fund 0203 Genetic Disease Testing Fund	2022 Budget Act	November Estimate	Change from Budget Act	Percent Change from Budget Act
Fiscal Year 2022-2023 Operational Support	\$35,453,000	\$35,453,000	\$0	0.0%
Fiscal Year 2023-2024 Operational Support	\$35,453,000	\$37,663,000	\$2,210,000	6.2%

STATE OPERATIONS EXPENDITURE PROJECTIONS

For 2022-23, the CDPH/GDSP estimates State Operations expenditures will total \$36.8 million, which is an increase of \$1.1 million or 3.0 percent compared to the 2022 Budget Act. The changes are attributed to baseline adjustments for employee compensation and pension contribution increases.

For 2023-24, the CDPH/GDSP estimates State Operations expenditures will total \$38.1 million, which is an increase of \$2.3 million or 6.4 percent compared to the 2022 Budget Act. The increase is attributed to baseline adjustments and additional personnel funding referenced in the New Assumption - 2023-24 Budget Change Proposal: California Newborn Screening Program Expansion.

Table 6 displays the difference between the 2022 Budget Act appropriation and the revised 2022-23 expenditures and proposed 2023-24 expenditures for the CDPH/GDSP State Operations costs.

Table 6. State Operations: Current Year and Budget Year Budget Summaries Compared to 2022 Budget Act

Fund 0203 Genetic Disease Testing Fund	2022 Budget Act	November Estimate	Change from Budget Act	Percent Change from Budget Act
Fiscal Year 2022-2023 State Operations	\$35,780,000	\$36,851,000	\$1,071,000	3.0%
Fiscal Year 2023-2024 State Operations	\$35,780,000	\$38,066,000	\$2,286,000	6.4%

REVENUE PROJECTIONS

COMBINED NBS AND PNS REVENUE

CDPH/GDSP has revenue estimates for 2022-23 totaling \$173 million, which is a decrease of \$1.4 million or 0.8 percent compared to the 2022 Budget Act amount of \$175 million. The decrease in revenue for the current year is attributed to the decline in the birthrate. For 2023-24, CDPH/GDSP projects revenue will total \$179 million, which is an increase of \$4.5 million or 2.5 percent compared to the 2022 Budget Act. The increase in revenue for the budget year is attributed to increase in projected billable caseload and additional revenue generated by the new fee structure of the PNS Program (cfDNA and NTD), which is calculated at a full fiscal year instead of nine months and a half when it was launched on September 19, 2022.

REVENUE METHODOLOGY

The PNS and NBS Programs each charge a fee for screening services provided to clients.

The PNS Program currently charges a fee for cfDNA screening of \$232.00, of which \$222.00 is deposited into the Genetic Disease Testing Fund (Fund 0203). Additionally, the PNS program also charges a separate fee for NTD of \$85, of which \$75.00 is deposited into the Genetic Disease Testing Fund (Fund 0203). The \$10 out of the NTD and cfDNA fees will be deposited into the Birth Defects Monitoring Program Fund (BDMP Fund 3114).

GDSP invoices and collects PNS payments from individual participants, private insurers, and Medi-Cal. GDSP can collect approximately 99 percent of all fees owed on behalf of Medi-Cal clients (which is approximately 60 percent of the total caseload) and approximately 95 percent of the fees owed by individuals with private insurance. CDPH/GDSP uses the following formula to estimate revenue generated from PNS fees:

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

The NBS Program currently charges a fee for newborn screening of \$211.00, of which the entire fee is deposited into the Genetic Disease Testing Fund (Fund 0203). The NBS program are driven by per case costs, there are baseline fixed 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 2022-23, NBS revenue is expected to total \$90.3 million, which is a slight decrease of \$544,000 or 0.6 percent compared to the 2022 Budget Act of \$90.8 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.

In 2023-24, GDSP projects NBS revenue will total \$90.4 million, which is a decrease of \$488,000 or 0.5 percent compared to the 2022 Budget Act of \$90.8 million. The decrease in revenue for the budget year is due to slight decrease in billable projected caseload compared to the billable projected caseload from the 2022 Budget Act.

PNS REVENUE (SEE APPENDIX C2)

In 2022-23, PNS revenue is expected to total \$83.1 million, which is a decrease of \$869,000 or 1 percent compared to the 2022 Budget Act amount of \$84 million. The decrease in the current year is due to the decrease in the projected billable caseload.

In 2023-24, CDPH/GDSP projects PNS revenue will total \$88.9 million, which is an increase of \$4.9 million or 5.9 percent compared to the 2022 Budget Act of \$84 million. The increase in the budget year is due to the increase in the projected billable caseload of cfDNA at a full year of screening (cfDNA screening started September 19, 2022) and increase of participation percentages for PNS program from 55 percent Medi-Cal/45 percent non Medi-Cal to 60 percent/40 percent. CDPH/GDSP's invoices and collects PNS payments from individual participants, non-Medi-Cal (private insurers) and Medi-Cal. CDPH/GDSP collects approximately 99 percent of all fees owed on behalf of Medi-Cal clients and approximately 95 percent of the fees owed by individuals with private insurance.

Table 7 shows the revised current year and budget year revenue compared to 2022 Budget Act.

Table 7. Genetic Disease Screening Program Revenue: Current Year and Budget Year Revenue Summaries Compared to 2022 Budget Act

Fund 0203 Genetic Disease Testing Fund	2022 Budget Act	November Estimate	Change from Budget Act	Percent Change from Budget Act
Fiscal Year 2022-2023 Total	\$174,825,000	\$173,412,000	\$(1,413,000)	-0.8%
Fiscal Year 2022-2023 Newborn Screening	\$90,846,000	\$90,302,000	\$(544,000)	-0.6%
Fiscal Year 2022-2023 Prenatal Screening	\$83,979,000	\$83,110,000	\$(869,000)	-1.0%
Fiscal Year 2023-2024 Total	\$174,825,000	\$179,281,000	\$4,456,000	2.5%

Fund 0203 Genetic Disease Testing Fund	2022 Budget Act	November Estimate	Change from Budget Act	Percent Change from Budget Act
Fiscal Year 2023-2024 Newborn Screening	\$90,846,000	\$90,358,000	\$(488,000)	-0.5%
Fiscal Year 2023-2024 Prenatal Screening	\$83,979,000	\$88,923,000	\$4,944,000	5.9%

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	2021-22	2022-23	2023-24
BEGINNING BALANCE	23,492	38,414	36,188
Prior Year Adjustment	17,743	0	0
Adjusted Beginning Balance	41,235	38,414	36,188

Table 9. REVENUES

REVENUES	2021-22	2022-23	2023-24
4123400 Genetic Disease Testing Fees	140,487	173,410	179,281
4163000 Income from Surplus Investments	118	118	118
4171400 Escheat of Unclaimed Checks & Warrants	103	103	103
9920 Transfers and Adjustments	2,127	0	0
TOTALS, REVENUES	142,835	173,631	179,502

Table 10. TOTAL RESOURCES

TOTAL RESOURCES	2021-22	2022-23	2023-24
Adjusted Beginning Balance	41,235	38,414	36,188
TOTAL REVENUES	142,835	173,631	179,502
TOTAL RESOURCES	184,070	212,045	215,690

Table 11. EXPENDITURES AND EXPENDITURE ADJUSTMENTS

EXPENDITURES AND EXPENDITURE ADJUSTMENTS	2021-22	2022-23	2023-24
4265 Department of Public Health (State Operations)	32,365	36,851	38,066
4265 Department of Public Health (Local Assistance)	111,058	137,089	146,322
8880 Financial Information System for California (State Operations)	0	0	0
9800 Lease Revenue Debt Service Adjustment	0	5	0
9892 Supplemental Pension Payments (State Operations)	496	496	496

EXPENDITURES AND EXPENDITURE ADJUSTMENTS	2021-22	2022-23	2023-24
9900 Statewide General Admin Exp (ProRata) (State Operations)	1,737	1,416	0
TOTAL EXPENDITURES AND EXPENDITURE ADJUSTMENTS	145,656	175,857	184,884

Table 12. FUND BALANCE

FUND BALANCE	2021-22	2022-23	2023-24
TOTAL RESOURCES	184,070	212,045	215,690
TOTAL EXPENDITURES AND EXPENDITURE ADJUSTMENTS	145,656	175,857	184,884
FUND BALANCE	38,414	36,188	30,806
Fund Balance as a percentage of Total Expenditures and Expenditure Adjustments	26%	21%	17%

Table 13. GDSP REVENUE PROJECTION 2022-2023 OF \$173,410,000

Number of Tests	Cost	Collection Rate	Revenue
432,294 NBS	\$211.00	Provider: 99%	\$90,302,000
25,852 PNS from 7/1/2022 thru 9/18/2022	\$211.60	Non Medi-Cal: 95%	\$5,197,000
38,778 PNS from 7/1/2022 thru 9/18/2022	\$211.60	Medi-Cal: 99%	\$8,123,000
98,238 cfDNA from 9/19/2022 thru 6/30/2023	\$222.00	Non Medi-Cal: 95%	\$20,718,000
147,357 cfDNA from 9/19/2022 thru 6/30/2023	\$222.00	Medi-Cal: 99%	\$32,386,000
91,361 NTD from 9/19/2022 thru 6/30/2023	\$75.00	Non Medi-Cal: 95%	\$6,509,000
137,042 NTD from 9/19/2022 thru 6/30/2023	\$75.00	Medi-Cal: 99%	\$10,175,000

Table 14. GDSP REVENUE PROJECTION 2023-2024 OF \$179,281,000

Number of Tests	Cost	Collection Rate	Revenue
432,563 NBS	\$211.00	Provider: 99%	\$90,358,000
125,171 cfDNA	\$222.00	Non Medi-Cal: 95%	\$26,399,000
187,757 cfDNA	\$222.00	Medi-Cal: 99%	\$41,265,000
116,409 NTD	\$75.00	Non Medi-Cal: 95%	\$8,294,000
174,614 NTD	\$75.00	Medi-Cal: 99%	\$12,965,000

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 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), follow-up systems, and the addition of new confirmatory testing.

Discretionary?: No

Reason for Adjustment/ Change:

CDPH/GDSP is statutorily required to expand statewide screening of newborns to include screening for any disease that is detectable in blood samples within two years of the disease being adopted by the federal RUSP.

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

Expenditures may increase by approximately \$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 NBS panel – spinal muscular atrophy (SMA), mucopolysaccharidosis type I (MPS I) and Pompe disease. 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 assess the fund reserve to assess the program's ability 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**2023-24 Budget Change Proposal: California Newborn Screening Program Expansion**Background:

H&S Code section 125001(d) specifically requires the CDPH NBS Program to continuously expand what is included in the statewide screening of newborns. Diseases that are detectable in blood samples and have been adopted by the federal Recommended Uniform Screening Panel (RUSP) must be included in the screening within two years of adoption. On August 2, 2022, newborn screening (NBS) for mucopolysaccharidosis type II (MPS II) was added to the RUSP; moreover, guanidinoacetate methyltransferase (GAMT) deficiency was recommended to be added by the Federal Advisory Committee in May 2022 and the official addition to the federal RUSP is still pending and likely to be added by early 2023. The deadline for including MPS II on the California NBS panel is August 2024, and GAMT deficiency is likely to be mandated later in 2024-25.

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

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

Description of Change:

By July 2024, CDPH will incorporate screening for MPS II and GAMT deficiency into the Newborn Screening panel. These additions will allow California to provide early detection and treatment to screen-positive newborns, preventing death and improving the quality of the child's life. By adding these two conditions, California will meet the national standard of care as recommended by the federal Advisory Committee on Heritable Disorders in Newborns and Children, aligning the NBS Program with the most up-to-date research, technology, laboratories, public health standards and practices, as well as maintaining compliance with H&S Code section 125001(d).

Screening for the two new conditions will require laboratory-developed testing produced at the Richmond Laboratory Campus as currently there are no FDA-approved kits for either disorder. Although existing instruments can be used, new reagents will be needed, and the development processes will be labor-intensive. Implementation activities will eventually involve fully evaluating and validating new FDA-approved kits before rolling out to the regional Newborn and Prenatal Screening (NAPS) laboratories. Once there is a release of FDA-approved test kits, our goal is to provide them to the NAPS laboratories within five years. Until there are FDA-approved test kits, testing will need to be done in a central location with a locally developed and maintained test methodology.

Through a 2023-24 Budget Change Proposal (BCP), CDPH/GDSP is requesting 4 permanent positions and funding for temporary help positions during the first three years of implementation to address the routine testing and workload associated with the addition of MPS II and GAMT deficiency. The BCP will also include Local Assistance expenditure authority increases to purchase the consumables, supplies, and reagents related to the ongoing screening and testing activities. This will also provide necessary resources to upgrade the Screening Information System (SIS) database which houses all newborn screening records and the Specimen Gate software to accommodate all new screening results transmitted.

Discretionary?: No

Reason for Adjustment/ Change: H&S Code section 125001(d) requires CDPH/GDSP to add MPS-II and GAMT deficiency to the NBS panel within two years of adoption by the federal RUSP. Screening is set to commence July 2024 and will require an increase in expenditures needed to perform the routine and ongoing workload for MPS II and GAMT disease screening.

Fiscal Impact (Range) and Fund Source(s): Approximately \$1.2 million in State Operations expenditure authority in 2023-24 through 2025-26 and approximately \$700,000 in 2026-27 and ongoing. An approximate increase in Local Assistance expenditure authority of \$2.2 million in 2023-24 and \$2 million in 2024-25 and ongoing. CDPH/GDSP will continue to monitor reserve balances to determine when a fee increase is needed which will likely be in 2024-25. The fund source is the Genetic Disease Testing Fund (GDTF) (Fund 0203).

Medi-Cal and non-Medi-Cal (Private Insurers) Participation Rate Change for Prenatal Screening (PNS)Background:

GDSP currently collects a PNS participation fee from patients or their health insurance group. The participation fee covers the blood test and follow-up services offered to pregnant individuals with positive screening results. Medi-Cal currently covers approximately 55 percent of the women participating in the PNS Program and non-Medi-Cal insurance companies covers approximately 45 percent of the pregnant individuals participating in the PNS Program.

Beginning 2017-18, CDPH has seen a rise in the percentage of individuals who have Medi-Cal and this necessitates a change in our Revenue Methodology calculation and will lead to an increase in PNS collections. The percentage of claims of individuals participating in the PNS Program that were covered under Medi-Cal increased from 55 percent to 60 percent while the percentage of claims covered under non-Medi-Cal private insurers has decreased from 45 percent to 40 percent.

The participation rates are used in CDPH/GDSP's estimates for revenue projections. GDSP invoices and collects PNS payments from individual participants, non-Medi-Cal (private insurers) and Medi-Cal. GDSP collects approximately 99 percent of all fees owed on behalf of Medi-Cal clients and approximately 95 percent of the fees owed by individuals with private insurance.

Description of Change:

Beginning 2022-23, GDSP will revise the participation percentages for its PNS Program from 55 percent Medi-Cal/45 percent non Medi-Cal to 60 percent/40 percent.

Discretionary?: Yes

Reason for Adjustment/ Change:

The PNS Program participation rates for Medi-Cal and non-Medi-Cal participants needs to be updated to reflect more accurate revenue projections.

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

An increase of 0.20 percent or approximately \$186,000 annually in projected PNS revenues. The fund source is the GDTF (Fund 0203).

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

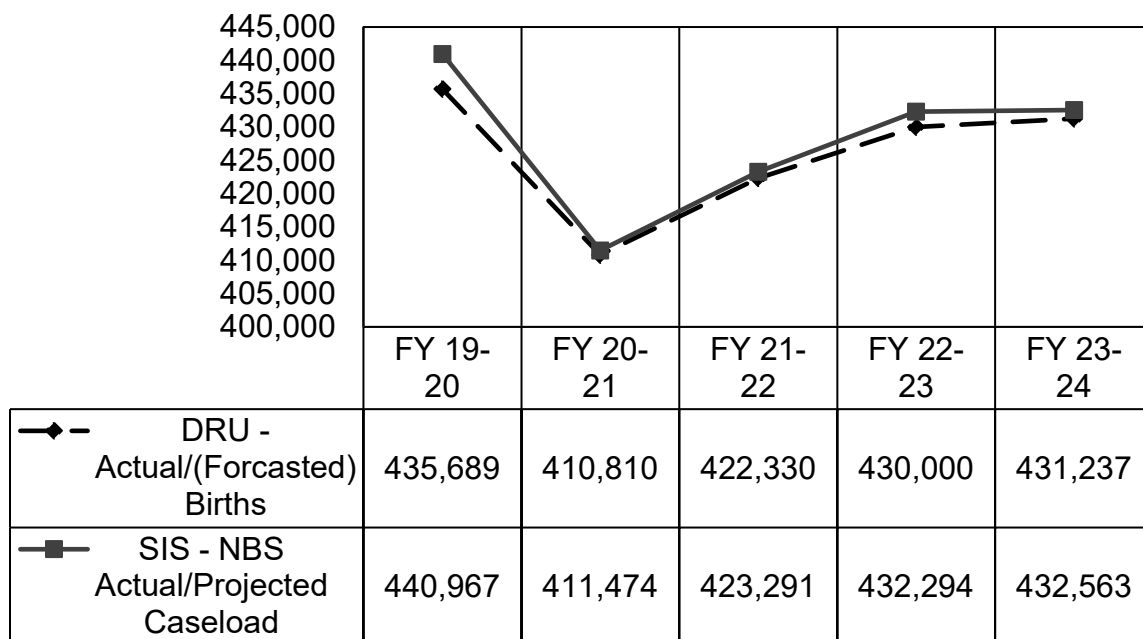
CONTRACT LABORATORIES

Overview: Laboratory testing of specimens is performed at regional screening laboratories contracted by the state to screen newborns for 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 2021-22 and 2022-23.

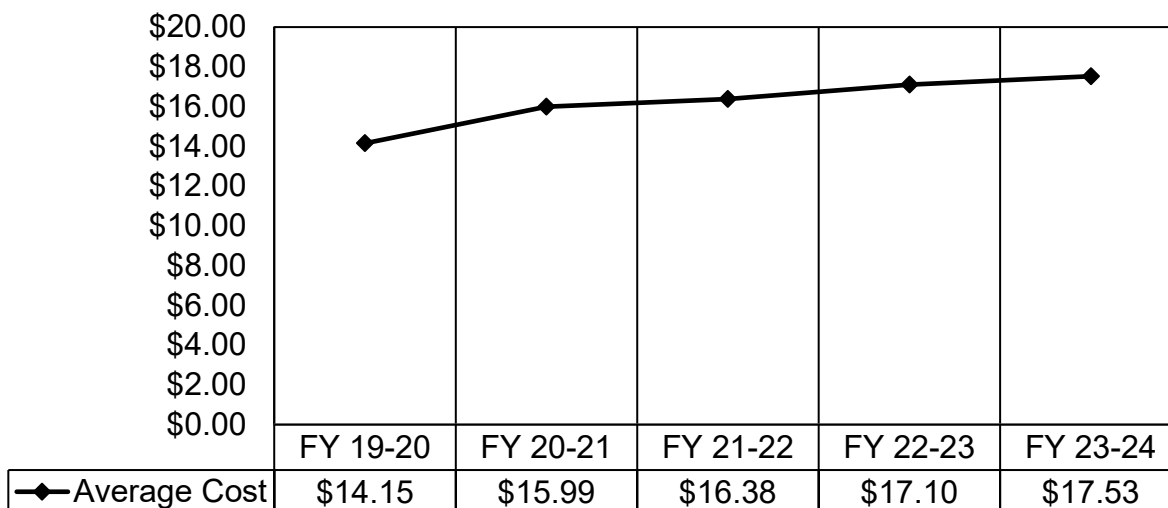
Total Caseload –CDPH/GDSP estimates current year caseload will total 432,294, an increase of 9,003 or 2 percent compared to the 2021-22 actual total caseload of 423,291. Caseload in 2023-24 is estimated at 432,563, which is an increase of 269 or 0.1 percent compared to the current year estimate. This 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.

NBS CASELOAD



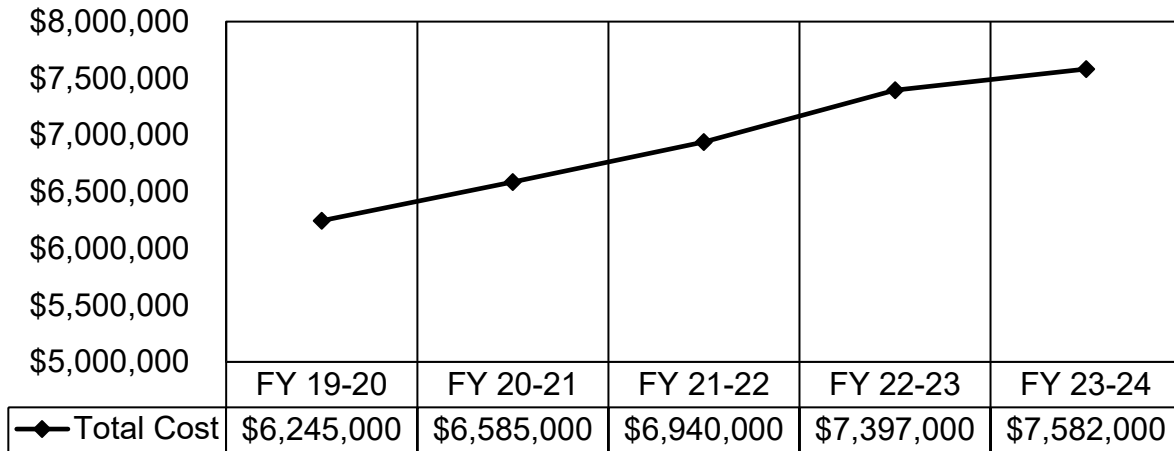
Contract Laboratory Average Cost Projections – CDPH/GDSP estimates current year average laboratory cost per participant will be \$17.10, which is an increase of \$0.72 or 4.4 percent compared to the 2021-22 actual average laboratory cost per participant of \$16.38. Average laboratory cost per participant in 2023-24 is estimated at \$17.53, which is an increase of \$0.43 or 2.5 percent compared to the current year estimate. The increase in cost rate is due to the increased caseload of the laboratory contracts due to increase in projected live births.

NBS CONTRACT LAB AVERAGE COST



Contract Laboratory Total Cost Projections – CDPH/GDSP estimates current year contract laboratory costs to total \$7.4 million, which is an increase of \$457,000 or 6.6 percent compared to 2021-22 actual contract laboratory costs of \$6.9 million. 2023-24 contract laboratory costs are projected to be \$7.6 million, which is an increase of \$185,000 or 2.5 percent compared to the current year.

NBS CONTRACT LAB TOTAL COST



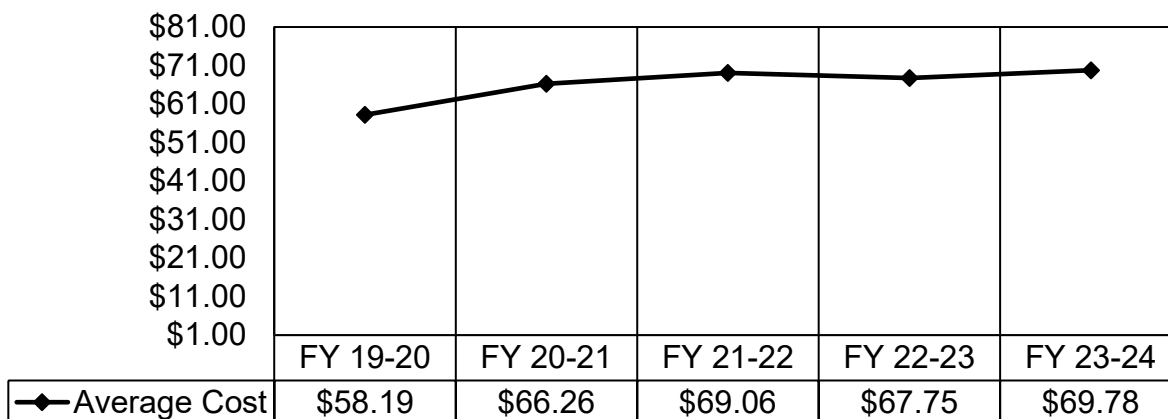
TECHNICAL AND SCIENTIFIC

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 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

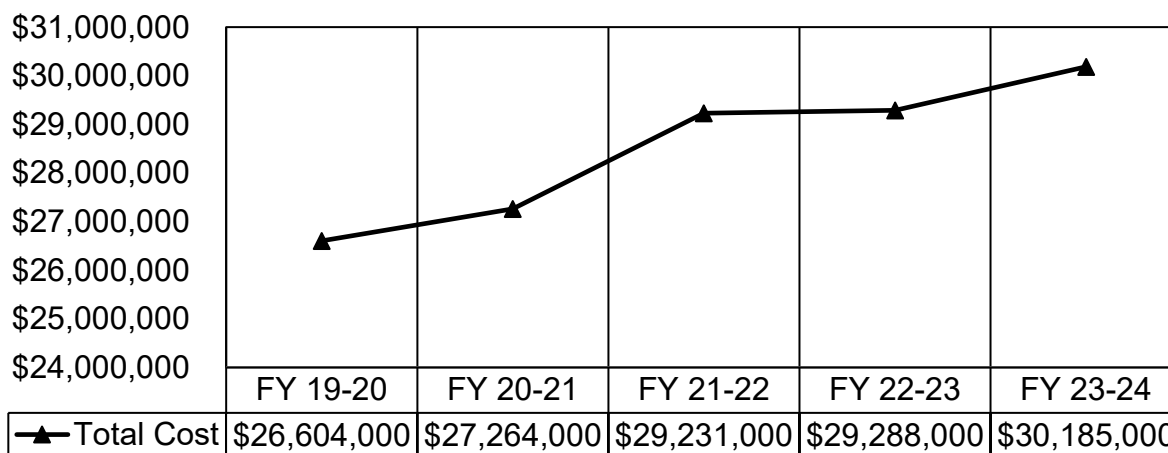
Technical and Scientific Average Cost – CDPH/GDSP estimates current year average Technical and Scientific cost per participant will be \$67.75, which is a decrease of \$1.31 or 2 percent compared to 2021-22 actual average Technical and Scientific cost per participant of \$69.06. Average Technical and Scientific cost per participant in 2023-24 is estimated at \$69.78, which is an increase of \$2.03 or 3 percent compared to the current year estimate.

NBS TECH & SCI AVERAGE COST



Technical and Scientific Total Cost – CDPH/GDSP estimates current year Technical and Scientific costs to total \$29.3 million, which is an increase of \$57,000 or 0.2 percent compared to 2021-22 actual technical and scientific costs of \$29.2 million. For 2023-24, the Technical and Scientific costs is estimated to be \$30.2 million, which is an increase of \$897,000 or 3 percent compared to the current year.

NBS TECH & SCI TOTAL COST



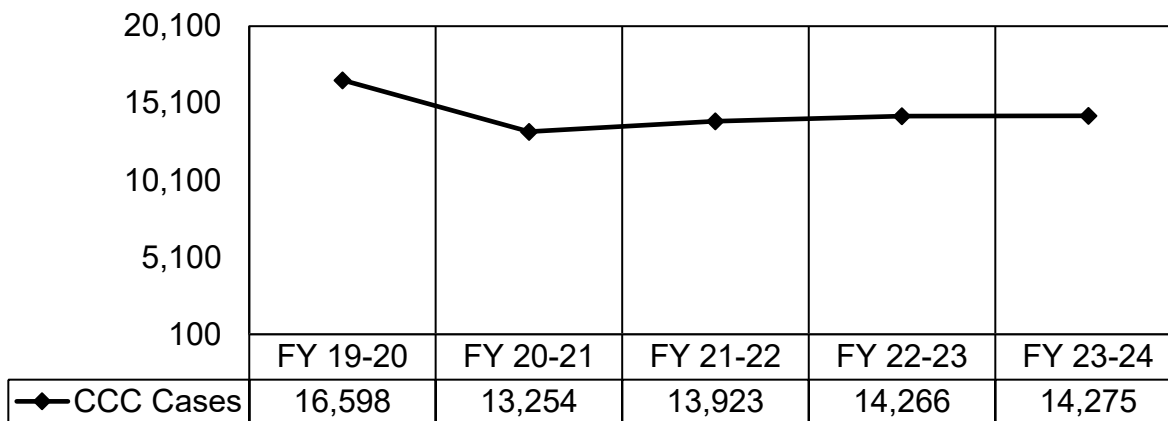
CASE MANAGEMENT AND COORDINATION SERVICES:

Overview- Services provided to infants who screen initial positive or have questionable screening test results for the 75+ genetic disorders screened. These services include time-sensitive coordination for specific confirmatory testing, family consultation – including consultation with the infant’s pediatrician, genetic disease counseling, family educational services, and coordinated care referrals to specialized medical institutions. The NBS Area Service Centers (ASC) provide critical coordination and tracking services to confirm that appropriate diagnostic measures are completed, and that affected infants

are provided with appropriate medical care and receive treatment within a critical timeframe. The ASCs are reimbursed based on caseload and the type of service performed along with a monthly base allocation; this funding supports a required core team of clinical professionals. Costs vary by ASC, dependent upon the geographical location as well as the volume of caseload served.

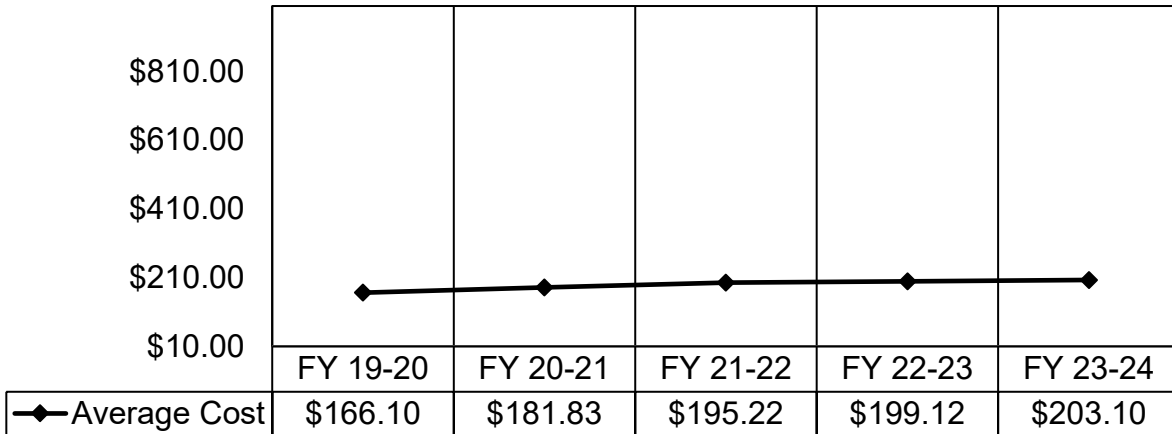
Case Management and Coordination Services (CMCS) Caseload – CDPH/GDSP estimates current year CMCS caseload will total 14,266, which is an increase of 343 or 2 percent compared to 2021-22 actual CMCS caseload of 13,923. CMCS caseload in 2023-24 is estimated at 14,275, which is a slight increase of 9 or 0.1 percent compared to the current year estimate.

NBS CCC (ASC) CASELOAD



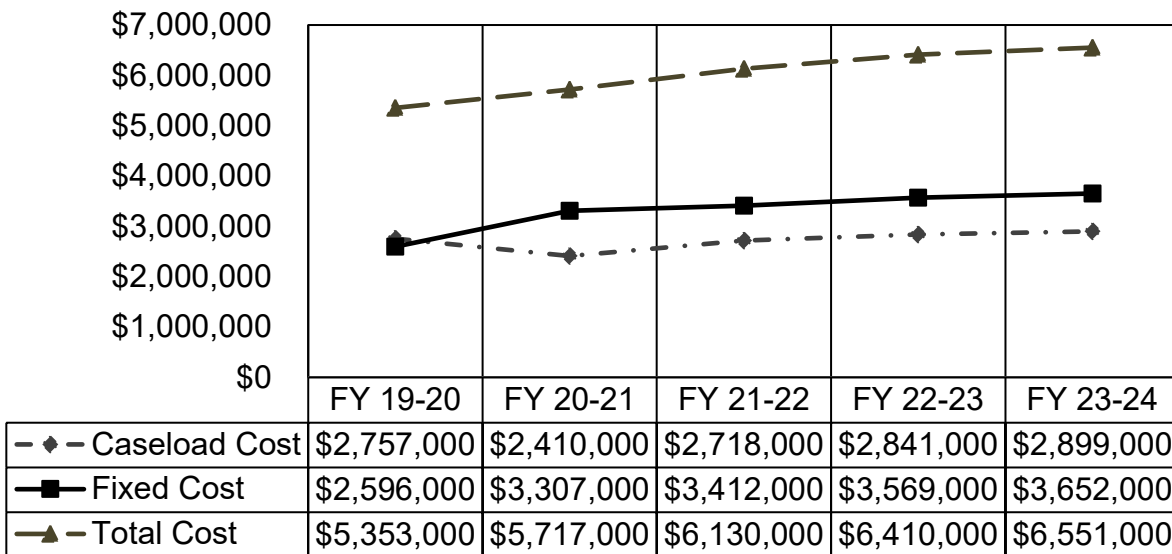
Case Management and Coordination Services (CMCS) Average Cost - CDPH/GDSP estimates current year average CMCS cost per participant will be \$199, which is an increase of \$4 or 2 percent compared to 2021-22 actual average CMCS cost per participant of \$195. Average CMCS cost per participant in 2023-24 is estimated at \$203, which is an increase of \$4 or 2 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.

NBS CCC (ASC) AVERAGE COST



Case Management and Coordination Services (CMCS) Total Cost - CDPH/GDSP estimates current year CMCS costs to total \$6.4 million, which is a slight increase of \$280,000 or 5 percent compared to 2021-22 actual CMCS total costs of \$6.1 million. CMCS costs in 2023-24 are estimated to total \$6.6 million, which is an increase of \$141,000 or 2 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 2023-24 due to the projected number of positive cases attributed to the implemented screening for SMA and increase in projected births. 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.

NBS CCC (ASC) TOTAL COST

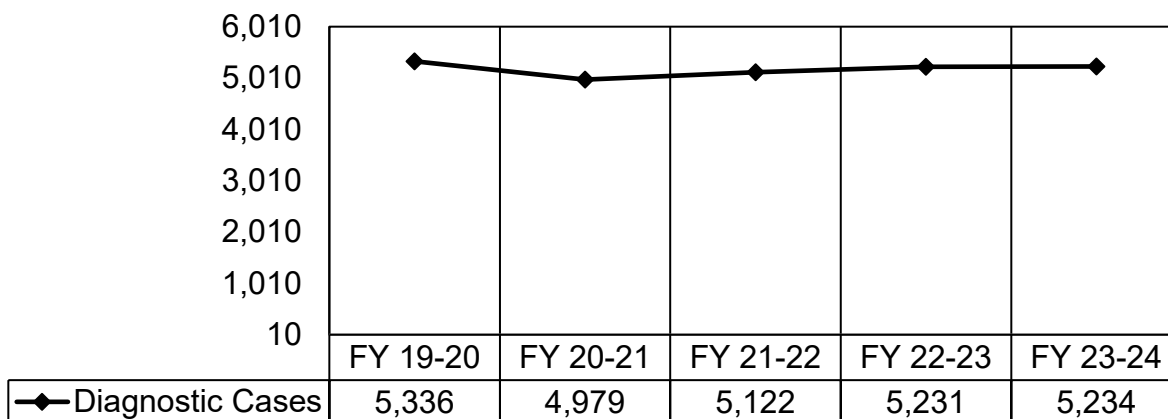


DIAGNOSTIC SERVICES

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

Diagnostic Services Caseload – CDPH/GDSP estimates current year Diagnostic caseload will total 5,231, based on projected new referral cases and annual patient summary cases, which is an increase of 109 or 2 percent compared to 2021-22 actual Diagnostic Services caseload of 5,122. Diagnostic caseload in 2023-24 is estimated at 5,234, which is a slight increase of 3 or 0.1 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.

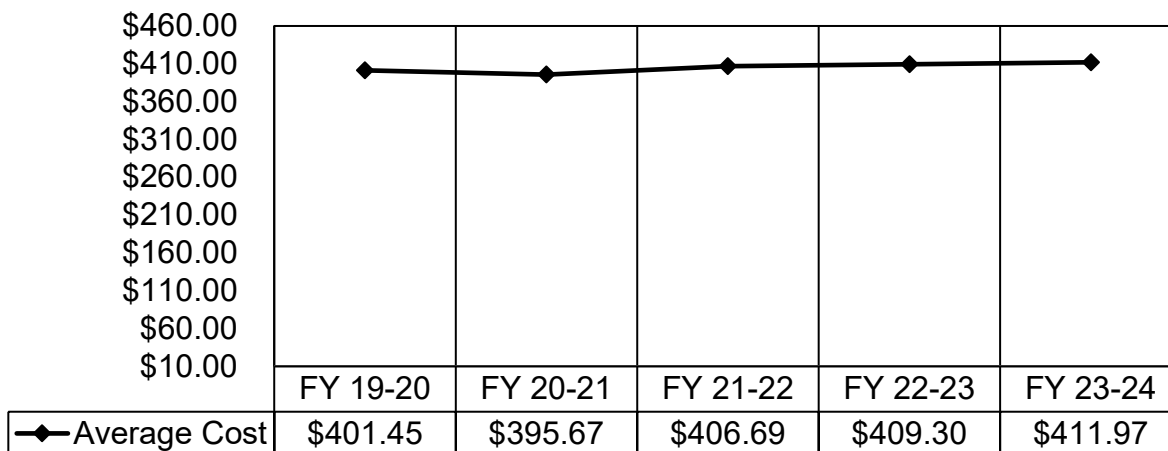
NBS FOLLOW-UP/DIAGNOSTIC CASELOAD



Diagnostic Services Average Cost - CDPH/GDSP estimates current year average Diagnostic Services cost per participant will be \$409, calculated based on projected new referral cases and annual patient summary cases, which is a slight increase of \$3 or 1 percent compared to 2021-22 actual average Diagnostic Services cost per participant of \$407. The average Diagnostic Services cost per participant in 2023-24

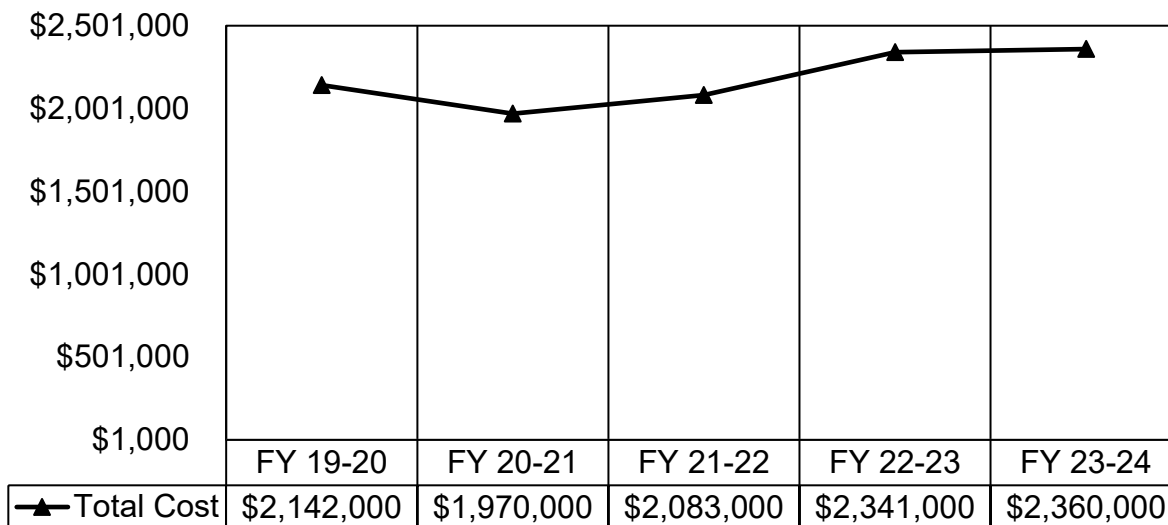
are estimated at \$412, which is also a slight increase of \$3 or 1 percent compared to the current year estimate. The slight increase in the current year and budget year is tied to the caseload increased due to increase in projected live births.

NBS AVG FOLLOW-UP/DIAGNOSTIC AVE COST



Diagnostic Services Total Cost - CDPH/GDSP estimates current year Diagnostic Services costs to total \$2.3 million, which is an increase of \$258,000 or 12 percent compared to 2021-22 actual Diagnostic Services total costs of \$2.1 million. Diagnostic Services costs in 2023-24 are estimated to total \$2.4 million, which is a slight increase of 19,000 or 1 percent compared to the current year estimate. The increases in total costs from the current to the budget year is attributed to caseload increases due to increase in projected live births.

NBS FOLLOW-UP/DIAGNOSTIC TOTAL COST

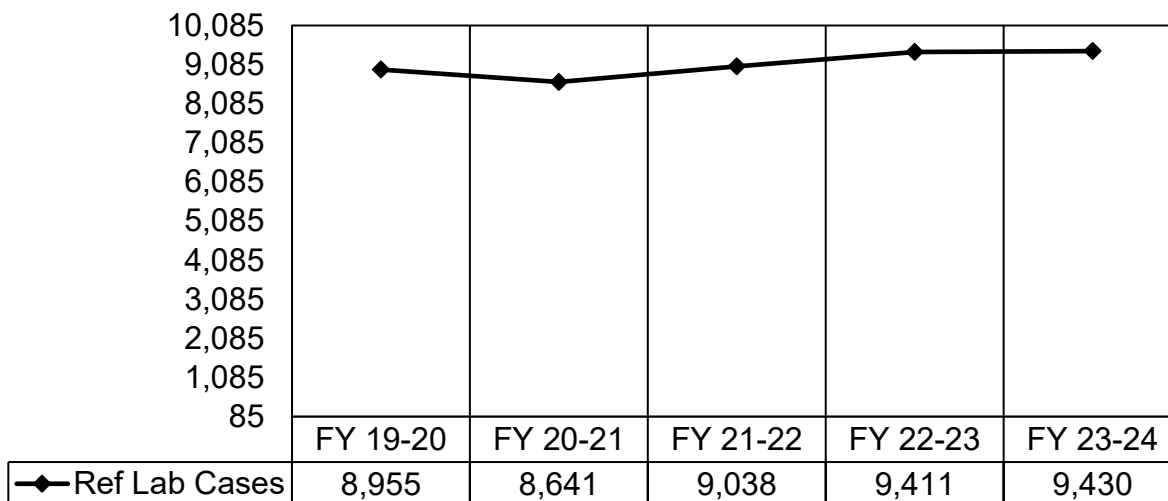


REFERENCE LABORATORIES

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

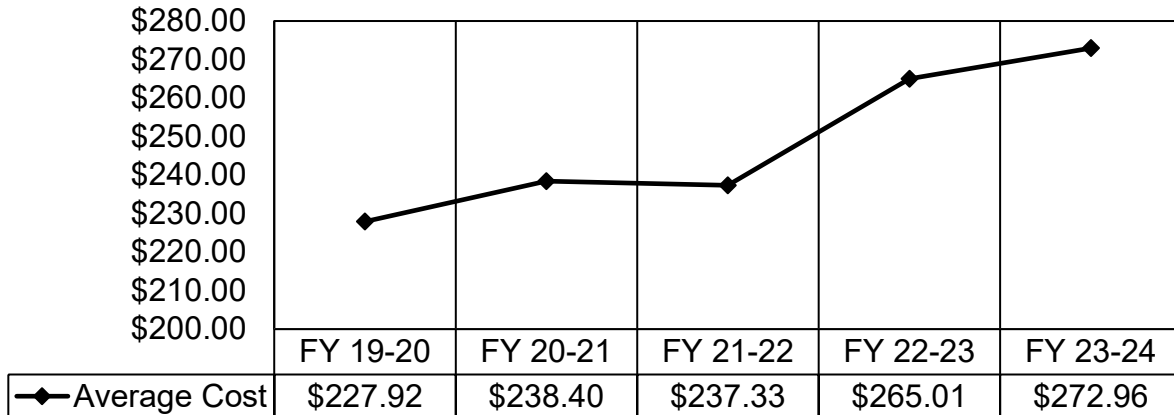
Reference Laboratory Caseload – CDPH/GDSP estimates current year Reference Laboratory caseload will total 9,411, which is an increase of 373 or 4 percent compared to 2021-22 actual Reference Laboratory caseload of 9,038. Reference Laboratory caseload in 2023-24 is estimated at 9,430, which is a slight increase of 19 or 0.2 percent compared to the current year estimate.

NBS REFERENCE LAB CASELOAD



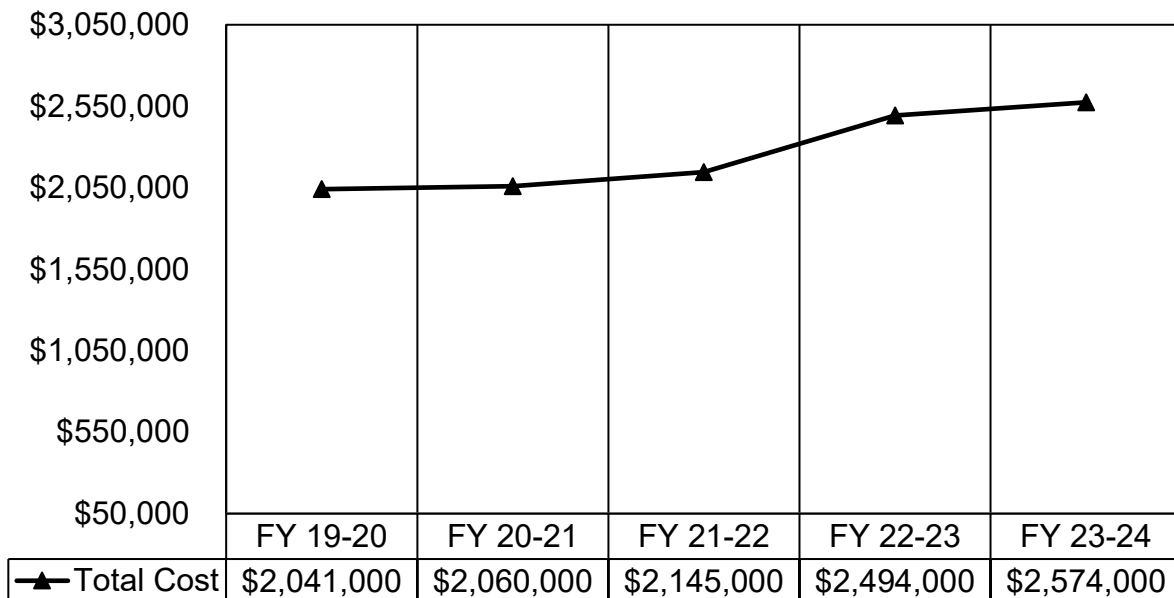
Reference Laboratory Average Cost – CDPH/GDSP estimates current year Reference Laboratory average cost per participant will be \$265, which is a decrease of \$27.68 or 12 percent compared to 2021-22 Reference Laboratory actual average cost per participant of \$237.33. Reference Laboratory average cost per participant in 2023-24 is estimated at \$273, which is an increase of \$8 or 3 percent compared to the current year estimate. The fluctuation in caseload is tied to the total costs.

NBS REFERENCE LAB AVERAGE COST



Reference Laboratory Total Cost – CDPH/GDSP estimates current year Reference Laboratory costs to total \$2.5 million, which is an increase of 349,000 or 16 percent compared to 2021-22 actual Diagnostic Services total costs of \$2.1 million. Reference Laboratory costs in 2023-24 are estimated to total \$2.4 million, which is an increase of 80,000 or 3 percent compared to the current year estimate. The slight cost increases from the current year to the budget year is attributed to the fluctuations in caseload and results of increase in projected live births.

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. 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.

On September 19, 2022, the California Prenatal Screening Program replaced GDSP’s conventional biochemical screening with cell-free DNA (cfDNA) screening for chromosome abnormalities and a simpler biochemical screening for neural tube defects (NTD). GDSP’s screening for neural tube defects remained part of the overall screening process. The changes to the California PNS Program established contracts successfully for new laboratories that carried out cfDNA screening; developed new structures for case management services provided by Case Coordination Centers and follow-up services provided by the Prenatal Diagnosis Centers (PDCs); and redesigned the SIS to accommodate the new screening results transmitted from the cfDNA laboratories, including redesigned test result mailers, established new algorithms to designate a case as screen-positive and the subsequent referral mechanisms to refer high risk cases to the PDCs for follow-up services.

Total Caseload/Specimens – CDPH/GDSP estimates budget year projected caseload for cfDNA at 312,928, which is 73 percent of the projected births from DOF/DRU updated birth rate projections. Only 308,763, which is 99 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 the second failure of cfDNA testing. There will be redraws, but the cfDNA company will invoice GDSP only once per pregnancy.

Table 15 shows the projected cfDNA cases by billable caseload, average cost and total cost for budget year 2023-24.

Table 15. cfDNA Projected Caseload and Costs

Fiscal Year cfDNA	Forecasted Births	Billable PNS Projected Caseload	PNS Projected Specimens	Average Cost	Total Cost
2022-2023	430,000	255,081	598,735	\$140	\$35,711,000
2023-2024	431,237	308,763	603,950	\$140	\$43,227,000

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.

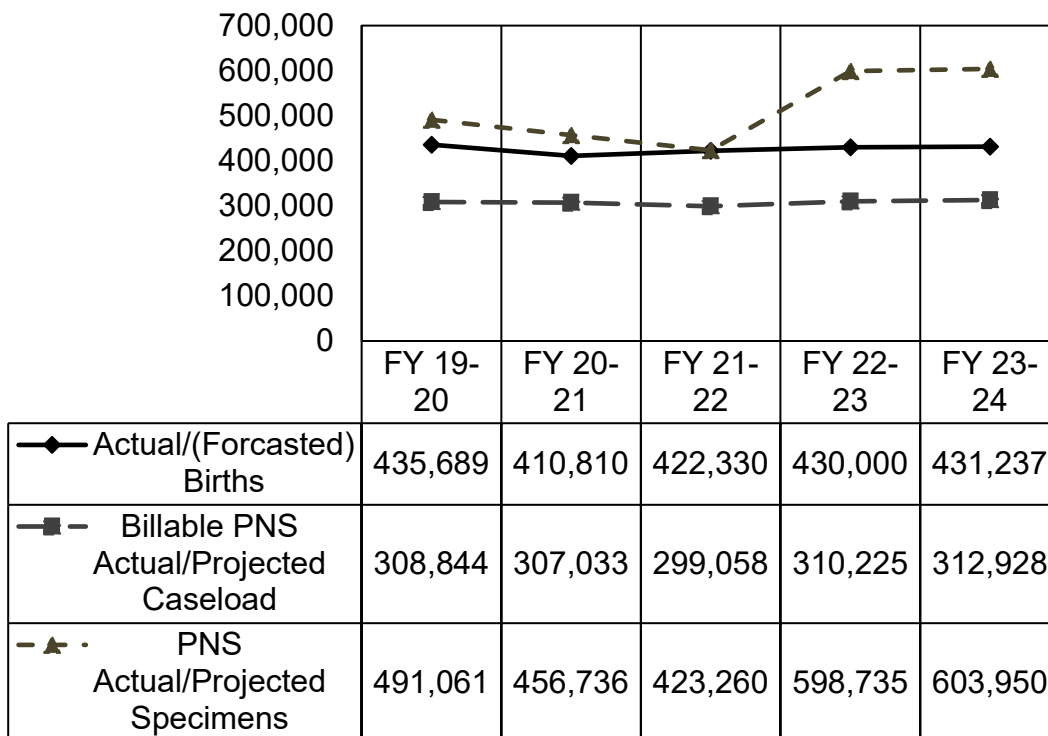
In the past CDPH/GDSP estimated the number of 1st trimester and 2nd trimester screens performed separately in the estimate. This is because the average cost of the 1st trimester screen was substantially less than the cost of the 2nd trimester screens. Currently, the regional laboratory cost of each test 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. On September 19, 2022, 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 598,735, which is an increase of 175,475 or 41.5 percent compared to 2021-22, actual total specimens of 423,260. The PNS program participation is estimated as a percentage of the DOF/DRU projected number of live births. In 2022-23, 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 2023-24, 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 72 percent (based on a three-year actual average) of the projected births will participate in the PNS program in 2022-23, and that the number of participants will increase to 73 percent in 2023-24. The 2022-23 projections do not increase with DOF/DRU birth rates because PNS participation has not remained

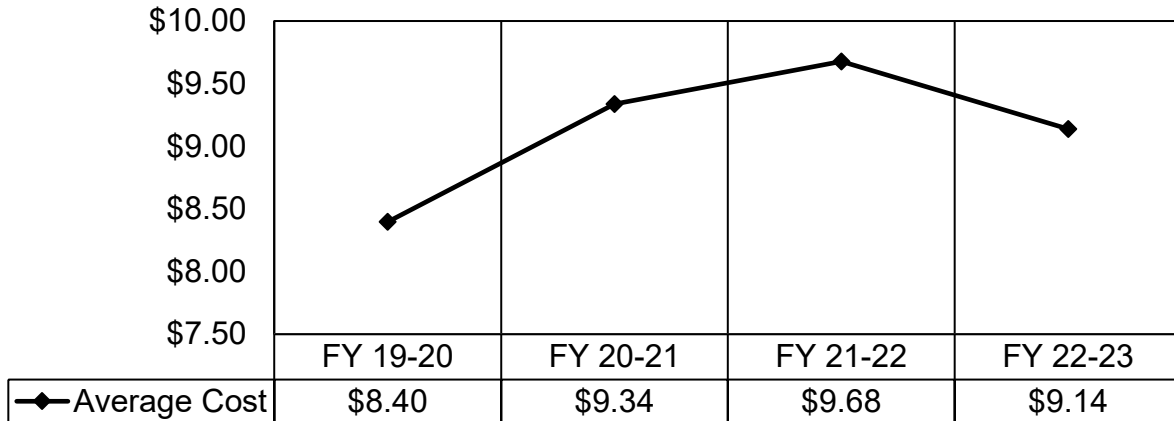
constant as a percent of DRU birth projections due to women choosing other types of prenatal testing offered outside of the State program. The following chart shows the actual PNS cases by year, along with our projected numbers for the remainder of the current year and budget year.

PNS CASELOAD/SPECIMENS



Contract Laboratory Average Cost Projections – CDPH/GDSP estimates current year average laboratory cost per participant will be \$9, which is a slight decrease of 1 or 6 percent compared to 2021-22 actual average laboratory cost per participant of \$10. The decrease in the current year is due to a decrease in contract costs while the projected caseload slightly increases. The contract regional NAPS lab only screen pregnant women for neural tube defects (NTD) beginning September 19, 2022, for which a separate fiscal analysis was performed.

PNS CONTRACT LAB AVERAGE COST



Contract Laboratory Total Cost Projections – CDPH/GDSP estimates current year contract laboratory cost to total \$884,000, which is a decrease of \$3.2 million or 78 percent compared to 2021-22 actual contract laboratory costs of \$4 million. Beginning September 19, 2022, the contract regional NAPS lab will only screen pregnant women for neural tube defects (NTD), for which a separate fiscal analysis was performed.

PNS CONTRACT LAB TOTAL COST

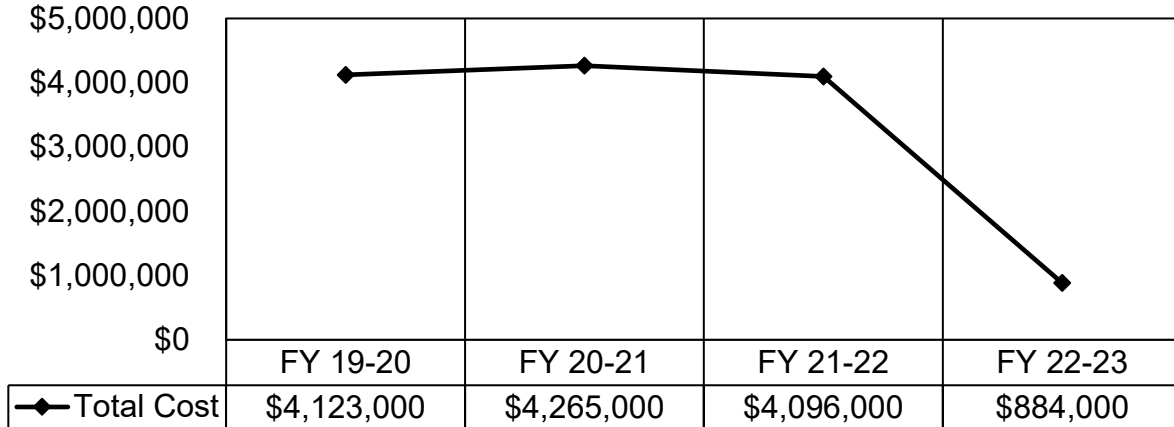


Table 16 shows the projected cases, average cost, and total cost for the prorated cases of the current prenatal program and for the neural tubes defects test only in budget year 2023-24 that will begin on September 19, 2022.

Table 16. Contract Laboratory Total and Average Costs

Fiscal Year Contract Lab	Number of Cases	Average Cost	Total Cost
2022-2023 Total Current PNS	96,782	\$9.14	\$884,000
2022-2023 Total NTD	228,403	\$9.90	\$2,261,000
2023-2024 Total NTD	291,023	\$10.20	\$2,968,000

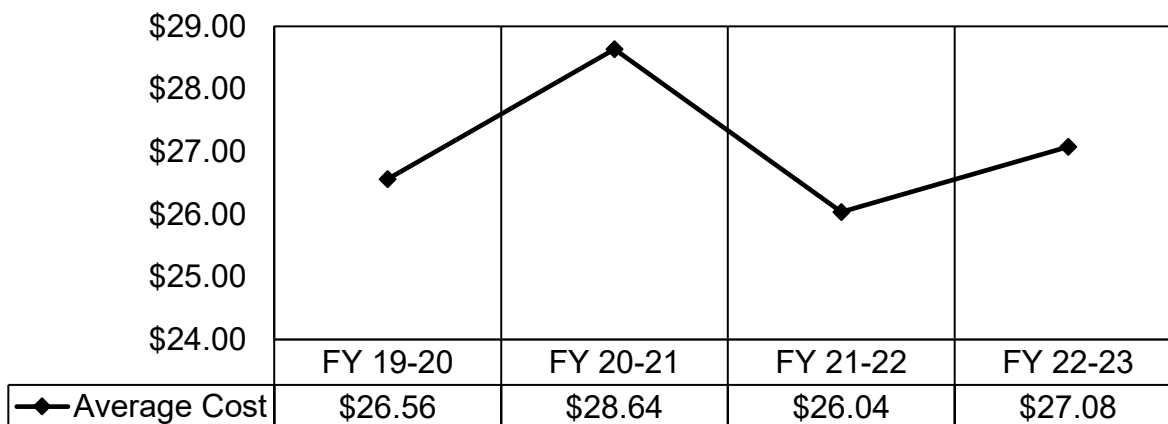
TECHNICAL AND SCIENTIFIC

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 \$27, which is an increase of \$1 or 4 percent compared to 2021-22 actual average Technical and Scientific cost per specimen of \$26. The increase in the current year is attributed to the decrease in total cost while the total projected specimens tested increases. Beginning 2022-23, NTD screen will use AFP kit lot for AFP testing only for which a separate fiscal analysis will be performed.

PNS TECH & SCI AVERAGE COSTS



Technical and Scientific Total Cost – CDPH/GDSP estimates current year Technical and Scientific costs to total \$2.6 million, which is a decrease of \$8.4 million or 76 percent compared to 2021-22 actual technical and scientific costs of \$11 million. Fluctuation in total cost is tied to the projected specimens and costs of reagents, supplies, and consumables. Beginning 2023-24, a simpler biochemical screening will be used for neural tube defects (NTD), for which a separate fiscal analysis will be performed.

PNS TECH & SCI TOTAL COST

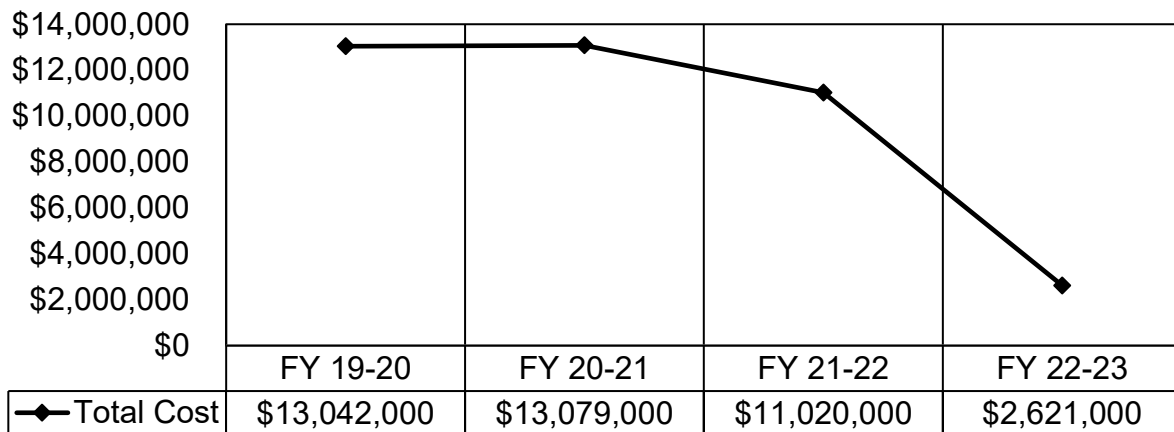


Table 17 shows the projected cases, average cost and total cost associated with technical and scientific cost for the current prenatal program and for the neural tubes defects test only in budget year 2023-24 that launched on September 19, 2022.

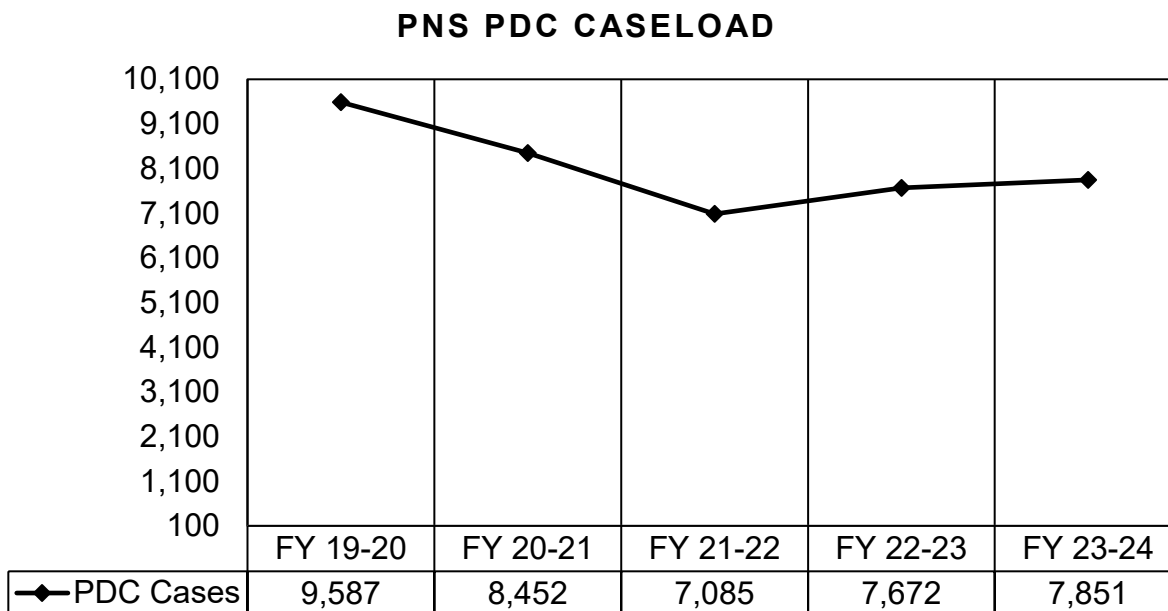
Table 17. Technical and Scientific Average and Total Costs

Fiscal Year Tech & Sci	Number of Cases	Average Cost	Total Cost
2022-23 Total Current PNS	96,782	\$27.08	\$2,621,000
2022-23 Total NTD	228,403	\$7.00	\$1,599,000
2023-24 Total NTD	291,023	\$7.21	\$2,098,000

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.

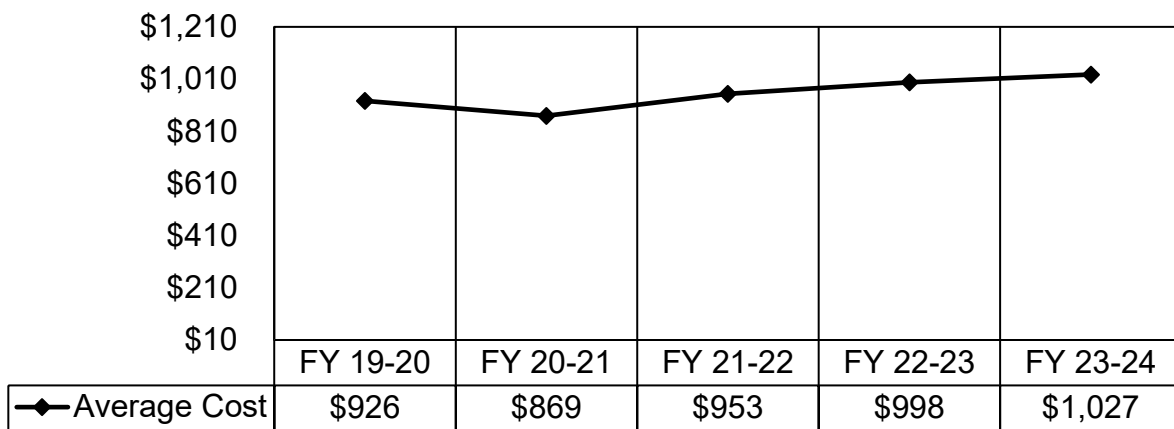
Prenatal Diagnostic Services Centers (PDC) Caseload – CDPH/GDSP estimates current year PDC caseload will total 7,672, which is an increase of 587 or 8 percent compared to the 2021-22 actual PDC caseload of 7,085. The increase is caused by a projected increase in women choosing to further pursue diagnostic care. Beginning 2023-24, cfDNA screened positive tests and with no result; and NTD screened positive tests will be referred for additional services which include confirmatory and diagnostic testing 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 \$998, which is an increase of \$44.27 or 5 percent compared to 2021-22 actual average PDC cost per participant of \$953.28. 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 tests screened positive and with no results; and NTD tests screened positive will have a separate cost analysis on diagnostic services.

PNS PDC AVERAGE COST



Prenatal Diagnostic Services Total Cost – CDPH/GDSP estimates current year PDC costs to total \$7.7 million, which is an increase of \$899,000 or 13 percent compared to 2021-22 actual PDC total costs of \$6.8 million. The change in total expenditures is attributable mainly to fluctuating projected PDC caseload. The 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.

PNS PDC TOTAL COST

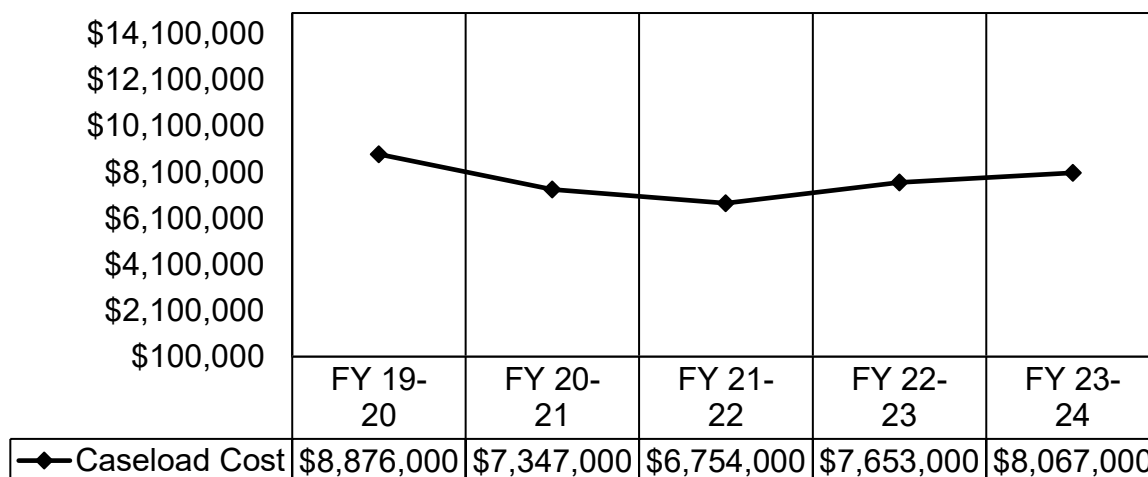


Table 18 shows the projected PDC cases, average cost and total cost associated for diagnostic follow up services per cfDNA (screened positive and with no results) and per screened positive neural tubes defects in budget year 2023-24.

Table 18. Projected Prenatal Diagnostic Center Costs

Fiscal Year Prenatal Diagnostic Centers	Total Specimens/Billable	Number of Cases	Caseload Cost	Average Cost	PDC as % of Total
2022-2023	590,137	7,672	\$7,653,000	\$998	1.3%
2023-2024	603,950	7,851	\$8,067,000	\$1,027	1.3%

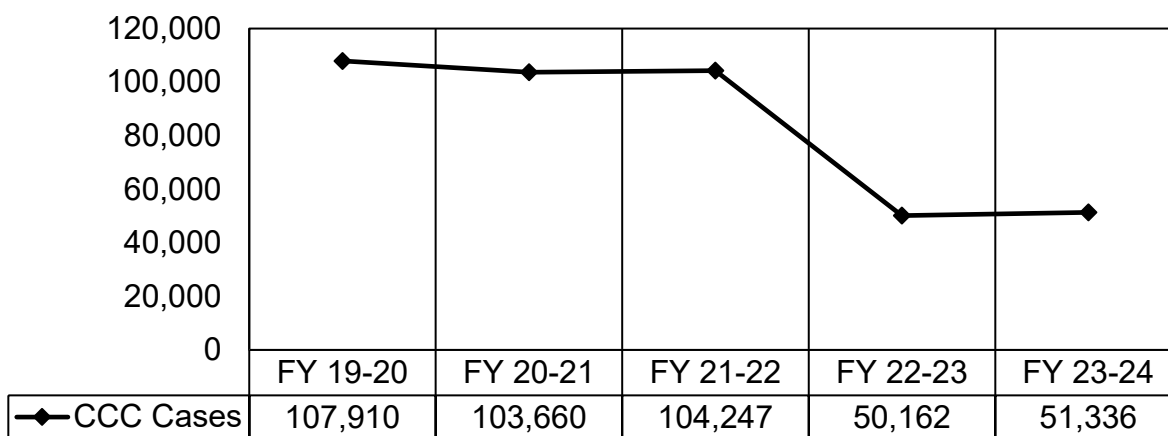
CASE MANAGEMENT AND COORDINATION SERVICES

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 verify that appointments are kept and patients seen within prescribed timeframes. Coordinators confirm and verify specific patient information as needed with the treating physician offices, and the Prenatal Diagnostic Centers. The CCCs are reimbursed based on caseload and the type of service performed along with a monthly base allocation. Base allocation costs vary by CCC dependent upon the geographic location.

Case Management and Coordination Services (CMCS) Caseload - CDPH/GDSP estimates current year CMCS caseload will total 50,162, which is a decrease of 54,085 or 52 percent compared to 2021-22 actual CMCS caseload of 104,247. This is due largely to changes in the DRU-based caseload. The cfDNA and NTD screened positive cases will be referred to a case coordinator for which separate services will be performed.

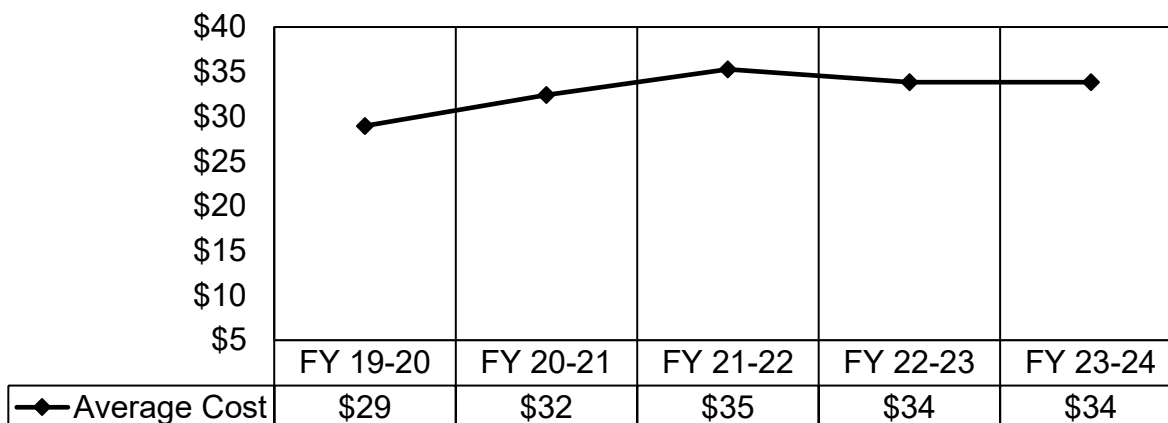
The following chart shows the actual CMCS cases by month, along with projected numbers for the remainder of the current year and budget year.

PNS CASE COORDINATION CASELOAD



Case Management and Coordination Services Average Cost - CDPH/GDSP estimates current year average CMCS cost per participant will be \$33.83, which is a slight decrease of \$1.44 or 4 percent compared to 2021-22 actual average CMCS cost per participant of \$35.27. The decrease in the current year is attributable to the changes in the DRU-based caseload but is offset by an increase in fixed costs. The cfDNA and NTD positive cases will be referred to a case coordinator for which a separate cost per participant is attributed.

PNS CASE COORDINATION AVERAGE COST



Case Management and Coordination Services Total Cost - CDPH/GDSP estimates current year CMCS costs to total \$3 million, which is a decrease of \$3.3 million or 53 percent compared to 2021-22 actual CMCS total costs of \$6.3 million. The decrease in the current year is attributable to the changes in the DRU-based caseload causing a decrease in the total cost despite slight increases in fixed costs. The cfDNA and NTD positive cases will be referred to a case coordinator for which contract rates is attributed on cost per test plus baseline adjustments.

PNS CASE COORDINATION TOTAL COST

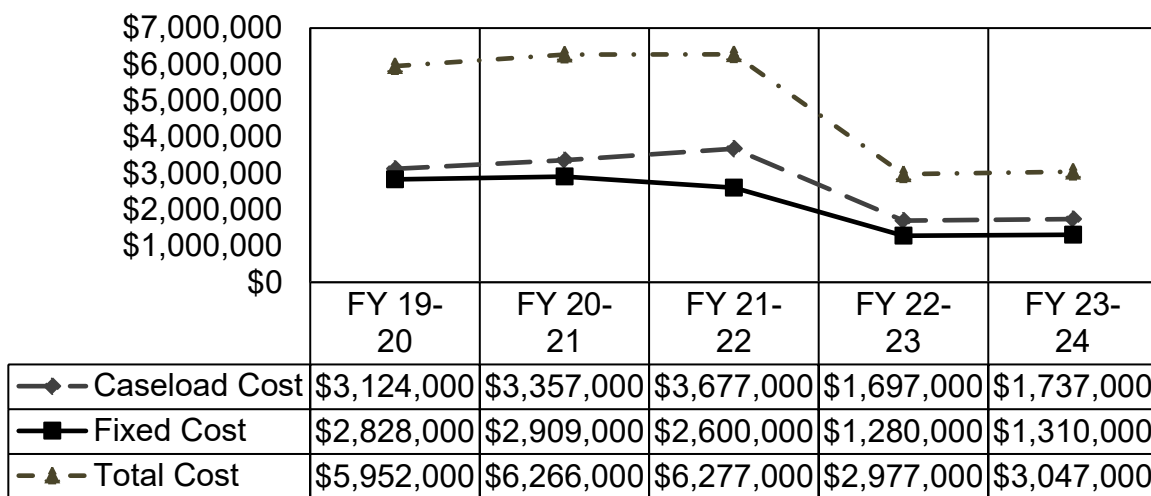


Table 19 shows the projected CCC cases, average cost, fixed cost, and total cost associated for clinician and patient consultation on referred positive cases per cfDNA and per neural tubes defects testing in budget year 2023-24.

Table 19. Projected Case Coordination Costs

Fiscal Year Case Coordination	Total Specimens/Billable	CCC Cases	Average Cost	Caseload Cost	Fixed Cost	Total Cost	CCC as % of Total
2022-2023	590,137	50,162	\$34	\$1,697,000	\$1,280,000	\$2,977,000	9%
2023-2024	603,950	51,336	\$34	\$1,737,000	\$1,310,000	\$3,047,000	9%

APPENDIX C: REVENUE PROJECTIONS

NBS REVENUE

Beginning July 1, 2022, Newborn Screening Program charges a fee of \$211. 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 20. NBS Revenue Projections

Fiscal Year	Fee (A)	Caseload (B)	Collection Rate (C)	Total Revenue (D) = (A) x (B) x (C)
FY 2022-23	\$211.00	432,294	99 percent	\$90,302,000
FY 2023-24	\$211.00	432,563	99 percent	\$90,358,000

PNS REVENUE

The Prenatal Screening Program charges a fee of 232.00 on September 19, 2022, to all participating women. Of the total fee, \$222.00 is deposited into the GDTF (Fund 0203), and \$10 is deposited into the California Birth Defect Monitoring Program Fund (Fund 3114). GDSP also added a separate fee of \$85 for neural tube defect (NTD) screening, of which \$75 is deposited into the GDTF (Fund 0203), and \$10 is deposited into the California Birth Defect Monitoring Program Fund (Fund 3114). 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 percent to non-Medi-Cal insurers. Approximately 60 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 21. PNS Revenue Projections

Fiscal Year	Fee (A) = \$221.60 - \$10	Caseload (B)	% Medi-Cal (C)	% Non-Medi-Cal (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 2022-23 7/1/22-9/18/22	\$211.60	64,630	60%	40%	99%	95%	38,778	25,852	\$13,320,000
FY 2022-23 9/19/22-6/30/23	\$222.00	245,595	60%	40%	99%	95%	147,357	98,238	\$53,105,000
FY 2023-24	\$222.00	312,928	60%	40%	99%	95%	187,757	125,171	\$67,664,000

Table 22. 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	228,403	60%	40%	99%	95%	137,042	91,361	\$16,685,000
FY 2023-24	\$75.00	291,023	60%	40%	99%	95%	174,614	116,409	\$21,259,000