

**Genetic Disease Screening Program
(GDSP)**

Fiscal Year 2023-24

May Revision Estimate



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ESTIMATES

PROGRAM OVERVIEW

The California Department of Public Health (CDPH), Genetic Disease Screening Program (GDSP) May Revision 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's 2023-24 Governor's Budget appropriation for 2022-23 is \$173.9 million, of which \$137 million is for Local Assistance and \$36.9 million is for State Operations. The CDPH/GDSP's May Revision estimates 2022-23 expenditures will be \$166 million, of which \$36.9 million is for State Operations and \$129 million is for Local Assistance. The \$7.9 million Local Assistance reduction is attributed to a drop in participation due to the state regulation [17 CCR 6523(e)] granting the PNS Program exclusivity for its screening panel, is currently not in effect due to a preliminary injunction issued on November 2, 2022. This ruling decreased the PNS caseload by approximately 20 percent as cfDNA laboratories that have not contracted with the PNS Program are able to screen for trisomy 13, trisomy 18, trisomy 21 and neural tube defects (NTDs) outside of the PNS Program.

The CDPH/GDSP's 2023-24 Governor's Budget appropriation for 2023-24 is \$184.4 million, of which \$146.3 million is for Local Assistance and \$38.1 million is for State Operations. The CDPH/GDSP's May Revision estimates 2023-24 expenditures will be \$187.6 million, of which \$38.1 million is for State Operations and \$150 million is for Local Assistance. Overall, there is an increase of \$3.2 million or 1.7 percent for 2023-24 compared to the 2023-24 Governor's Budget. The Local Assistance increase is attributed to higher contract rates and caseload increases for some services in both programs.

Table 1 shows the difference between GDSP's 2023-24 Governor's Budget appropriation, the revised 2022-23 expenditures, and the 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 (Dollars in Thousands)

Fund 0203 Genetic Disease Testing Fund	2022 Budget Act	Governor's Budget	2023 May Revision	Change from Governor's Budget to May Revision	Percent Change from Governor's Budget to May Revision
Fiscal Year 2022-2023 Total	\$173,046	\$173,945	\$166,013	(\$7,932)	-4.6%
Fiscal Year 2022-2023 State Operations	\$35,780	\$36,856	\$36,856	\$0	0.0%
Fiscal Year 2022-2023 Local Assistance	\$137,266	\$137,089	\$129,157	(\$7,932)	-5.8%
Fiscal Year 2023-2024 Total	\$173,046	\$184,388	\$187,608	\$3,220	1.7%
Fiscal Year 2023-2024 State Operations	\$35,780	\$38,066	\$38,066	\$0	0.0%
Fiscal Year 2023-2024 Local Assistance	\$137,266	\$146,322	\$149,542	\$3,220	2.2%

LOCAL ASSISTANCE EXPENDITURE PROJECTIONS

CURRENT YEAR (2022-23)

The 2023-24 Governor's Budget appropriation for CDPH/GDSP's Local Assistance is \$137 million in 2022-23. The CDPH/GDSP's May Revision estimates revised 2022-23 Local Assistance expenditures of \$129 million, which is a decrease of \$8 million or 5.8 percent compared to the 2023-24 Governor's budget. The decrease in Local Assistance is attributed to the New Assumption: Methodology Change in Projecting Prenatal Screening Caseload. This assumption makes a projection using the actual number of PNS program participants from November 2022 to January 2023 rather than projecting caseload as a percentage of the Demographic Research Unit's (DRU) projected number of live births. GDSP needs to temporarily align its budget in the current year to account for the impact of the injunction. The usual PNS methodology which was used in previous estimates is based on a three-year average of prenatal percentages of birth rates and estimated PNS caseload to be around 72 percent of births. The new temporary methodology estimates PNS caseload at approximately 60 percent of births.

Budget Year (2023-24)

For 2023-24, CDPH/GDSP's May Revision estimates Local Assistance expenditures will total \$150 million, which is an increase of \$3.2 million or 2.2 percent compared to the 2023-24 Governor's Budget amount of \$146.3 million. The net increase in Local Assistance is attributed mainly to contract rate increases and projected caseload increases in Case Management and Coordination Services and Contract Regional Laboratories, which is partially offset by a decrease in caseload for Prenatal Diagnostic Centers. For Budget Year, GDSP reverts to its usual methodology of projecting PNS caseload using a three-year average percentage of prenatal screening participation applied to the most recent Department of Finance Demographic Research Unit's (DRU) projection of live births as the legal ruling on screening exclusivity has not yet been determined.

Table 2 shows the difference between the 2023-24 Governor's Budget appropriation, the revised 2023-24 expenditures, and the 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 (Dollars in Thousands)

Fund 0203 Genetic Disease Testing Fund	2022 Budget Act	Governor's Budget	2023 May Revision	Change from Governor's Budget to May Revision	Percent Change from Governor's Budget to May Revision
Fiscal Year 2022-2023 Local Assistance Total	\$137,266	\$137,089	\$129,157	(\$7,932)	-5.8%
Fiscal Year 2022-2023 Newborn Screening	\$47,914	\$47,930	\$47,204	(\$726)	-1.5%
Fiscal Year 2022-2023 Prenatal Screening	\$53,899	\$53,706	\$46,500	(\$7,206)	-13.4%
Fiscal Year 2022-2023 Operational Support	\$35,453	\$35,453	\$35,453	\$0	0.0%
Fiscal Year 2023-2024 Local Assistance Total	\$137,266	\$146,322	\$149,542	\$3,220	2.2%
Fiscal Year 2023-2024 Newborn Screening	\$47,914	\$49,252	\$50,182	\$930	1.9%
Fiscal Year 2023-2024 Prenatal Screening	\$53,899	\$59,407	\$61,697	\$2,290	3.9%

Fund 0203 Genetic Disease Testing Fund	2022 Budget Act	Governor's Budget	2023 May Revision	Change from Governor's Budget to May Revision	Percent Change from Governor's Budget to May Revision
Fiscal Year 2023-2024 Operational Support	\$35,453	\$37,663	\$37,663	\$0	0.0%

EXPENDITURE METHODOLOGY (KEY DRIVERS OF COST)

The CDPH/GDSP Local Assistance expenditures are split into three areas: PNS, NBS and Operational Support. Operational Support costs do not fluctuate greatly with changes in caseload. For both PNS and NBS Program areas, the key drivers of cost are the following:

1. NBS and PNS projected caseloads/specimens for the following:
 - a. Total clients served
 - b. Cases that receive case management
 - c. Cases that are referred for diagnostic services
 - d. Cases that are referred to reference laboratories (NBS only)
2. Average Case Cost for the following services:
 - a. Contract laboratories
 - b. Technology & Scientific supplies (Tech & Sci)
 - c. Case Management and Coordination Services (CMCS)
 - d. Follow-up Diagnostic Services (FDS)
 - e. Reference laboratories (NBS only)

To calculate the total projected Local Assistance costs, CDPH projects NBS and PNS caseloads/specimens and multiplies them by their respective projected average cost, plus the baseline cost. They are then added to the Operational Support costs to calculate the total CDPH/GDSP Local Assistance cost.

- NBS total costs equal the sum of:
 - Total clients served x Contract laboratory average cost
 - Total clients served x Technology and Scientific average cost
 - Case Management cases x Case Management and Coordination average cost + applicable Baseline cost
 - Diagnostic Services cases x Diagnostic Services average cost + applicable Baseline cost

- Reference laboratory cases x Reference laboratory average cost
- PNS total costs equal the sum of:
 - Total specimen tested x Contract laboratory average cost
 - Total specimen tested x Technology and Scientific average cost
 - Case Management cases x Case Management and Coordination average cost+ applicable Baseline cost
 - Diagnostic Services cases x Diagnostic Services average cost
- Operational Support Costs are the sum of various service contracts that support CDPH/GDSP, including Information Technology (IT), billing and collection system 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's May Revision estimates NBS Local Assistance expenditures will total \$47.2 million, which is a slight decrease of \$726,000 or 1.5 percent compared to the 2023-24 Governor's budget of \$47.9 million. The net decrease of \$726,000 is attributed to cost reductions in reagent test kits in the Technology and Scientific caused by lower projected caseload, as well as cost reduction in Case Coordination and Follow-up Diagnostic Services due to lower projected caseload volume .

For 2023-24, CDPH/GDSP projects that NBS Local Assistance expenditures will total \$50.2 million, which is a slight increase of \$930,000 or 1.9 percent compared to the 2023-24 Governor's budget of \$49.3 million. The net increase is attributed to the contract rate increases in the Contract Labs, Case Management and Coordination Services, and Reference Labs categories. These cost increases are somewhat offset by decreasing costs in Technology and Scientific and Follow-up Diagnostic Services categories resulting from lower caseload projections compared to Governor's Budget.

Table 3 shows the difference between the 2023-24 Governor's Budget appropriation, the revised 2022-23 expenditures, and the 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 (Dollars in Thousands)

Fund 0203 Genetic Disease Testing Fund	2022 Budget Act	Governor's Budget	2023 May Revision	Change from Governor's Budget to May Revision	Percent Change from Governor's Budget to May Revision
Fiscal Year 2022-2023 Total	\$47,914	\$47,930	\$47,204	(\$726)	-1.5%
Fiscal Year 2022-2023 Contract Lab	\$7,506	\$7,397	\$7,461	\$64	0.9%
Fiscal Year 2022-2023 Tech Sci	\$29,464	\$29,288	\$28,650	(\$638)	-2.2%
Fiscal Year 2022-2023 Reference Lab	\$2,263	\$2,494	\$2,579	\$85	3.4%
Fiscal Year 2022-2023 CMCS	\$6,358	\$6,410	\$6,332	(\$78)	-1.2%
Fiscal Year 2022-2023 Diagnostic Services	\$2,323	\$2,341	\$2,182	(\$159)	-6.8%
Fiscal Year 2023-2024 Total	\$47,914	\$49,252	\$50,182	\$930	\$49,252
Fiscal Year 2023-2024 Contract Lab	\$7,506	\$7,582	\$8,425	\$843	\$7,582
Fiscal Year 2023-2024 Tech Sci	\$29,464	\$30,185	\$29,772	(\$413)	\$30,185
Fiscal Year 2023-2024 Reference Lab	\$2,263	\$2,574	\$2,705	\$131	\$2,574

Fund 0203 Genetic Disease Testing Fund	2022 Budget Act	Governor's Budget	2023 May Revision	Change from Governor's Budget to May Revision	Percent Change from Governor's Budget to May Revision
Fiscal Year 2023-2024 CMCS	\$6,358	\$6,551	\$6,930	\$379	\$6,551
Fiscal Year 2023-2024 Diagnostic Services	\$2,323	\$2,360	\$2,350	(\$10)	\$2,360

PNS EXPENDITURES PROJECTIONS (SEE APPENDICES B1-B4)

For 2022-23, CDPH/GDSP's May Revision estimates PNS Local Assistance expenditures will total \$46.5 million, which is a net decrease of \$7.2 million or 13.4 percent compared to the 2023-24 Governor's budget amount of \$53.7 million. The decrease in the current year is attributed to lower than expected actual caseload due to the loss of screening exclusivity and the New Assumption: Methodology Change in Projecting Prenatal Screening Caseload which uses recent actual participant caseload rather than a three-year average of prenatal percentages of birth rates.

For 2023-24, CDPH/GDSP projects that PNS Local Assistance expenditures will total \$61.7 million, which is an increase of \$2.3 million or 3.9 percent compared to the 2023-24 Governor's budget amount of \$59.4 million. The net increase in the budget year is attributed to the increased cost of cell-free DNA (cfDNA) screening laboratories caused by an increase in specimens due to low fetal fraction and increases in contract rates, fixed costs, and projected caseload for Case Management and Coordination Services, which is partially offset by a decrease in projected caseload for Prenatal Diagnostic Centers. For Budget Year, GDSP reverts to its usual methodology of projecting PNS caseload using a three-year average percentage of prenatal screening participation applied to the most recent Department of Finance Demographic Research Unit's (DRU) projection of live births as the legal ruling on screening exclusivity has not yet been determined.

Table 4 shows the difference between the 2023-24 Governor's Budget appropriation, the revised 2022-23 expenditures, and the proposed 2023-24 expenditures for the Prenatal Screening program costs by category type.

Table 4. Prenatal Screening: Current Year and Budget Year Budget Summaries Compared to 2022 Budget Act (Dollars in Thousands)

Fund 0203 Genetic Disease Testing Fund	2022 Budget Act	Governor's Budget	2023 May Revision	Change from Governor's Budget to May Revision	Percent Change from Governor's Budget to May Revision
Fiscal Year 2022-2023 Total	\$53,899	\$53,706	\$46,500	(\$7,206)	-13.4%
Fiscal Year 2022-2023 cfDNA	\$36,159	\$35,711	\$27,940	(\$7,771)	-21.8%
Fiscal Year 2022-2023 Contract Lab	\$3,180	\$3,145	\$2,766	(\$379)	-12.1%
Fiscal Year 2022-2023 Tech & Sci	\$4,591	\$4,220	\$4,052	(\$168)	-4.0%
Fiscal Year 2022-2023 CMCS	\$2,495	\$2,977	\$5,040	\$2,063	69.3%
Fiscal Year 2022-2023 PDC	\$7,474	\$7,653	\$6,702	(\$951)	-12.4%
Fiscal Year 2023-2024 Total	\$53,899	\$59,407	\$61,697	\$2,290	3.9%
Fiscal Year 2023-2024 cfDNA	\$36,159	\$43,227	\$43,949	\$722	1.7%
Fiscal Year 2023-2024 Contract Lab	\$3,180	\$2,968	\$2,970	\$2	0.1%
Fiscal Year 2023-2024 Tech & Sci	\$4,591	\$2,098	\$2,100	\$2	0.1%
Fiscal Year 2023-2024 CMCS	\$2,495	\$3,047	\$6,058	\$3,011	98.8%
Fiscal Year 2023-2024 PDC	\$7,474	\$8,067	\$6,620	(\$1,447)	-17.9%

OPERATIONAL SUPPORT PROJECTIONS

For 2022-23, the CDPH/GDSP's revised Operational Support expenditures total is \$35.5 million, which is no change from the 2023-24 Governor's Budget.

For 2023-24, the CDPH/GDSP projects operational support expenditures will total \$37.7 million, which is no change from the 2023-24 Governor's Budget.

Table 5 shows the difference between the 2023-24 Governor's Budget appropriation, the revised 2022-23 expenditures, and the 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 (Dollars in Thousands)

Fund 0203 Genetic Disease Testing Fund	2022 Budget Act	Governor's Budget	2023 May Revision	Change from Governor's Budget to May Revision	Percent Change from Governor's Budget to May Revision
Fiscal Year 2022-2023 Operational Support	\$35,453	\$35,453	\$35,453	\$0	0.0%
Fiscal Year 2023-2024 Operational Support	\$35,453	\$37,663	\$37,663	\$0	0.0%

STATE OPERATIONS EXPENDITURE PROJECTIONS

For 2022-23, the CDPH/GDSP estimates revised State Operations expenditures will total \$36.9 million, which is no change from the 2023-24 Governor's Budget.

For 2023-24, the CDPH/GDSP estimates State Operations expenditures will total \$38.1 million, which is no change from the 2023-24 Governor's Budget.

Table 6 shows the difference between the 2023-24 Governor's Budget appropriation, the revised 2022-23 expenditures, and the 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 (Dollars in Thousands)

Fund 0203 Genetic Disease Testing Fund	2022 Budget Act	Governor's Budget	2023 May Revision	Change from Governor's Budget to May Revision	Percent Change from Governor's Budget to May Revision
Fiscal Year 2022-2023 State Operations	\$35,780	\$36,856	\$36,856	\$0	0.0%
Fiscal Year 2023-2024 State Operations	\$35,780	\$38,066	\$38,066	\$0	0.0%

REVENUE PROJECTIONS

COMBINED NBS AND PNS REVENUE

CDPH/GDSP has revised revenue estimates for 2022-23 totaling \$158.2 million, which is a decrease of \$15.2 million or 8.8 percent compared to the 2022-23 Governor's budget amount of \$173.4 million. The decrease in revenue for the current year is attributed to the decrease in projected billable caseload caused by the decline in participation due to the injunction. An additional factor of the decrease in revenue is the New Assumption: Methodology Change in Projecting Prenatal Screening Caseload using actual prenatal participants and accounting for only the most recent data rather than using the previous methodology which was based on a three-year average of prenatal percentages of birth rates.

For 2023-24, CDPH/GDSP's May Revision projects revenue will total \$176.2 million, which is a decrease of \$3.1 million or 1.7 percent compared to the 2023-24 Governor's Budget appropriation. The decrease in revenue for the budget year is attributed to decrease in projected billable caseload due to a decline in the DRU's projection of live births.

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 \$88.1 million, which is a decrease of \$2.2 million or 2.4 percent compared to the 2023-24 Governor's Budget amount of \$90.3 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 \$88.9 million, which is a decrease of \$1.5 million or 1.6 percent compared to the 2023-24 Governor's budget amount of \$90.4 million. The decrease in revenue for the budget year is due to the decrease in billable projected caseload based on the DRU's projection of live births compared to the billable projected caseload from the 2023-24 Governor's Budget.

PNS REVENUE (SEE APPENDIX C2)

In 2022-23, PNS revenue is expected to total \$70.1 million, which is a decrease of \$13 million or 15.6 percent compared to the 2023-24 Governor's Budget amount of \$83.1

million. The decrease in the current year is due to lower actual billable caseload than projected in the 2023-24 Governor's Budget and the decrease in the projected billable caseload using the New Assumption: Methodology Change in Projecting Prenatal Screening Caseload. This new methodology uses actual recent participation data (November 2022 to January 2023) to calculate caseloads for both cfDNA and NTD screening tests

In 2023-24, CDPH/GDSP projects PNS revenue will total \$87.3 million, which is a decrease of \$1.7 million or 1.9 percent compared to the 2023-24 Governor's Budget amount of \$88.9 million. The decrease in the budget year is due to the decrease in the projected billable caseload based on a lower projected birthrate compared to the 2023-24 Governor's Budget.

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 (Dollars in Thousands)

Fund 0203 Genetic Disease Testing Fund	2022 Budget Act	Governor's Budget	2023 May Revision	Change from Governor's Budget to May Revision	Percent Change from Governor's Budget to May Revision
Fiscal Year 2022-2023 Total	\$174,825	\$173,412	\$158,235	(\$15,177)	-8.8%
Fiscal Year 2022-2023 Newborn Screening	\$90,846	\$90,302	\$88,123	(\$2,179)	-2.4%
Fiscal Year 2022-2023 Prenatal Screening	\$83,979	\$83,110	\$70,112	(\$12,998)	-15.6%
Fiscal Year 2023-2024 Total	\$174,825	\$179,281	\$176,165	(\$3,116)	-1.7%

Fund 0203 Genetic Disease Testing Fund	2022 Budget Act	Governor's Budget	2023 May Revision	Change from Governor's Budget to May Revision	Percent Change from Governor's Budget to May Revision
Fiscal Year 2023-2024 Newborn Screening	\$90,846	\$90,358	\$88,908	(\$1,450)	-1.6%
Fiscal Year 2023-2024 Prenatal Screening	\$83,979	\$88,923	\$87,257	(\$1,666)	-1.9%

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	\$28,944
Prior Year Adjustment	17,743	0	0
Adjusted Beginning Balance	41,235	38,414	28,944

Table 9. REVENUES

REVENUES	2021-22	2022-23	2023-24
4123400 Genetic Disease Testing Fees	140,487	158,234	176,165
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
TOTAL REVENUES	142,835	158,455	176,386

Table 10. TOTAL RESOURCES

TOTAL RESOURCES	2021-22	2022-23	2023-24
Adjusted Beginning Balance	41,235	38,414	28,944
TOTAL REVENUES	142,835	158,455	176,386
TOTAL RESOURCES	184,070	196,869	205,330

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	36,856	38,066
4265 Department of Public Health (Local Assistance)	111,058	129,157	149,542
9892 Supplemental Pension Payments (State Operations)	496	496	496
9900 Statewide General Admin Exp (ProRata) (State Operations)	1,737	1,416	0
TOTAL EXPENDITURES AND EXPENDITURE ADJUSTMENTS	145,656	167,925	188,104

Table 12. FUND BALANCE

FUND BALANCE	2021-22	2022-23	2023-24
TOTAL RESOURCES	184,070	196,869	205,330
TOTAL EXPENDITURES AND EXPENDITURE ADJUSTMENTS	145,656	167,925	188,104
FUND BALANCE	38,414	28,944	17,226
Fund Balance as a percentage of Total Expenditures and Expenditure Adjustments	26%	17%	9%

Table 13. GDSP REVENUE PROJECTION 2022-2023 OF \$158,234,000

Number of Tests	Cost	Collection Rate	Revenue
421,863 NBS from 7/1/2022 to 9/18/2022	\$211.00	Provider: 99%	\$88,123,000
28,731 PNS from 7/1/2022 to 9/18/2022	\$211.60	Non-Medi-Cal: 95%	\$5,776,000
43,097 PNS from 7/1/2022 to 9/18/2022	\$211.60	Medi-Cal: 99%	\$9,028,000
78,085 cfDNA from 9/19/2022 to 6/30/2023	\$222.00	Non-Medi-Cal: 95%	\$16,468,000
117,128 cfDNA from 9/19/2022 to 6/30/2023	\$222.00	Medi-Cal: 99%	\$25,742,000
71,715 NTD from 9/19/2022 to 6/30/2023	\$75.00	Non-Medi-Cal: 95%	\$5,110,000
107,572 NTD from 9/19/2022 to 6/30/2023	\$75.00	Medi-Cal: 99%	\$7,987,000

Table 14. GDSP REVENUE PROJECTION 2023-2024 OF \$176,165,000

Number of Tests	Cost	Collection Rate	Revenue
425,620 NBS	\$211.00	Provider: 99%	\$88,908,000
122,826 cfDNA	\$222.00	Non-Medi-Cal: 95%	\$25,904,000
184,239 cfDNA	\$222.00	Medi-Cal: 99%	\$40,492,000
114,228 NTD	\$75.00	Non-Medi-Cal: 95%	\$8,139,000
171,342 NTD	\$75.00	Medi-Cal: 99%	\$12,722,000

GENERAL ASSUMPTIONS

FUTURE FISCAL ISSUES

Senate Bill (SB) 1095: Newborn Screening Program

Background:

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

Description of Change:

Screening for additional diseases will require start-up costs, additional laboratory equipment, 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 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

Prenatal Screening for Sex Chromosome Aneuploidies

Background:

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

Description of Change:

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

Discretionary?: No

Reason for Adjustment/ Change:

H&S Code section 125055(g)(1) states that Public Health “shall expand prenatal screening to include all tests that meet or exceed the current standard of care as recommended by nationally recognized medical or genetic organizations.” In December 2022, ACMG published a “strong” recommendation to offer cfDNA SCA screening for all pregnant patients and CDPH/GDSP is anticipating making prenatal SCA screening available through the PNS Program in 2023-24.

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

Fiscal impact is unknown at this time. CDPH/GDSP will provide updates on the fiscal impact and if, and when, a fee increase is needed in the 2024-25 November Estimate. CDPH/GDSP plans to begin the SCA screening addition on April 1, 2024. To the extent CDPH/GDSP requires additional resources to implement SCA screening in 2023-24, the

May Revision proposes provisional language that authorizes the Department of Finance to augment GDSP's expenditure authority for these activities. The fund source is the Genetic Disease Testing Fund (GDTF) (Fund 0203).

Further details on any fee increases and identifiable impacts to the Medi-Cal and non-Medi-Cal insurers from this proposal are currently under review by GDSP.

Methodology Change in Projecting Prenatal Screening Caseload

Background:

The previous Prenatal Screening (PNS) Program total caseload was determined as a percentage of the Department of Finance Demographic Research Unit (DRU)'s projected number of live births. GDSP has been using a historical three-year average of Prenatal percent (%) of Birth Rate to estimate the projected caseloads for current and budget year revenue and cost projections in the estimate process. The previous methodology is not applicable for the PNS program for the current year as GDSP will use the actual participation to calculate caseloads for both cfDNA and NTD screening tests. In addition, the state regulation [17 CCR 6523(e)] granting the PNS Program exclusivity for its screening panel is currently not in effect due to a preliminary injunction issued on November 2, 2022. The effects of the injunction decreased the PNS caseload by approximately 20 percent, since cfDNA laboratories that have not contracted with the PNS Program are currently able to screen for trisomy 13, trisomy 18, trisomy 21 and neural tube defects (NTDs) outside of the PNS Program. A final ruling on 17 CCR 6523(e) has not yet been made.

Providers may continue to additionally offer other expanded prenatal screening options to their patients when there is appropriate patient understanding about the benefits, limitations, and alternatives of such testing. Expanded screening options are not currently included as services covered in the comprehensive public health PNS Program and will be separately billed to patients or insurance payers.

Description of Change:

Rather than projecting caseload as a percentage of the DRU's projected number of live births, GDSP is proposing to use the program's most recent actual participation numbers to project current year caseload to account for the effects of the injunction.

Discretionary?: Yes

Reason for Adjustment/ Change:

GDSP is aligning its 2022-23 budget with projected caseload and assumes the injunction is only temporary by using actual prenatal participants and accounting for only the most recent data since the injunction was initiated (November through March 2023), rather than using the previous methodology which was based on a three-year average of prenatal percentages of birth rates. The previous methodology had estimated PNS caseload to be around 72 percent of births, while the new methodology estimates PNS caseload at approximately 60 percent of births.

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

It is estimated that this temporary methodology change in calculating prenatal caseload will reflect an approximate 16 percent decrease in prenatal participants, a revenue decrease of approximately \$15 million or 16 percent, and an expenditure decrease of approximately \$7 million or 11 percent in 2022-23. CDPH/GDSP will assess the fund reserve to determine if, and when, a fee increase would be needed. Any necessary fee increase would be done through the regulatory rulemaking process. The fund source is the Genetic Disease Testing Fund (GDTF, Fund 0203).

EXISTING (SIGNIFICANTLY CHANGED) ASSUMPTIONS/PREMISES

There are no Existing (Significantly Changed) Assumptions/Premises

UNCHANGED 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. On January 4, 2023, guanidinoacetate methyltransferase (GAMT) deficiency was added to the federal RUSP. The deadline for including MPS II on the California NBS panel is August 2024, and for including GAMT deficiency is January 2025.

MPS II is a genetic condition that can lead to intellectual disabilities and life-threatening cardiac and pulmonary complications due to a metabolic disorder that impairs the processing of complex sugars, causing the molecules to build up in various parts of the

body. The condition can be treated by enzyme replacement through periodic intravenous infusions to help prevent storage complications, thereby improving health outcomes.

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

Description of Change:

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

The California Department of Public Health (CDPH) requests \$3.5 million in 2023-24, \$3.3 million in 2024-25 and 2025-26, and \$2.7 million in 2026-27 and ongoing from the Genetic Disease Testing Fund to comply with Health and Safety Code (HSC) Section 125001(d) and expand newborn screening to include mucopolysaccharidosis type II (MPS II) and guanidinoacetate methyltransferase (GAMT) deficiency.

Approximately \$1.2 million in State Operations expenditure authority would be spent 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 would be required.

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, which 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 0.21 percent or approximately \$131,000 annually in projected PNS revenues. The fund source is the GDTF (Fund 0203).

DISCONTINUED ASSUMPTIONS/PREMISES

There are no Discontinued Assumptions/Premises.

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

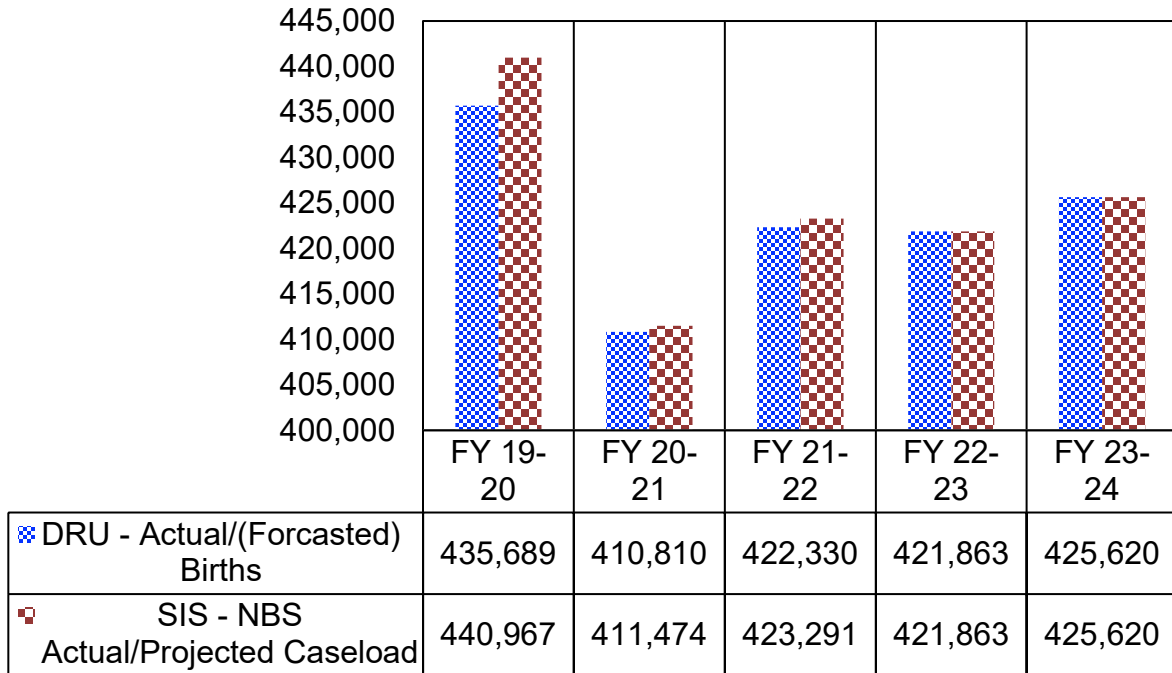
CONTRACT LABORATORIES

Overview: Laboratory testing of specimens is performed at regional screening laboratories contracted by the state to screen newborns for 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 Department of Finance (DOF)/DRU projected births will participate in the NBS program in 2022-23 and 2023-24.

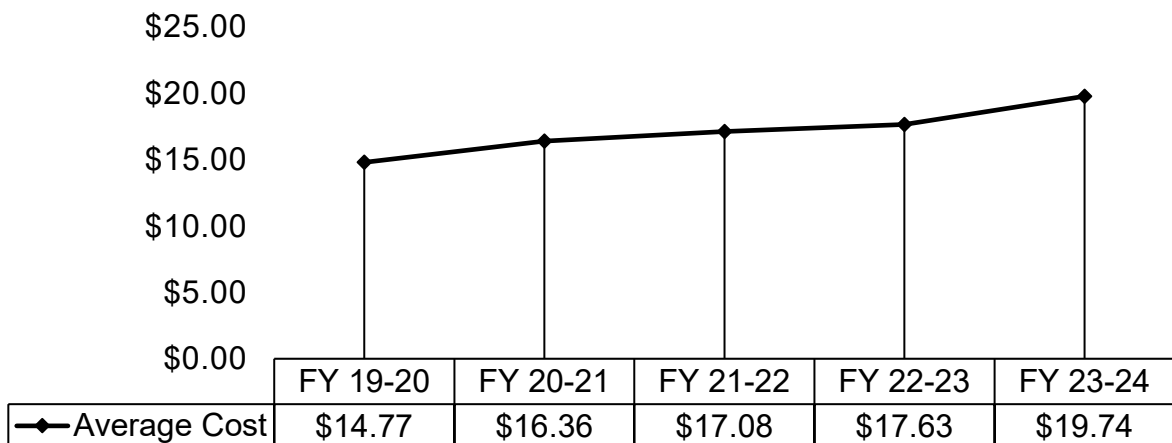
Total Caseload –CDPH/GDSP estimates current year caseload will total 421,863, a decrease of 1,428 or 0.3 percent compared to the 2021-22 actual total caseload of 423,291. Caseload in 2023-24 is estimated at 425,620, which is an increase of 3,757 or 0.9 percent compared to the current year estimate. This 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



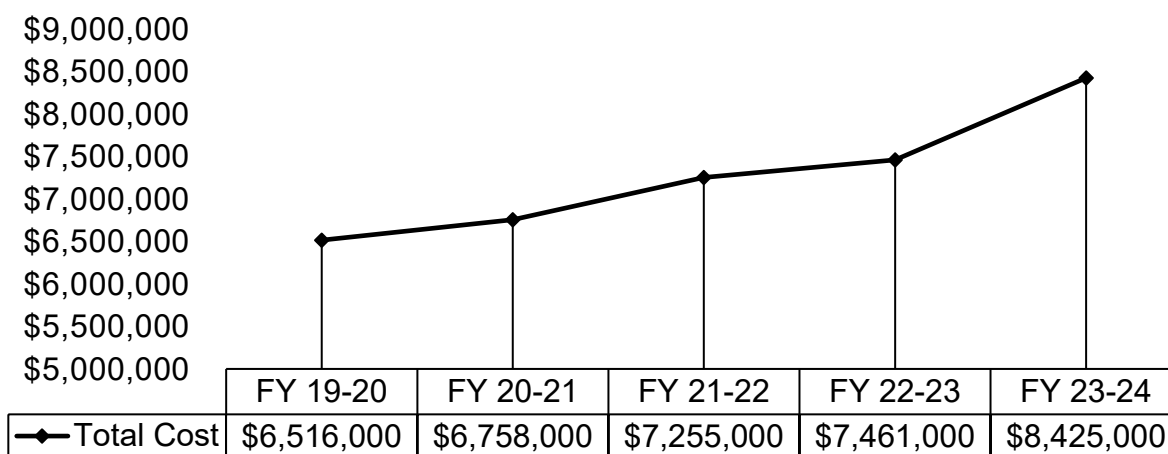
Contract Laboratory Average Cost Projections – CDPH/GDSP estimates current year average laboratory cost per participant will be \$17.63, which is an increase of \$0.55 or 3.2 percent compared to the 2021-22 actual average laboratory cost per participant of \$17.08. Average laboratory cost per participant in 2023-24 is estimated at \$19.74, which is an increase of \$2.11 or 12 percent compared to the current year estimate. The increase in cost rate is due to inflationary rate increases including higher cost-of-living and salaries paid to their staff.

NBS Contract Lab Average Cost



Contract Laboratory Total Cost Projections – CDPH/GDSP estimates current year contract laboratory costs to total \$7.5 million, which is an increase of \$206,000 or 2.8 percent compared to 2021-22 actual contract laboratory costs of \$7.3 million. 2023-24 contract laboratory costs are projected to be \$8.4 million, which is an increase of \$964,000 or 12.9 percent compared to the current year.

NBS Contract Lab Total Cost



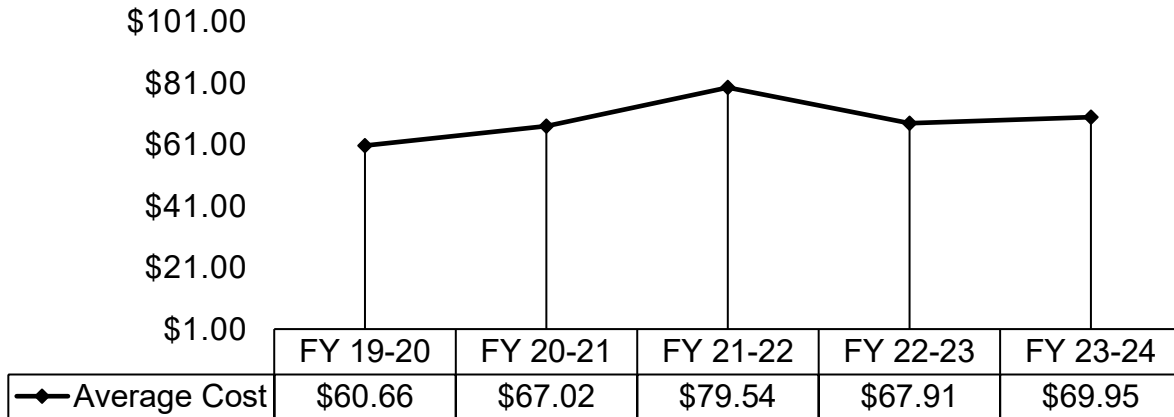
TECHNICAL AND SCIENTIFIC

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

Technical and Scientific Caseload: See Appendix A 1

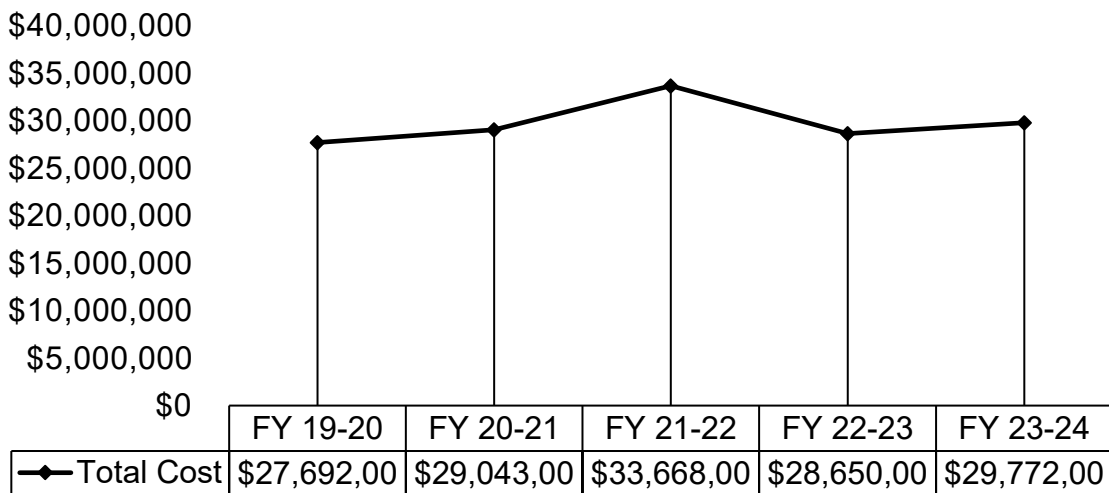
Technical and Scientific Average Cost – CDPH/GDSP estimates current year average Technical and Scientific cost per participant will be \$67.91, which is a decrease of \$11.63 or 15 percent compared to 2021-22 actual average Technical and Scientific cost per participant of \$79.54. Average Technical and Scientific cost per participant in 2023-24 is estimated at \$69.95, which is an increase of \$2.04 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 million, which is a decrease of \$5 million or 15 percent compared to 2021-22 actual technical and scientific costs of \$34 million. For 2023-24, the Technical and Scientific costs is estimated to be \$30 million, which is an increase of \$1.1 million or 4 percent compared to the current year.

NBS Tech & Sci Total Cost

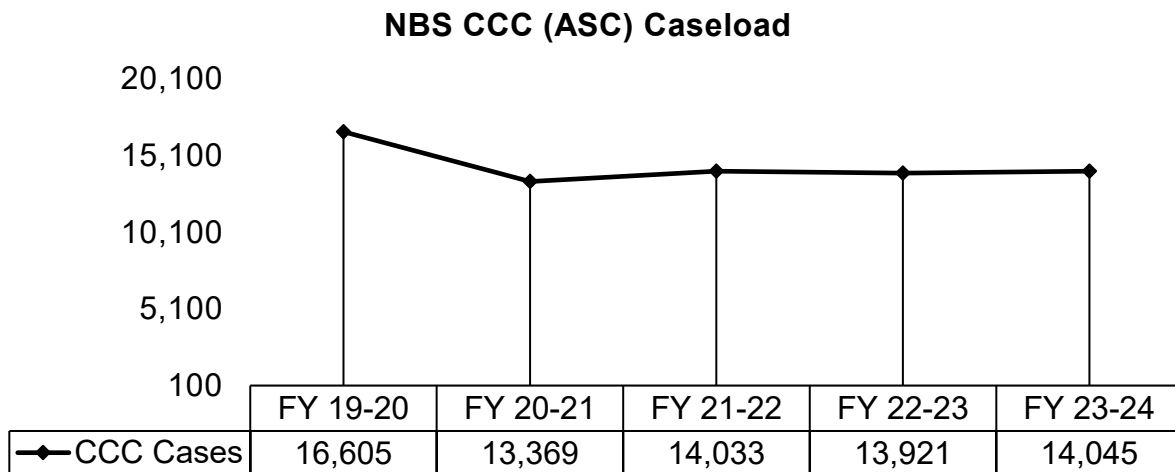


CASE MANAGEMENT AND COORDINATION SERVICES:

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

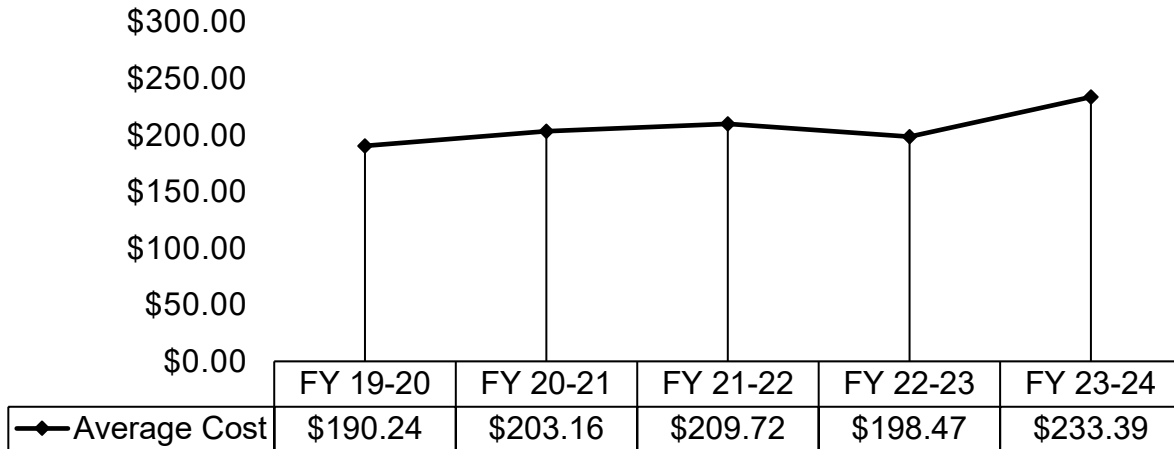
to confirm that appropriate diagnostic measures are completed, and that affected infants are provided with appropriate medical care and receive treatment within a critical timeframe. The ASCs are reimbursed based on caseload and the type of service performed along with a monthly base allocation; this 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 13,921, which is a decrease of 112 or 1 percent compared to 2021-22 actual CMCS caseload of 14,033. CMCS caseload in 2023-24 is estimated at 14,045, which is an increase of 124 or 1 percent compared to the current year estimate.



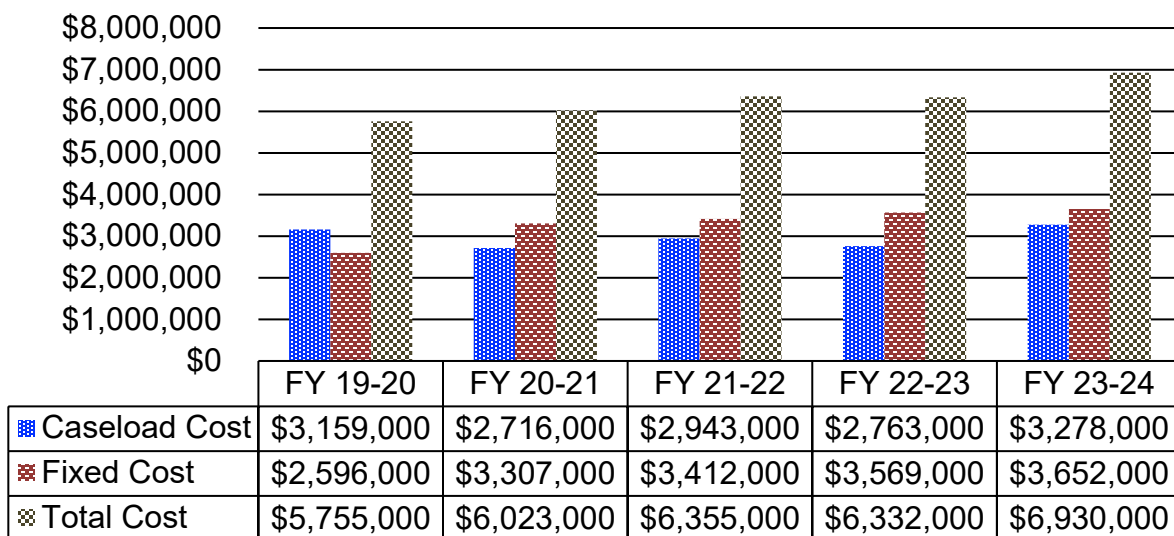
Case Management and Coordination Services (CMCS) Average Cost - CDPH/GDSP estimates current year average CMCS cost per participant will be \$198, which is a decrease of \$11 or 5 percent compared to 2021-22 actual average CMCS cost per participant of \$210. Average CMCS cost per participant in 2023-24 is estimated at \$233, which is an increase of \$35 or 18 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 \$6.3 million, which is a decrease of \$23,000 or 0.4 percent compared to 2021-22 actual CMCS total costs of \$6.4 million. CMCS costs in 2023-24 are estimated to total \$6.9 million, which is an increase of \$598,000 or 9 percent compared to the current year estimate. The decrease in current year reflects the projected decrease 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

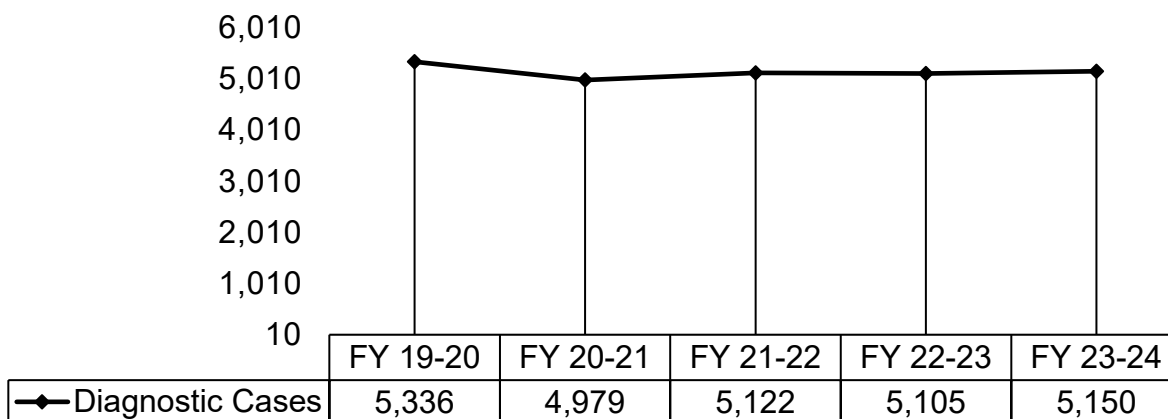


DIAGNOSTIC SERVICES

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.

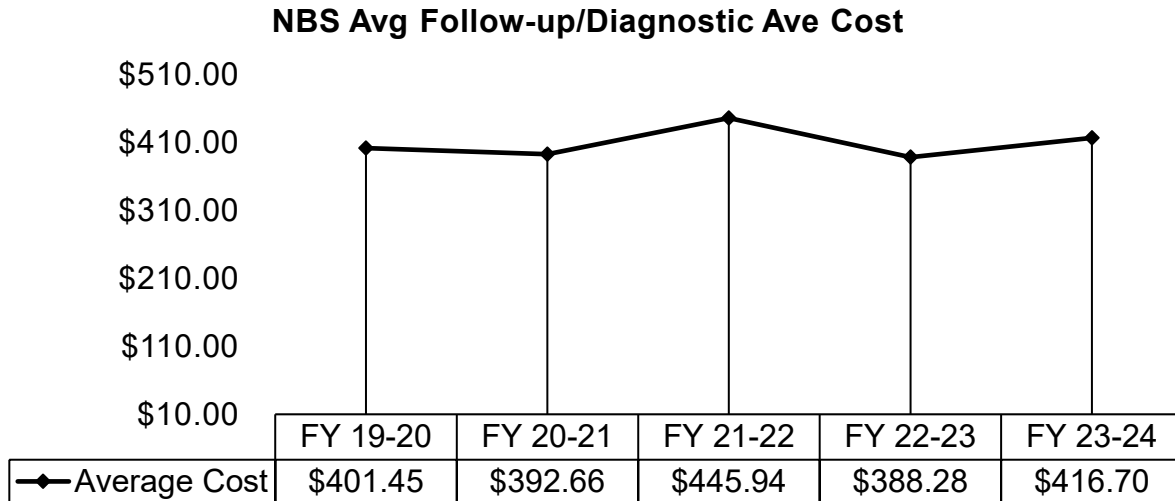
Diagnostic Services Caseload – CDPH/GDSP estimates current year Diagnostic caseload will total 5,105, based on projected new referral cases and annual patient summary cases, which is a decrease of 17 or 0.3 percent compared to 2021-22 actual Diagnostic Services caseload of 5,122. Diagnostic caseload in 2023-24 is estimated at 5,150, which is a slight increase of 45 or 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

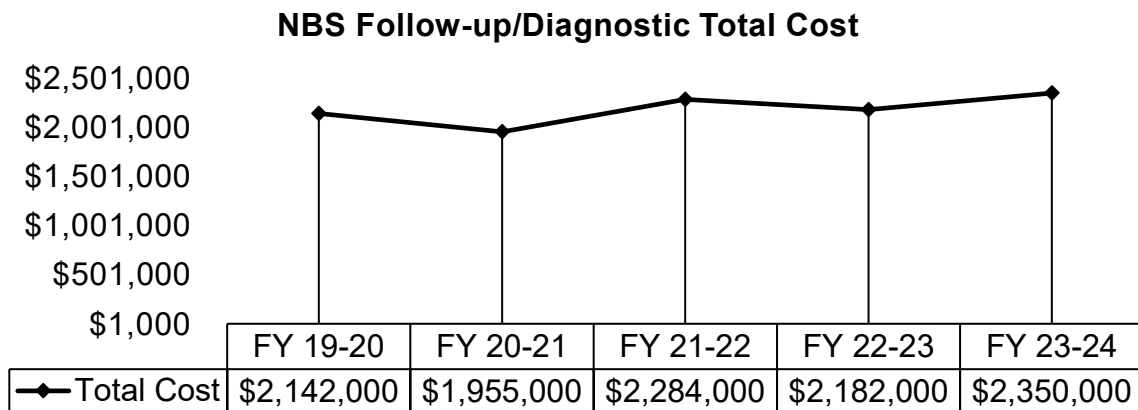


Diagnostic Services Average Cost - CDPH/GDSP estimates current year average Diagnostic Services cost per participant will be \$388, calculated based on projected new referral cases and annual patient summary cases, which is a decrease of \$58 or 13 percent compared to 2021-22 actual average Diagnostic Services cost per participant of \$446. The average Diagnostic Services cost per participant in 2023-24 are estimated at

\$417, which is also an increase of \$28 or 7 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.



Diagnostic Services Total Cost - CDPH/GDSP estimates current year Diagnostic Services costs to total \$2.2 million, which is a decrease of \$102,000 or 4 percent compared to 2021-22 actual Diagnostic Services total costs of \$2.3 million. Diagnostic Services costs in 2023-24 are estimated to total \$2.4 million, which is an increase of 168,000 or 8 percent compared to the current year estimate. The increases in total costs from the current to the budget year is attributed to caseload increases based on the projected increase in DOU’s live births.



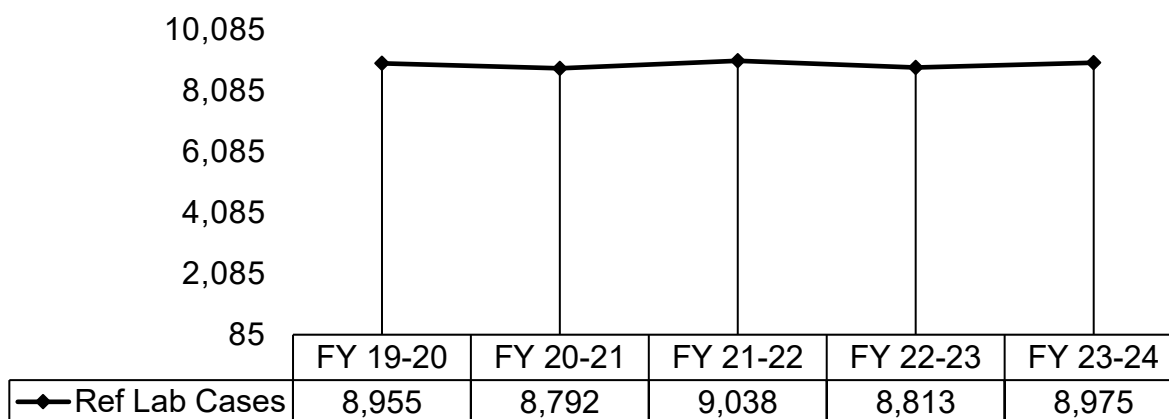
REFERENCE LABORATORIES

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.

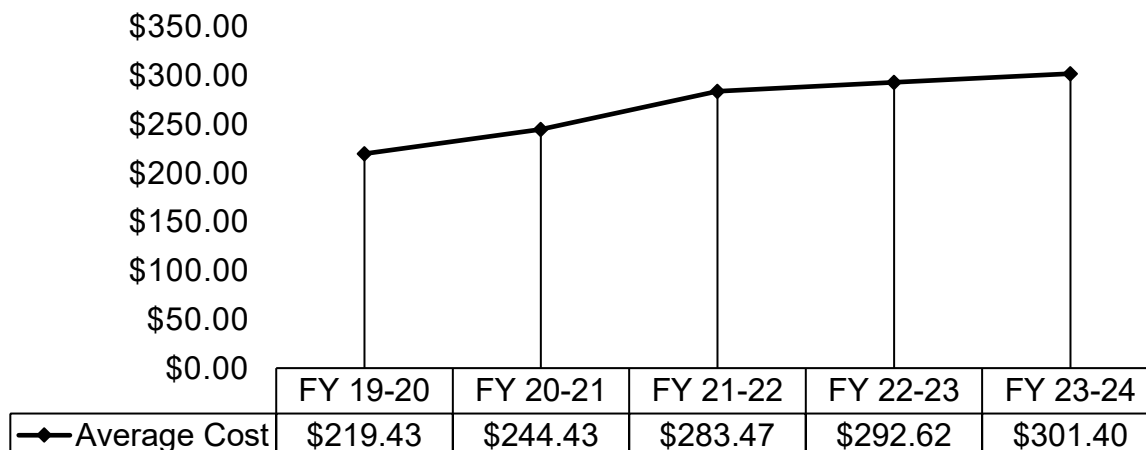
Reference Laboratory Caseload – CDPH/GDSP estimates current year Reference Laboratory caseload will total 8,813, which is a decrease of 225 or 2 percent compared to 2021-22 actual Reference Laboratory caseload of 9,038. Reference Laboratory caseload in 2023-24 is estimated at 8,975, which is a slight increase of 162 or 2 percent compared to the current year estimate.

NBS Reference Lab Caseload



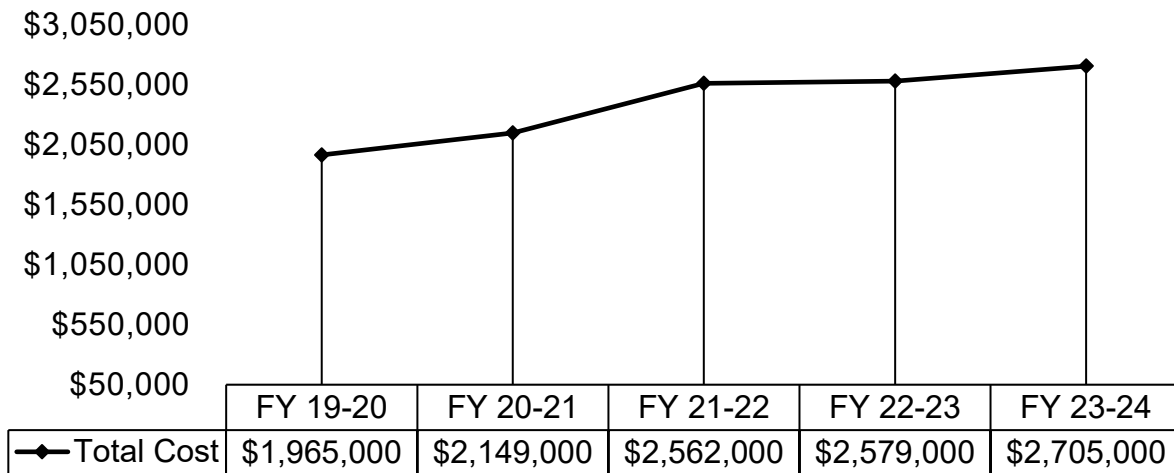
Reference Laboratory Average Cost – CDPH/GDSP estimates current year Reference Laboratory average cost per participant will be \$293, which is an increase of \$9.15 or 3 percent compared to 2021-22 Reference Laboratory actual average cost per participant of \$283.47. Reference Laboratory average cost per participant in 2023-24 is estimated at \$301, which is an increase of \$9 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 \$2.6 million, which is a slight increase of 17,000 or 1 percent compared to 2021-22 actual Diagnostic Services total costs of \$2.6 million. Reference Laboratory costs in 2023-24 are estimated to total \$2.7 million, which is an increase of 126,000 or 5 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 is 313,920. Only 1.2 percent of the projected cfDNA specimen will be referred for PDC follow up services 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	Forecast Births	PNS Projected Caseload	Average Cost	Total Cost
2022-2023	421,863	199,571	\$140	\$27,940,000
2023-2024	425,620	313,920	\$140	\$43,949,000

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.

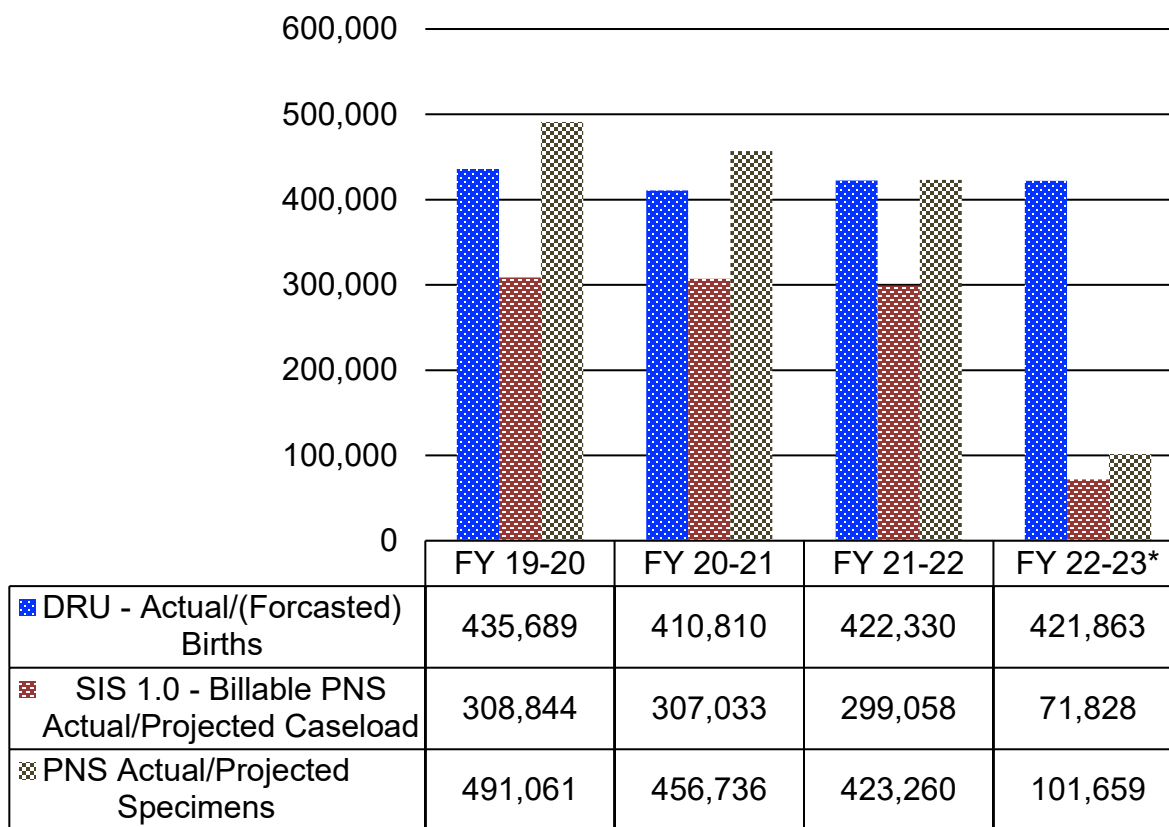
In the past CDPH/GDSP estimated the number of 1st trimester and 2nd trimester screens performed separately in the estimate. This is because the average cost of the 1st trimester screen was substantially less than the cost of the 2nd trimester screens. Currently, the regional laboratory cost of each test 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 new PNS program with one for cfDNA screening at a cfDNA laboratory and the other one for NTD screening at a NAPs laboratory for which separate contract laboratory costs will be incurred.

Total Caseload/Specimens – In the beginning of 2022-23, between July 1 and September 18, 2022, 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 is done in one NAPs laboratory processing.

CDPH/GDSP estimates current year specimens from the old PNS Biochemical Screening test (SIS 1.0) will total 101,659 actual caseloads. The lower cases in the old PNS Program is due to the fact that the caseload is only for 2.5 months (date of service from July 1, 2022, through September 18, 2022), and cases were completed in December 2022.

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

PNS Caseload/Specimens (SIS 1.0)

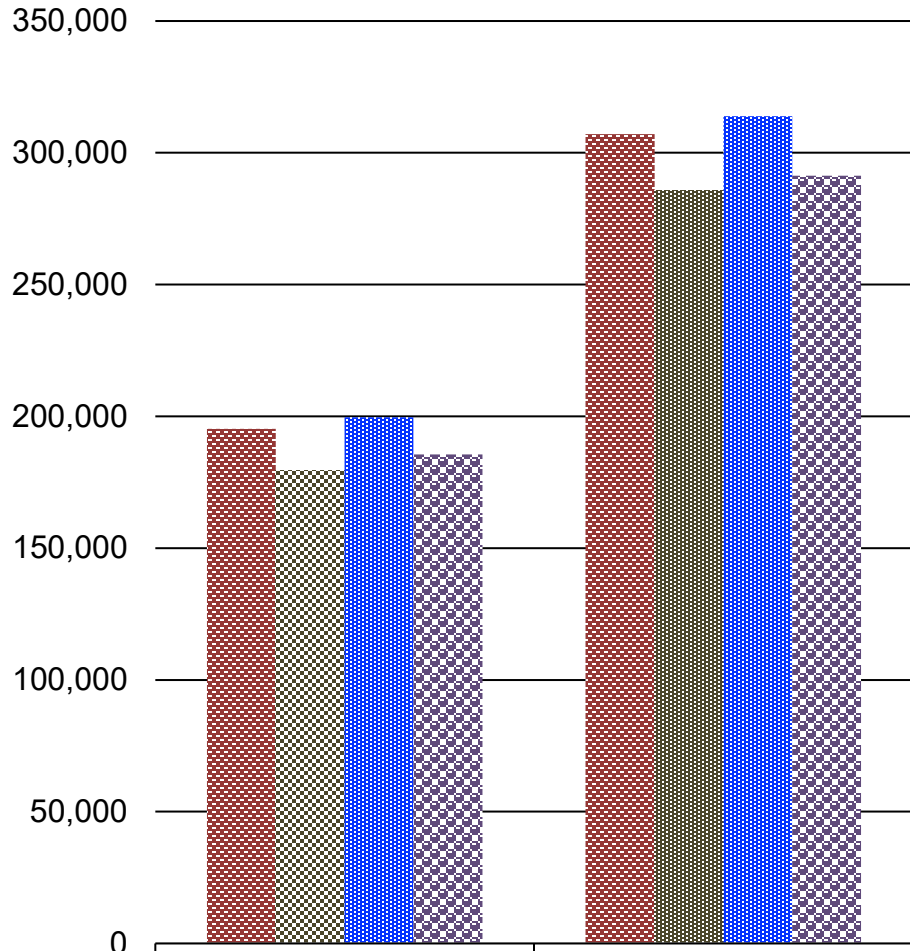


*from date of service 7/1/2022 through 9/18/2022

For the remainder of 2022-23, between September 19, 2022, and June 30, 2023, two specimens need to be collected for the new PNS Program, with one for cfDNA and the other one for NTD screening. The CDPH/GDSP estimates current year specimens from the new PNS Program (SIS 2.0) will total 199,571 for cfDNA and 185,591 for NTD. The new PNS Program specimen is estimated based on the percentage of the DOF/DRU projected number of live births, including no call low fetal fraction, and actual specimen for the date of service from September 19, 2022, through January 31, 2023.

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

PNS Caseload/Specimens (SIS 2.0)



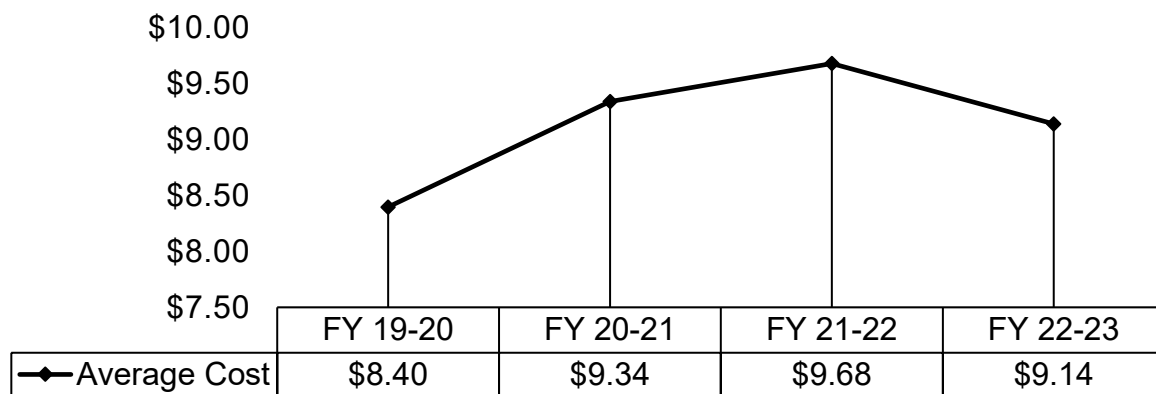
	FY 22-23*	FY 23-24
■ SIS 2.0 - Billable PNS Actual/Projected Caseload (Revenue Projection) cfDNA	195,213	307,065
■ SIS 2.0 - Billable PNS Actual/Projected Caseload (Revenue Projection) NTD	179,287	285,571
■ SIS 2.0 - Number of PNS Actual/Projected Specimens (Expenditure Projection) cfDNA	199,571	313,919
■ SIS 2.0 - Number of PNS Actual/Projected Specimens (Expenditure Projection) NTD	185,591	291,282

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

CDPH/GDSP estimates that 46 percent (based on a three-month actual average) of the projected caseload will participate in the PNS Program in 2022-23, and that the number of participants will increase to 73 percent in 2023-24.

Contract Laboratory Average Cost Projections – CDPH/GDSP estimates current year average laboratory cost per participant will be \$9.14, which is a slight decrease of \$0.54 or 6 percent compared to 2021-22 actual average laboratory cost per participant of \$9.68. In 2022-23, the decrease in the average cost from the old PNS Program is attributed to a lower-case volume for date of service from July 1 through September 18, 2022, as well as the effect of the preliminary injunction on November 2, 2022.

PNS Contract Lab Average Cost



Contract Laboratory Total Cost Projections – CDPH/GDSP estimates current year contract laboratory cost to total \$2.8 million, which is a decrease of \$1.3 million or 32 percent compared to 2021-22 actual contract laboratory costs of \$4.1 million. In 2022-23, the decrease in the total cost from the old PNS Program is attributed to a lower-case volume for date of service from July 1, 2022, through September 18, 2022, as well as the effect of the preliminary injunction on November 2, 2022.

PNS Contract Lab Total Cost

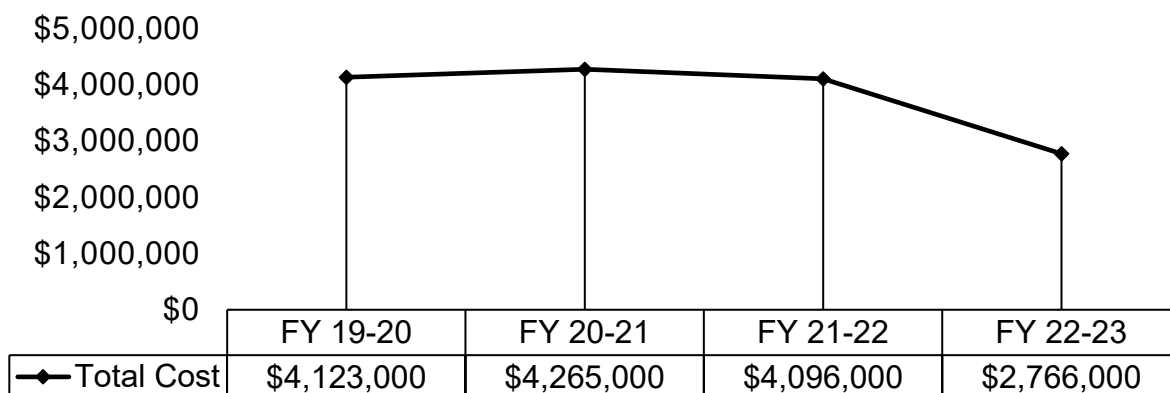


Table 16 shows the actual/projected caseload for cfDNA and NTD tests in the current and budget year beginning September 19, 2022.

Table 16. Contract Laboratory Total and Average Costs

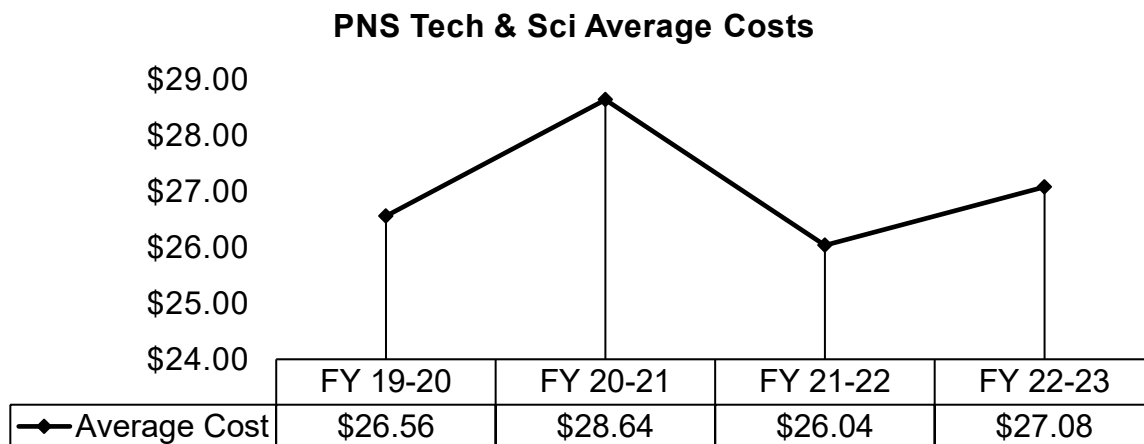
Fund 0203 Genetic Disease Testing Fund	PNS Projected Caseload	Average Cost	Total Cost
Fiscal Year 2022-2023 cfDNA	199,571	\$140.00	\$27,940,000
Fiscal Year 2023-2024 cfDNA	313,920	\$140.00	\$43,949,000
Fiscal Year 2022-2023 NTD	185,591	\$9.90	\$1,837,000
Fiscal Year 2023-2024 NTD	291,282	\$10.20	\$2,970,000

TECHNICAL AND SCIENTIFIC

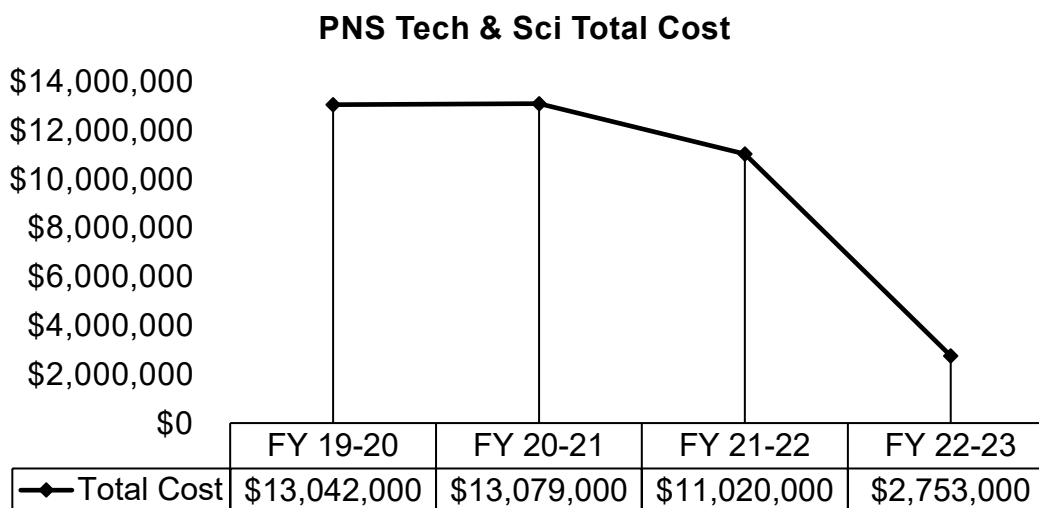
Overview - Costs associated with screening services provided at the laboratory include reagent kits, limited maintenance and support (as it directly relates to the reagents) of laboratory equipment, supplies, and processing. In addition, there are several costs associated with screening including: blood 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 average cost is attributed to the decrease in the caseload, which is driven by the total number of supplies, kits and consumables for PNS.



Technical and Scientific Total Cost – In 2022-23, CDPH/GDSP estimates current year Technical and Scientific costs to total \$2.8 million, which is a decrease of \$8.3 million or 75 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.



Since September 19, 2022, a simpler biochemical screening has been used for neural tube defects (NTD) test, for which a separate cost is incurred. In 2023-24, CDPH/GDSP estimates that the NTD costs will increase from the increasing NTD tests throughout the fiscal year.

Table 17 shows the actual/projected cases, average cost and total cost associated with technical and scientific cost for the NTD test in the current and budget year.

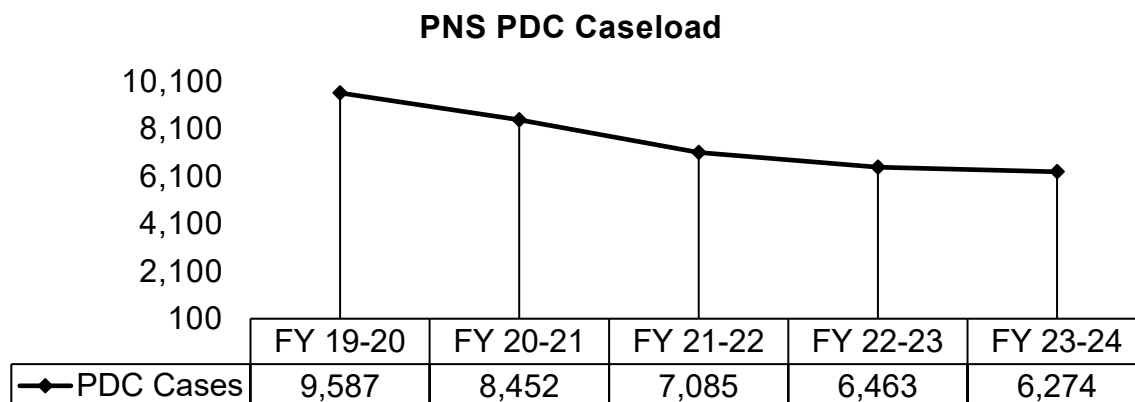
Table 17. Technical and Scientific Average and Total Costs

Fiscal Year	Total NTD	Average Cost	Total Cost
2022-2023	185,591	\$7.00	\$1,299,000
2023-2024	291,282	\$7.21	\$2,100,000

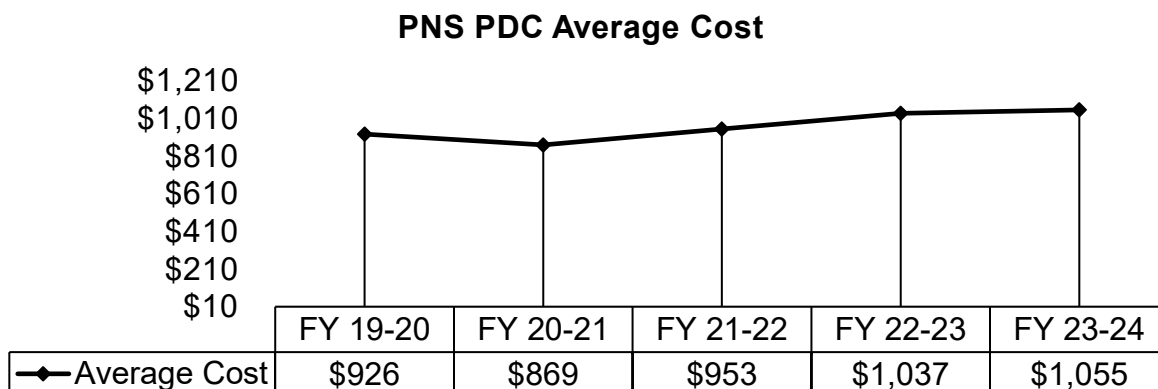
PRENATAL DIAGNOSTIC SERVICES CENTERS

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.

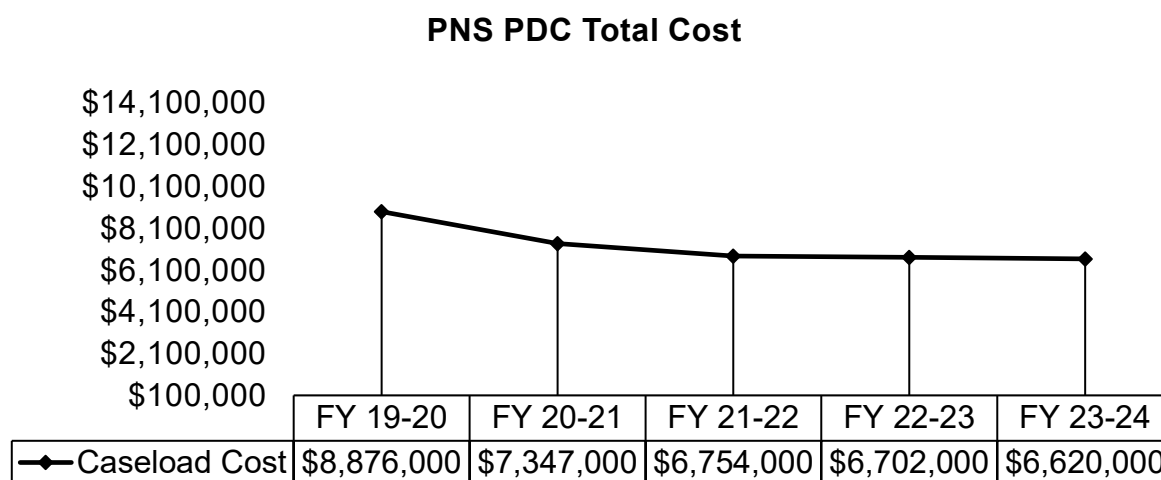
Prenatal Diagnostic Services Centers (PDC) Caseload – CDPH/GDSP estimates current year PDC caseload will total 6,463, which is a decrease of 622 or 9 percent compared to the 2021-22 actual PDC caseload of 7,085. The decrease is caused by a projected decrease in referrals. In 2023-24, CDPH/GDSP estimates the budget year PDC caseload will total 6,274, which is a decrease of 189 cases or 3 percent compared to the 2022-23 actual PDC caseload. The slight decrease is due to the projected caseload decrease from the projected participants and referrals.



Prenatal Diagnostic Services Average Cost – CDPH/GDSP estimates current year average PDC cost per participant will be \$1,037, which is an increase of \$83.72 or 9 percent compared to 2021-22 actual average PDC cost per participant of \$953.28. For 2023-24, CDPH/GDSP estimates that average PDC cost per participant will be \$1,055, which is an increase of \$18.15 or 2 percent compared to 2022-23 actual average PDC cost. The increase in average cost in the current year and the budget year is due to the 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.



Prenatal Diagnostic Services Total Cost – CDPH/GDSP estimates current year PDC costs to total \$6.7 million, which is a decrease of \$52,000 or 1 percent compared to 2021-22 actual PDC total costs of \$6.8 million. The CDPH/GDSP estimates budget year PDC costs to total \$6.6 million, which is a decrease of \$82,000 or 1 percent compared to the 2022-23 PDC total costs. The change in total expenditures is a result of changes in the types of procedures used to diagnose genetic diseases.



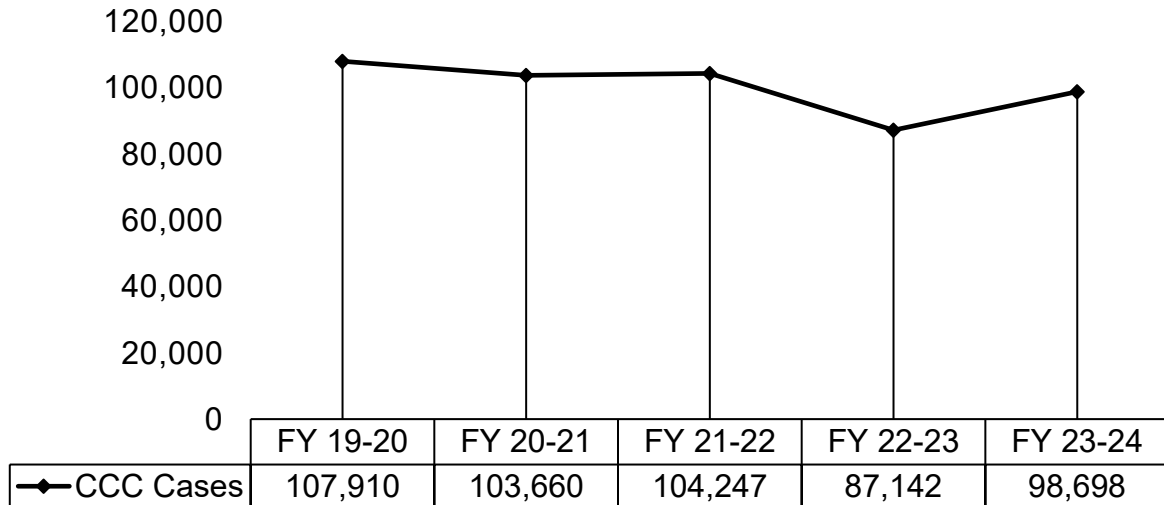
CASE MANAGEMENT AND COORDINATION SERVICES

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 87,142, which is a decrease of 17,105 or 16 percent compared to 2021-22 actual CMCS caseload of 104,247. The CDPH/GDSP estimates budget year CMCS caseload will total 98,698, which is an increase of 11,556 or 13.3 percent compared to 2022-23 CMCS caseload. The cfDNA and NTD screened positive cases will be referred to a case coordinator for which separate services will be performed.

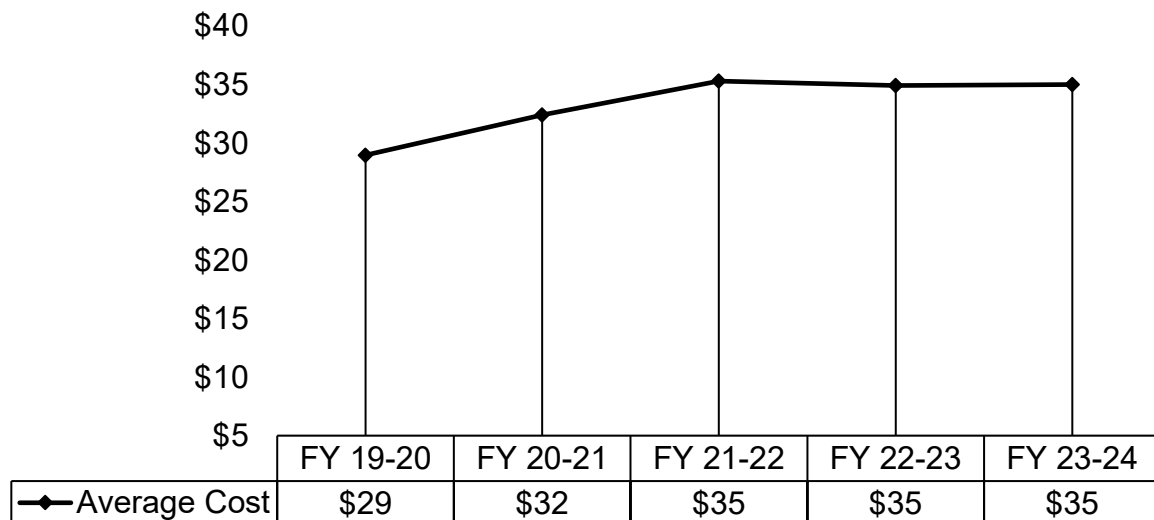
The following chart shows the actual CMCS cases by month, along with projected numbers for the remainder of the current year and budget year.

PNS Case Coordination Caseload



Case Management and Coordination Services Average Cost - CDPH/GDSP estimates current year average CMCS cost per participant will be \$34.89, which is a slight decrease of \$0.39 or 1 percent compared to 2021-22 actual average CMCS cost per participant of \$35.27. The decrease in the current year is largely attributable to the decrease in the CMCS caseload and the fixed cost. CDPH/GDSP estimates budget year average CMCS cost per participant will be \$35, which is a slight increase of \$0.10 or 0.3 percent compared to 2022-23 average CMCS cost. The increase in the budget year is attributable to the increase in the CMCS caseload and the fixed cost.

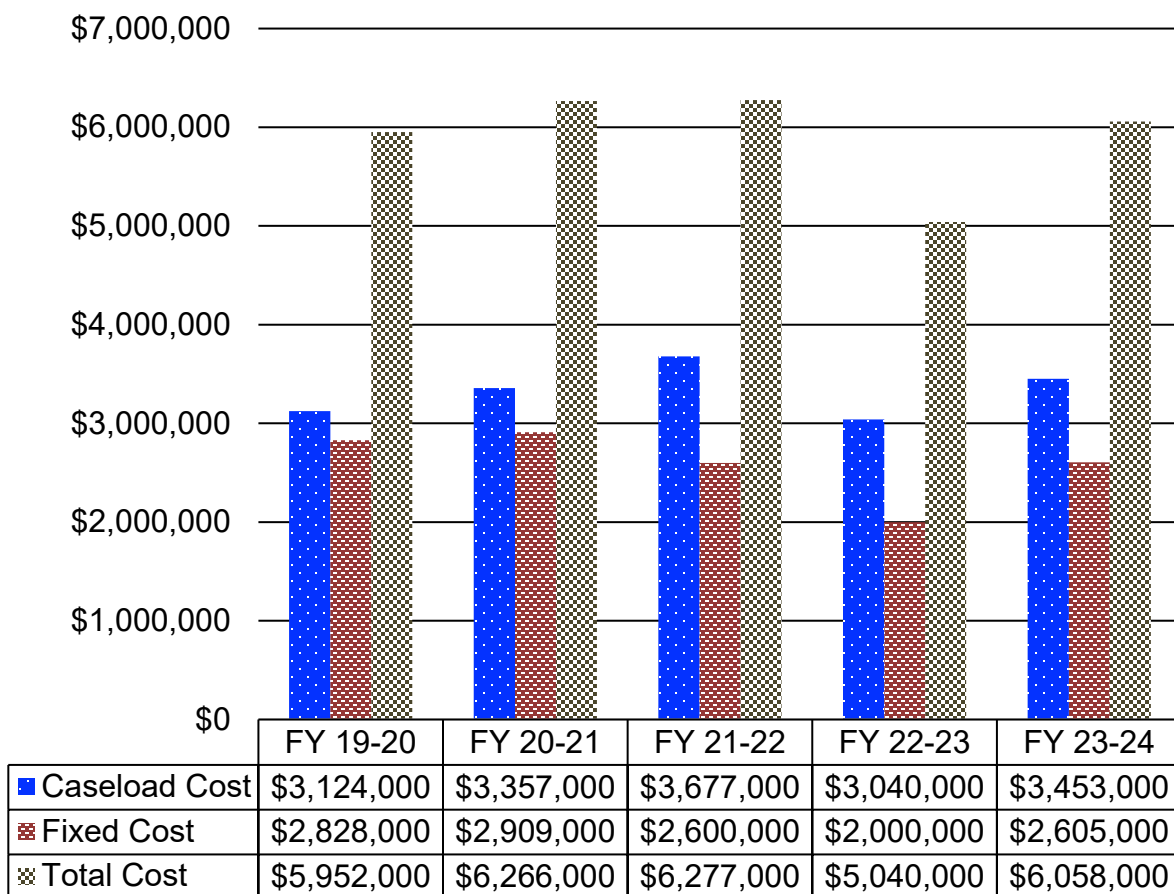
PNS Case Coordination Average Cost



Case Management and Coordination Services Total Cost - CDPH/GDSP estimates current year CMCS costs to total \$5 million, which is a decrease of \$1.2 million or 20 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 CMCS caseload and slight increase in fixed cost.

CDPH/GDSP estimates budget year CMCS costs to total \$6.1 million, which is an increase of \$1 million or 20 percent compared to the 2022-23 total costs. The increase is due to the increase in the projected caseloads and an increase in the fixed costs.

PNS Case Coordination Total Cost



APPENDIX C: REVENUE PROJECTIONS**NBS REVENUE**

The NBS Program currently charges a fee for newborn screening of \$211.00. In most cases, the fee is paid 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. 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:

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

18. 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	421,863	99 percent	\$88,123,000
FY 2023-24	\$211.00	425,620	99 percent	\$88,908,000

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 99 percent of all claims submitted to Medi-Cal, and approximately 95 percent of all claims submitted to private insurance companies and other payers. Approximately 60 percent of all PNS participants are enrolled in Medi-Cal.

PNS revenue is estimated using the following formula:

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

19. 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 2022-2023 7/1/22-9/18/22	\$211.60	71,828	60%	40%	99%	95%	43,097	28,731	\$14,804,000
FY 2022-2023 9/19/22-6/30/23	\$222.00	195,213	60%	40%	99%	95%	117,128	78,085	\$42,211,000
FY 2023-24	\$222.00	307,065	60%	40%	99%	95%	184,239	122,826	\$66,396,000

20. 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	179,287	60%	40%	99%	95%	107,572	71,715	\$13,097,000
FY 2023-24	\$75.00	285,571	60%	40%	99%	95%	171,342	114,228	\$20,861,000