

GENETIC DISEASE SCREENING PROGRAM

**2021-22
May Revision Estimate**



Tomás J. Aragón, MD, Dr.PH
Director and State Public Health Officer

California Department of Public Health

Table of Contents

I. Estimate 2

 A. Program Overview 2

 B. Combined State Operations and Local Assistance Expenditure Overview 2

 C. Local Assistance Expenditure Projections 3

 i. Current Year (2020-21) 3

 ii. Budget Year (2021-22) 3

 iii. Expenditure Methodology / Key Drivers of Cost 4

 iv. NBS Expenditure Projections (See Appendices A1-A5) 5

 v. PNS Expenditures Projections (See Appendices B1-B4) 6

 vi. Operational Support Projections 7

 D. State Operations Expenditure Projections 8

 E. Revenue Projections 8

 i. Combined NBS and PNS Revenue 8

 ii. Revenue Methodology 8

 iii. NBS Revenue (See Appendix C-1) 9

 iv. PNS Revenue (See Appendix C2) 9

II. Fund Condition Statement 11

III. General Assumptions 12

 F. Future Fiscal Issues 12

 G. New Assumptions/ Premises 12

 H. Existing (Significantly Changed) Assumptions/Premises 12

 I. Unchanged Assumptions/Premises 12

 J. Discontinued Assumptions/Premises 14

IV. Appendices Appendix A: NBS Assumptions and Rationale 15

 K. Contract Laboratories 15

 L. Technical and Scientific 18

 M. Case Management and Coordination Services (CMCS): 20

 N. Diagnostic Services: 24

 O. Reference Laboratory Cases: 28

V. APPENDIX B: PNS Program Assumptions and Rationale 31

 P. Contract Laboratories: 31

 Q. Technical and Scientific 34

 R. Prenatal Diagnostic Services Centers 36

 S. Case Management and Coordination Services: 39

VI. APPENDIX C: Revenue Projections 42

 T. NBS Revenue 42

 U. PNS Revenue 43

I. Estimate

A. Program Overview

The California Department of Public Health (CDPH), Genetic Disease Screening Program (GDSP) May Revision Estimate provides a revised projection of 2020-21 expenditures along with projected costs for 2021-22 Local Assistance and State Operations budget.

The CDPH/GDSP's 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.

B. Combined State Operations and Local Assistance Expenditure Overview

The CDPH/GDSP's 2021-22 Governor's Budget appropriation for 2020-21 was \$140.8 million, of which \$107.9 million was for Local Assistance and \$32.9 million was for State Operations. The CDPH/GDSP May Revision estimates 2020-21 expenditures will be \$140.5 million, of which \$32.9 million is for State Operations and \$107.6 million is for Local Assistance. Overall, this is a decrease of \$263,000 million or 0.19 percent compared to the 2021-22 Governor's Budget.

The CDPH/GDSP's 2021-22 Governor's Budget appropriation for 2021-22 was \$145.3 million. The CDPH/GDSP May Revision estimates 2021-22 budget expenditures will be \$145.7 million, of which \$33.3 million is for State Operations and \$112.3 million is for Local Assistance. Overall, this is an increase of \$394,000 or 0.28 percent compared to the 2021-22 Governor's Budget.

Table 1. GDSP's Governor's Budget Appropriation Compared to Revised and Proposed Expenditures for 2020-21 and 2021-22

Fund 0203 Genetic Disease Testing Fund	2020 Budget Act	2021-22 Governor's Budget	2021 May Revision	Change from Governor's Budget to May Revision	Percent Change from Governor's Budget to May Revision
Fiscal Year 2020-2021 Total	\$142,529,000	\$140,758,000	\$140,495,000	-\$263,000	-0.19%
FY20-21 State Operations	\$32,873,000	\$32,873,000	\$32,873,000	No Change	0.00%
FY20-21 Local Assistance	\$109,656,000	\$107,885,000	\$107,622,000	-\$263,000	-0.24%
Fiscal Year 2021-2022 Total	\$142,529,000	\$145,261,000	\$145,655,000	\$394,000	0.28%
FY21-22 State Operations	\$32,873,000	\$33,322,000	\$33,322,000	No Change	0.00%
FY21-22 Local Assistance	\$109,656,000	\$111,939,000	\$112,333,000	\$394,000	0.35%

Table 1 displays the difference between GDSP's 2021-22 Governor's Budget appropriation, the revised 2020-21 expenditures, and the proposed 2021-22 expenditures.

C. Local Assistance Expenditure Projections

i. Current Year (2020-21)

The 2020-21 Governor's Budget appropriation for CDPH/GDSP's Local Assistance is \$107.9 million. The CDPH/GDSP May Revision anticipates revised 2020-21 Local Assistance expenditures of \$107.6 million, which is a decrease of \$263,000 or 0.24 percent compared to the 2021-22 Governor's Budget. Although, there is a slight increase in NBS expenditures due to higher contract rates, the net overall decrease is due to the decline in caseload results based on Department of Finance's Demographic Research Unit's (DRU) projection of live births.

ii. Budget Year (2021-22)

For 2021-22, the CDPH/GDSP May Revision estimates Local Assistance expenditures will total \$112.3 million, which is an increase of \$394,000 or 0.35 percent compared to the 2021-22 Governor's Budget amount of \$111.9 million. Although caseload decreased from 2021-22 Governor's Budget levels, the projected overall expenditure increase can be entirely attributed to higher NBS contract rates associated with a Specimen Gate Laboratory Information Management System upgrade and new reagent kits that are necessary for more efficient lab instrument validation.

**Table 2. Local Assistance Total: Current Year and Budget Year Budget Summaries
Compared to 2021-22 Governor's Budget**

Fund 0203 Genetic Disease Testing Fund	2020 Budget Act	2021-22 Governor's Budget	2021 May Revision	Change from Governor's Budget to May Revision	Percent Change from Governor's Budget to May Revision
Fiscal Year 2020-2021 Local Assistance Total	\$109,656,000	\$107,885,000	\$107,622,000	-\$263,000	-0.24%
FY20-21 Newborn Screening	\$47,234,000	\$46,091,000	\$46,366,000	\$275,000	0.60%
FY20-21 Prenatal Screening	\$35,022,000	\$34,394,000	\$33,856,000	-\$538,000	-1.56%
FY20-21 Operational Support	\$27,400,000	\$27,400,000	\$27,400,000	No Change	0.00%
Fiscal Year 2021-2022 Local Assistance Total	\$109,656,000	\$111,939,000	\$112,333,000	\$394,000	0.35%
FY21-22 Newborn Screening	\$47,234,000	\$46,594,000	\$47,233,000	\$639,000	1.37%
FY21-22 Prenatal Screening	\$35,022,000	\$34,021,000	\$33,776,000	-\$245,000	-0.72%
FY21-22 Operational Support	\$27,400,000	\$31,324,000	\$31,324,000	No Change	0.00%

Table 2 displays the difference between the 2021-22 Governor's Budget appropriation, the revised 2020-21 expenditures and proposed 2021-22 expenditures for GDSP Local Assistance.

iii. 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:

NBS and PNS projected caseloads for the following:

- Total clients served
- Cases that receive case management
- Cases that are referred for diagnostic services
- Cases that are referred to reference laboratories (NBS only)

Average Case Cost for the following services:

- Contract laboratories
- Technology & Scientific supplies (Tech & Sci)
- Case Management and Coordination Services (CMCS)
- Follow-up Diagnostic Services (FDS)
- 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 clients tested x Contract laboratory average cost
 - Total clients 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 are the projections summarized for each of the cost drivers for the NBS and PNS programs. More detailed descriptions of the assumptions and rationale underlying each cost component is presented in the appendices.

iv. NBS Expenditure Projections (See Appendices A1-A5)

For 2020-21, the CDPH/GDSP estimates NBS Local Assistance expenditures will total \$46.4 million, which is a slight increase of \$275,000 or 0.60 percent compared to the 2021-22 Governor's Budget of \$46.1 million. For 2021-22, the CDPH/GDSP estimates that NBS Local Assistance expenditures will total \$47.2 million, which is an increase of \$639,000 or 1.37 percent compared to the 2021-22 Governor's Budget of \$46.6 million.

The increase in the current year and budget year is attributed to higher contract rates associated with a Specimen Gate Laboratory Information Management System upgrade and new reagent kits that are necessary for more efficient lab instrument validation.

Table 3. Newborn Screening: Current Year and Budget Year Budget Summaries Compared to 2021-22 Governor's Budget

Fund 0203 Genetic Disease Testing Fund	2020 Budget Act	2021-22 Governor's Budget	2021 May Revision	Change from Governor's Budget to May Revision	Percent Change from Governor's Budget to May Revision
Fiscal Year 2020-2021 Total	\$47,234,000	\$46,091,000	\$46,366,000	\$275,000	0.60%
FY20-21 Lab Dollars	\$7,132,000	\$7,254,000	\$7,090,000	-\$164,000	-2.26%
FY20-21 Tech & Sci	\$28,133,000	\$27,605,000	\$28,044,000	\$439,000	1.59%
FY20-21 Reference Lab	\$2,494,000	\$2,484,000	\$2,484,000	No Change	0.00%
FY20-21 CMCS	\$6,783,000	\$6,023,000	\$6,023,000	No Change	0.00%
FY20-21 Diagnostic Services	\$2,692,000	\$2,725,000	\$2,725,000	No Change	0.00%
Fiscal Year 2021-2022 Total	\$47,234,000	\$46,594,000	\$47,233,000	\$639,000	1.37%
FY21-22 Lab Dollars	\$7,132,000	\$7,468,000	\$7,386,000	-\$82,000	-1.10%
FY21-22 Tech & Sci	\$28,133,000	\$27,705,000	\$28,478,000	\$773,000	2.79%
FY21-22 Reference Lab	\$2,494,000	\$2,496,000	\$2,469,000	-\$27,000	-1.08%
FY21-22 CMCS	\$6,783,000	\$6,174,000	\$6,174,000	No Change	0.00%
FY21-22 Diagnostic Services	\$2,692,000	\$2,751,000	\$2,726,000	-\$25,000	-0.91%

Table 3 displays the 2021-22 Governor's Budget appropriation, the revised 2020-21 expenditures and proposed 2021-22 expenditures for NBS costs by client type.

v. PNS Expenditures Projections (See Appendices B1-B4)

For 2020-21, the CDPH/GDSP estimates PNS Local Assistance expenditures will total \$33.9 million, which is a decrease of \$538,000 or 1.56 percent compared to the 2021-22 Governor's Budget of \$34.4 million. For 2021-22, the CDPH/GDSP estimates PNS Local Assistance expenditures will total \$33.8 million, which is a slight decrease of \$245,000 or 0.72 percent compared to the 2021-22 Governor's Budget of \$34 million.

The net decrease in both years is due to the decline in caseload results based on the DRU's projection of live births.

Table 4. Prenatal Screening: Current Year and Budget Year Budget Summaries Compared to 2021-22 Governor's Budget

Fund 0203 Genetic Disease Testing Fund	2020 Budget Act	2021-22 Governor's Budget	2021 May Revision	Change from Governor's Budget to May Revision	Percent Change from Governor's Budget to May Revision
Fiscal Year 2020-2021 Total	\$35,022,000	\$34,394,000	\$33,856,000	-\$538,000	-1.56%
FY20-21 Contract Lab	\$4,608,000	\$4,551,000	\$4,459,000	-\$92,000	-2.02%
FY20-21 Tech & Sci	\$12,574,000	\$13,274,000	\$13,005,000	-\$269,000	-2.03%
FY20-21 CMCS	\$6,393,000	\$6,586,000	\$6,611,000	\$25,000	0.38%
FY20-21 PDC	\$11,447,000	\$9,983,000	\$9,781,000	-\$202,000	-2.02%
Fiscal Year 2021-2022 Total	\$35,022,000	\$34,021,000	\$33,776,000	-\$245,000	-0.72%
FY21-22 Contract Lab	\$4,608,000	\$4,597,000	\$4,556,000	-\$41,000	-0.89%
FY21-22 Tech & Sci	\$12,574,000	\$13,061,000	\$12,944,000	-\$117,000	-0.90%
FY21-22 CMCS	\$6,393,000	\$6,633,000	\$6,633,000	No Change	0.00%
FY21-22 PDC	\$11,447,000	\$9,730,000	\$9,643,000	-\$87,000	-0.89%

Table 4 shows the 2021-22 Governor's Budget appropriation, the revised 2020-21 expenditures and proposed 2021-22 expenditures for PNS program costs by client type.

vi. Operational Support Projections

For 2020-21, the CDPH/GDSP's revised operational support expenditures total is \$27.4 million which is no change compared to the 2021-22 Governor's Budget.

For 2021-22, the CDPH/GDSP projects operational support expenditures will total \$31.3 million, which is no change compared to the 2021-22 Governor's Budget.

Table 5. Operational Support: Current Year and Budget Year Budget Summaries Compared to 2021-22 Governor's Budget

Fund 0203 Genetic Disease Testing Fund	2020 Budget Act	2021-22 Governor's Budget	2021 May Revision	Change from Governor's Budget to May Revision	Percent Change from Governor's Budget to May Revision
Fiscal Year 2020-2021 Operational Support	\$27,400,000	\$27,400,000	\$27,400,000	No Change	0.00%
Fiscal Year 2021-2022 Operational Support	\$27,400,000	\$31,324,000	\$31,324,000	No Change	0.00%

Table 5 displays the difference between the 2021-22 Governor's Budget appropriation, the revised 2020-21 expenditures and proposed 2021-22 expenditures for Operational Support costs.

D. State Operations Expenditure Projections

For 2020-21, the CDPH/GDSP estimates State Operations expenditures will total \$32.9 million, which is no change from the 2021-22 Governor's Budget.

For 2021-22, the CDPH/GDSP estimates State Operations expenditures will total \$33.3 million, which is no change compared to the 2021-22 Governor's Budget.

Table 6. State Operations: Current Year and Budget Year Budget Summaries Compared to 2021-22 Governor's Budget

Fund 0203 Genetic Disease Testing Fund	2020 Budget Act	2021-22 Governor's Budget	2021 May Revision	Change from Governor's Budget to May Revision	Percent Change from Governor's Budget to May Revision
Fiscal Year 2020-2021 State Operations	\$32,873,000	\$32,873,000	\$32,873,000	No Change	0.00%
Fiscal Year 2021-2022 State Operations	\$33,322,000	\$33,322,000	No Change	0.00%	\$33,322,000

Table 6 displays the difference between the 2021-22 Governor's Budget appropriation, the revised 2020-21 expenditures and proposed 2021-22 expenditures for GDSP State Operations costs.

E. Revenue Projections**i. Combined NBS and PNS Revenue**

The CDPH/GDSP has revised revenue estimates for 2020-21 totaling \$138.7 million, which is a decrease of \$3.3 million or 2.34 percent compared to the 2021-22 Governor's Budget amount of \$142 million. For 2021-22, the CDPH/GDSP projects revenue will total \$140.8 million, which is a decrease of \$1.7 million or 1.21 percent compared to the 2021-22 Governor's Budget amount of \$142.5 million.

The May Revision Estimate projects the 2020-21 NBS caseload at 434,178, which is a decrease of 10,056 cases or 2.26 percent compared to the 2021-22 Governor's Budget caseload projection of 444,234. For 2021-22, the May Revision Estimate projects the NBS caseload at 440,910, which is a decrease of 4,930 cases or 1.11 percent compared to the 2021-22 Governor's Budget caseload projection of 445,840.

The May Revision Estimate projects the 2020-21 PNS caseload at 307,180, which is a decrease of 7,658 cases or 2.43 percent compared to the 2021-22 Governor's Budget caseload projection of 314,838 cases. For 2021-22, the May Revision Estimate projects the PNS caseload at 311,510, which is a decrease of 4,210 cases or 1.33 percent compared to the 2021-22 Governor's Budget caseload projection of 315,720 cases.

ii. Revenue Methodology

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

The PNS program charges a fee of \$221.60, of which \$211.60 is deposited into the Genetic Disease Testing Fund (GDTF) (Fund 0203). The remaining \$10 is deposited into the Birth Defects Monitoring Program Fund (Fund 3114).

The CDPH/GDSP invoices and collects PNS payments from individual participants, private insurers, and Medi-Cal. Within a two-year collection period, the CDPH/GDSP has been able to collect approximately 98 percent of all fees owed on behalf of Medi-Cal clients (which is approximately 55 percent of the total caseload) and approximately 94 percent of the fees owed by individuals with private insurances. The CDPH/GDSP uses the following formula to estimate revenue generated from PNS fees:

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

The NBS program charges a fee of \$177.25. Unlike PNS, where the CDPH/GDSP bills patients and collects fees from insurers, the 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. The CDPH/GDSP uses the following formula to estimate revenue generated from NBS fees:

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

iii. NBS Revenue (See Appendix C-1)

In 2020-21, NBS revenue is expected to total \$76.2 million, which is a decrease of \$1.8 million or 2.26 percent from the 2020-21 Governor's Budget amount of \$78 million.

In 2021-22, the CDPH/GDSP projects NBS revenue will total \$77.4 million, which is a decrease of over \$800,000 or 1.11 percent compared to the 2021-22 Governor's Budget of \$78.2 million.

The decreases in both current year and budget year are due to the lower projected billable caseload.

iv. PNS Revenue (See Appendix C2)

In 2020-21, PNS revenue is expected to total \$62.5 million, which is a decrease of \$1.6 million or 2.43 percent compared to the 2021-22 Governor's Budget amount of \$64.1 million.

In 2021-22, the CDPH/GDSP projects PNS revenue will total \$63.4 million, which is a decrease of \$857,000 or 1.33 percent compared to the 2021-22 Governor's Budget of

\$64.3 million.

The decreases in both current year and budget year are due to the lower projected billable caseload.

Table 7. Genetic Disease Screening Program Revenue: Current Year and Budget Year Revenue Summaries Compared to 2021-22 Governor's Budget

Fund 0203 Genetic Disease Testing Fund	2020 Budget Act	2021-22 Governor's Budget	2021 May Revision	Change from Governor's Budget to May Revision	Percent Change from Governor's Budget to May Revision
Fiscal Year 2020-2021 Total	\$142,698,000	\$142,041,000	\$138,718,000	-\$3,323,000	-2.34%
FY20-21 Newborn Screening	\$79,025,000	\$77,953,000	\$76,189,000	-\$1,764,000	-2.26%
FY20-21 Prenatal Screening	\$63,673,000	\$64,088,000	\$62,529,000	-\$1,559,000	-2.43%
Fiscal Year 2021-2022 Total	\$142,698,000	\$142,503,000	\$140,781,000	-\$1,722,000	-1.21%
FY21-22 Newborn Screening	\$79,025,000	\$78,235,000	\$77,370,000	-\$865,000	-1.11%
FY21-22 Prenatal Screening	\$63,673,000	\$64,268,000	\$63,411,000	-\$857,000	-1.33%

Table 7 displays the revised current year revenue projections for current year and budget year compared to 2020-21 Governor's Budget

II. 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	2019-2020	2020-2021	2021-2022
BEGINNING BALANCE	\$30,775	\$21,133	\$13,850
Prior Year Adjustment	-566	0	0
Adjusted Beginning Balance	30,209	21,133	13,850

Table 9. REVENUES

REVENUES	2019-2020	2020-2021	2021-2022
121100 Genetic Disease Testing Fees	537	451	451
150300 Income from Surplus Investments	82	1	1
161000 Escheat of Unclaimed Checks & Warrants	126,148	139,170	141,233
TOTALS, REVENUES	125,529	138,718	140,781

Table 10. TOTAL RESOURCES

TOTAL RESOURCES	2019-20	2020-2021	2021-22
Adjusted Beginning Balance	30,209	21,133	13,850
TOTALS, REVENUES	125,529	138,718	140,781
TOTAL RESOURCES	\$156,357	\$160,303	\$155,083

Table 11. EXPENDITURES AND EXPENDITURE ADJUSTMENTS

EXPENDITURES AND EXPENDITURE ADJUSTMENTS	2019-2020	2020-2021	2021-2022
4265 Department of Public Health (State Operations)	31,945	32,873	33,322
4265 Department of Public Health (Local Assistance)	101,749	107,622	112,333
8880 Financial Information System for California (State Operations)	-4	0	0
9800 Employee Compensation (State Operations)	0	957	957
Control Section 3.60 Retirement	0	233	233
Lease Revenue Debt Service Adjustment	0	4	4
Supplemental Pension Payments (State Operations) [9892]	496	496	496
Statewide General Admin Exp (ProRata) (State Operations) [9900]	1,038	1,268	1,268
Loan Transfer to Other Funds [9920]	0	3,000	0
TOTAL EXPENDITURES AND EXPENDITURE ADJUSTMENTS	135,224	146,453	148,613
FUND BALANCE	21,133	13,850	6,470
Fund Balance as a Percentage of Total Expenditures and Expenditure Adjustments	16%	9%	4%

Table 12. GDSP REVENUE PROJECTION 2020-2021 of \$138,718,000

Number of Tests	Cost	Collection Rate	Revenue
434,178 NBS	\$177.25	Providers: 99%	\$76,189,000
138,231 PNS	\$211.60	Non Medi-Cal: 94%	\$27,495,000
168,949 PNS	\$211.60	Medi-Cal: 98%	\$35,034,000

Table 13. GDSP REVENUE PROJECTION 2021-2022 of \$140,781,000

Number of Tests	Cost	Collection Rate	Revenue
440,910 NBS	\$177.25	Providers: 99%	\$77,370,000
140,180 PNS	\$211.60	Non Medi-Cal: 94%	\$27,495,000
171,331 PNS	\$211.60	Medi-Cal: 98%	\$35,034,000

III. General Assumptions

F. Future Fiscal Issues

Senate Bill (SB) 1095: Newborn Screening Program

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

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

Discretionary?: No

Reason for Adjustment/ Change: Passage of SB 1095 requires CDPH/GDSP to expand statewide screening of newborns to include screening for any disease that is detectable in blood samples within two years of the disease being adopted by the federal RUSP.

Fiscal Impact (Range) and Fund Source(s): Expenditures may increase by approximately \$2 million to \$4 million per year for any new disorder adopted by the RUSP. This range is only an estimate and is based on costs from the last three additions to the Newborn Screening panel – Spinal Muscular Atrophy (SMA), Mucopolysaccharidosis Type 1 (MPS-I) and Pompe disease. Furthermore, as additional diseases are added to the RUSP, there may one-time resources needed to plan, prepare for, and implement the additional required screening. Public Health/GDSP will assess the fund reserve to ensure the program is able to absorb the increase in expenditures and determine if, and when, a fee increase is needed. The fund source is the Genetic Disease Testing Fund (Fund 0203).

G. New Assumptions/ Premises

There are no New Assumptions/Premises

H. Existing (Significantly Changed) Assumptions/Premises

There are no Existing (Significantly Changed) Assumptions/Premises.

I. Unchanged Assumptions/Premises

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

Background: A new screening methodology has been developed and over time has demonstrated improved performance for prenatal screening. It is called “Cell-free DNA”

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

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

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

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

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

Discretionary?: Yes

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

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

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

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

\$449,000 increase in State Operations expenditure in 2021-22 and ongoing. A one-time Local Assistance expenditure increase of \$3.9 million in 2021-22 and a \$20.2 million Local Assistance expenditure increase in 2022-23 and ongoing.

As part of the plans to improve the PNS program and ensure appropriate fees are charged to support the program and its new screening activities, a change in the fee structure will be necessary beginning 2022-23 (current revenue levels are sufficient to offset expenditure increases only through the end of 2021-22). Beginning July 2022, CDPH will charge a fee of \$221.60 for cfDNA, which is the same amount that is charged for the current PNS biochemical screening. However, the NTD screening test in the second trimester, which is currently included in the PNS biochemical screening fees, will now require a new separate fee of \$75 and will be established through the rulemaking process. These fee structure changes will generate sufficient ongoing revenue to offset the additional laboratory screening costs.

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

J. Discontinued Assumptions/Premises

Newborn Screening Fee Increase

Why is Change Needed/ Reason for Adjustment: The NBS fee increase of \$35 was implemented on July 1, 2020. The new NBS fee is \$176.25

Accounts Receivables (AR) Collection Rate Change for PNS and NBS

Why is Change Needed/ Reason for Adjustment: Collection rates of 94 percent for PNS non-Medi-Cal patients, 98 percent for PNS Medi-Cal patients, and 99 percent for Client billing are now being used to reflect accurate revenue figures.

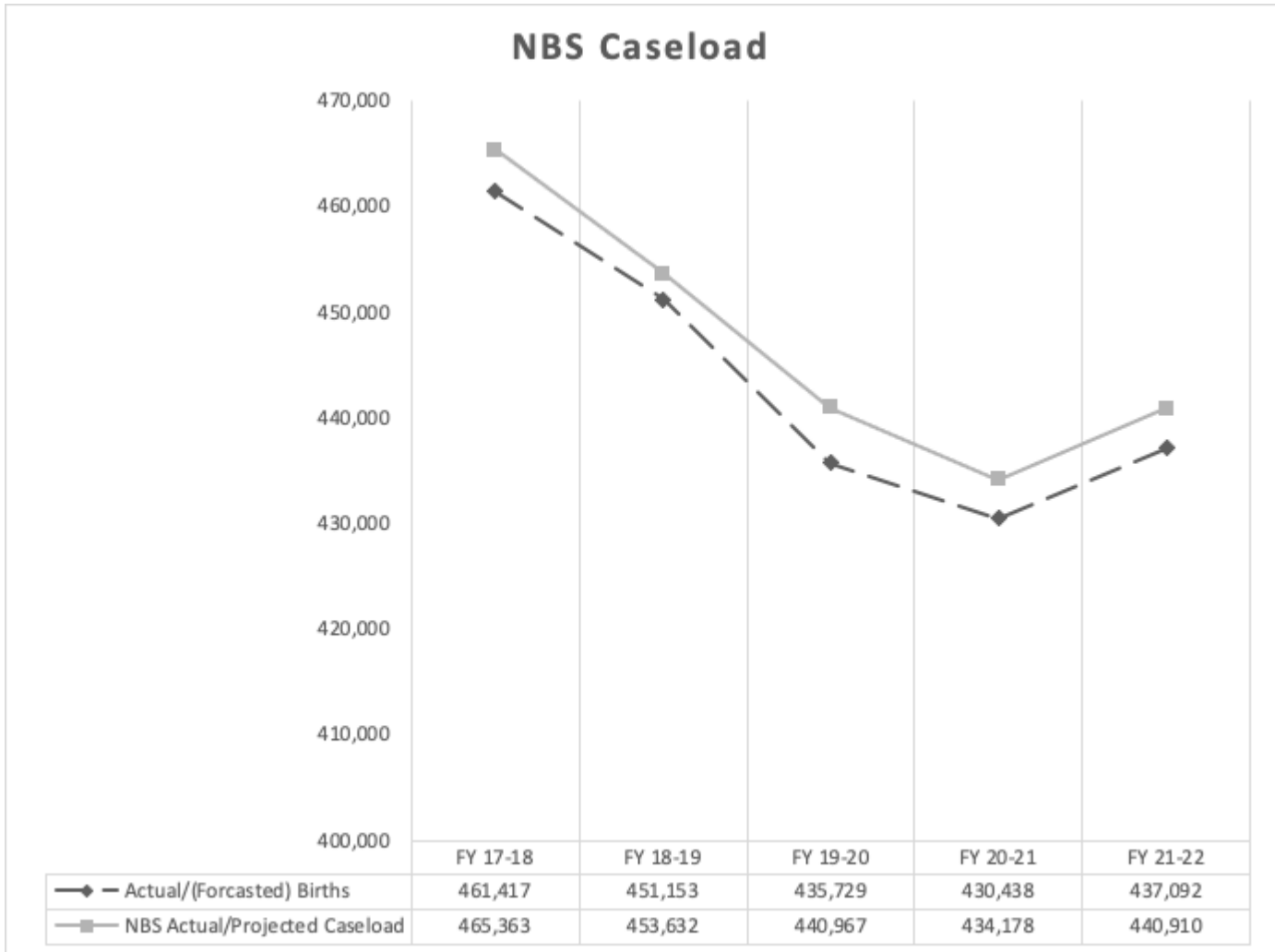
IV. Appendices Appendix A: NBS Assumptions and Rationale

K. Contract Laboratories

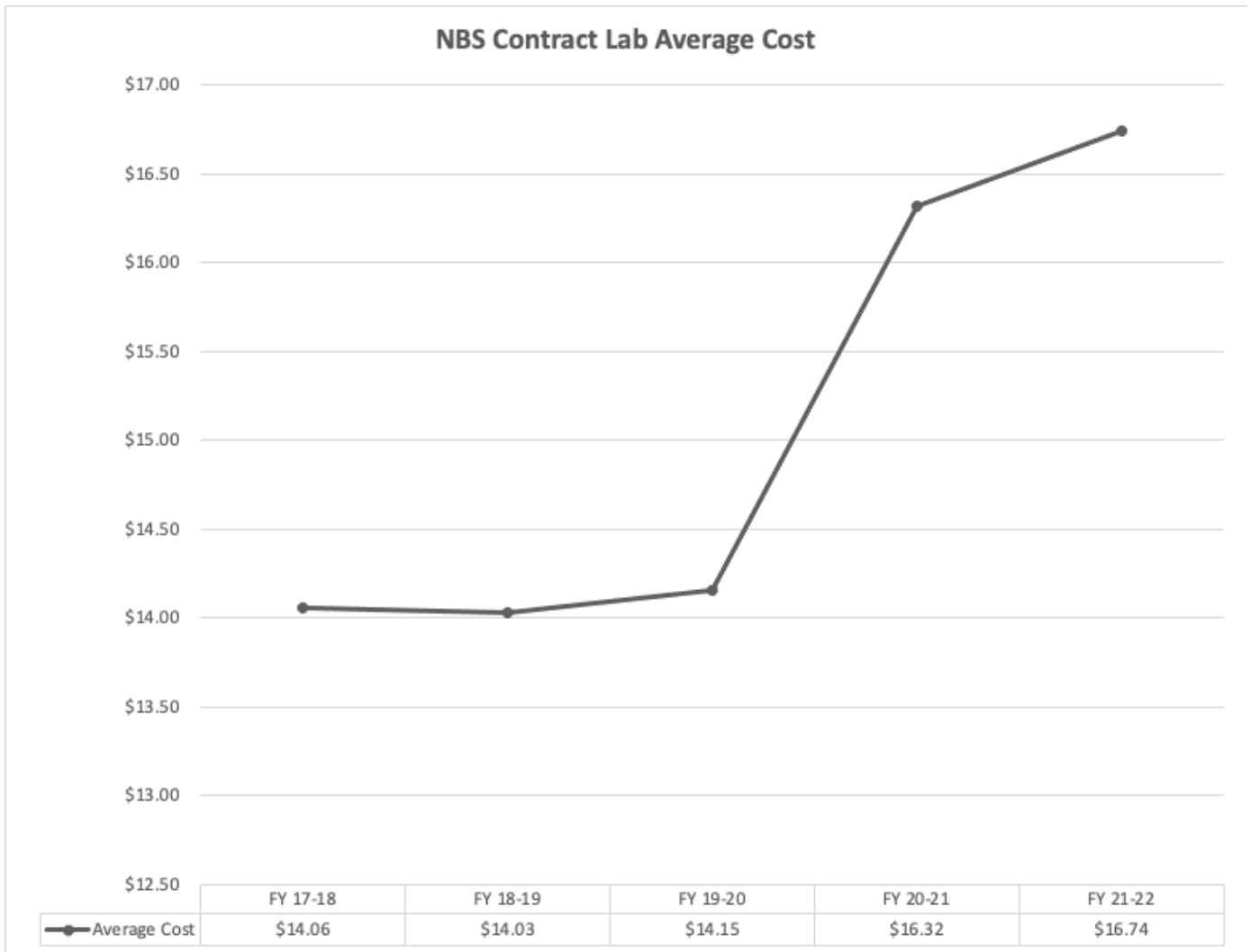
Overview: Laboratory testing of specimens is performed at regional screening laboratories contracted by the state to screen newborns for at least 75 specific genetic disorders. Costs include laboratory services for processing genetic screening tests. Screening laboratories ascertain the possible presence 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 laboratories that are paid on a per specimen basis.

Costs associated with contracted laboratories and technical and scientific supplies are both driven by the total number of clients the NBS program 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 DRU's projected births will participate in the NBS program in 2020-21 and 2021-22.

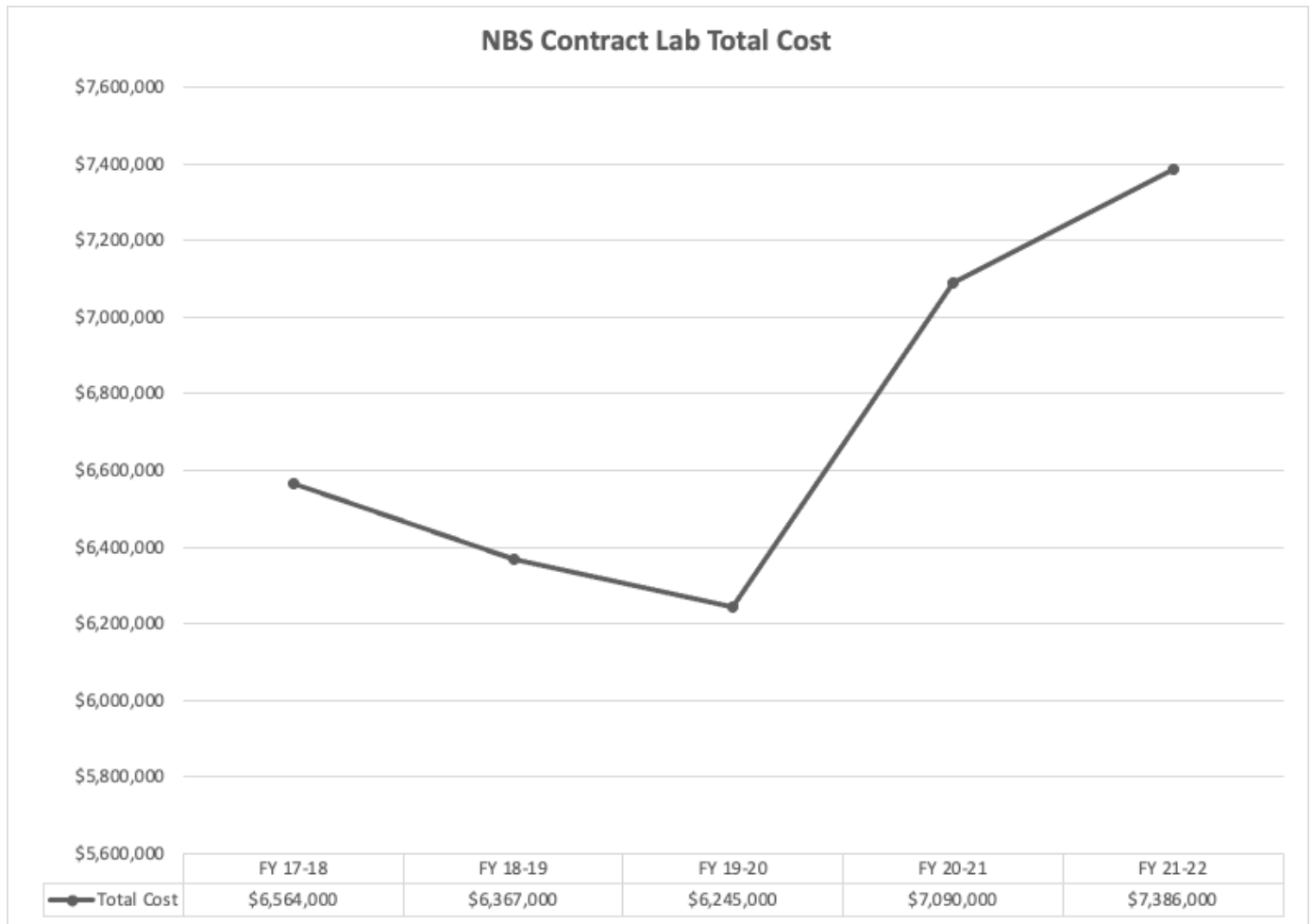
Total Caseload – The CDPH/GDSP estimates current year caseload will total 434,178, a decrease of 6,789 or 1.5 percent compared to the 2019-20 actual total caseload of 440,967. Caseload in 2021-22 is estimated at 440,910, which is an increase of 6,732 or 1.6 percent compared to the current year estimate. This year-over-year change is due to DRU's projected number of live births. The CDPH/GDSP assumes that up to 99 percent of births will participate in the NBS program each year. The following chart shows the actual NBS cases by month along with projected numbers for the remainder of the current year and budget year.



Contract Laboratory Average Cost Projections – The CDPH/GDSP estimates current year average laboratory costs per participant will be \$16.32, which is an increase of \$2.17 or 15.3 percent compared to the 2019-20 actual average laboratory cost per participant of \$14.15. The Average laboratory cost per participant in 2021-22 is estimated at \$16.74, which is an increase of 42 cents or 2.6 percent compared to the current year estimate. The increase in the current year and the budget year is due to the increased costs of the laboratory contracts.



Contract Laboratory Total Cost Projections – The CDPH/GDSP estimates current year contract laboratory costs to total \$7.1 million which is an increase of \$845,000 or 13.5 percent compared to 2019-20 actual contract laboratory costs of \$6.2 million. The 2021-22 contract laboratory costs are projected to be \$7.4 million, which is an increase of \$296,000 or 4.2 percent compared to the current year.



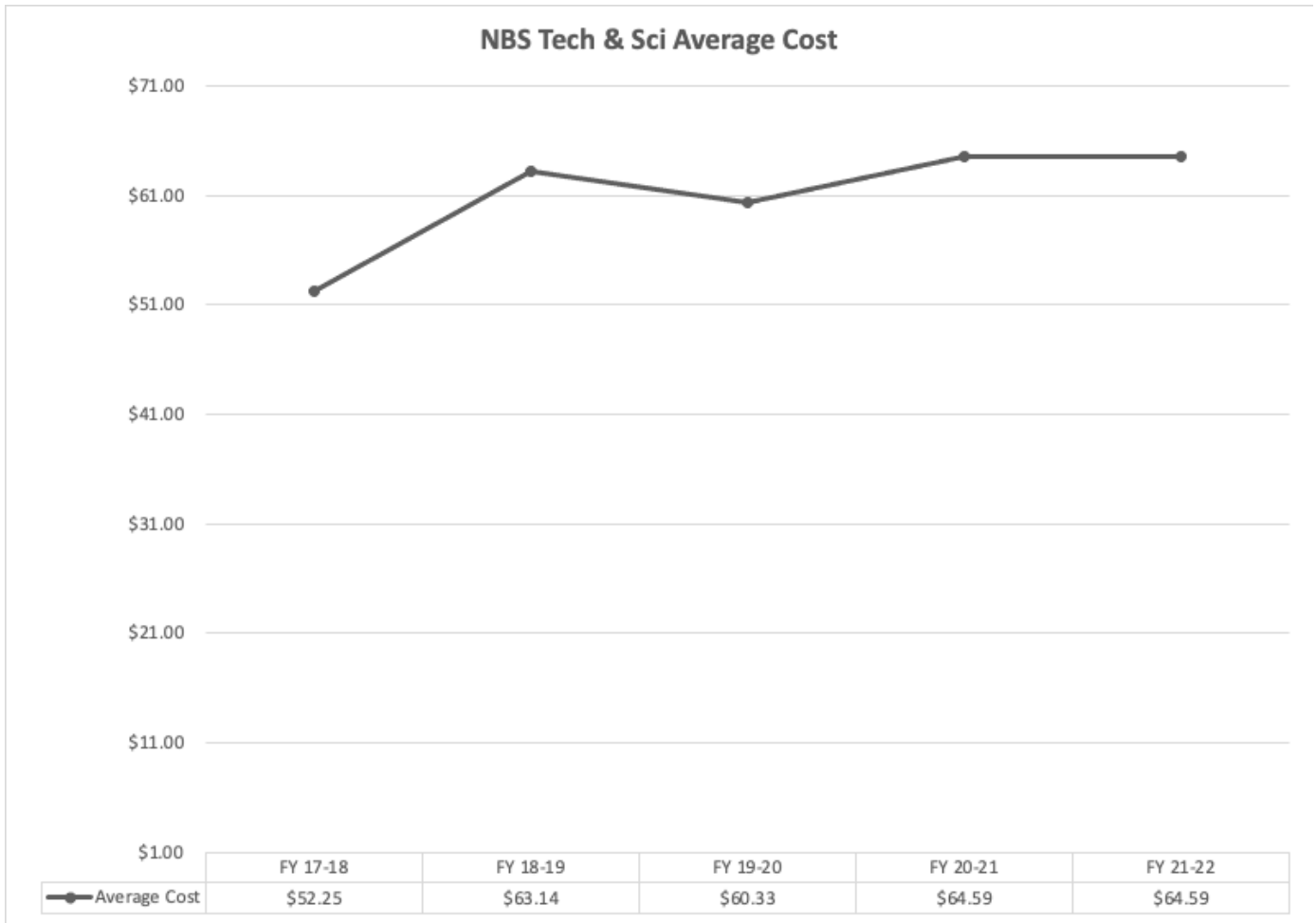
L. Technical and Scientific

Overview: Costs associated with specimen screening include reagents kits, supplies, processing and limited maintenance and support (as it directly relates to the reagents) of laboratory equipment that is with the contract laboratories. 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 kits, which are 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.

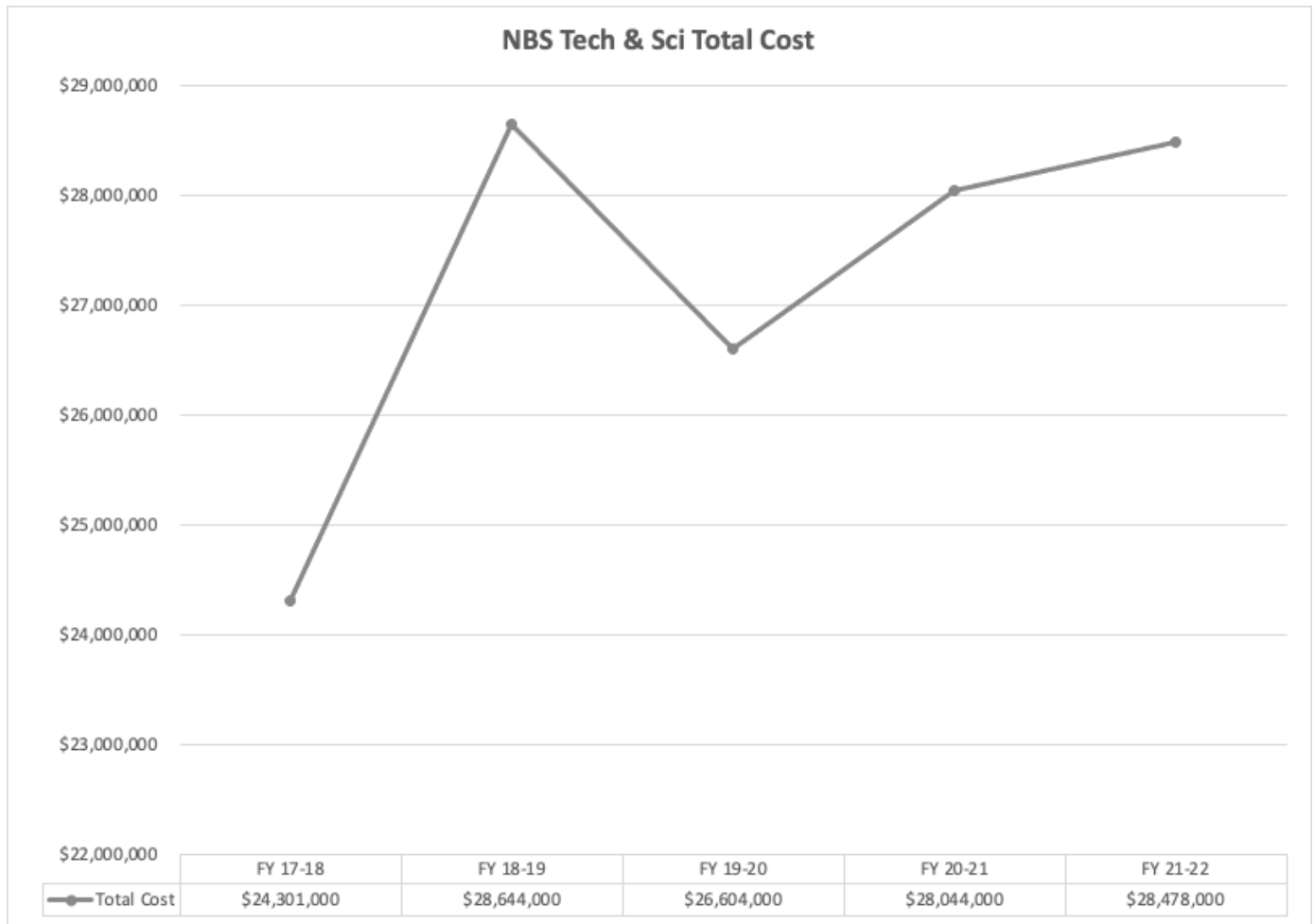
Technical and Scientific Caseload: See Appendix A 1

Technical and Scientific Average Cost – The CDPH/GDSP estimates current year average technical and scientific cost per participant will be \$64.59, which is an increase of \$4.26 or 7 percent compared to 2019-20 actual average cost per participant of \$60.33. The Average laboratory cost per participant in 2021-22 is estimated at \$64.59 which is no change from the current year estimate. The current year increase in

average cost is attributed to the contract rate increase due to the new reagent kits for the new lab instruments.



Technical and Scientific Total Cost – The CDPH/GDSP estimates current year technical and scientific costs to total \$28 million, which is an increase of \$1 million or 5 percent compared to 2019-20 actual costs of \$27 million. For 2021-22, the technical and scientific costs are estimated to be \$28.5 million, which is an increase of \$434,000 or 2 percent compared to the current year. The current year increase in cost is tied to contract rate increase due to the new reagent kits for the validation of the new lab instruments. The budget year increase in cost is tied to the anticipated increase in purchases of consumables, supplies and reagents needed for screening disorders.

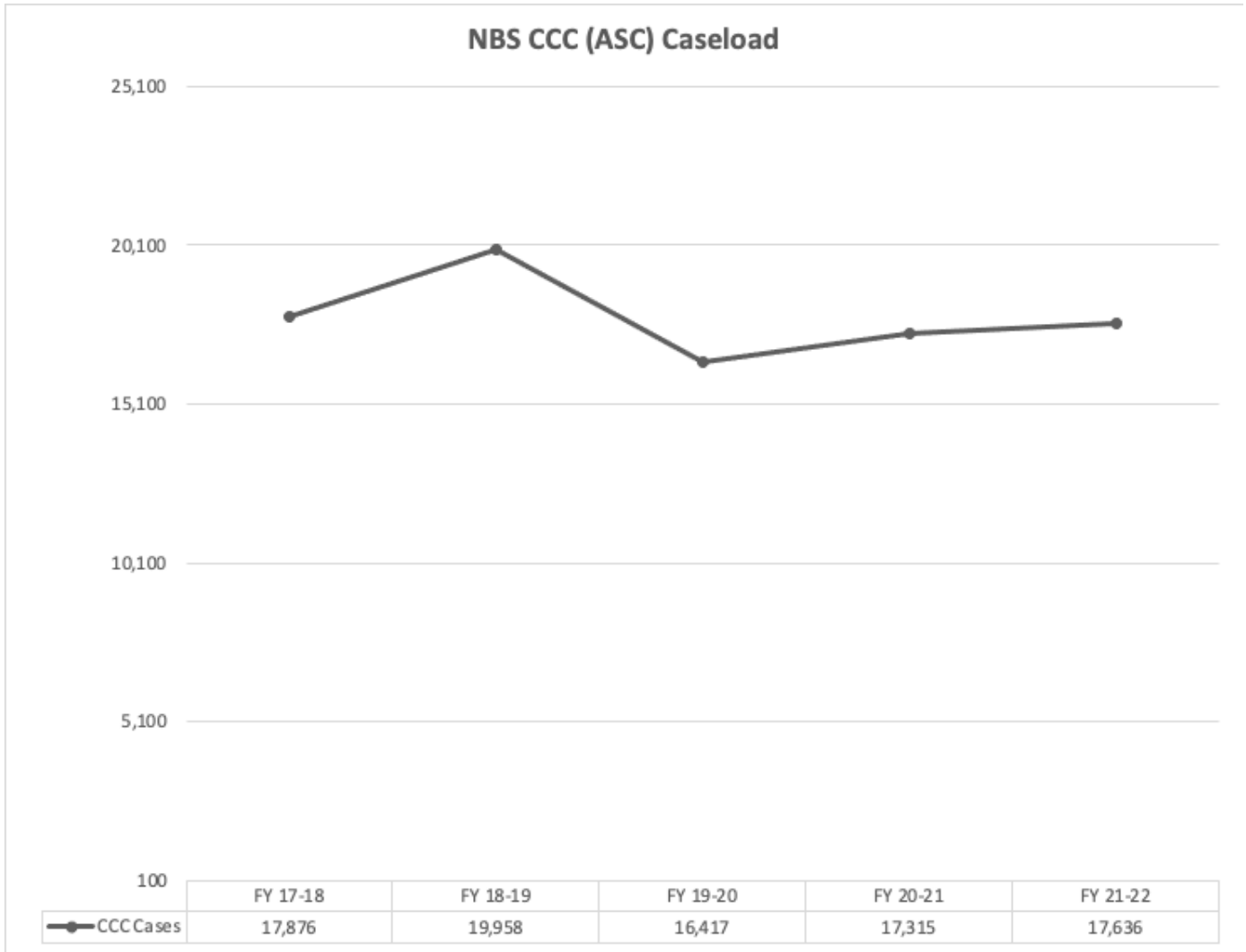


M. Case Management and Coordination Services (CMCS):

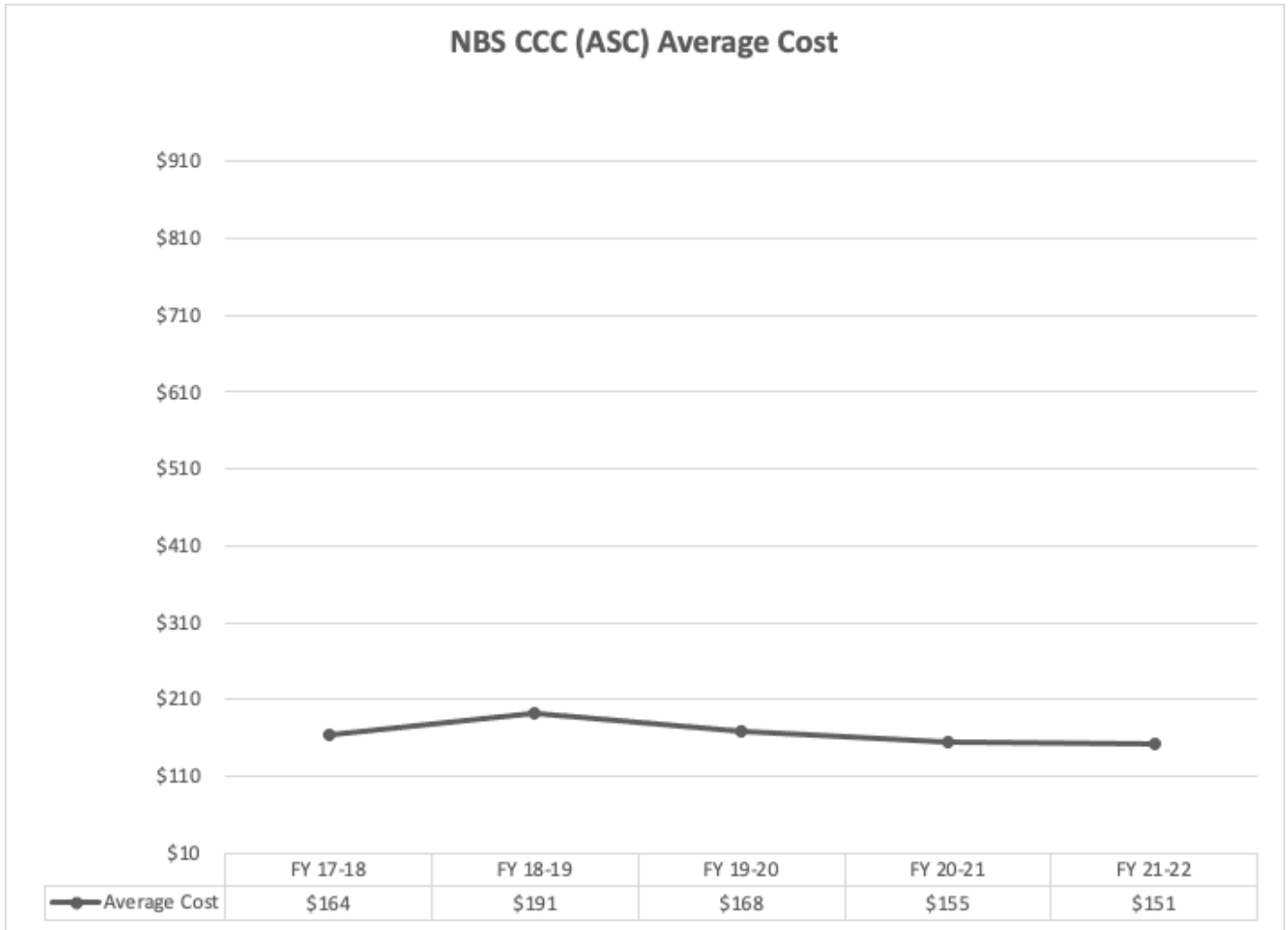
Overview- Services are provided to infants who screen an initial positive or have questionable screening test results for the 75 plus genetic disorders tested. These services include: time- sensitive coordination for specific confirmatory testing, family consultation – including consultation with the infant’s pediatrician, genetic disease counseling, family educational services, and coordinated care referrals to specialized medical institutions. The NBS ASCs provide critical coordination and tracking services to ensure appropriate diagnostic measures are completed, and that affected infants are provided with appropriate medical care and receive treatment within a critical timeframe. The ASCs are reimbursed based on caseload and the type of services performed; this funding supports a required core team of clinical professionals. Costs vary by ASC dependent upon the geographical location as well as the volume of caseload served.

Case Management and Coordination Services (CMCS) Caseload – The CDPH/GDSP estimates current year CMCS caseload will total 17,315, which is an increase of 898 or 5 percent compared to 2019-20 actual CMCS caseload of 16,417. The increase is attributed to the newest disorders added to the screening panel. The CMCS caseload in

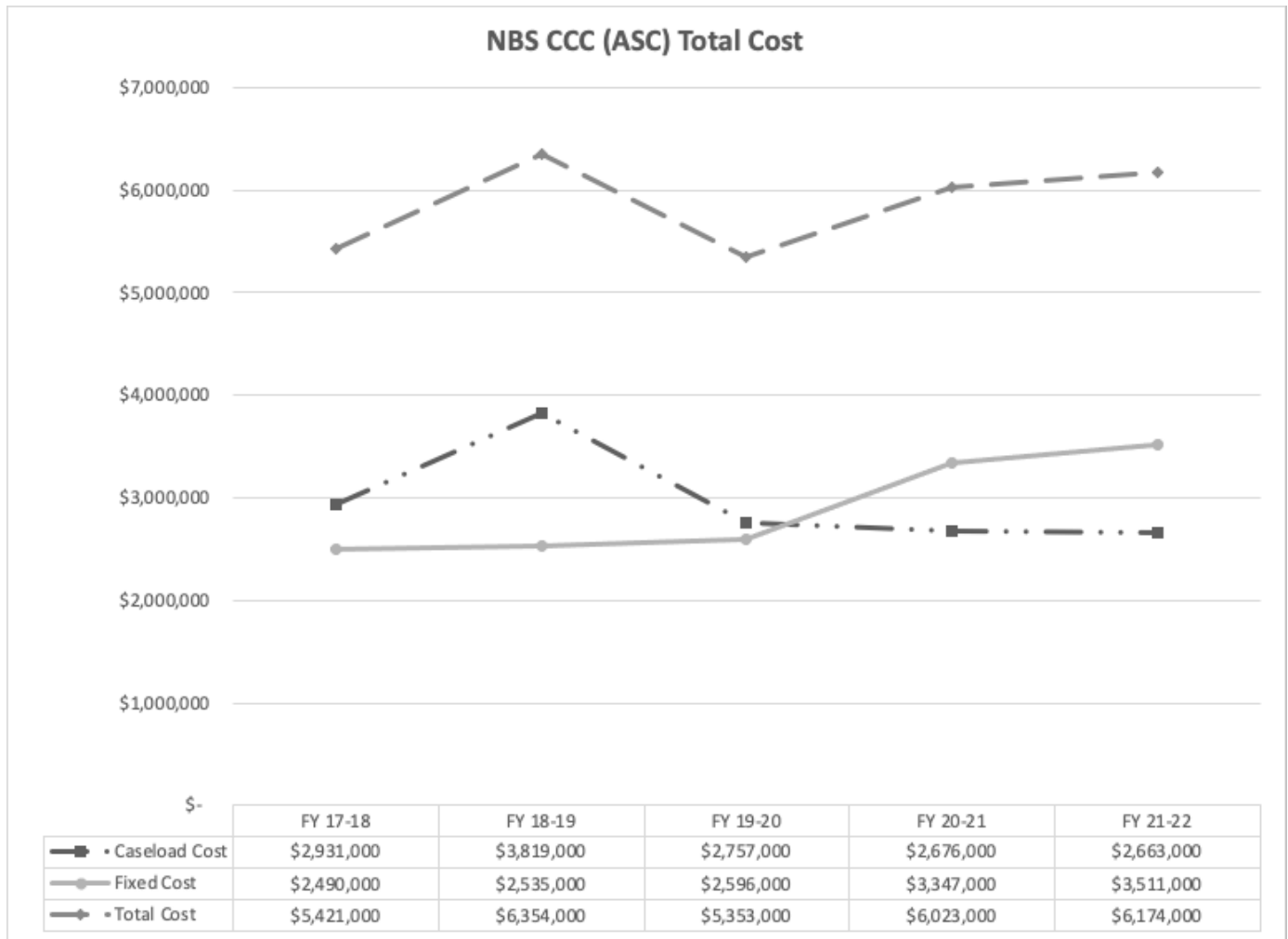
2021-22 is estimated at 17,636, which is an increase of 322 or 2 percent compared to the current year estimate.



Case Management and Coordination Services (CMCS) Average Cost – The CDPH/GDSP estimates current year average CMCS cost per participant will be \$155, which is a decrease of \$13 or 8 percent compared to 2019-20 actual average cost of \$168. The average CMCS cost per participant in 2021-22 is estimated at \$151, which is a decrease of \$4 or 2 percent compared to the current year estimate. The CMCS costs are a combination of fixed costs and incremental (per case) reimbursement. The fluctuation in the average cost is tied directly to the total cost and additional specialized follow-up centers for ongoing newborn testing.



Case Management and Coordination Services (CMCS) Total Cost – The CDPH/GDSP estimates current year CMCS costs to total \$6 million, which is an increase of \$670,000 or 13 percent compared to 2019-20 actual CMCS costs of \$5.4 million. The CMCS costs in 2021-22 are estimated to total \$6.2 million, which is an increase of \$151,000 or 3 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 2021-22 due to the projected number of positive cases attributed to the implemented screening for SMA. In addition, we considered a combination of increased fixed costs, and incremental (per case) reimbursement, which includes administrative costs, rent, equipment, travel and administrative staff.

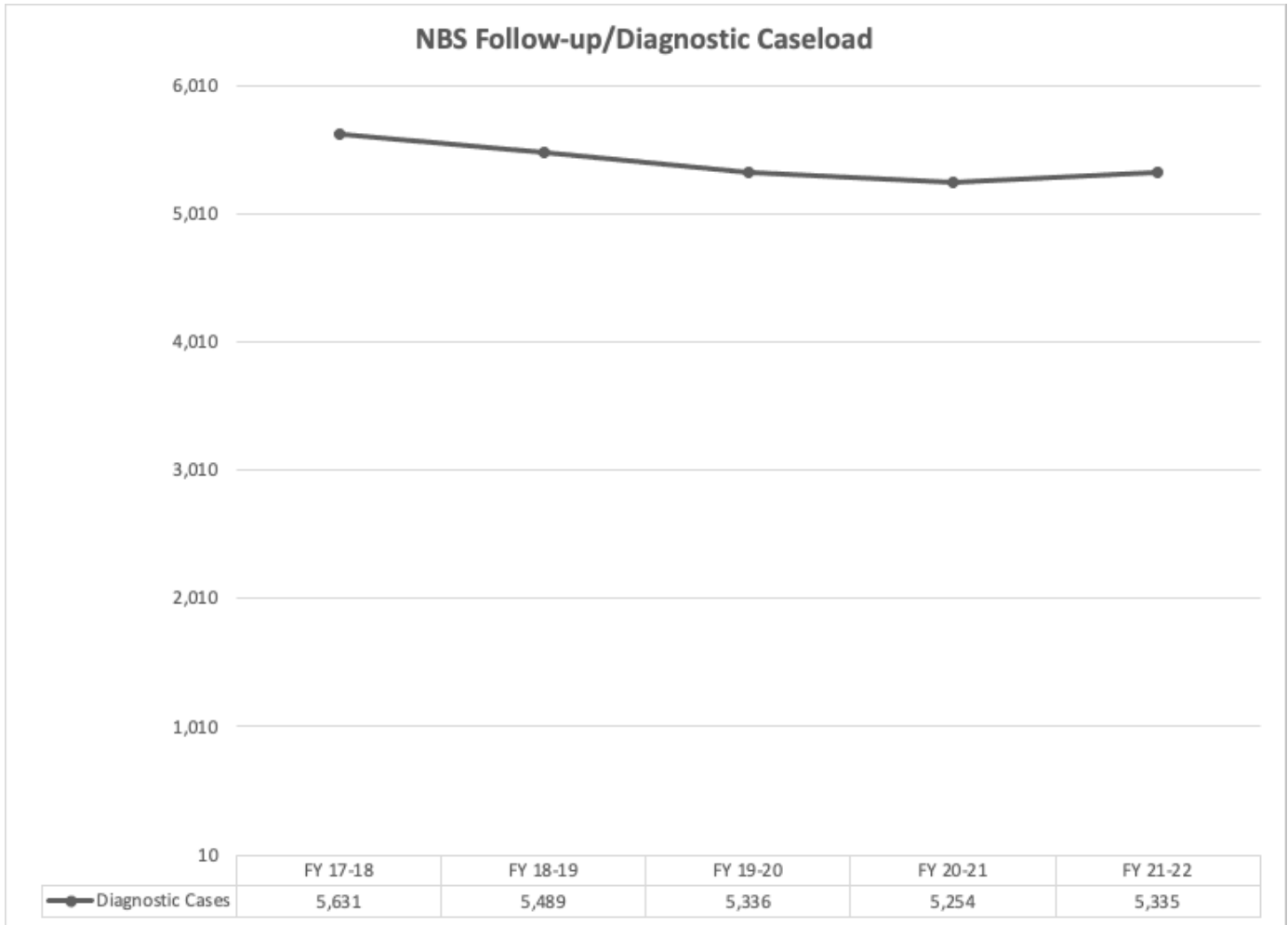


N. Diagnostic Services:

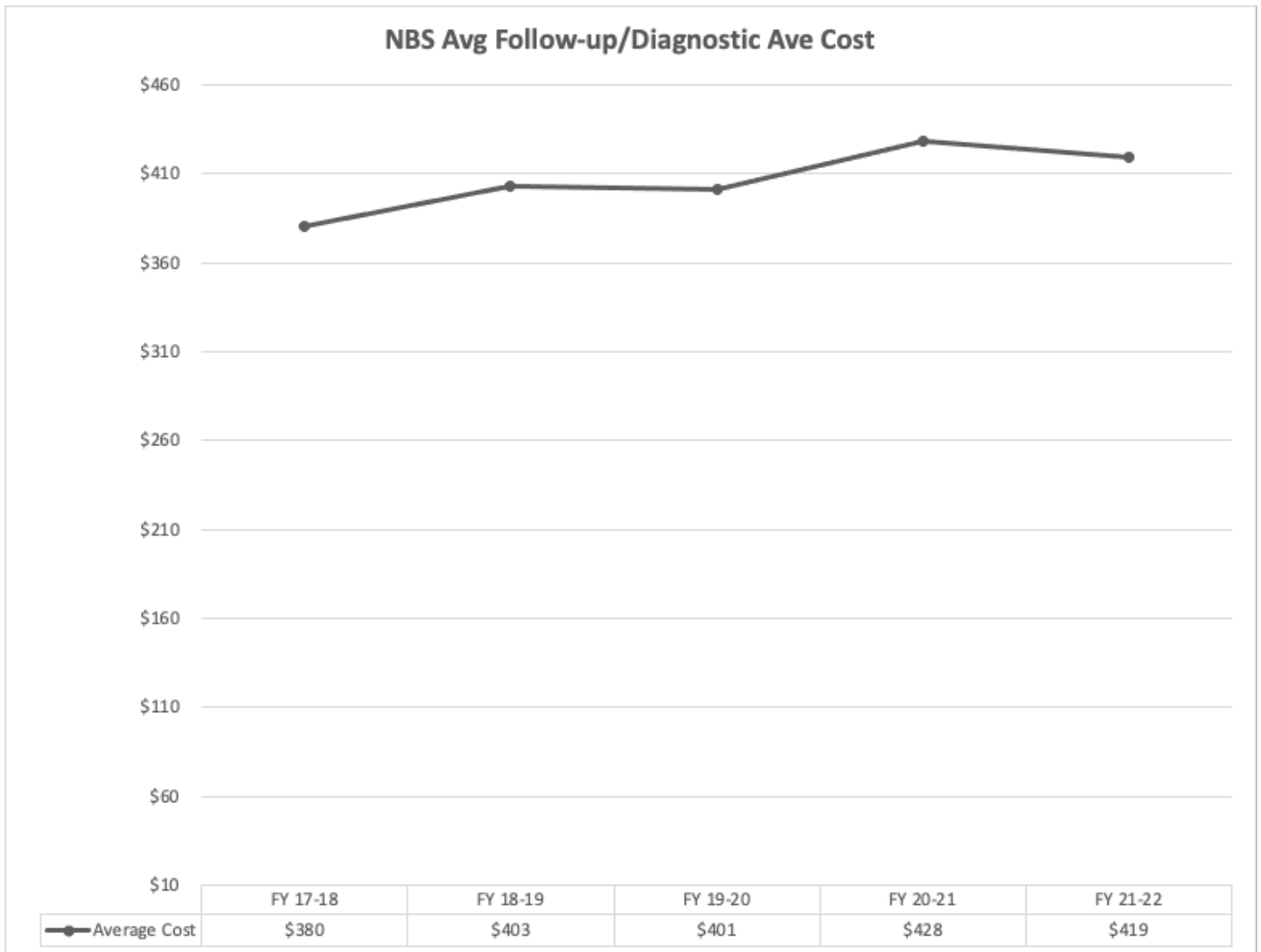
Overview- Diagnostic Services are for infants who require extended monitoring while undergoing confirmatory testing and diagnosis. Clinical outcome data is collected on infants once diagnosis is made as a means of tracking, confirming, evaluating, and refining program standards. Services include: coordination with the NBS ASCs and 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, 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.

Diagnostic Services Caseload – The CDPH/GDSP estimates current year diagnostic caseload will total 5,254, which is a decrease of 82 or 2 percent compared to 2019-20 actual caseload of 5,336. Diagnostic caseload in 2021-22 is estimated at 5,335, which is an increase of 81 or 2 percent compared to the current year estimate. The

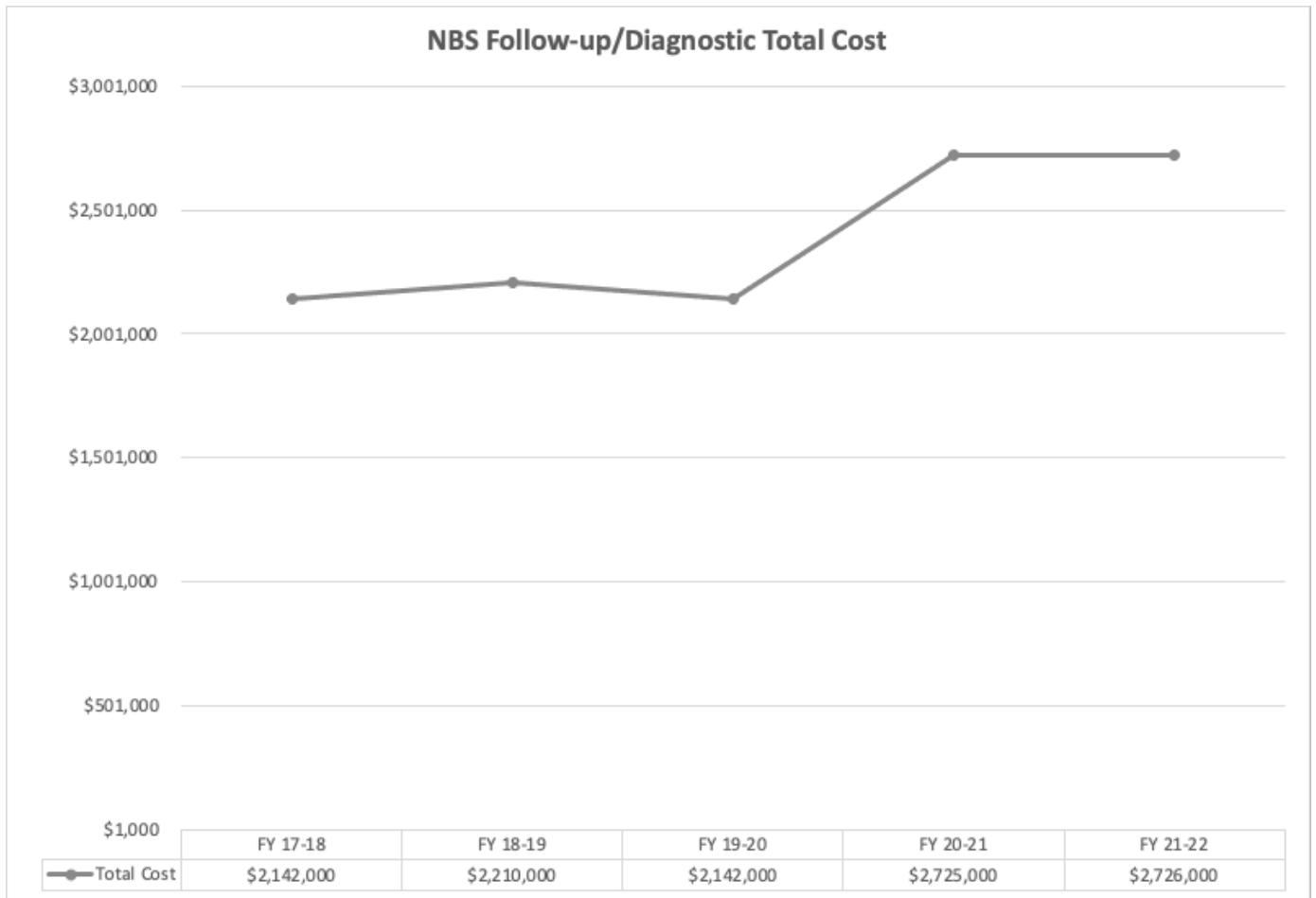
fluctuations are tied to overall DRU-based caseload. In addition, we considered a combination of increased fixed costs, and incremental (per case) reimbursement, which includes administrative costs, rent, equipment, travel and administrative staff.



Diagnostic Services Average Cost – The CDPH/GDSP estimates current year average diagnostic services cost per participant will be \$428, which is an increase of \$27 or 7 percent compared to 2019-20 actual average diagnostic services cost per participant of \$401. Average diagnostic services cost per participant in 2021-22 are estimated at \$419, which is a decrease of \$9 or 2 percent compared to the current year estimate. The increase in the current year is tied to the increase in total costs and decline in caseload. The reduction in the budget year is tied to the decrease in total cost and growth in caseload.



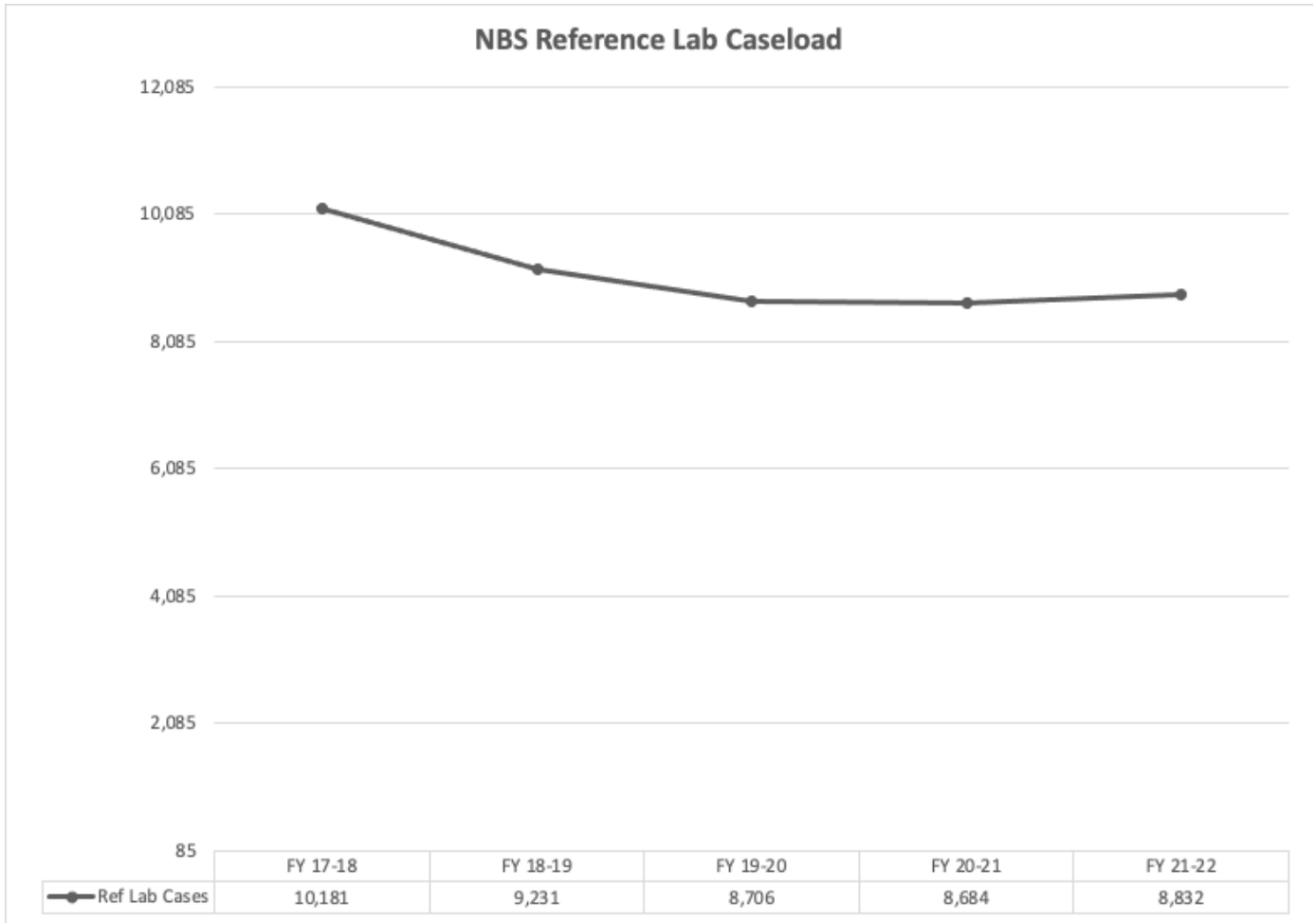
Diagnostic Services Total Cost – The CDPH/GDSP estimates current year diagnostic services costs to total \$2.7 million, which is an increase of \$583,000 or 27 percent compared to 2019-20 actual costs of \$2 million. Diagnostic services costs in 2021-22 are estimated to total \$2.7 million, which is a slight increase of \$1,000 or 0.04 percent compared to the current year estimate. The current year increase in total cost is attributable to the increase in fixed cost. The increase in the budget year can be attributed to the increase in variable cost associated with the projected increase in caseload.



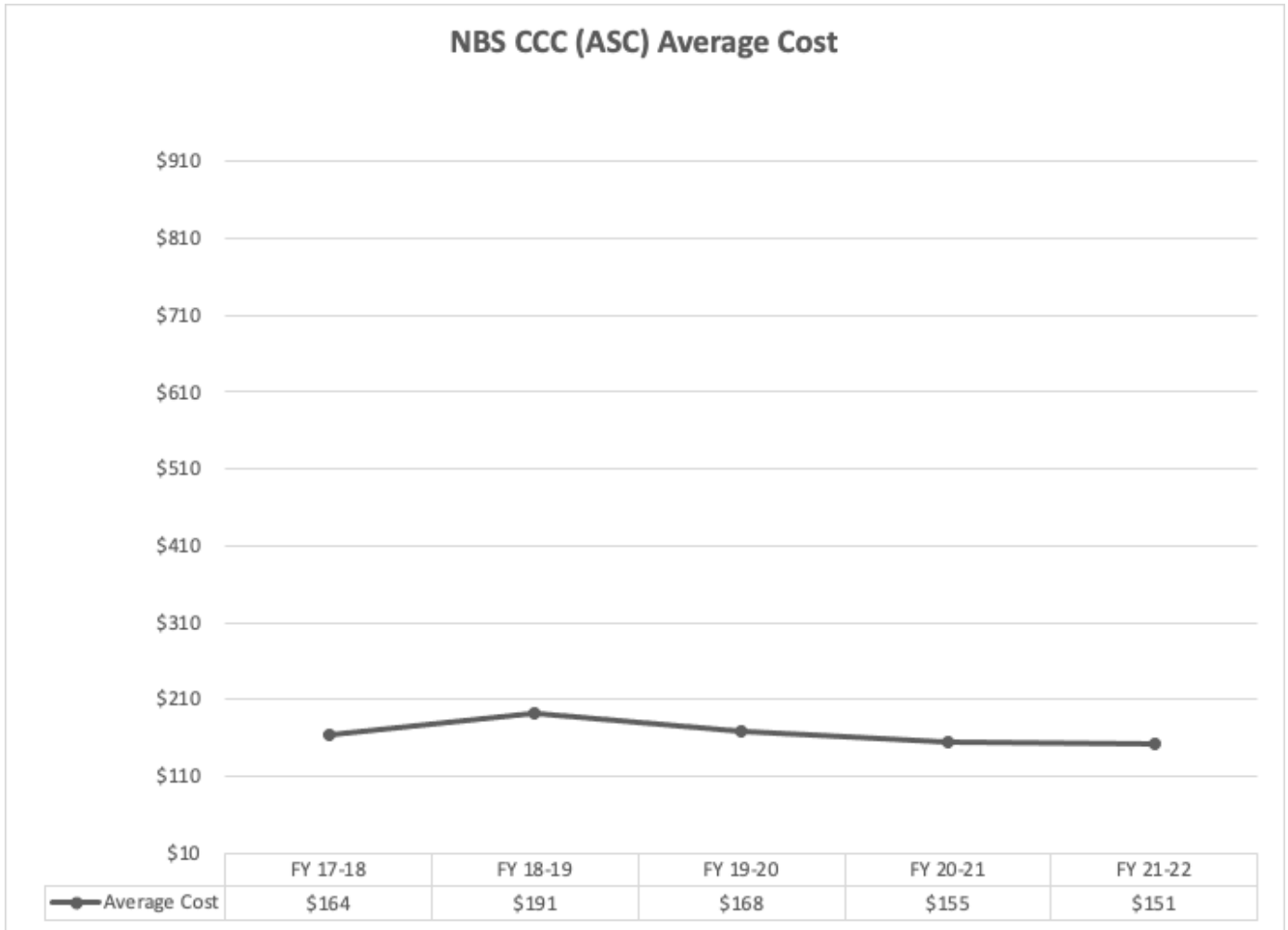
O. Reference Laboratory Cases:

Overview – Cases that result in a positive screening tests 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.

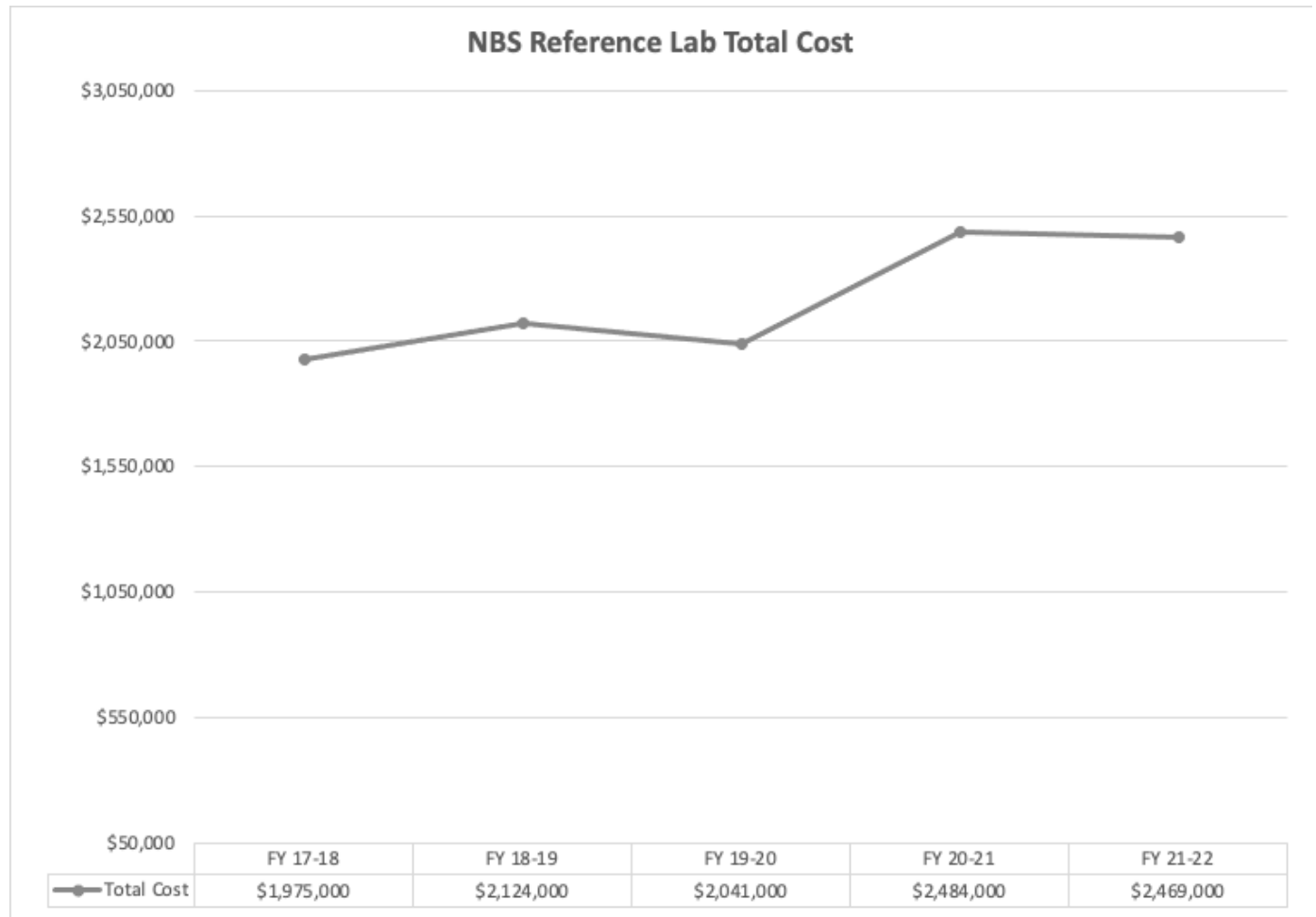
Reference Laboratory Caseload – The CDPH/GDSP estimates current year reference laboratory caseload will total 8,684, which is a slight decrease of 22 or 0.26 percent compared to 2019-20 actual caseload of 8,706. Reference Laboratory caseload in 2021-22 is estimated at 8,832, which is an increase of 148 or 2 percent compared to the current year estimate. The decrease in the current year is due to the decline in DRU’s reported number of live births during pandemic. We anticipate an increase in caseload for the budget year.



Reference Laboratory Average Cost – The CDPH/GDSP estimates current year reference laboratory average cost per participant will be \$286, which is an increase of \$51.62 or 22 percent compared to 2019-20 actual average cost per participant of \$234.44. Reference laboratory average cost per participant in 2021-22 is estimated at \$280 which is a decrease of \$6 or 2 percent compared to the current year estimate. Fluctuation is tied to the total costs.



Reference Laboratory Total Cost – The CDPH/GDSP estimates current year reference laboratory costs to total \$2.5 million, which is an increase of \$443,000 or 22 percent compared to 2019-20 actual total costs of \$2 million. Reference laboratory costs in 2021-22 are estimated to total \$2.5 million, which is virtually no change compared to the current year estimate. The increase in the current year is attributed to the additional cost for adding confirmatory DNA sequencing for new disorders and contract increases for sickle cell trait follow-up, and fluctuations in caseloads.



V. APPENDIX B: PNS Program Assumptions and Rationale

P. Contract Laboratories:

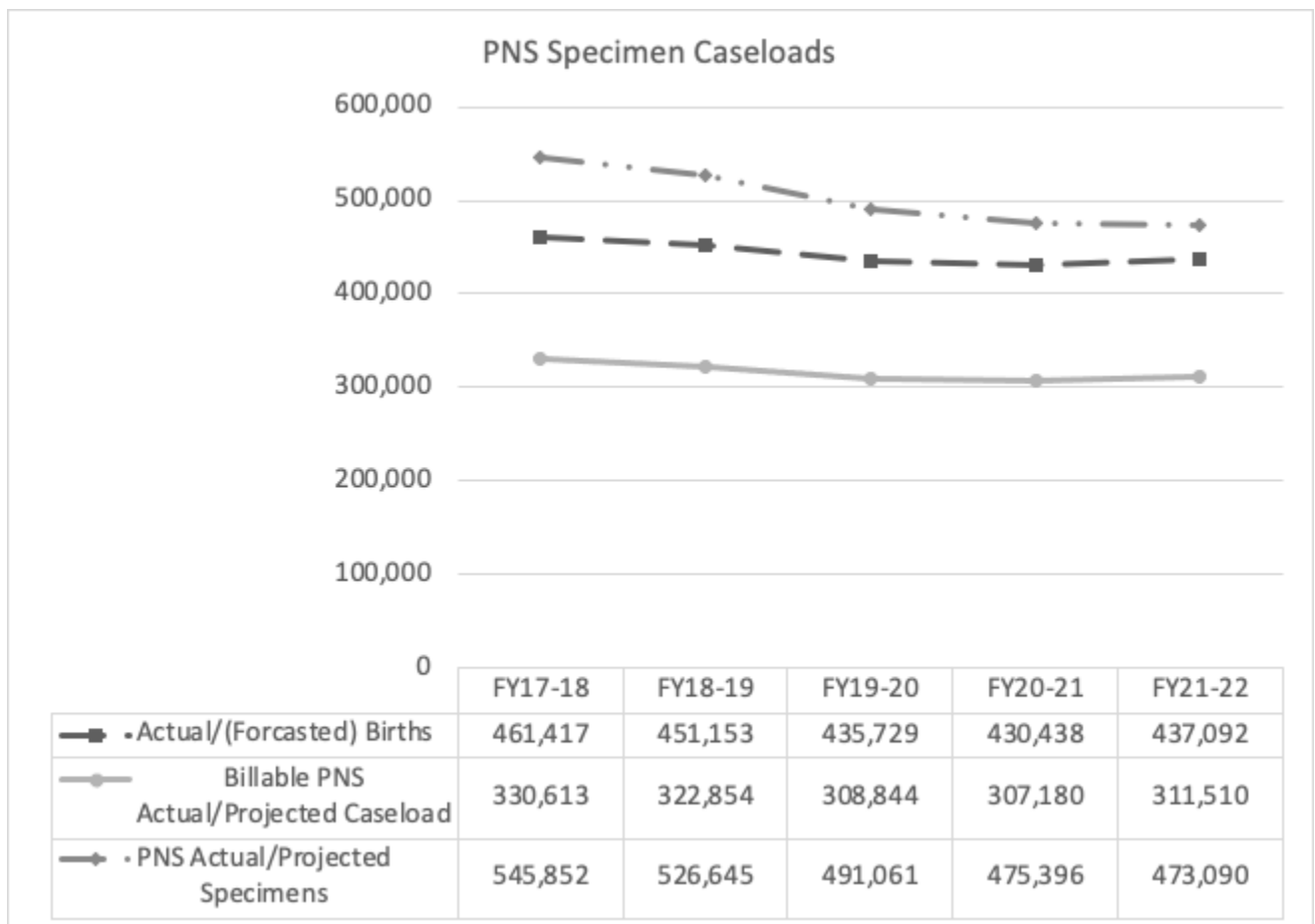
Overview – Laboratory testing to screen pregnant women for genetic and congenital disorders, such as Trisomy 21, Trisomy 18, Smith-Lemli-Opitz Syndrome (SLOS), and Neural Tube Defects. Costs include laboratory services for performing prenatal genetic screening tests. The screening test estimates the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

In the past, the CDPH/GDSP estimated the number of the 1st trimester and 2nd trimester screens performed separately. 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 the CDPH/GDSP will estimate the average cost to provide both screens without

differentiating between the two tests a participant may receive.

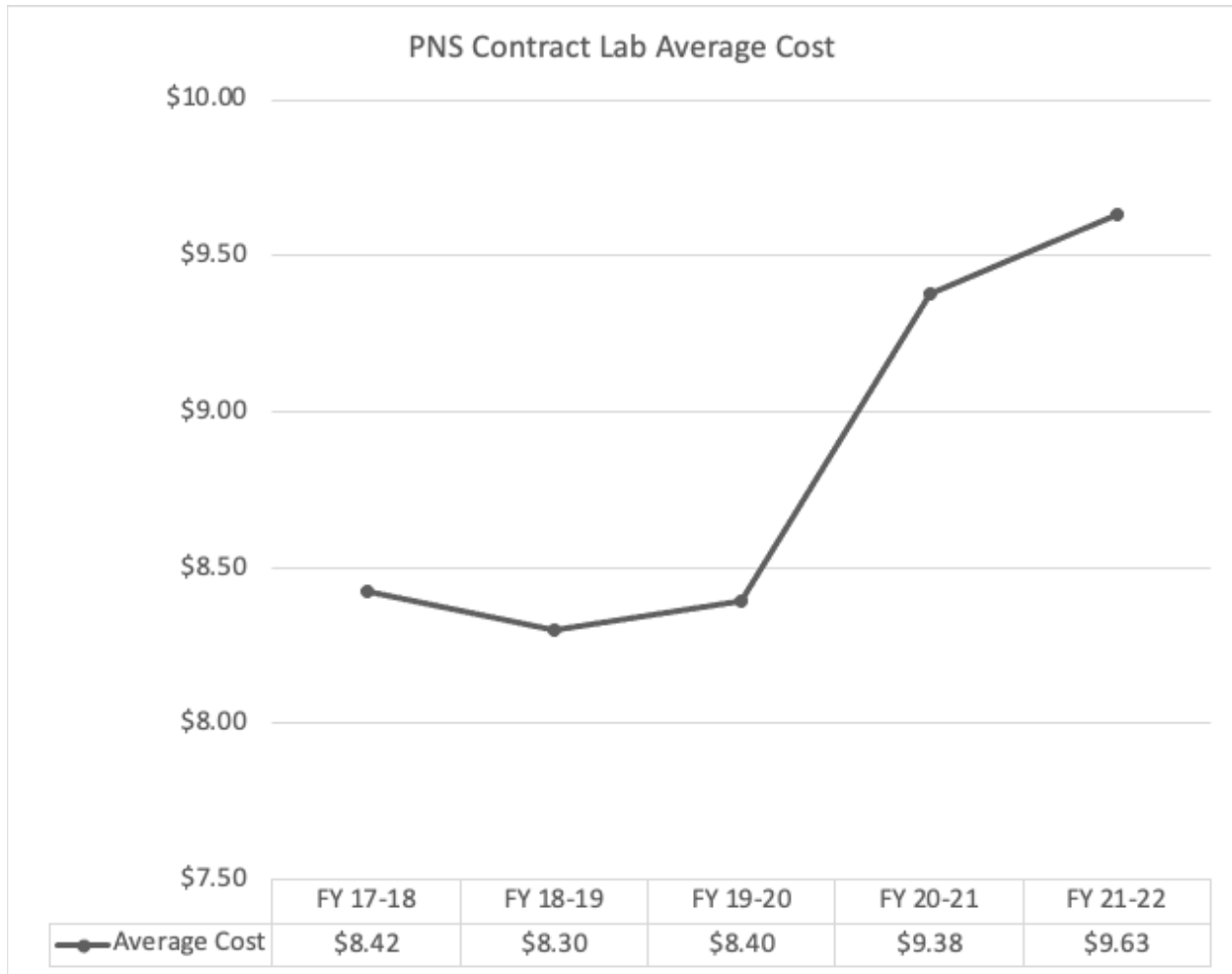
Total Caseload/Specimens – The CDPH/GDSP estimates current year specimen caseload will total 475,396, which is a decrease of 15,665 or 3.2 percent compared to 2019-20 actual total caseload of 491,061. Caseload in 2021-22 is estimated at 473,090, which is a decrease of 2,306 or 0.5 percent compared to the current year estimate. The PNS program participation is estimated based on a percentage of DRU’s projected number of live births.

The CDPH/GDSP estimates that 71 percent (based from a three-year actual average) of the projected births will participate in the PNS program in 2020-21 and that the number of participants will remain constant in 2021-22. The 2021-22 projections does not increase based on DRU’s projected 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 along with projected numbers for the remainder of the current year and budget year.

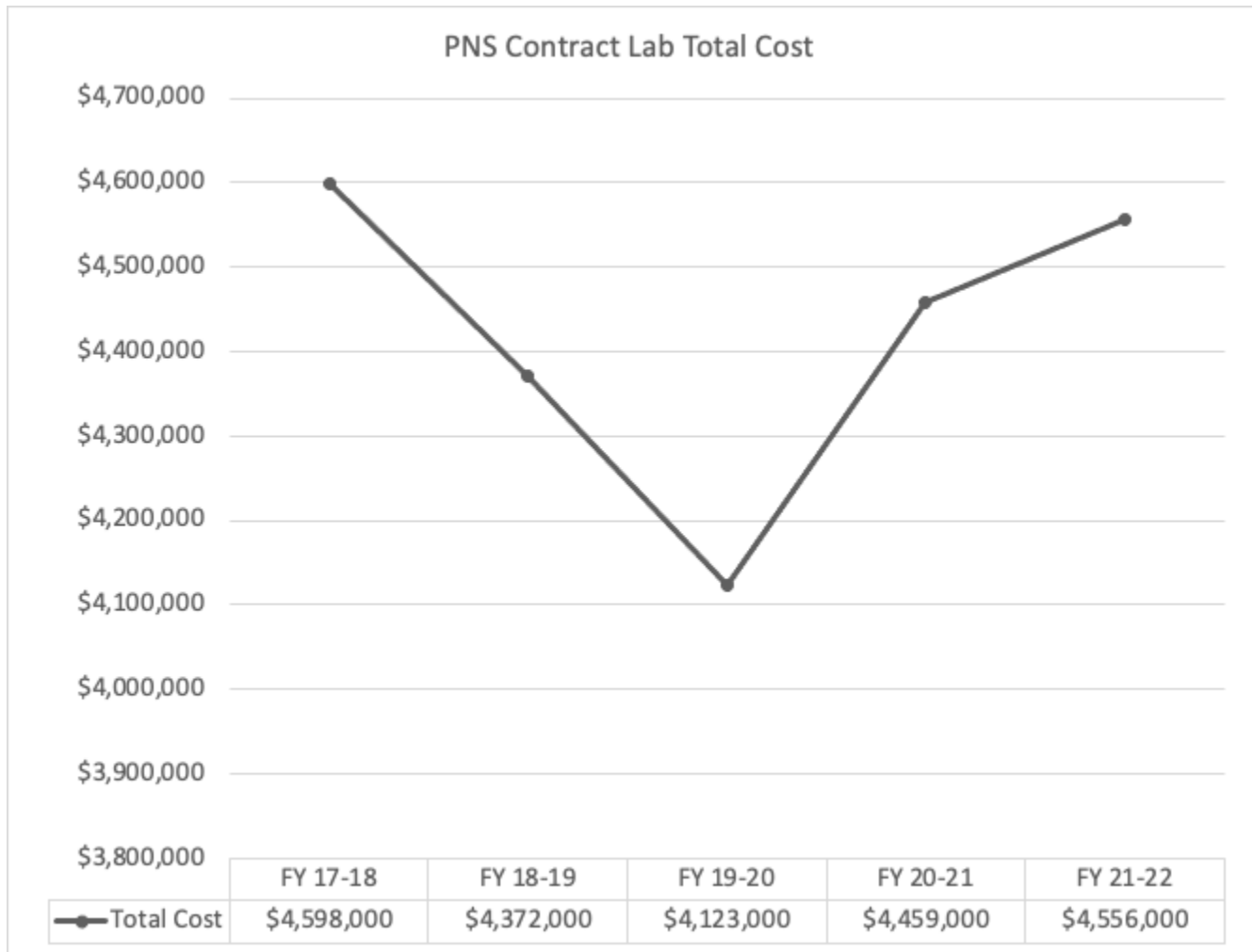


Contract Laboratory Average Cost Projections – The CDPH/GDSP estimates current

year average laboratory cost per participant will be \$9.38, which is an increase of \$1 or 12 percent compared to 2019-20 actual average laboratory cost per participant of \$8.40. Average laboratory cost per participant in 2021-22 is estimated at \$9.63, which is an increase of \$0.25 or 3 percent compared to current year estimate. The increase in average cost in the current and budget year is attributed to the increase in fixed costs.



Contract Laboratory Total Cost Projections – The CDPH/GDSP estimates current year contract laboratory cost to total \$4.5 million, which is an increase of \$336,000 or 8 percent compared to 2019-20 actual contract laboratory costs of \$4 million. Laboratory costs in 2021-22 are estimated to total \$4.6 million, which is an increase of \$97,000 or 2 percent compared to the current year estimate. The increase in total cost in the current and budget year is due to the increase in contract costs.



Q. Technical and Scientific

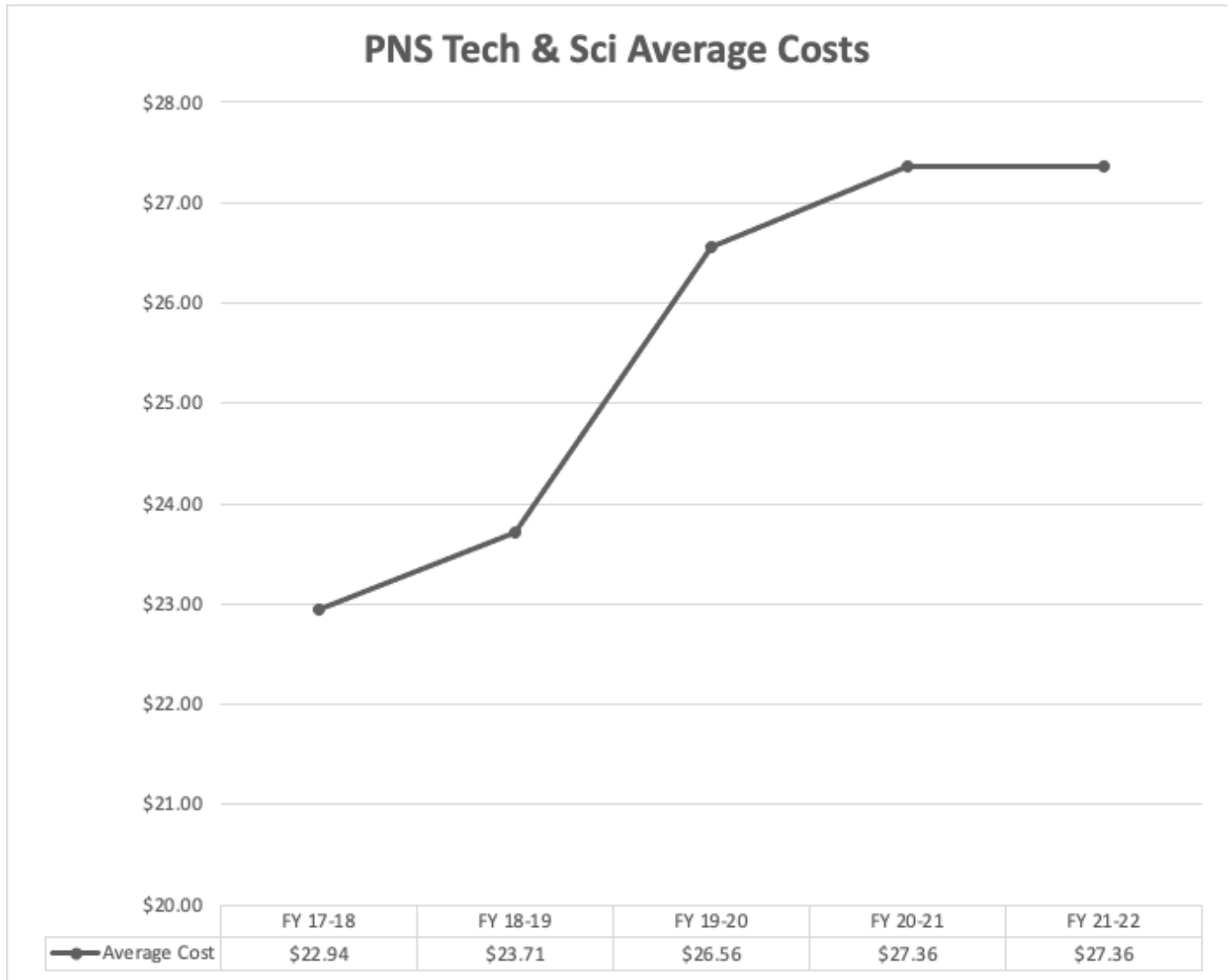
Overview - Costs associated with screening services provided at the laboratory include: reagent kits, limited maintenance and support (as it directly relates to the reagents) of laboratory equipment, supplies, and processing. In addition, there are several costs associated with screening including: blood 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 caseload.

Reagents vary in cost depending upon the type of screening

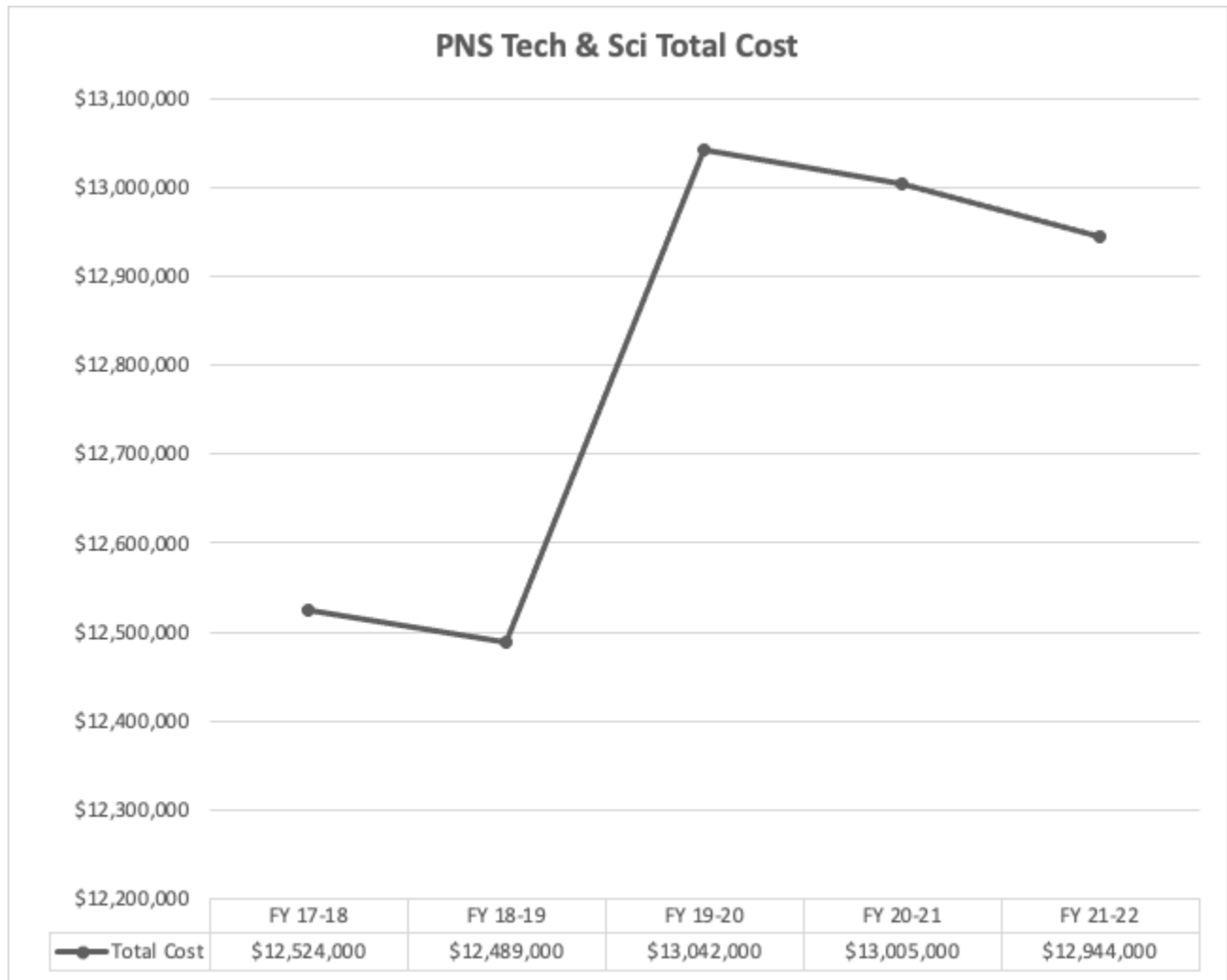
performed. Technical and Scientific Caseload: See appendix B 1

Technical and Scientific Average Cost – The CDPH/GDSP estimates current year average technical and scientific cost per participant will be \$27.36, which is an increase of \$0.80 or 3 percent compared to 2019-20 actual average cost per participant of \$26.56. The increase in the current year is attributed to the increase in total cost of

reagents, supplies, and consumables, and is tied to the total projected specimens tested. Average laboratory cost per participant in 2021-22 is estimated at \$27.36 which is no change compared to the current year estimate.



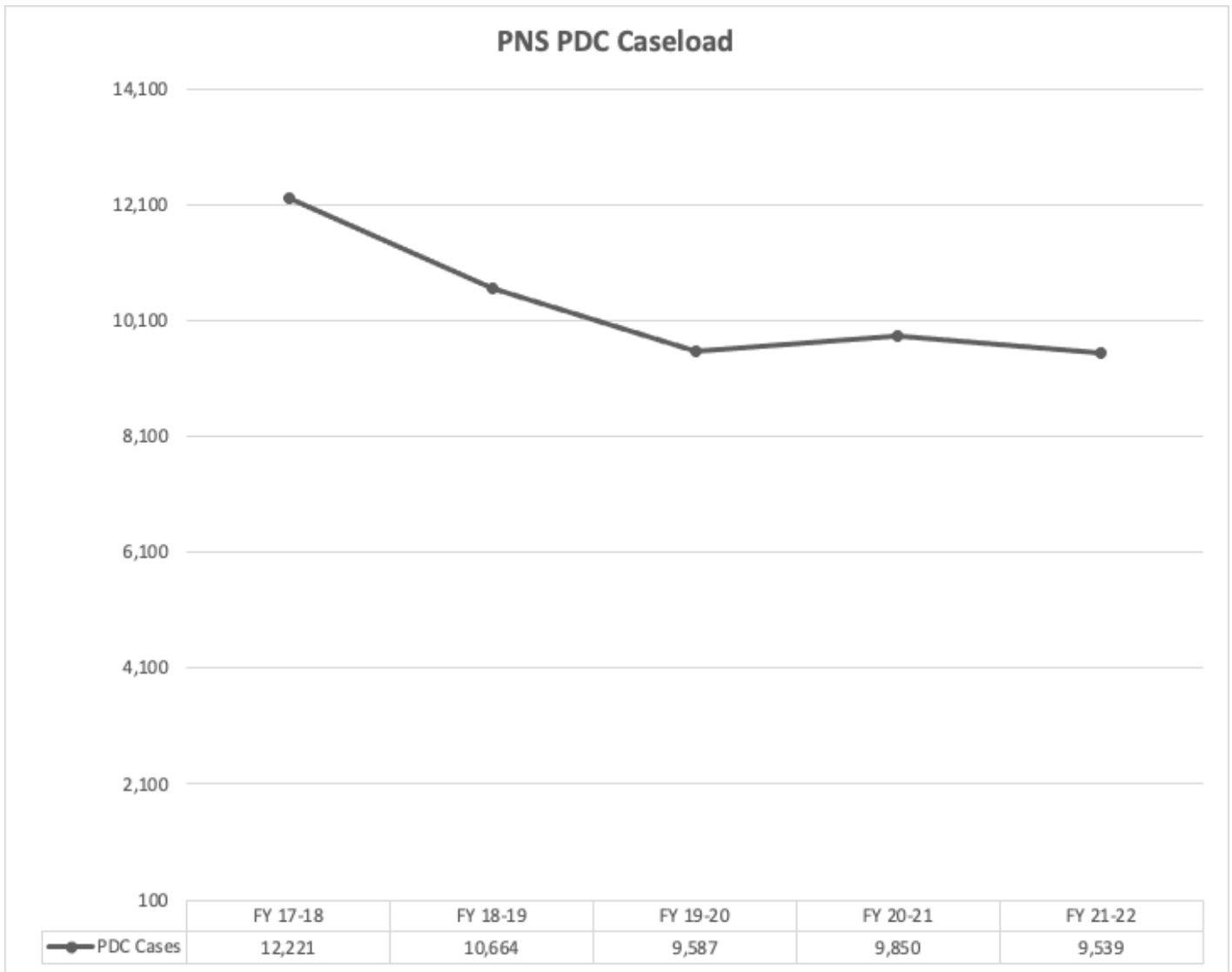
Technical and Scientific Total Cost – The CDPH/GDSP estimates current year technical and scientific costs to total \$13 million, which is virtually no change from 2019-20 costs. Technical and scientific costs in 2021-22 are estimated to total \$12.9 million, which reflects a slight decrease of \$61,000 or 0.5 percent compared to the current year estimate. Fluctuations in total costs are tied to caseloads and changes in costs of reagents, supplies, and consumables.



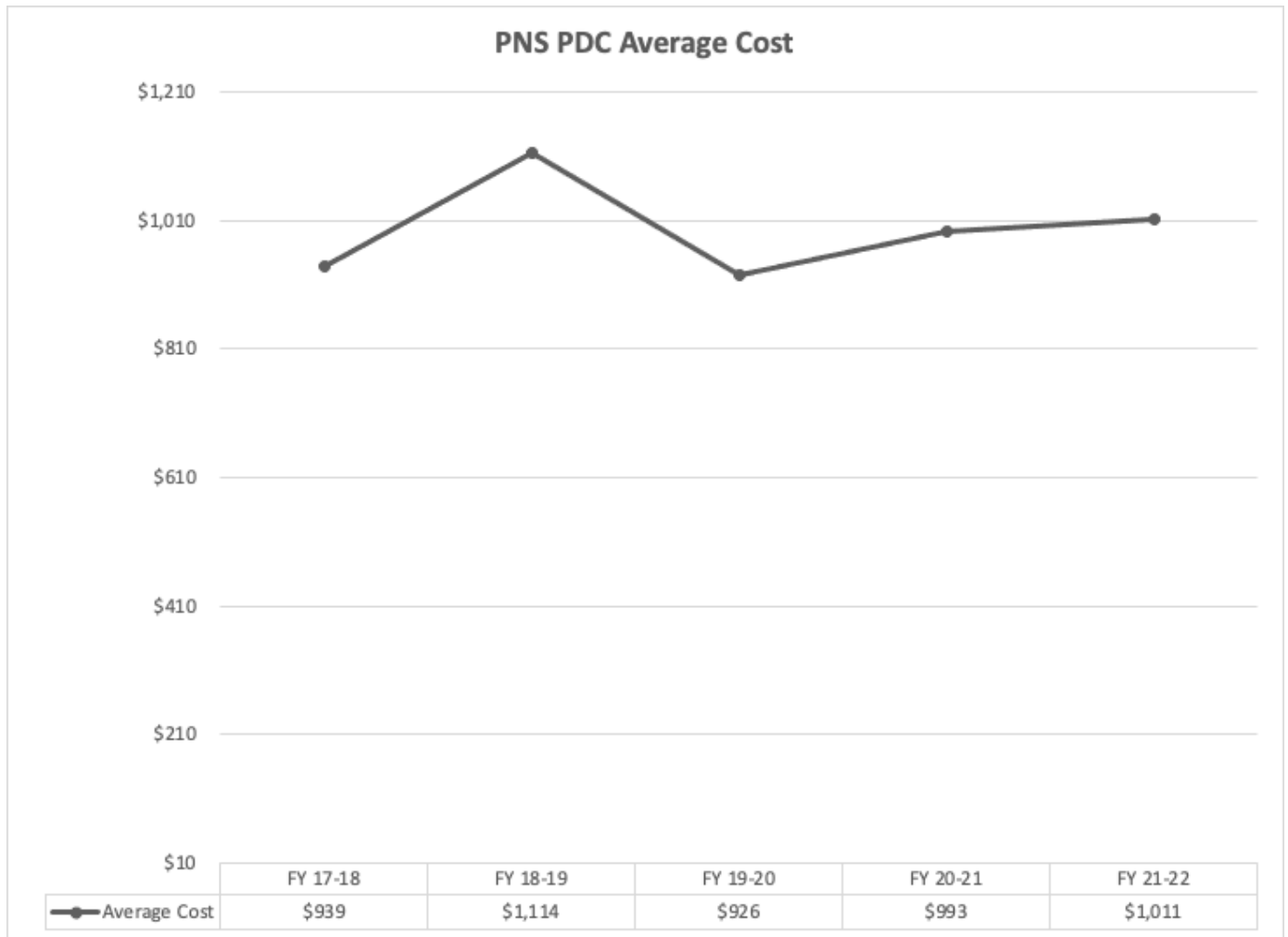
R. Prenatal Diagnostic Services Centers

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

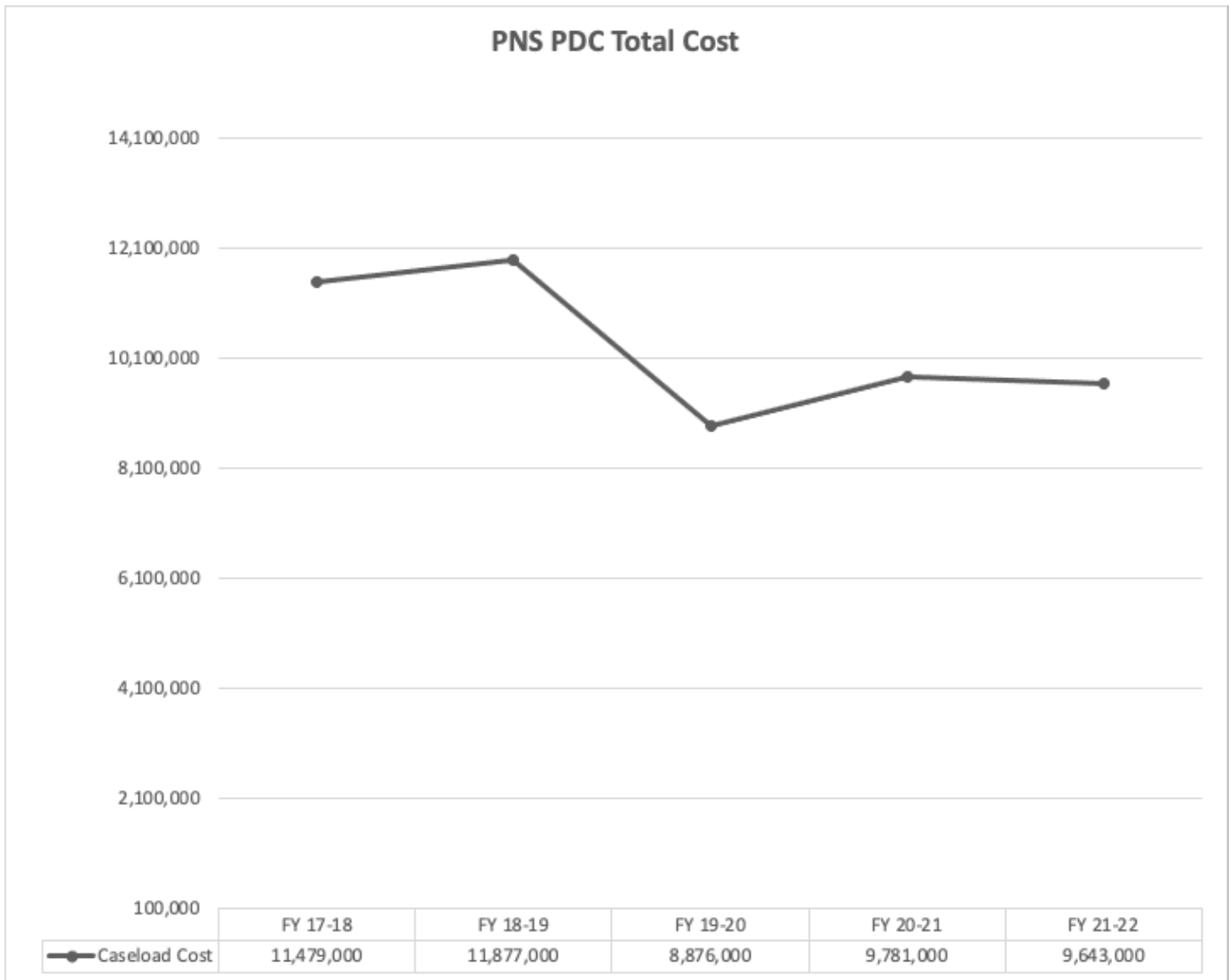
PDSC Caseload – The CDPH/GDSP estimates current year PDSC caseload will total 9,850, which is an increase of 263 or 3 percent compared to the 2019-20 actual caseload of 9,587. The increase is caused by a projected uptick in women choosing to further pursue diagnostic care. PDSC caseload in 2021-22 is estimated to total 9,539 which is a decrease of 311 or 3 percent compared to the current year estimate.



Prenatal Diagnostic Services Average Cost – The CDPH/GDSP estimates current year average cost per participant will be \$993, which is an increase of \$67 or 7 percent compared to 2019-20 actual average cost per participant of \$926. Average cost per participant in 2021-22 is estimated at \$1,011 which is an increase of \$18 or 2 percent compared to the current year estimate. The increase in average cost in the current year is the result of increased costs in the types of procedures used to diagnose genetic diseases. The increase in average cost in the budget year is due to increased contract costs. Procedures like Non-Invasive Prenatal Testing and Micro Array can be offered to women in lieu of more invasive and costly procedures such amniocentesis. Women who would previously have declined prenatal diagnostic services are now choosing these non-invasive procedures.



Prenatal Diagnostic Services Total Cost – The CDPH/GDSP estimates current year costs to total \$9.8 million, which is an increase of \$905,000 or 10 percent compared to 2019-20 actual total costs of \$8.9 million. Prenatal diagnostic costs in 2021-22 are estimated to total \$9.6 million, which is a decrease of \$138,000 or 1 percent compared to the current year estimate. The change in total expenditures is attributable mainly to fluctuating projected PDC caseload.

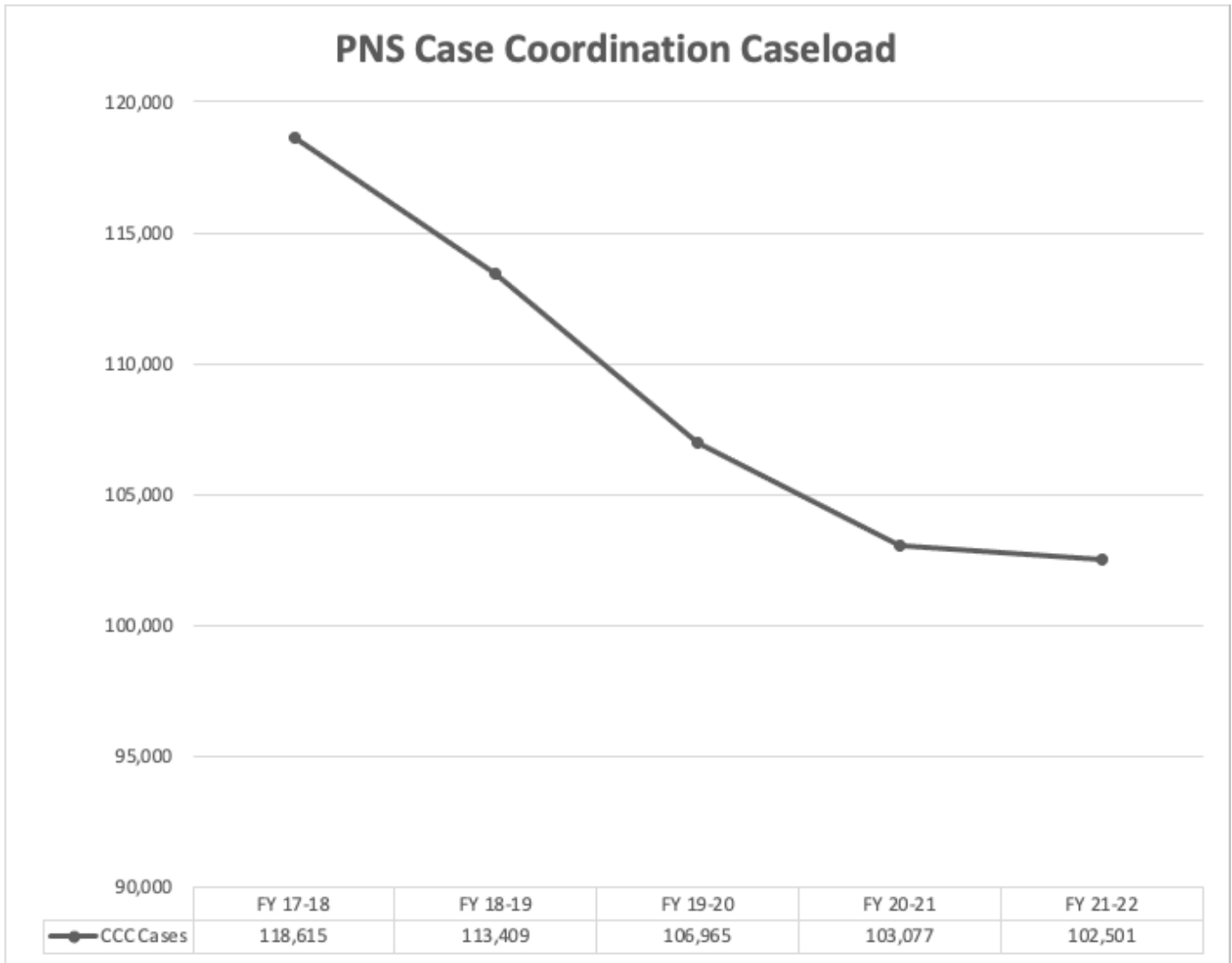


S. Case Management and Coordination Services:

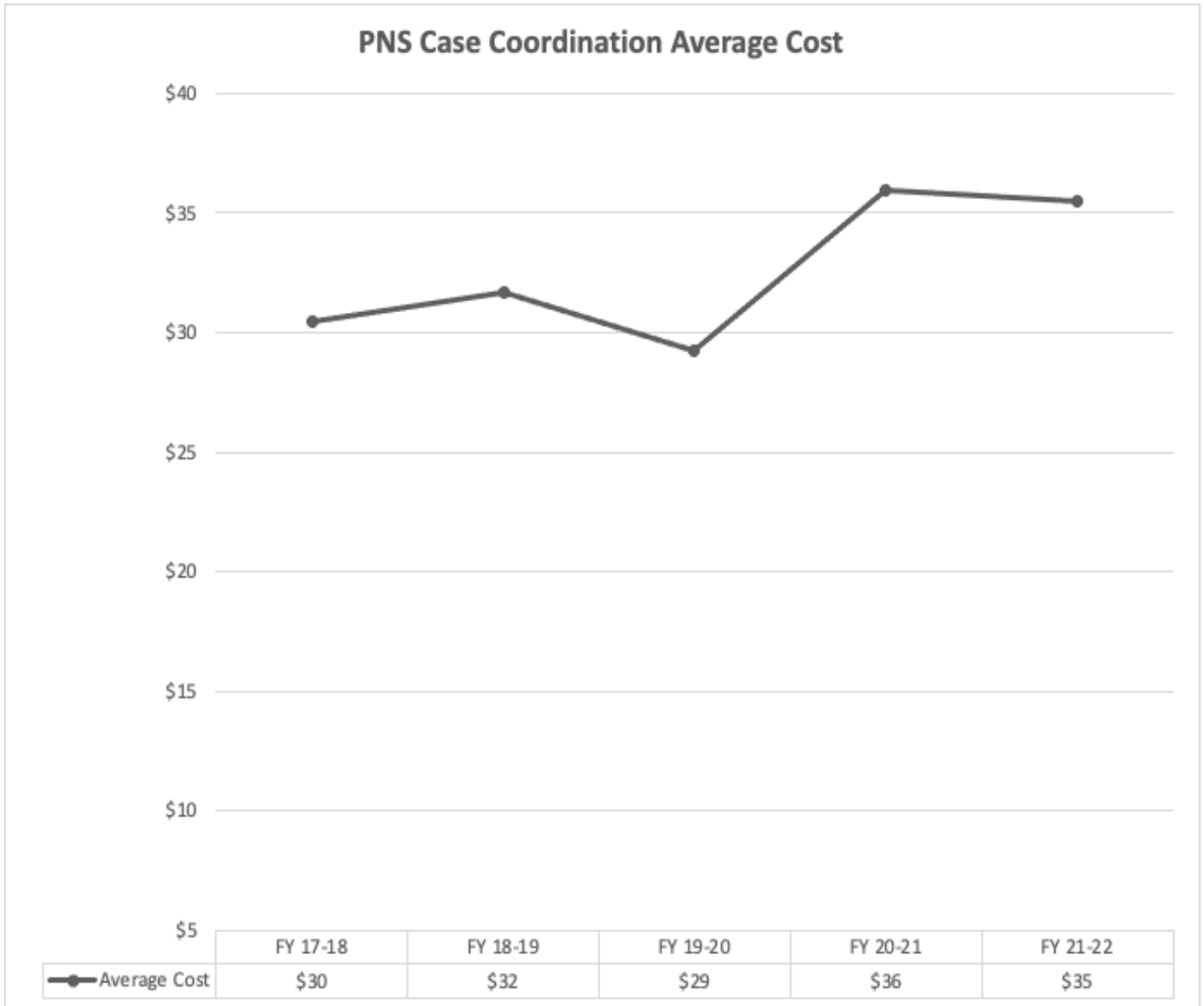
Overview - Services provided to pregnant women who screen positive or have questionable results include coordination of the first and second trimester screens and ultrasounds, identifying patients whose blood specimens were drawn too early or were inadequate, requiring additional blood draws. The PNS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

Case Management and Coordination Services (CMCS) Caseload – The

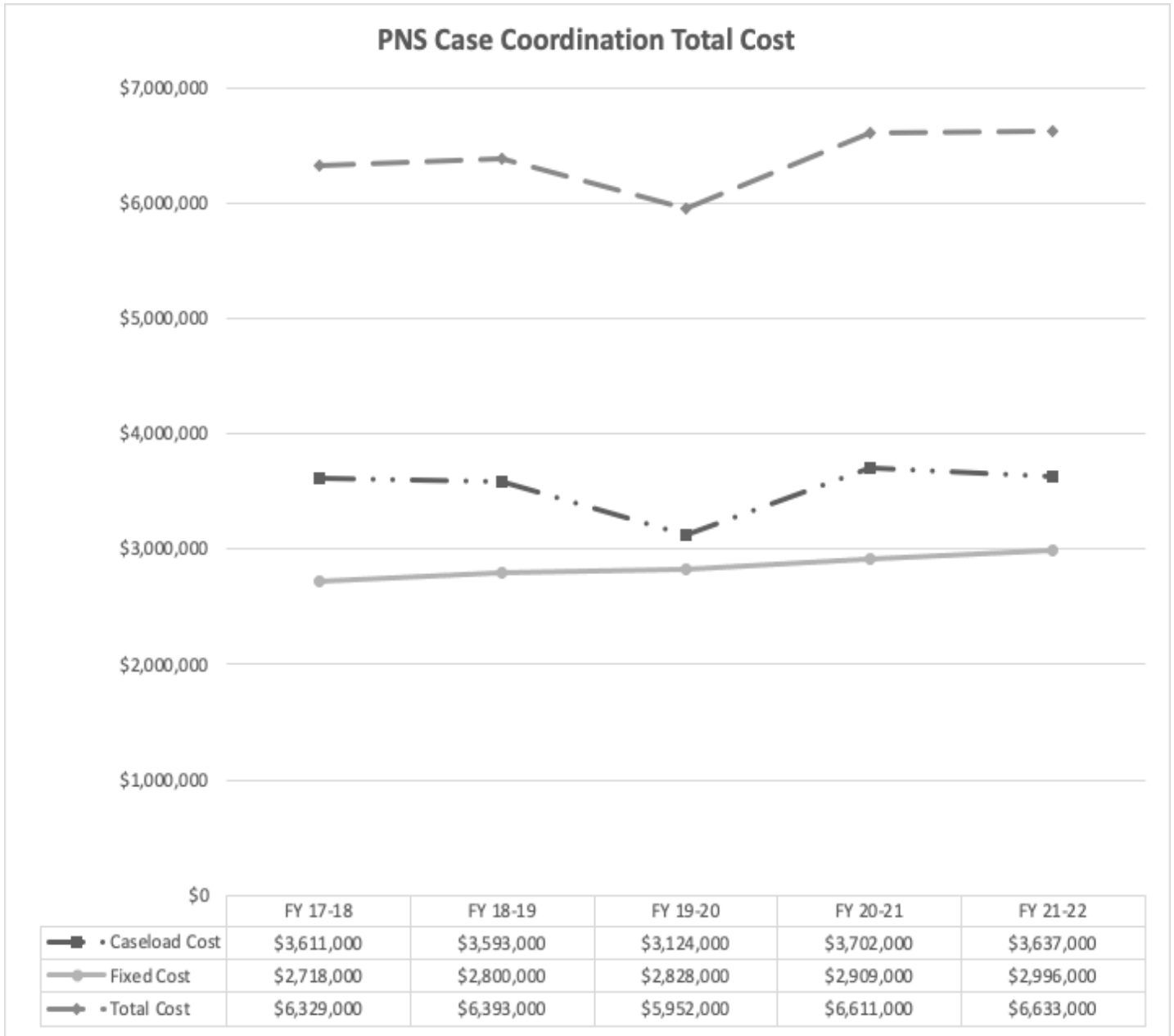
CDPH/GDSP estimates current year CMCS caseload will total 103,077, which is a decrease of 3,888 or 4 percent compared to 2019-20 actual caseload of 106,965. CMCS caseload in 2021-22 is estimated at 102,501, which is decrease of 576 or 0.6 percent compared to the current year estimate. This is largely due to changes in the DRU-based caseload. The following chart shows the actual CMCS cases by month along with projected numbers for the remainder of the current year and budget year.



Case Management and Coordination Services (CMCS) Average Cost – The CDPH/GDSP estimates current year average CMCS cost per participant will be \$36, which is an increase of \$6.71 or 23 percent compared to 2019-20 actual average cost per participant of \$29. Average CMCS cost per participant in 2021-22 is estimated at \$35, which is a slight decrease of 43 cents or 1.2 percent compared to the current year estimate. The changes in the average costs are attributable to the fluctuations in total fixed costs.



Case Management and Coordination Services (CMCS) Total Cost – The CDPH/GDSP estimates current year CMCS costs to total \$6.6 million, which is a slight increase of \$659,000 or 11 percent compared to 2019-20 actual total costs of \$6 million. CMCS costs in 2021-22 are estimated to total \$6.6 million, which is virtually no change from the current year estimate. The increase in the current year is attributable to the increase in contract rates and slight increase in fixed cost causing an increase in the total cost.



VI. APPENDIX C: Revenue Projections

T. NBS Revenue

Newborn Screening Program charges a fee of \$177.25. In most cases, the fee is paid to directly to the CDPH/GDSP by hospitals. For births that occur outside of a hospital, the CDPH/GDSP invoices 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 the 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:

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

Table 14. NBS Revenue Projections

Fiscal Year	Fee (A)	Caseload (B)	Collection Rate (C)	Total Revenue (D) = (A) x (B) x (C)
FY 2020-21	\$177.25	434,178	99%	\$76,189,000
FY 2021-22	\$177.25	440,910	99%	\$77,370,000

U. PNS Revenue

The Prenatal Screening Program charges a fee of \$221.60 to all participating women. Of the total fee, \$211.60 is deposited into the GDTF (Fund 0203) and \$10 is deposited into the California Birth Defect Monitoring Program Fund (Fund 3114). 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. Approximately 55 percent of all PNS participants are enrolled in Medi-Cal. PNS revenue is estimated using the following formula:

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

Table 15. PNS Revenue Projections

Fiscal Year	Fee (A) = \$221.60 - \$10	Caseload (B)	% Medi-Cal (C)	% Non-Medical (D) = 1 - C	Medi-Cal Collection Rate (E)	Private Insurance Collection Rate (F)	Medi-Cal Cases (G) = B x C	Non Medi-Cal Cases (H) = B x D	Total Revenue (I) = G x A x E + H x A x F
20-21	\$211.60	307,180	55%	45%	98%	94%	168,949	138,231	\$62,529,000
21-22	\$211.60	311,510	55%	45%	98%	94%	171,331	140,180	\$63,411,000