Genetic Disease Screening Program (GDSP)

Fiscal Year 2020-21

November Estimate

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Director and State Public Health Officer

California Department of Public Health
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A. Program Overview
The California Department of Public Health (Public Health), Genetic Disease Screening Program (GDSP) Estimate provides a revised projection of Fiscal Year (FY) 2019-20 expenditures along with projected costs for FY 2020-21 Local Assistance and State Operations budget for Public Health/GDSP.

The Public Health/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.

B. Expenditure Overview
The Public Health/GDSP 2019 Budget Act appropriation is $143 million, of which $111.6 million is for Local Assistance and $31.4 million is for State Operations. The Public Health/GDSP estimates for FY 2019-20 expenditures of $143 million, which is no change compared to the 2019 Budget Act. The combined State Operations and Local Assistance budget expenditures for FY 2020-21 total $143 million, which is a decrease of $409,000 or -0.3 percent compared to the 2019 Budget Act. The increase in State Operations can be attributed to full year cost adjustments for staff resources supporting the screening of spinal muscular atrophy (SMA). The net decrease in Local Assistance is attributed to decreasing one-time costs for SMA, increasing NAPS Lab contract rates due to adrenoleukodystrophy (ALD) rollout to regional laboratories, and fluctuations in caseloads.

Table 1 shows the difference between the 2019 Budget Act appropriation and the revised FY 2019-20 expenditures and proposed FY 2020-21 expenditures for Public Health/GDSP.

<table>
<thead>
<tr>
<th>Fund 0203 Genetic Disease Testing Fund</th>
<th>FY 2019-20 Budget Act</th>
<th>Change from Budget Act</th>
<th>Percent Change from Budget Act</th>
<th>November Estimate FY 2020-21</th>
<th>Change from Budget Act</th>
<th>Percent Change from Budget Act</th>
</tr>
</thead>
<tbody>
<tr>
<td>Total</td>
<td>$142,975,000</td>
<td>$142,975,000</td>
<td>-</td>
<td>$142,566,000</td>
<td>(409,000)</td>
<td>-0.3%</td>
</tr>
<tr>
<td>State Operations</td>
<td>$31,351,000</td>
<td>$31,351,000</td>
<td>-</td>
<td>$31,675,000</td>
<td>$328,000</td>
<td>1.0%</td>
</tr>
<tr>
<td>Local Assistance</td>
<td>$111,624,000</td>
<td>$111,624,000</td>
<td>-</td>
<td>$110,887,000</td>
<td>($737,000)</td>
<td>-0.7%</td>
</tr>
</tbody>
</table>
C. Local Assistance Expenditure Projections

Current Year (FY 2019-20)
The 2019 Budget Act appropriation for Public Health/GDSP’s Local Assistance is $111.6 million in FY 2019-20. GDSP anticipates no change compared to the 2019 Budget Act.

Budget Year (FY 2020-21)
For FY 2020-21, Public Health/GDSP estimates Local Assistance expenditures will total $111 million, which is a net decrease of $737,000 or -0.7 percent compared to the 2019 Budget Act amount of $111.6 million. The decrease in Local Assistance of $737,000 is attributed to an overall net decrease in Operational Support of $2.9 million due to one-time funding adjustments for newly implemented screenings, a net increase in NBS of $2.2 million due to contract rate increases and a slight decrease of $26,000 in PNS after adjusting for caseload.

Table 2 shows the difference between the 2019 Budget Act appropriation and the revised FY 2019-20 expenditures and proposed FY 2020-21 expenditures for Public Health/GDSP Local Assistance.

### Table 2: Local Assistance Total: Current Year and Budget Year Budget Summaries Compared to 2019 Budget Act

<table>
<thead>
<tr>
<th></th>
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<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Local Assistance Total</td>
<td>$111,624,000</td>
<td>$111,624,000</td>
<td>$0</td>
<td>0.0%</td>
<td>$110,887,000</td>
<td>$737,000</td>
<td>-0.7%</td>
</tr>
<tr>
<td>NBS</td>
<td>$45,344,000</td>
<td>$45,883,000</td>
<td>$540,000</td>
<td>1.2%</td>
<td>$47,576,000</td>
<td>$2,233,000</td>
<td>4.9%</td>
</tr>
<tr>
<td>PNS</td>
<td>$35,037,000</td>
<td>$35,397,000</td>
<td>$540,000</td>
<td>-1.5%</td>
<td>$35,911,000</td>
<td>$26,000</td>
<td>-0.1%</td>
</tr>
<tr>
<td>Operational Support</td>
<td>$30,344,000</td>
<td>$30,344,000</td>
<td>$0</td>
<td>0.0%</td>
<td>$27,400,000</td>
<td>$2,944,000</td>
<td>-9.7%</td>
</tr>
</tbody>
</table>

Expenditure Methodology / Key Drivers of Cost
The Public Health/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 servedCases that receive case management
   b. Cases that are referred for diagnostic services
   c. 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 Public Health/GDSP Local Assistance cost.

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

- **PNS total costs equal the sum of:**
  o Total specimen tested x Contract laboratory average cost
  o Total specimen tested x Technology and Scientific average cost
  o Case Management cases x Case Management and Coordination average cost + applicable Baseline cost
  o Diagnostic Services cases x Diagnostic Services average cost

- **Operational Support Costs** are the sum of various service contracts that support Public Health/GDSP, including Information Technology (IT) and courier services.

Below the projections are summarized for each of the drivers of cost for the NBS and PNS Programs. More detailed descriptions of the assumptions and rationale underlying each component of cost is presented in the appendices.

**NBS Expenditure Projections (See Appendices A1-A5)**
For FY 2019-20, Public Health/GDSP estimates NBS Local Assistance expenditures to total $45.9 million, which is an increase of $540,000 or 1.2 percent compared to the 2019 Budget Act of $45.3 million. The increase cost is attributed to an increase in headline cases for follow-up on initial NBS positives.

For FY 2020-21, Public Health/GDSP estimates that NBS Local Assistance expenditures will total $47.6 million, which is an increase of $2.2 million or 4.9 percent compared to the 2019 Budget Act of $45.3 million. The increase in the budget year funding is associated with increases in contract rates with regional testing laboratories for ALD rollout, Area
Services Centers, specialized follow-up centers, and diagnostic testing labs as well as scientific supply companies.

Table 3 shows the 2019 Budget Act appropriation and the revised FY 2019-20 expenditures and proposed FY 2020-21 expenditures for the Newborn Screening Program costs by cost center type.

### Table 3

<table>
<thead>
<tr>
<th>Cost Center Type</th>
<th>FY 2019-20 Budget Act</th>
<th>November Estimate FY 2019-20</th>
<th>Change from Budget Act</th>
<th>Percent Change from Budget Act</th>
<th>November Estimate FY 2020-21</th>
<th>Change from Budget Act</th>
<th>Percent Change from Budget Act</th>
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</thead>
<tbody>
<tr>
<td>Total</td>
<td>$45,243,000</td>
<td>$458,383,000</td>
<td>$540,000</td>
<td>1.2%</td>
<td>$47,576,000</td>
<td>$2,333,000</td>
<td>4.9%</td>
</tr>
<tr>
<td>Lab Dollars</td>
<td>$6,942,000</td>
<td>$6,875,000</td>
<td>$(67,000)</td>
<td>-1.0%</td>
<td>$7,188,000</td>
<td>$246,000</td>
<td>3.5%</td>
</tr>
<tr>
<td>Tech Sci</td>
<td>$27,493,000</td>
<td>$27,493,000</td>
<td>$0.000</td>
<td>0.0%</td>
<td>$28,354,000</td>
<td>$861,000</td>
<td>3.1%</td>
</tr>
<tr>
<td>Reference Lab</td>
<td>$2,426,000</td>
<td>$2,426,000</td>
<td>$0.000</td>
<td>0.0%</td>
<td>$2,513,000</td>
<td>$87,000</td>
<td>3.6%</td>
</tr>
<tr>
<td>CMCs</td>
<td>$6,093,000</td>
<td>$6,102,000</td>
<td>$171,000</td>
<td>2.8%</td>
<td>$6,807,000</td>
<td>$796,000</td>
<td>12.8%</td>
</tr>
<tr>
<td>Diagnostic Services</td>
<td>$2,451,000</td>
<td>$2,887,000</td>
<td>$436,000</td>
<td>17.8%</td>
<td>$2,734,000</td>
<td>$263,000</td>
<td>10.7%</td>
</tr>
</tbody>
</table>

**PNS Expenditures Projections (See Appendices B1-B4)**

For FY 2019-20, Public Health/GDSP estimates PNS Local Assistance expenditures total $35.4 million, which is a decrease of $540,000 or 1.5 percent compared to the 2019 Budget Act. The decrease cost is due to continued reductions in caseload.

For FY 2020-21, Public Health/GDSP estimates that PNS Local Assistance expenditures will total $36 million, which is no change compared to the 2019 Budget Act.

Table 4 shows the 2019 Budget Act appropriation and the revised FY 2019-20 expenditures and proposed FY 2020-21 expenditures for the Prenatal Screening program costs by client type.

### Table 4

<table>
<thead>
<tr>
<th>Client Type</th>
<th>FY 2019-20 Budget Act</th>
<th>November Estimate FY 2019-20</th>
<th>Change from Budget Act</th>
<th>Percent Change from Budget Act</th>
<th>FY 2020-21</th>
</tr>
</thead>
<tbody>
<tr>
<td>Total</td>
<td>$35,917,000</td>
<td>$35,397,000</td>
<td>$(540,000)</td>
<td>-1.5%</td>
<td>$35,911,000</td>
</tr>
<tr>
<td>Contract Lab</td>
<td>$4,685,000</td>
<td>$4,621,000</td>
<td>$(64,000)</td>
<td>-1.4%</td>
<td>$4,952,000</td>
</tr>
<tr>
<td>Tech &amp; Sci</td>
<td>$12,862,000</td>
<td>$12,686,000</td>
<td>$(176,000)</td>
<td>-1.4%</td>
<td>$12,627,000</td>
</tr>
<tr>
<td>CMCs</td>
<td>$6,389,000</td>
<td>$6,586,000</td>
<td>$197,000</td>
<td>3.1%</td>
<td>$6,633,000</td>
</tr>
<tr>
<td>PDC</td>
<td>$12,001,000</td>
<td>$11,504,000</td>
<td>$(497,000)</td>
<td>-4.1%</td>
<td>$11,699,000</td>
</tr>
</tbody>
</table>

**Operational Support Projections**

For FY 2019-20, the Public Health/GDSP revised operational support expenditures total was $30.3 million, which is no change compared to the 2019 Budget Act.

In FY 2020-21, Public Health/GDSP projects operational support expenditures will total $27.4 million, which is a decrease of $2.9 million or -9.7 percent compared to the 2019
Budget Act. The net change in Operational Support is due to a decrease in one-time funding for SMA equipment and database upgrades.

Table 5 shows the difference between the 2019 Budget Act appropriation and the revised FY 2019-20 expenditures and proposed FY 2020-21 expenditures for the Program Operational Support costs.

### Table 5

<table>
<thead>
<tr>
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</tr>
</thead>
<tbody>
<tr>
<td>Operational Support</td>
<td>$30,344,000</td>
<td>$30,344,000</td>
<td>-</td>
<td>0.0%</td>
<td>$27,400,000</td>
<td>$ (2,944,000)</td>
<td>-9.7%</td>
</tr>
</tbody>
</table>

**D. State Operations Expenditure Projections**

In FY 2019-20 revised estimate, Public Health/GDSP estimates that State Operations expenditures will total $31.4 million, which is no change compared to the 2019 Budget Act amount of $31.4 million.

In FY 2020-21, Public Health/GDSP estimates State Operations expenditures will total $31.7 million, which is an increase of $328,000 or 1 percent from the 2019 Budget Act amount of $31.4 million. The increased cost is attributed to $325,000 approved in the 2019 budget proposal for additional SMA resources and $3,000 baseline adjustments.

Table 6 shows the difference between the 2019 Budget Act appropriation and the revised FY 2019-20 expenditures and proposed FY 2020-21 expenditures for the Public Health/GDSP State Operations costs.

### Table 6

<table>
<thead>
<tr>
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<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>State Operations</td>
<td>$31,351,000</td>
<td>$31,351,000</td>
<td>-</td>
<td>0.0%</td>
<td>$31,679,000</td>
<td>$328,000</td>
<td>1.0%</td>
</tr>
</tbody>
</table>

**E. Revenue Projections**

**Combined NBS and PNS Revenue**

Public Health/GDSP has revised revenue estimates for FY 2019-20 totaling $129.8 million, which is an increase of $466,000 or 0.4 percent compared to the 2019 Budget Act amount of $129.3 million. The increase, despite billable caseload decreases, is due
to higher collection rates. The rates increased from 90 percent to 94 percent for prenatal screening participants with private insurance and from 98 to 99 percent increase in collection rate for newborn screening.

For FY 2020-21, Public Health/GDSP projects revenue will total $145.1 million, which is an increase of $15.8 million or 12.2 percent compared to the 2019 Budget Act amount of $129.4 million. The increase is due to the increase in the newborn fee from $142.25 to $177.25, an increase of $35.00 per newborn.

All other assumptions and calculations remain unchanged from the 2019 Budget Act.

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 (Fund 0203). The remaining $10 is deposited into the Birth Defects Monitoring Program Fund (Fund 3114).

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

\[
\text{Revenue} = (\text{Fee} \times \text{PNS Participants} \times \text{Medi-Cal Participation Rate} \times \text{Medi-Cal Collection Rate}) + (\text{Fee} \times \text{PNS Participants} \times [1 - \text{Medi-Cal Participation Rate}] \times \text{Private Payer Collection Rate})
\]

Starting July 1, 2020, NBS participants will be charged a fee of $177.25, an increase of $35. The increase is needed in part to support the increase in expenditures to perform the routine and ongoing workload for SMA screening. Unlike PNS, where Public Health/GDSP bills patients and collects fees from insurers, Public Health/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. Public Health/GDSP uses the following formula to estimate revenue generated from NBS fees:

\[
\text{NBS Revenue} = \text{Fee} \times \# \text{ of Projected Newborns screened} \times \text{Collection Rate}
\]

NBS Revenue (See Appendix C-1)
In FY 2019-20, NBS revenue is expected to total $64.2 million, which is an increase of $31,000 compared to the 2019 Budget Act of $64.1 million.
In FY 2020-21, GDSP projects NBS revenue will total $79.6 million, which is an increase of $15.5 million compared to the 2019 Budget Act of $64.1 million.

The increase in revenue for the budget year is due to the $35.00 increase in newborn screening fee and the increase in collection rate from 98 to 99 percent.

**PNS Revenue (See Appendix C2)**

In FY 2019-20, PNS revenue is expected to total $66 million, which is an increase of $435,000 or 0.7 percent compared to the 2019- Budget Act amount of $65.2 million.

In FY 2020-21, Public Health/GDSP projects PNS revenue will total $65.5 million, which is an increase of $253,000 or 0.4 percent compared to the 2019 Budget Act of $65.2 million.

The increase in both the current year and the budget year is due to the change in collection rate from 90 percent to 94 percent for individuals with private insurances.

Table 7 shows the revised current year revenue projections for current year and budget year compared to 2019 Budget Act.

<table>
<thead>
<tr>
<th></th>
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<th></th>
<th></th>
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<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Total</td>
<td>$129,381,000</td>
<td>$129,827,000</td>
<td>$466,000</td>
<td>0.4%</td>
<td>$145,110,000</td>
<td>$15,749,000</td>
<td>$466,000</td>
<td>3.2%</td>
</tr>
<tr>
<td>NBS</td>
<td>$64,148,000</td>
<td>$64,179,000</td>
<td>$31,000</td>
<td>0.6%</td>
<td>$79,649,000</td>
<td>$15,410,000</td>
<td>$31,000</td>
<td>24.7%</td>
</tr>
<tr>
<td>PNS</td>
<td>$65,233,000</td>
<td>$65,648,000</td>
<td>$415,000</td>
<td>0.7%</td>
<td>$65,466,000</td>
<td>$253,000</td>
<td>$415,000</td>
<td>0.4%</td>
</tr>
</tbody>
</table>
## California Department of Public Health

### Genetic Disease Screening Program

**FY 2020-21 November Estimate**

### GENETIC DISEASE TESTING FUND

#### FUND CONDITION REPORT

**Dollars in Thousands**

<table>
<thead>
<tr>
<th>RESOURCES</th>
<th>2016-19</th>
<th>2019-20</th>
<th>2020-21</th>
</tr>
</thead>
<tbody>
<tr>
<td>BEGINNING BALANCE</td>
<td>$26,498</td>
<td>$21,429</td>
<td>$5,550</td>
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<tr>
<td>Prior Year Adjustment</td>
<td>0</td>
<td>0</td>
<td>0</td>
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<tr>
<td>Adjusted Beginning Balance</td>
<td>26,498</td>
<td>21,429</td>
<td>5,550</td>
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#### REVENUES

<table>
<thead>
<tr>
<th>Description</th>
<th>2016-19</th>
<th>2019-20</th>
<th>2020-21</th>
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<tbody>
<tr>
<td>12106 Genetic Disease Testing Fees</td>
<td>130,011</td>
<td>129,627</td>
<td>145,110</td>
</tr>
<tr>
<td>150300 Income from Surplus Investments</td>
<td>45</td>
<td>45</td>
<td>45</td>
</tr>
<tr>
<td>161000 Escheat of Unclaimed Checks &amp; Warrants</td>
<td>2</td>
<td>2</td>
<td>2</td>
</tr>
<tr>
<td><strong>TOTALS, REVENUES</strong></td>
<td>130,058</td>
<td>129,674</td>
<td>145,157</td>
</tr>
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</table>

**TOTAL RESOURCES** $156,556 $151,303 $150,007

### EXPENDITURES AND EXPENDITURE ADJUSTMENTS

<table>
<thead>
<tr>
<th>Description</th>
<th>2016-19</th>
<th>2019-20</th>
<th>2020-21</th>
</tr>
</thead>
<tbody>
<tr>
<td>4265 Department of Public Health (State Operations)</td>
<td>36,593</td>
<td>31,351</td>
<td>31,879</td>
</tr>
<tr>
<td>4265 Department of Public Health (Local Assistance)</td>
<td>163,228</td>
<td>111,624</td>
<td>110,887</td>
</tr>
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<td>8880 Financial Information System for California (State Operations)</td>
<td>3</td>
<td>.4</td>
<td>0</td>
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<tr>
<td>9800 Employee Compensation (State Operations)</td>
<td>0</td>
<td>913</td>
<td>957</td>
</tr>
<tr>
<td>Control Section 3.60 Retirement</td>
<td>0</td>
<td>233</td>
<td>233</td>
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<tr>
<td>Lease Revenue Debt Service Adjustment</td>
<td>0</td>
<td>1</td>
<td>4</td>
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<td>9892 Supplemental Pension Payments (State Operations)</td>
<td>202</td>
<td>466</td>
<td>496</td>
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<td>9999 Statewide General Admin Exp (ProRata) (State Operations)</td>
<td>1,131</td>
<td>1,656</td>
<td>1,289</td>
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<tr>
<td><strong>TOTAL EXPENDITURES AND EXPENDITURE ADJUSTMENTS</strong></td>
<td>135,127</td>
<td>145,653</td>
<td>145,524</td>
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**FUND BALANCE** 21,429 5,650 5,283

16% 4% 4%

### REVENUE PROJECTIONS

#### 2019-20

<table>
<thead>
<tr>
<th>Description</th>
<th>2019-20 NBS FEES BASED ON</th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>455,729 TESTS @</td>
<td>$142.25</td>
<td>AND 99% Provider</td>
<td>$64,179,000</td>
</tr>
<tr>
<td>145,128 TESTS @</td>
<td>$211.60</td>
<td>AND 94% Non Medi-Cal</td>
<td>28,856,000</td>
</tr>
<tr>
<td>177,375 TESTS @</td>
<td>$211.60</td>
<td>AND 98% Medi-Cal</td>
<td>36,732,000</td>
</tr>
<tr>
<td><strong>TOTAL</strong></td>
<td>322,502</td>
<td></td>
<td>65,648,000</td>
</tr>
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**GDSNP Total** $125,827,000

#### 2020-21

<table>
<thead>
<tr>
<th>Description</th>
<th>2020-21 NBS FEES BASED ON</th>
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<tr>
<td>453,869 TESTS @</td>
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<td>176,884 TESTS @</td>
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<td><strong>TOTAL</strong></td>
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<td></td>
<td>65,468,000</td>
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</table>

**GDSNP Total** $145,110,000

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1/ NBS Fees based on 99% hospital and other provider collection rate
2/ PNS Fees based on 94% of private payer/insurance collection rate for
3/ PNS Fees based on 98% Medi-Cal Collection rate
II. General Assumptions

Future Fiscal Issues

Senate Bill (SB) 1095: Newborn Screening Program

Background: Senate Bill (SB) 1095 (Chapter 393, Statutes of 2016) amends Sections 124977 and 125001 of the Health and Safety Code (H&S Code) and requires the Public Health/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 Public Health 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 $1 million to $2.5 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 two additions to the Newborn Screening panel – Mucopolysaccharidosis Type 1 (MPS-I) and Pompe disease. Furthermore, as additional diseases are added to the RUSP, there may one-time resources needed to plan, prepare for, and implement the additional required screening. Public Health/GDSP will assess the fund reserve to ensure the program is able to absorb the increase in expenditures and determine if, and when, a fee increase is needed. The fund source is the Genetic Disease Testing Fund (GDTF) (Fund 0203).

Modernization of the California Prenatal Screening Program

Background: A new screening test known as “Cell-free DNA” (cfDNA) has been developed and became available to the public in 2011 and over time has demonstrated value for prenatal screening. With cfDNA testing it is now possible to detect fetal DNA circulating freely in a pregnant woman’s blood. The cfDNA screening can be used to detect the same chromosome abnormalities as the current PNS Program’s conventional biochemical screening but with a significantly lower false positive rate, plus it can detect
an additional chromosome abnormality for which the current screening does not screen for (i.e., Trisomy 13).

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 statement from the American College of Medical Genetics and Genomics 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 will replace GDSP’s current conventional biochemical screening for chromosome abnormalities with cfDNA screening in July 2021. 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, expected to take place in July 2021: 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 cost $4 million. The actual laboratory screening replacement is expected to be contracted out to private laboratories and preliminary estimates indicate the costs will increase net PNS program expenditures between 20 to 30 percent or $12.4 to $18.6 million annually after factoring savings from a lower false positive rate.

**Discretionary:** Yes.

**Reason for Adjustment/Change:** The cfDNA screening yields a much better chromosome abnormality detection rate than the PNS Program’s current screening method, 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, 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.

Fiscal Impact (Range) and Fund Source(s): A $4 million one-time increase in Local Assistance expenditure authority in FY 2020-21. Local Assistance expenditures may increase between $12.4 million to $18.6 million annually beginning FY 2021-22. The fund source is the GDTF (Fund 0203).

New Assumptions/ Premises

Newborn Screening Fee Increase

Background: Senate Bill (SB) 1095 (Chapter 393, Statutes of 2016) established H&S Code section 125001(d) and required the Public Health Newborn Screening (NBS) Program to expand statewide screening of newborns by adding new tests within two years of the disease screen being adopted by the federal Recommended Uniform Screening Panel (RUSP). Since this mandate was introduced, the Public Health NBS has added screening for two additional disorders to the NBS panel in August 2018 – mucopolysaccharidoses (MPS) Type I and Pompe disease – requiring NBS fee increases in July 2018 to support the additional expenditures.

On July 2, 2018 Spinal Muscular Atrophy (SMA) was added to the federal RUSP by the Secretary of Health and Human Services. This requires the GDSP to implement newborn screening for the disorder in California within two years of that date.

This addition will allow California to meet the national standard of care as recommended by the federal Advisory Committee on Heritable Disorders in Newborns and Children and the US Department of Health and Human Services and will bring the NBS Program into alignment with the most up-to-date research, technology, laboratory, public health standards, and practices, as well as H&S Code section 125001(d). Similar to MPS Type I and Pompe disease, GDSP will need to increase fees to offset the additional expenditures of needing to screen for SMA.

Additionally, over the past two years, GDSP has been experiencing an increase in the contracted rates for screening which can be attributed to normal costs of doing
business. GDSP has experienced an increased rate in referrals for case management and coordination and diagnostic services. Additional contract rate increases with regional testing laboratories for ALD rollout, Area Service Centers, specialized follow-up centers, and diagnostic testing labs, as well as scientific supply companies are expected in budget year. These rate and caseload increases were included in prior, current, and budget year estimates, and although additional budget authority was authorized, fees were not increased to offset the additional expenditures.

Description of Change: The 2019 Budget Act includes the necessary additional expenditure authority ($4.3 million in FY 2019-20, and $2.6 million in FY 2020-21 and ongoing) to support SMA screening. A fee increase of approximately $9 will be needed to offset these costs. An additional fee increase of approximately $26 will be needed to offset the increased expenditures related to higher contract rates for screening and higher costs associated with increased referrals for case management/coordination and diagnostic services.

Discretionary: No

Reason for Adjustment/Change: SB 1095 requires Public Health 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. The higher screening rates can be attributed to standard increasing costs of doing business. The increases in case management and coordination and diagnostic services are likely an unplanned impact from the increasing numbers of disorders that are being screened under the NBS Program.

Fiscal Impact (Range) and Fund Source(s): An increase in revenues of approximately $15.7 million annually beginning FY 2020-21 due to a $35 NBS fee increase that will be approved through the rulemaking process. The fund source is the GDTF (Fund 0203).

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

Background: In FY 2016-17, GDSP fully transitioned its in-house patient billing process to an outsourced vendor, Sutherland Healthcare Solutions (SHS). With the in-house process using call center staff, GDSP had an approximate 83 percent collection rate within two years collection time. Over the two previous fiscal years when patient billing process was outsourced, the collection rate has increased to 90 percent collection rate within two years collection time from non-Medi-Cal insurers for Prenatal Screening. This rate was used for Public Health GDSP’s FY 2019-20 estimates for revenue projections. Public Health contracted with SHS due to its powerful billing system, customer care expertise, deep knowledge of healthcare policy and programs, and state of the art
technology. The goal was to accelerate revenue collections, reduce the overall risk and cost to collect, and reduce uncollectable accounts.

As the patient billing collection rate progresses under a new AR system (outsourced vendor), the client billing collection rate increased from 98 percent to 99 percent. During the transition process of removing patient billing from the existing Infor, AR system, GDSP staff worked on improving the processes of client billing by sending out invoices electronically via secured email rather than sending them by mail. In the same year that GDSP transitioned the patient billing process to SHS, GDSP staff received requests from 20 large hospital providers indicating that they do prefer electronic billing via email than the paper invoices. This new process helped GDSP not only increase the collection rate to 99 percent, but it also reduced the timeline of collecting revenue from 1 year to 6 months. The remaining 1 percent belongs to one hospital provider that filed for bankruptcy and since this is an unsecured claim, the court scheduled the Chapter 9 to be paid out beginning in 2025 through 2029. Eventually, once the bankruptcy case is finalized, the remaining balance will be discharged from accountability.

Description of Change: Since GDSP contracted with Sutherland for the Prenatal Screening Program (PNS) billing and collection, the collection rate for non-Medi-Cal participants has improved from 84 percent to 94 percent. The NBS collection rate has improved from 98 percent to 99 percent.

Discretionary: Yes

Reason for Adjustment/ Change: The rate of collection for PNS non-Medi-Cal participants, as well as NBS participants needs to be updated to reflect accurate revenue figures.

Fiscal Impact (Range) and Fund Source(s): An annual increase for PNS in projected revenues is $1.2 million. The annual increase for NBS in projected revenues is $654,000. The fund source is the GDTF (Fund 0203).

Existing (Significantly Changed) Assumptions/Premises

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

Unchanged Assumptions/Premises

There are no Unchanged Assumptions/Premises.

Discontinued Assumptions/Premises
Projecting Screening Costs - Reagents, Supplies, Equipment Rental and Purchases, and Consulting Services

Public Health/GDSP has changed the methodology to estimate the rates of expenditures per participant for current and budget year cost projections in the estimate process using the participant rates from current executed contracts as its base rate for the current year estimate and factoring in an inflation rate based on a three year historical trend of prior contract rate changes, if the current executed contracts do not extend into the budget year.

Accounts Receivables through Sutherland Healthcare Solutions (SHS)

The rate of collection for non-Medi-Cal participants has been updated to the increased rate of 90 percent to reflect accurate revenue figures.

Budget Change Proposal: Implementation of Newborn Screening for Spinal Muscular Atrophy (SMA) in California

The statewide screening of newborns has included SMA to the screening panel as required by SB 1095 to include screening of any disease that is detectable in blood samples within two years of the disease being adopted by the federal RUSP.
Appendix A: NBS Assumptions and Rationale

1. Contract Laboratories

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

Costs associated with Contract Laboratories and Technical and Scientific supplies are both driven by the total number of clients NBS serves. The total caseload is determined as a percentage of the DRU’s projected number of live births. This estimate assumes that 100 percent of the DOF/DRU projected births will participate in the NBS program in FY 2018-19 and 2019-20.

Total Caseload – Public Health/GDSP estimates current year caseload will total 455,729, an increase of 2,096 or 0.5 percent compared to the FY 2018-19 actual total caseload of 453,633. Caseload in FY 2020-21 is estimated at 453,869, which is a decrease of 1,859 or 0.4 percent compared to the current year estimate. This year over year change is due to the DOF/DRU’s projected number of live births. The following chart shows the actual NBS cases by fiscal year, along with our projected numbers for the remainder of the current year and budget year.
Appendix A.1

Contract Laboratory Average Cost Projections – Public Health/GDSP estimates current year average laboratory cost per participant will be $15.04, which is an increase of $1.01 or 7.2 percent compared to the FY 2018-19 actual average laboratory cost per participant of $14.03. Average laboratory cost per participant in FY 2020-21 is estimated at $15.79, which is an increase of $0.75 or 5 percent compared to the current year estimate. The increase is due to the increased cost of the laboratory contracts.
Contract Laboratory Total Cost Projections – Public/Health GDSP estimates current year contract laboratory costs to total $6.9 million, which is an increase of $508,000 or 8 percent compared to FY 2018-19 actual contract laboratory costs of $6.4 million. FY 2020-21 contract laboratory costs are projected to be $7.2 million which is an increase of $313,000 or 4.6 percent compared to the current year.

2. Technical and Scientific

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

Technical and Scientific Caseload: See Appendix A 1

Technical and Scientific Average Cost – Public Health/GDSP estimates current year average Technical and Scientific cost per participant will be $60.33, which is a decrease of $2.82 or 4 percent compared to FY 2018-19 actual average Technical and Scientific cost per participant of $63.14. Average Technical and Scientific cost per participant in FY 2020-21 is estimated at $62.47, which is an increase of $2.14 or 4 percent compared to the current year estimate.
Technical and Scientific Total Cost – Public Health/GDSP estimates current year Technical and Scientific costs to total $27.5 million, which is a decrease of $1.2 million or 4 percent compared to FY 2018-19 actual technical and scientific costs of $28.6 million. For FY 2020-21 the Technical and Scientific costs is estimated to be $28.4 million, which is an increase of $861,000 million or 3 percent compared to the current year. The current year decrease in cost is tied to the fluctuations of caseload. The average cost decreases with an increase in the consumables and reagents needed for screening disorders. The budget year increase in average cost is tied to the declining caseloads.

3. Case Management and Coordination Services:

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

Case Management and Coordination Services (CMCS) Caseload – Public Health/GDSP estimates current year CMCS caseload will total 20,052, which is an increase of 252 or 1 percent compared to FY 2018-19 actual CMCS caseload of 19,800. CMCS caseload in FY 2020-21 is estimated at 19,970, which is a decrease of 82 compared to the current year estimate.

<table>
<thead>
<tr>
<th></th>
<th>FY 16-17</th>
<th>FY 17-18</th>
<th>FY 18-19</th>
<th>FY 19-20</th>
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Case Management and Coordination Services (CMCS) Average Cost - Public Health/GDSP estimates current year average CMCS cost per participant will be $177, which is a decrease of $16 or 8 percent compared to FY 2018-19 actual average CMCS cost per participant of $193. Average CMCS cost per participant in FY 2020-21 is estimated at $206, which is an increase of $5 or 2 percent compared to the current year estimate. Fluctuation in the Average Cost is tied directly to the Total Cost and additional specialized follow-up centers for SMA testing.
Case Management and Coordination Services (CMCS) Total Cost - Public Health/GDSP estimates current year CMCS costs to total $6.2 million, which is a decrease of $152,000 or 2 percent compared to FY 2018-19 actual CMCS total costs of $6.4 million. CMCS costs in FY 2020-21 are estimated to total $6.8 million, which is an increase of $605,000 or 10 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 expenditures in FY 2020-21 is due to the projected number of positive cases attributed to the new 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.
4. 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 – Public Health/GDSP estimates current year Diagnostic caseload will total 5,514, based on projected new referral cases and annual patient summary cases, which is virtually no change compared to FY 2018-19 actual Diagnostic Services caseload of 5,489. Diagnostic caseload in FY 2020-21 is estimated at 5,492, which is virtually no change compared to the current year estimate. Fluctuations are tied to overall DRU-based caseload.

<table>
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<th>NBS Follow-up/Diagnostic Caseload</th>
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<td>5,877</td>
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</table>

Diagnostic Services Average Cost - Public Health/GDSP estimates current year average Diagnostic Services cost per participant will be $524, calculated based on projected new referral cases and annual patient summary cases, which is an increase of $121 or 30 percent compared to FY 2018-19 actual average Diagnostic Services cost per participant of $403. The Average Diagnostic Services cost per participant in FY
2020-21 are estimated at $494, which is a decrease of $29 or 6 percent compared to the current year average cost. The increase in current year is tied to the increase in total cost and increase caseload. The decrease in the budget year is tied to the decrease in total cost and decrease caseload.

**Diagnostic Services Total Cost** - Public Health/GDSP estimates current year Diagnostic Services costs to total $2.8 million, which is an increase of $677,000 or 31 percent compared to FY 2018-19 actual Diagnostic Services total costs. Diagnostic Services costs in FY 2020-21 are estimated to total $2.7 million, which is a decrease of $173,000 or 6 percent compared to the current year estimate. The increase in current year total cost is attributable to the contract increases and increase in caseload. The decrease in budget year total cost is due to the decrease in caseload.
5. Reference Laboratory Cases:

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 – Public Health/GDSP estimates current year Reference Laboratory caseload will total 9,434, which is an increase of 203 or 2 percent compared to FY 2018-19 actual Reference Laboratory caseload of 9,231. Reference Laboratory caseload in FY 2020-21 is estimated at 9,520, which is an increase of 86 or 1 percent compared to the current year estimate.

Reference Laboratory Average Cost – Public Health/GDSP estimates current year Reference Laboratory average cost per participant will be $257, which is an increase of $27.06 or 12 percent compared to FY 2018-19 Reference Laboratory actual average cost per participant of $230.09. Reference Laboratory average cost per participant in FY 2020-21 is estimated at $264, which is an increase of $7 or 3 percent compared to the current year estimate. The increase in cost for current year and budget year is attributed to an increase in contracts with specialized follow-up centers that account for additional expenses since we implemented Pompe and MPS1 screening and the implementation of SMA.
Reference Laboratory Total Cost – Public Health/GDSP estimates current year Reference Laboratory costs to total $2.4 million, which is an increase of 302,000 compared to FY 2018-19 actual Diagnostic Services total costs of $2.1 million. Reference Laboratory costs in FY 2020-21 are estimated to total $2.5 million, which is an increase of $87,000 or 4 percent compared to the current year estimate. The increase is attributed to the additional cost for adding confirmatory DNA sequencing for new disorders and contract increases for sickle cell trait follow-up.
APPENDIX B: Prenatal Screening Program Assumptions and Rationale

1. 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 7 regional laboratories, currently the state contracts with five regional contract laboratories that are paid on a per specimen basis.

In the past Public Health/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 however 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.

Total Caseload/Specimens – Public Health/GDSP estimates current year specimens will total 535,509, which is an increase of 8,864 or 2 percent compared to FY 2018-19, actual total specimens of 526,645. Specimens in FY 2020-21 is estimated at 533,006 which is a decrease of 2,503 or 0.5 percent compared to the current year estimate. The PNS program participation is estimated as a percentage of the DOF/DRU projected number of live births.

Public Health/GDSP estimates that 71 percent (based from a three-year actual average) of the projected births will participate in the PNS program in FY 2019-20, and that the number of participants will remain constant in FY 2020-21. The FY 2020-21 projections do not increase with DOF/DRU birth rates because PNS participation has not remained constant as a percent of DRU birth projections due to women choosing other types of prenatal testing offered outside of the State program. The following chart shows the actual PNS cases by year, along with our projected numbers for the remainder of the current year and budget year.
Appendix B.1

**Contract Laboratory Average Cost Projections** – Public Health/GDSP estimates current year average laboratory cost per participant will be $8.63, which is an increase of $0.63 or 4 percent compared to FY 2018-19 actual average laboratory cost per participant of $8. Average laboratory cost per participant in FY 2020-21 is estimated at $9.29, which is an increase of $0.66 or 8 percent compared to current year estimate.

**Contract Laboratory Total Cost Projections** – Public Health/GDSP estimates current year contract laboratory cost to total $4.6 million, which is a decrease of $249,000 or 6
percent compared to FY 2018-19 actual contract laboratory costs of $4.4 million. Laboratory costs in FY 2020-21 are estimated to total $5 million, which is an increase of $331,000 or 7 percent compared to the current year estimate.

### 2. 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** – Public Health/GDSP estimates current year average Technical and Scientific cost per participant will be $23.69, which is a decrease of $0.80 or 3 percent compared to FY 2018-19 actual average Technical and Scientific cost per specimen of $24.49. Average laboratory cost per specimen in FY 2020-21 is estimated at $23.69, which is no change compared to the current year estimate. The decrease in the current year and budget year is attributed to the decrease in total cost and is tied to the total projected specimens tested.
Technical and Scientific Total Cost – Public Health/GDSP estimates current year Technical and Scientific costs to total $12.7 million, which is a decrease of $212,000 or 2 percent compared to FY 2018-19 actual technical and scientific costs of $12.9 million. Technical and Scientific costs in FY 2020-21 are estimated to total $12.6 million which is a decrease of $59,000 or 0.5 percent compared to the current year estimate. Fluctuation in total cost is tied to caseload.

3. 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 – Public Health/GDSP estimates current year PDC caseload will total 12,029, which is an increase of 1,435 or 14 percent compared to the FY 2018-19 actual PDC caseload of 10,594. The increase is caused by a projected uptick in women choosing to further pursue diagnostic care. PDC caseload in FY 2020-21 is estimated to total 11,960, which is a decrease of 69 or 1 percent compared to the current year estimate.

Prenatal Diagnostic Services Average Cost – Public Health/GDSP estimates current year average PDC cost per participant will be $956.36, which is a decrease of $50.06 or 5 percent compared to FY 2018-19 actual average PDC cost per participant of $1,006.42. Average laboratory cost per participant in FY 2020-21 is estimated at $978.21, which is an increase of $21.85 or 2 percent compared to the current year estimate. The reduction in average cost in the current year is the 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, like amniocentesis. Women who would previously have declined PDC services are now choosing these non-invasive procedures. The increase in average cost in the budget year is due to the increased contract costs.
Prenatal Diagnostic Services Total Cost – Public Health/GDSP estimates current year PDC costs to total $11.5 million, which is an increase of $842,000 or 8 percent compared to FY 2018-19 actual PDC total costs of $10.7 million. PDC costs in FY 2020-21 are estimated to total $11.7 million, which is an increase of $195,000 or 2 percent compared to the current year estimate. The change in total expenditures is attributable mainly to fluctuating projected PDC caseload.

4. Case Management and Coordination Services:

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

Case Management and Coordination Services (CMCS) Caseload - Public/GDSP estimates current year CMCS caseload will total 117,804, which is an increase of 1,342 or 1 percent compared to FY 2018-19 actual CMCS caseload of 119,146. CMCS caseload in FY 2020-21 is estimated at 117,816, which is an increase of 12 or 0.01 percent compared to the current year estimate. This is due largely to changes in the DRU-based caseload. CMCS caseload has remained relatively flat regardless of overall program participation. 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](image)

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<th>FY 18-19</th>
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Case Management and Coordination Services (CMCS) Average Cost - Public Health/GDSP estimates current year average CMCS cost per participant will be $31.90, which is a decrease of $1.89 or 6 percent compared to FY 2018-19 actual average CMCS cost per participant of $33.79. The decrease in the current year is attributable to a slight decrease in caseload. Average CMCS cost per participant in FY 2020-21 is
estimated at $32.01, which is an increase of $0.11 or 0.4 percent compared to the current year estimate. The increase is attributable to the fluctuation in total cost.

Case Management and Coordination Services (CMCS) Total Cost - Public Health/GDSP estimates current year CMCS costs to total $6.6 million, which is an increase of $199,000 or 3 percent compared to FY 2018-19 actual CMCS total costs of $6.4 million. The increase is attributable to the increase in caseload causing a decrease in the average cost. CMCS costs in FY 2020-21 are estimated to total $6.6 million, which is an increase of $47,000 or 1 percent compared to the current year estimate.

APPENDIX C: Revenue Projections

1. NBS Revenue
On July 1, 2020, the NBS fee will increase by $35.00 and new fee will be $177.25. In most cases the fee is paid to directly to Public Health/GDSP by hospitals. For births that occur outside of a hospital Public Health/GDSP invoice the appropriate fee to the family of the infant or their insurance company. Since the majority of births happen within a hospital, billing and receiving payment for NBS services is greatly streamlined and efficient. Past actual collection amounts indicate that Public Health/GDSP collects approximately 98 percent of all revenue related to providing NBS services. Beginning the current year, the collection rate increased to 99 percent. As such, NBS revenue is estimated using the following formula:

\[ \text{NBS Revenue} = \text{#of Projected Newborns screened} \times \text{Fee} \times 99\% \]

### NBS Revenue Projections

<table>
<thead>
<tr>
<th></th>
<th>A</th>
<th>B</th>
<th>C</th>
<th>D=(A<em>B</em>C)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Fee</td>
<td>Caseload</td>
<td>Collection Rate</td>
<td>Total Revenue</td>
</tr>
<tr>
<td>FY 2019-20</td>
<td>$142.25</td>
<td>455,729</td>
<td>99%</td>
<td>$64,179,000</td>
</tr>
<tr>
<td>FY 2020-21</td>
<td>$177.25</td>
<td>453,869</td>
<td>99%</td>
<td>$79,644,000</td>
</tr>
</tbody>
</table>

2. 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:

\[ \text{PNS Revenue} = (\text{Fee} \times \text{PNS Participants} \times \text{Medi-Cal Participation Rate} \times \text{Medi-Cal Collection Rate}) + (\text{Fee} \times \text{PNS Participants} \times \text{Private Payer Rate} \times \text{Private Payer Collection Rate}) \]

### PNS Revenue Projections

<table>
<thead>
<tr>
<th>Fiscal Year</th>
<th>Fee</th>
<th>Caseload</th>
<th>% Medi-Cal</th>
<th>% Non-Medical</th>
<th>Medi-Cal Collection Rate</th>
<th>Medi-Cal Cases</th>
<th>Non Medi-Cal Cases</th>
<th>Total Revenue</th>
</tr>
</thead>
<tbody>
<tr>
<td>FY 2019-20</td>
<td>$211.60</td>
<td>322,502</td>
<td>55%</td>
<td>45%</td>
<td>98%</td>
<td>177,376</td>
<td>165,128</td>
<td>$66,688,789</td>
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<tr>
<td>FY 2020-21</td>
<td>$211.60</td>
<td>321,607</td>
<td>55%</td>
<td>45%</td>
<td>98%</td>
<td>176,894</td>
<td>144,723</td>
<td>$66,466,062</td>
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</tbody>
</table>