GENETIC DISEASE SCREENING PROGRAM (GDSP)

Fiscal Year 2019-20
May Revision Estimate

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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) 2018-19 expenditures along with projected costs for FY 2019-20 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. Combined State Operations and Local Assistance Expenditure Overview

The Public Health/GDSP FY 2019-20 Governor’s Budget appropriation for FY 2018-19 is $134.1 million, of which $103.5 million is for Local Assistance and $30.6 million is for State Operations. At May Revision, Public Health/GDSP estimates FY 2018-19 expenditures will be $133.8 million, which is a decrease of $273,000 or 0.20 percent compared to the FY 2019-20 Governor’s Budget.

The Public Health/GDSP FY 2019-20 Governor’s Budget appropriation for FY 2019-20 is $141.2 million. At May Revision, the Public Health/GDSP estimates FY 2019-20 budget expenditures will be $143 million, of which $31.4 million is for State Operations and $111.6 million is for Local Assistance. Overall, this is an increase of $1.8 million or 1.34 percent compared to the FY 2019-20 Governor’s Budget.

Table 1 shows the difference between the FY 2019-20 Governor’s Budget appropriation and the revised FY 2018-19 expenditures and proposed FY 2019-20 expenditures for Public Health/GDSP.

<table>
<thead>
<tr>
<th>Fund 003 Genetic Disease Testing Fund</th>
<th>2018 Budget Act</th>
<th>2019-20 Governor’s Budget</th>
<th>2019 May Revision</th>
<th>Change from Governor’s Budget to May Revision</th>
<th>Percent Change from Governor’s Budget to May Revision</th>
<th>2019-20 Governor’s Budget</th>
<th>2019 May Revision</th>
<th>Change from Governor’s Budget to May Revision</th>
<th>Percent Change from Governor’s Budget to May Revision</th>
</tr>
</thead>
<tbody>
<tr>
<td>Total</td>
<td>$132,952,000</td>
<td>$134,094,000</td>
<td>$133,820,000</td>
<td>$(273,000)</td>
<td>-2.00%</td>
<td>$141,176,000</td>
<td>$142,975,000</td>
<td>$(1,799,000)</td>
<td>1.34%</td>
</tr>
<tr>
<td>State Operations</td>
<td>$25,451,000</td>
<td>$30,593,000</td>
<td>$30,593,000</td>
<td>-</td>
<td>0.00%</td>
<td>$31,351,000</td>
<td>$31,351,000</td>
<td>-</td>
<td>0.00%</td>
</tr>
<tr>
<td>Local Assistance</td>
<td>$103,501,000</td>
<td>$103,501,000</td>
<td>$103,228,000</td>
<td>$(273,000)</td>
<td>-2.63%</td>
<td>$109,825,000</td>
<td>$111,624,000</td>
<td>$(1,799,000)</td>
<td>1.44%</td>
</tr>
</tbody>
</table>

C. Local Assistance Expenditure Projections

Current Year (FY 2018-19)

The FY 2018-19 Governor’s Budget appropriation for Public Health/GDSP’s Local Assistance is $103.5 million. Public Health/GDSP anticipates revised FY 2018-19 Local Assistance
expenditures of $103.2 million, which is a decrease of $273,000 or 0.26 percent compared to the FY 2019-20 Governor’s Budget. The decrease is due to the decrease in caseload results from the Department of Finance’s (DOF) Demographic Research Unit’s (DRU) projection of live births.

Budget Year (FY 2019-20)

For FY 2019-20, Public Health/GDSP estimates Local Assistance expenditures will total $111.6 million, which is an increase of $1.8 million or 1.64 percent compared to the FY 2019-20 Governor’s Budget amount of $109.8 million. The increase is attributed to increasing laboratory supply and equipment costs and an increasing need for case management and coordination services for newborn screening.

Table 2 shows the difference between the FY 2019-20 Governor’s Budget appropriation and the revised FY 2018-19 expenditures and proposed FY 2019-20 expenditures for Public Health/GDSP Local Assistance.

Expenditure Methodology / Key Drivers of Cost

The CDPH/GDSP Local Assistance expenditures are split into three areas: Prenatal Screening (PNS), Newborn Screening (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 for the following:
   a. Total clients served
   b. Cases that receive case management
   c. Cases that are referred for diagnostic services
   d. Cases that are referred to reference laboratories (NBS only)

2. Average Case Cost for the following services:
   a. Contract laboratories
   b. Technology & Scientific supplies (Tech & Sci)
   c. Case Management and Coordination Services (CMCS)
   d. Follow-up Diagnostic Services (FDS)
   e. Reference laboratories (NBS only)

To calculate the total projected Local Assistance costs, CDPH projects NBS and PNS caseloads 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:
- 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, we summarize the projections 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 2018-19, Public Health/GDSP estimates NBS Local Assistance expenditures to total $41.1 million, which is an increase of $64,000 or 0.16 percent compared to the FY 2019-20 Governor’s Budget of $41 million. For FY 2019-20, Public Health/GDSP estimates that NBS Local Assistance expenditures will total $45.3 million, which is an increase of $2.4 million or 5.4 percent compared to FY 2019-20 Governor’s Budget of $43 million.

The increase in the current year and the budget year funding is associated with the increase in the contracted newborn screening rate costs. These costs include additional reagents, other consumables, and rental equipment. In the budget year, there is also an increase in the referrals for case management and coordination and diagnostic services which are based on the number of positive screenings and the disease/disorder. The number of referrals is not always contingent on the newborn population.

Table 3 shows the FY 2019-20 Governor’s Budget appropriation and the revised FY 2018-19 expenditures and proposed FY 2019-20 expenditures for the Newborn Screening Program costs.
For FY 2018-19, Public Health/GDSP estimates PNS Local Assistance expenditures total $34.7 million, which is a decrease of $337,000 or 0.96 percent compared to the FY 2019-20 Governor’s Budget of $35 million. For FY 2019-20, Public Health/GDSP estimates that PNS Local Assistance expenditures will total $35.9 million, which is a decrease of $522,000 or 1.43 percent compared to the FY 2019-20 Governor’s Budget of $36.5 million.

The decreases in both current year and budget year are due to the decrease in PNS caseload.

Table 4 shows the FY 2019-20 Governor’s Budget appropriation and the revised FY 2018-19 expenditures and proposed FY 2019-20 expenditures for the Prenatal Screening program costs by client type.

### Operational Support Projections

For FY 2018-19, the Public Health/GDSP revised operational support expenditures total was $27.5 million, which is no change compared to the 2019-20 Governor’s Budget.

In FY 2019-20, Public Health/GDSP projects operational support expenditures will total $30.3 million, which is no change compared to the 2019-20 Governor’s Budget.

Table 5 shows the difference between the 2019-20 Governor’s Budget appropriation and the revised FY 2018-19 expenditures and proposed FY 2019-20 expenditures for the program Operational Support costs.
D. State Operations Expenditure Projections

In FY 2018-19, Public Health/GDSP estimates that State Operations expenditures will total $30.6 million, which is no change from the FY 2019-20 Governor’s Budget amount of $30.6 million.

In FY 2019-20, Public Health/GDSP estimates State Operations expenditures will total $31.4 million, which is no change from the FY 2019-20 Governor’s Budget amount of $31.4 million.

Table 6 shows the difference between the FY 2019-20 Governor’s Budget appropriation and the revised FY 2018-19 expenditures and proposed FY 2019-20 expenditures for the Public Health/GDSP State Operations costs.

E. Revenue Projections

Combined NBS and PNS Revenue

Public Health/GDSP has revised revenue estimates for FY 2018-19 totaling $130 million, which is a decrease of $2.1 million or 1.66 percent compared to the 2019-20 Governor’s Budget amount of $132.2 million.

For FY 2019-20, Public Health/GDSP projects revenue will total $129.4 million, which is a decrease of $2.3 million or 1.74 percent compared to the 2019-20 Governor’s Budget amount of $131.7 million.

The 2019 May Revision Estimate projects the FY 2018-19 NBS caseload at 461,083, which is a decrease of 8,067 cases or 1.72 percent compared to the 2019-20 Governor’s Budget caseload projection of 469,150 cases for FY 2018-19. For FY 2019-20, the 2019 May Revision Estimate projects the NBS caseload at 460,153, which is a decrease of 8,540 cases or 1.82 percent compared to the 2019-20 Governor’s Budget caseload projection of 468,693 for FY 2019-20.

The 2019 May Revision Estimate projects the FY 2018-19 PNS caseload at 329,081, which is a decrease of 5,349 cases or 1.60 percent compared to the 2019-20 Governor’s Budget caseload projection of 334,430 cases for FY 2018-19. For FY 2019-20, the 2019 May Revision Estimate...
projects the PNS caseload at 326,472, which is a decrease of 5,507 cases or 1.66 percent compared to the 2019-20 Governor's Budget caseload projection of 331,979 for FY 2019-20.

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, $211.60 of which is deposited into the Genetic Disease Testing Fund (Fund 0203). The remaining $10 is deposited into the Birth Defects Monitoring Program Fund (Fund 3114).

Public Health/GDSP invoices and collects PNS payments from individual participants, private insurers and Medi-Cal. Within a two-year collection period, Public Health/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 90 percent of the fees owed by individuals with private insurances. Public Health/GDSP uses the following formula to estimate revenue generated from PNS fees:

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

NBS participants are charged a fee of $142.25. 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 98 percent collection rate over a two-year collection period. Public Health/GDSP uses the following formula to estimate revenue generated from NBS fees:

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

NBS Revenue (See Appendix C-1)

In FY 2018-19, NBS revenue is expected to total $64.2 million, which is a decrease of $1.1 million or 1.72 percent compared to the 2019-20 Governor’s Budget of $65.4 million.

In FY 2019-20, Public Health/GDSP projects NBS revenue will total $64.1 million, which is a decrease of $1.2 million or 1.82 percent compared to the 2019-20 Governor’s Budget of $65.3 million.

The decrease in both current year and budget year is due to the decrease in billable caseload.

PNS Revenue (See Appendix C2)

In FY 2018-19, PNS revenue is expected to total $65.7 million, which is a decrease of $1.1 million or 1.6 percent compared to the 2019-20 Governor’s Budget amount of $66.8 million.
In FY 2019-20, Public Health/GDSP projects PNS revenue will total $65.2 million, which is a decrease of $1.1 million or 1.66 percent compared to the 2019-20 Governor’s Budget of $66.3 million.

The decrease in both current year and budget year is due to the decrease in billable caseload.

Table 7 shows the revised current year revenue projections for current year and budget year compared to 2019-20 Governor’s Budget.

<table>
<thead>
<tr>
<th>Fund 0203 Genetic Disease Testing Fund</th>
<th>2018 Budget Act</th>
<th>2019-20 Governor’s Budget</th>
<th>2019 May Revision</th>
<th>Percent Change from Governor’s Budget to May Revision</th>
<th>2019-20 Governor’s Budget</th>
<th>2019 May Revision</th>
<th>Percent Change from Governor’s Budget to May Revision</th>
</tr>
</thead>
<tbody>
<tr>
<td>Total</td>
<td>$131,709,000</td>
<td>$132,295,000</td>
<td>$130,011,000</td>
<td>($2,284,000)</td>
<td>$131,651,000</td>
<td>$129,361,000</td>
<td>($2,290,000)</td>
</tr>
<tr>
<td>Newborn Screening</td>
<td>$66,854,000</td>
<td>$65,402,000</td>
<td>$64,227,000</td>
<td>($1,175,000)</td>
<td>$65,338,000</td>
<td>$64,148,000</td>
<td>($1,190,000)</td>
</tr>
<tr>
<td>Prenatal Screening</td>
<td>$65,055,000</td>
<td>$65,893,000</td>
<td>$65,784,000</td>
<td>($1,069,000)</td>
<td>$66,313,000</td>
<td>$65,213,000</td>
<td>($1,100,000)</td>
</tr>
</tbody>
</table>
## II. Fund Condition Statement

### GENETIC DISEASE TESTING FUND

#### FUND CONDITION REPORT

<table>
<thead>
<tr>
<th>DOLLARS IN THOUSANDS</th>
<th>2017-18</th>
<th>2018-19</th>
<th>2019-20</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>RESOURCES</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>BEGINNING BALANCE</strong></td>
<td>321,751</td>
<td>320,498</td>
<td>321,429</td>
</tr>
<tr>
<td>Prior Year Adjustment</td>
<td>8,814</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td><strong>Adjusted Beginning Balance</strong></td>
<td>315,937</td>
<td>320,498</td>
<td>321,429</td>
</tr>
<tr>
<td><strong>REVENUES</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>121100 Genetic Disease Testing Fees $1</td>
<td>124,506</td>
<td>130,011</td>
<td>129,391</td>
</tr>
<tr>
<td>150300 Income from Surplus Investments</td>
<td>217</td>
<td>45</td>
<td>45</td>
</tr>
<tr>
<td>101000 Escheat of Unclaimed Checks &amp; Warrants</td>
<td>36</td>
<td>2</td>
<td>2</td>
</tr>
<tr>
<td><strong>TOTALS. REVENUES</strong></td>
<td>124,839</td>
<td>130,058</td>
<td>129,798</td>
</tr>
<tr>
<td><strong>TOTAL RESOURCES</strong></td>
<td>$156,414</td>
<td>$156,546</td>
<td>$150,837</td>
</tr>
</tbody>
</table>

### EXPENDITURES AND EXPENDITURE ADJUSTMENTS

<table>
<thead>
<tr>
<th></th>
<th>2017-18</th>
<th>2018-19</th>
<th>2019-20</th>
</tr>
</thead>
<tbody>
<tr>
<td>4225 Department of Public Health (State Operations)</td>
<td>30,093</td>
<td>30,093</td>
<td>31,351</td>
</tr>
<tr>
<td>4225 Department of Public Health (Local Assistance)</td>
<td>103,228</td>
<td>103,228</td>
<td>111,024</td>
</tr>
<tr>
<td>0640 State Controller (State Operations)</td>
<td>0</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>0880 Financial Information System for California (State Operations)</td>
<td>3</td>
<td>3</td>
<td>-8</td>
</tr>
<tr>
<td>6602 Supplemental Pension Payments (State Operations)</td>
<td>202</td>
<td></td>
<td>466</td>
</tr>
<tr>
<td>9900 Statewide General Admin Exp (ProvRate) (State Operations)</td>
<td>1,191</td>
<td>1,191</td>
<td>1,050</td>
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<tr>
<td><strong>TOTAL EXPENDITURES</strong></td>
<td>125,166</td>
<td>135,127</td>
<td>144,052</td>
</tr>
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</table>

### FUND BALANCE

<table>
<thead>
<tr>
<th></th>
<th>2017-18</th>
<th>2018-19</th>
<th>2019-20</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>FUND BALANCE</strong></td>
<td>26,498</td>
<td>21,429</td>
<td>6,335</td>
</tr>
</tbody>
</table>

### REVENUE PROJECTIONS

#### 2019-20

| 2019-20 NBS FEES BASED ON | 460,153 TESTS @ $142.25 AND 98% Provider $1 | = $64,148,000 |
| 2019-20 PNS FEES BASED ON | 148,913 TESTS @ $211.60 AND 60% Non Medi-Cal $2 | = $32,202,000 |
| 2019-20 PNS FEES BASED ON | 178,570 TESTS @ $211.60 AND 96% Medi-Cal $3 | = $37,255,000 |
| **GDSP Total**             | $139,561,000 |

---

1/ NBS Fees based on 98% hospital and other provider collection rate
2/ PNS Fees based on 90% of private payer/insurance collection rate
3/ PNS Fees based on 96% Medi-Cal Collection rate
III. 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 (Fund 0203).

New Assumptions/Premises

There are no New Assumptions/Premises.

Existing (Significantly Changed) Assumptions/Premises

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

Unchanged Assumptions/Premises

Projecting Screening Costs - Reagents, Supplies, Equipment Rental and Purchases, and Consulting Services

Background: Public Health/GDSP has been using a historical three year average of actual expenditures to estimate the rates of expenditures per participant for current and budget year cost projections in the estimate process. The current methodology used in prior estimates does
not take into account the current and future rates charged per participant of already executed contracts.

Description of Change: Rather than projecting costs per participant using a three year historical average of actual expenditures, Public Health/GDSP is proposing to use participant rates from current executed contracts as its base rate for current year estimates. If the contracts do not extend into the budget year, Public Health/GDSP is proposing to factor in an inflation rate based on a three year historical trend of prior contract rate changes.

Discretionary: Yes.

Reason for Adjustment/Change: This will provide Public Health/GDSP the ability to align the budget more accurately with current costs of doing business.

Fiscal Impact (Range) and Fund Source(s): It is estimated that contracted rates per participant increase approximately 2 to 4 percent every year. Based on Public Health/GDSP’s $103.5 million Local Assistance budget in the 2018 Budget Act, the annual increase would be approximately $2.1 million to $4.1 million. The fund source is the Genetic Disease Testing Fund (Fund 0203).

Accounts Receivables through Sutherland Healthcare Solutions (SHS)

Background: In Fiscal Year (FY) 2016-17, GDSP fully transitioned the in-house patient billing process to an outsourced vendor, SHS. With the in-house process using call center staff, GDSP had an approximate 83 percent collection rate from non-Medi-Cal insurers for prenatal screening. This has been the rate used in Public Health/GDSP’s estimates for revenue projection. GDSP contracted with SHS due to its expertise in billing systems, customer care expertise, and 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.

Description of Change: Since Public Health/GDSP contracted with Sutherland for the Prenatal Screening Program (PNS) billing and collection, the collection rate over a two-year collection period for non-Medi-Cal participants has improved from 83 percent to 90 percent.

Discretionary: Yes.

Reason for Adjustment/Change: The rate of collection for non-Medi-Cal participants needs to be updated to the increased rate to reflect accurate revenue figures.

Fiscal Impact (Range) and Fund Source(s): An annual increase in projected revenues of approximately $2.8 million. The fund source is the GDTF (Fund 0203).

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

Background: SB 1095 (Chapter 393, Statutes of 2016) established H&S Code section 125001(d) and required the Public Health Newborn Screening Program (NBS) 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). The Secretary
of Health and Human Services added SMA to the federal RUSP on July 2, 2018; the Public Health/GDSP has up to two years to implement newborn screening for the disorder in California.

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).

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

**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.

**Fiscal Impact (Range) and Fund Source(s):** FY 2019-20 expenditures will increase by $4.3 million which consists of $3.4 million in Local Assistance and $907,000 in State Operations to fund eight permanent positions. FY 2020-21 and ongoing expenditures will amount to $2.5 million annually ($1.4 million in Local Assistance and $1.2 million in State Operations). This request will not result in a GDTF fee increase in 2019-20. However, a fee increase may be assessed beyond 2019-20.

**Discontinued Assumptions/Premises**

There are no Discontinued Assumptions/Premises.
IV. Appendices

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 461,083, a decrease of 4,280 or 0.9 percent compared to the FY 2017-18 actual total caseload of 465,363. Caseload in FY 2019-20 is estimated at 460,153, which is a decrease of 930 or 0.2 percent compared to the current year estimate. This year over year change is due to the DOF/DRU’s projected number of live births, Public Health/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 our projected numbers for the remainder of the current year and budget year.

![NBS Caseload Chart](chart.png)

Contract Laboratory Average Cost Projections – Public Health/GDSP estimates current year average laboratory cost per participant will be $14.82, which is an increase of $0.76 or
5.4 percent compared to the FY 2017-18 actual average laboratory cost per participant of $14.06. The increase is due to the decrease in caseload which cause the cost per specimen to increase. Average laboratory cost per participant in FY 2019-20 is estimated at $15.04, which is an increase of $0.22 or 1.5 percent compared to the current year estimate.

Contract Laboratory Total Cost Projections – Public Health/GDSP estimates current year contract laboratory costs to total $6.9 million, which is an increase of $291,000 or 4.4 percent compared to FY 2017-18 actual contract laboratory costs of $6.6 million. FY 2019-20 contract laboratory costs are projected to be $6.9 million which is an increase of $88,000 or 1.3 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 (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 & 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 $53.90, an increase of $1.65 or 3.2 percent compared to FY 2017-18 actual average Technical and Scientific cost per participant of $52.25. Average laboratory cost per participant in FY 2019-20 is estimated at $59.75, which is an increase of $5.85 or 10.9 percent compared to the current year estimate.

<table>
<thead>
<tr>
<th>Year</th>
<th>NBS Tech &amp; Sci Average Cost</th>
</tr>
</thead>
<tbody>
<tr>
<td>FY 15-16</td>
<td>$47.43</td>
</tr>
<tr>
<td>FY 16-17</td>
<td>$51.31</td>
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<tr>
<td>FY 17-18</td>
<td>$52.25</td>
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<tr>
<td>FY 18-19</td>
<td>$53.90</td>
</tr>
<tr>
<td>FY 19-20</td>
<td>$59.75</td>
</tr>
</tbody>
</table>

Technical and Scientific Total Cost – Public Health/GDSP estimates current year Technical and Scientific costs to total $25 million, which is an increase of $717,000 or 2.3 percent compared to FY 2017-18 actual technical and scientific costs of $24.3 million. For FY 2019-18 the Technical and Scientific costs are estimated to be $27.5 million, which is an increase of $2.5 million or 9.8 percent compared to the current year. The increase in the current year and budget year is due to the additional costs associated with consumables, reagents, DNA sequencing and supplies needed for the new disorders Pompe and MPS I Screening.
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; 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 17,825, which is an increase of 36 or 0.2 percent compared to FY 2017-18 actual CMCS caseload of 17,789. The increase is attributed to the newest disorders added to the screening panel. CMCS caseload in FY 2019-20 is estimated at 17,789, which is a decrease of 36 or 0.2 percent compared to the current year estimate.
Case Management and Coordination Services (CMCS) Average Cost - Public Health/GDSP estimates current year average CMCS cost per participant will be $165, which is an increase of $46 or 38.7 percent compared to FY 2017-18 actual average CMCS cost per participant of $119. Average CMCS cost per participant in FY 2019-20 is estimated at $207, which is an increase of $42 or 25.5 percent compared to the current year estimate. CMCS costs are a combination of fixed costs and incremental (per case) reimbursement. Average cost increased for both current and budget year because of an increase in Total Cost for both years.

Case Management and Coordination Services (CMCS) Total Cost – Public Health/GDSP estimates current year CMCS costs to total $5.3 million, which is an increase of $767,000 or 17 percent compared to FY 2017-18 actual CMCS total costs of $4.5 million. CMCS costs in FY 2019-20 are estimated to total $6 million, which is an increase of $764,000 or 14.5 percent compared to the current year estimate. The increases reflect the change to estimating costs
based on projected caseload and actual contracts as opposed to projected expenditures. In addition, Public Health/GDSP considered a combination of increased fixed costs, and incremental (per case) reimbursement, which includes administrative costs, rent, equipment, travel and administrative staff as well as an increased number of positive cases attributed to the new screening for Pompe disease and MPSI.

<table>
<thead>
<tr>
<th>Year</th>
<th>Caseload Cost</th>
<th>Fixed Cost</th>
<th>Total Cost</th>
</tr>
</thead>
<tbody>
<tr>
<td>FY 15-16</td>
<td>$2,648,000</td>
<td>$2,299,000</td>
<td>$4,947,000</td>
</tr>
<tr>
<td>FY 16-17</td>
<td>$3,067,000</td>
<td>$2,368,000</td>
<td>$5,435,000</td>
</tr>
<tr>
<td>FY 17-18</td>
<td>$2,116,000</td>
<td>$2,384,000</td>
<td>$4,500,000</td>
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<tr>
<td>FY 18-19</td>
<td>$2,941,000</td>
<td>$2,326,000</td>
<td>$5,267,000</td>
</tr>
<tr>
<td>FY 19-20</td>
<td>$3,682,000</td>
<td>$2,349,000</td>
<td>$6,031,000</td>
</tr>
</tbody>
</table>

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 CDPH/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.

Diagnostic Services Caseload – Public Health/GDSP estimates current year Diagnostic caseload will total 5,579, which is a decrease of 52 or 0.9 percent compared to FY 2017-18 actual Diagnostic Services caseload of 5,631. Diagnostic caseload in FY 2019-20 is estimated at 5,568, which is a decrease of 11 or 0.2 percent compared to the current year estimate. The change in the current year and the budget year is due decreasing projected caseload. The following chart shows the actual Diagnostic Services cases, along with our projected numbers for the remainder of the current year and budget year.
Diagnostic Services Average Cost – Public Health/GDSP estimates current year average Diagnostic Services cost per participant will be $373, which is an increase of $86.38 or 30.1 percent compared to FY 2017-18 actual average Diagnostic Services cost per participant of $287. Average Diagnostic Services cost per participant in FY 2019-20 are estimated at $425, which is an increase of $52 or 13.9 percent compared to the current year estimate. The increases are tied to the increase in total costs.

Diagnostic Services Total Cost - Public Health/GDSP estimates current year Diagnostic Services costs to total $2.1 million, which is an increase of $467,000 or 28.9 percent compared to FY 2017-18 actual Diagnostic Services total costs of $1.6 million. Diagnostic Services costs in FY 2019-20 are estimated to total $2.5 million, which is an increase of $370,000 or
17.8 percent compared to the current year estimate. The increases in total costs are attributable to the contract increases.

<table>
<thead>
<tr>
<th></th>
<th>FY 15-16</th>
<th>FY 16-17</th>
<th>FY 17-18</th>
<th>FY 18-19</th>
<th>FY 19-20</th>
</tr>
</thead>
<tbody>
<tr>
<td>Total Cost</td>
<td>$1,869,000</td>
<td>$1,708,000</td>
<td>$1,614,000</td>
<td>$2,081,000</td>
<td>$2,451,000</td>
</tr>
<tr>
<td>NBS Follow-up/Diagnostic Total Cost</td>
<td>$3,001,000</td>
<td>$2,501,000</td>
<td>$2,001,000</td>
<td>$1,501,000</td>
<td>$1,001,000</td>
</tr>
</tbody>
</table>

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 10,085, which is a decrease of 94 or 0.92 percent compared to FY 2017-18 actual Reference Laboratory caseload of 10,179. Reference Laboratory caseload in FY 2019-20 is estimated at 10,065, which is a decrease of 20 or 0.2 percent compared to the current year estimate. The decreases are due to the decrease in projected caseload. The following chart shows the actual Reference Laboratory cases along with projected caseload for the remainder of the current year and budget year.
Reference Laboratory Average Cost – Public Health/GDSP estimates current year Reference Laboratory average cost per participant will be $182, which is a decrease of $12.03 or 6.2 percent compared to FY 2017-18 Reference Laboratory actual average cost per participant of $194. Reference Laboratory average cost per participant in FY 2019-20 is estimated at $241, which is an increase of $59 or 32.4 percent compared to the current year estimate. Fluctuation is tied to the total costs.

Reference Laboratory Total Cost – Public Health/GDSP estimates current year Reference Laboratory costs to total $1.8 million, which is a decrease of $139,000 or 7 percent compared to FY 2017-18 actual Diagnostic Services total costs of $2 million. The decrease is attributed to the projected decrease in Reference Laboratory caseload. Reference Laboratory costs in
FY 2019-20 are estimated to total $2.4 million which is an increase of $590,000 or 32.1 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 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 Specimen Caseload – Public Health/GDSP estimates current year specimen caseload will total 548,990, which is an increase of 3,138 or 1 percent compared to FY 2017-18, actual total caseload of 545,852. Caseload in FY 2019-20 is estimated at 542,909 which is a decrease of 6,081 or 1.1 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 2018-19, and that the number of participants will remain constant in FY 2019-20. The FY 2019-20 projections does 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 along with our projected numbers for the remainder of the current year and budget year.
**Contract Laboratory Average Cost Projections** – Public Health/GDSP estimates current year average laboratory cost per participant will be $8.05, which is a decrease of $0.37 or 4.4 percent compared to FY 2017-18 actual average laboratory cost per participant of $8.42. Average laboratory cost per participant in FY 2019-20 is estimated at $8.63, which is an increase of $0.58 or 7.2 percent compared to current year estimate. Fluctuation in average cost is attributed to a corresponding fluctuation in specimen caseload.

**Contract Laboratory Total Cost Projections** – Public Health/GDSP estimates current year contract laboratory cost to total $4.4 million, which is a decrease of $179,000 or 2.3 percent compared to FY 2017-18 actual contract laboratory costs of $4.6 million. Laboratory costs in FY 2019-20 are estimated to total $4.7 million, which is an increase of $266,000 or 6 percent.
compared to the current year estimate. Fluctuation in total cost is attributed to a corresponding fluctuation in specimen caseload.

![PNS Contract Lab Total Cost](image)

### 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 & 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 – Public Health/GDSP estimates current year average Technical and Scientific cost per participant will be $23.69, which is an increase of $0.81 or 3.5 percent compared to FY 2017-18 actual average Technical and Scientific cost per participant of $22.88. The increase in the average cost is the result of increases in the cost of reagents and consumables. Average laboratory cost per participant in FY 2019-20 is estimated at $23.69, which is no change compared to the current year estimate.
Technical and Scientific Total Cost – Public Health/GDSP estimates current year Technical and Scientific costs to total $13 million, which is an increase of $517,000 or 4.1 percent compared to FY 2017-18 actual technical and scientific costs of $12.5 million. Technical and Scientific costs in FY 2019-20 are estimated to total $12.9 million which is a decrease of $144,000 or 1.1 percent compared to the current year estimate. Fluctuation in total costs are 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 12,389, which is an increase of 168 or 1.4 percent compared to the FY 2017-18 actual PDC caseload of 12,221. The increase is caused by a projected uptick in women choosing to further pursue diagnostic care. PDC caseload in FY 2019-20 is estimated to total 12,220, which is a decrease of 169 or 1.4 percent compared to the current year estimate.

<table>
<thead>
<tr>
<th>FY</th>
<th>PDC Cases</th>
</tr>
</thead>
<tbody>
<tr>
<td>2015-16</td>
<td>13,529</td>
</tr>
<tr>
<td>2016-17</td>
<td>12,892</td>
</tr>
<tr>
<td>2017-18</td>
<td>12,221</td>
</tr>
<tr>
<td>2018-19</td>
<td>12,389</td>
</tr>
<tr>
<td>2019-20</td>
<td>12,220</td>
</tr>
</tbody>
</table>

Prenatal Diagnostic Services Average Cost – Public Health/GDSP estimates current year average PDC cost per participant will be $907.24, which is a decrease of $60.03 or 6.2 percent compared to FY 2017-18 actual average PDC cost per participant of $967.27. 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. Average PDC cost per participant in FY 2019-20 is estimated at $982.07, which is an increase of $74.83 or 8.2 percent compared to the current year estimate. 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 $11.2 million, which is a decrease of $581,000 or 4.9 percent compared to FY 2017-18 actual PDC total costs of $11.8 million. PDC costs in FY 2019-20 are estimated to total $12 million, which is an increase of $761,000 or 6.8 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 Area Service Centers (ASC) 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. Costs are fixed for a required core team of medical professionals for the PNS ASC to ensure adequate personnel and infrastructure needs are always in place to provide for all cases referred. Costs associated with these services vary by ASC dependent upon the geographic location and thus the geographic distribution of caseload as well.

Case Management and Coordination Services (CMCS) Caseload – Public Health/GDSP estimates current year CMCS caseload will total 146,031, which is an increase of 1,223 or 0.8 percent compared to FY 2017-18 actual CMCS caseload of 144,808. CMCS caseload in FY 2019-20 is estimated at 144,414, which is decrease of 1,617 or 1.1 percent compared to the current year estimate. This is due largely to changes in the caseload, and Public Health/GDSP noted that the trend for CMCS caseload has remained relatively flat regardless of overall program participation. The following chart shows the actual CMCS cases by month, along with our projected numbers for the remainder of the current year and budget year.

![PNS Case Coordination Caseload](chart)

Case Management and Coordination Services (CMCS) Average Cost - Public Health/GDSP estimates current year average CMCS cost per participant will be $22.05, which is a decrease of $2.80 or 11.3 percent compared to FY 2017-18 actual average CMCS cost per participant of $24.85. Average CMCS cost per participant in FY 2019-20 is estimated at $24.66, which is an increase of $2.61 or 11.8 percent compared to the current year estimate. The changes in the average costs are attributable to the fluctuation in total costs.
Case Management and Coordination Services (CMCS) Total Cost – Public Health/GDSP estimates current year CMCS costs to total $6 million, which is a decrease of $378,000 or 5.9 percent compared to FY 2017-18 actual CMCS total costs of $6.4 million. The decrease is attributable to the slight increase in caseload causing a decrease in the average cost. CMCS costs in FY 2019-20 are estimated to total $6.4 million, which is an increase of $369,000 or 6.1 percent compared to the current year estimate. The increase is due to the increase in the contract cost.
APPENDIX C: Revenue Projections

1. NBS Revenue

In most cases the $142.25 NBS fee is paid directly to Public Health/GDSP by hospitals. For births that occur outside of a hospital, Public Health/GDSP invoices the infant’s family or their insurance company. Since the majority of births happen within a hospital, billing and collection is more streamlined and efficient than PNS. Past actual collection amounts indicate that Public Health/GDSP collects approximately 98 percent of all revenue related to providing NBS services. The collection rate remains unchanged. As such NBS revenue is estimated using the following formula:

\[
\text{#of Projected Newborns screened} \times \text{Fee} \times 98\%
\]

<table>
<thead>
<tr>
<th>NBS Revenue Projections</th>
<th>Fee</th>
<th>Caseload</th>
<th>Collection Rate</th>
<th>Total Revenue</th>
</tr>
</thead>
<tbody>
<tr>
<td>FY 2018-19</td>
<td>$142.25</td>
<td>461,083</td>
<td>98%</td>
<td>$64,277,000</td>
</tr>
<tr>
<td>FY 2019-20</td>
<td>$142.25</td>
<td>460,153</td>
<td>98%</td>
<td>$64,148,000</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 Genetic Disease Testing Fund (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 90 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:

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

<table>
<thead>
<tr>
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</thead>
<tbody>
<tr>
<td>Fiscal Year</td>
<td>Fee</td>
<td>Caseload</td>
<td>% Medi-Cal</td>
<td>% Non-Medical</td>
<td>Medi-Cal Collection Rate</td>
<td>Private Insurance Collection Rate</td>
<td>Medi-Cal Cases</td>
<td>Non Medi-Cal Cases</td>
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</tr>
<tr>
<td>FY 2018-19</td>
<td>$211.60</td>
<td>329,081</td>
<td>55%</td>
<td>45%</td>
<td>98%</td>
<td>90%</td>
<td>180,994</td>
<td>148,086</td>
<td>$65,734,000</td>
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<tr>
<td>FY 2019-20</td>
<td>$211.60</td>
<td>326,472</td>
<td>55%</td>
<td>45%</td>
<td>98%</td>
<td>90%</td>
<td>179,560</td>
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