GENETIC DISEASE SCREENING PROGRAM (GDSP)

Fiscal Year 2019-20
November Estimate

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A. Program Overview

The California Department of Public Health (CDPH), 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 CDPH/GDSP.

The CDPH/GDSP Local Assistance budget funds two distinct programs: the Newborn Screening Program (NBS) and the Prenatal Screening Program (PNS). NBS is a mandatory program that screens all infants born in California for genetic diseases. Parents may opt their newborns out of the program by claiming religious exemptions. PNS is an opt-in program for women who desire to participate. The screening test provides the pregnant woman with a risk profile. Screenings that meet or exceed a specified risk threshold are identified and further testing and genetic counseling/diagnostic services are offered at no additional expense to the participant.

B. Expenditure Overview

The CDPH/GDSP 2018 Budget Act appropriation is $133 million, of which $103.5 million is for Local Assistance and $29.5 million is for State Operations. CDPH/GDSP estimates revised FY 2018-19 expenditures of $134.1 million, which is an increase of $1.1 million or 0.9 percent compared to the 2018 Budget Act. The increase is due to the baseline adjustments for employee compensation and retirement. The combined State Operations and Local Assistance budget expenditures for FY 2019-20 total $141.2 million, which is an increase of $8.2 million or 6.2 percent compared to the 2018 Budget Act. The increase in State Operations expenditure authority for FY 2019-20 is due to $1.0 million in baseline adjustments for employee compensation and retirement and $907,000 to fund Spinal Muscular Atrophy (SMA) positions beginning July 1, 2019. Local Assistance expenditure authority increased by $6.3 million. Of the $6.3 million, $3.4 million is for equipment, software upgrades, and maintenance costs identified in the SMA proposal. The remaining $2.9 million is due to the changing methodology for estimating caseload, specimen, and service rates for prenatal and newborn screening.

Table 1 shows the difference between the 2018 Budget Act appropriation and the revised FY 2018-19 expenditures and proposed FY 2019-20 expenditures for CDPH/GDSP.

| TABLE 1 | GDSP: Current Year and Budget Year Budget Summaries Compared to 2018 Budget Act |
|---|---|---|---|---|---|---|---|---|---|---|
| **Fund 0203 Genetic Disease Testing Fund** | **FY 2018-19 Budget Act** | **November Estimate FY 2018-19** | **Change from Budget Act** | **Percent Change from Budget Act** | **FY 2019-20** | **November Estimate FY 2019-20** | **Change from Budget Act** | **Percent Change from Budget Act** |
| Total | $132,952,000 | $134,094,000 | $1,142,000 | 0.9% | $141,176,000 | $8,224,000 | 6.2% |
| State Operations | $29,451,000 | $30,594,000 | $1,142,000 | 3.9% | $31,351,000 | $900,000 | 6.5% |
| Local Assistance | $103,501,000 | $103,501,000 | - | 0.0% | $109,825,000 | $6,324,000 | 6.1% |

*Figure 1 GDSP Current Budget 2018*
C. Local Assistance Expenditure Projections

Current Year (FY 2018-19)

The 2018 Budget Act appropriation for CDPH/GDSP’s Local Assistance is $103.5 million. CDPH/GDSP anticipates revised FY 2018-19 Local Assistance expenditures of $103.5 million, which is no changed compared to the 2018 Budget Act.

Budget Year (FY 2019-20)

For FY 2019-20, CDPH/GDSP estimates Local Assistance expenditures will total $109.8 million, which is an increase of $6.3 million or 6.1 percent compared to the 2018 Budget Act amount of $103.5 million. The increase is attributed to an increasing rates per case/service and the BCP costs impacting newborn and Operational Support costs.

Table 2 shows the difference between the 2018 Budget Act appropriation and the revised FY 2018-19 expenditures and proposed FY 2019-20 expenditures for CDPH/GDSP Local Assistance.

<table>
<thead>
<tr>
<th>Expenditure Methodology / Key Drivers of Cost</th>
</tr>
</thead>
<tbody>
<tr>
<td>The CDPH/GDSP Local Assistance expenditures are split into three areas: PNS, NBS and Operational Support. Operational Support costs do not fluctuate greatly with changes in caseload. For both PNS and NBS Program areas, the key drivers of cost are the following:</td>
</tr>
<tr>
<td>1. NBS and PNS projected caseloads/specimens for the following:</td>
</tr>
<tr>
<td>a. Total clients served</td>
</tr>
<tr>
<td>b. Cases that receive case management</td>
</tr>
<tr>
<td>c. Cases that are referred for diagnostic services</td>
</tr>
<tr>
<td>d. Cases that are referred to reference laboratories (NBS only)</td>
</tr>
<tr>
<td>2. Average Case Cost for the following services:</td>
</tr>
<tr>
<td>a. Contract laboratories</td>
</tr>
<tr>
<td>b. Technology &amp; Scientific supplies (Tech &amp; Sci)</td>
</tr>
<tr>
<td>c. Case Management and Coordination Services (CMCS)</td>
</tr>
<tr>
<td>d. Follow-up Diagnostic Services (FDS)</td>
</tr>
<tr>
<td>e. Reference laboratories (NBS only)</td>
</tr>
</tbody>
</table>
To calculate the total projected Local Assistance costs, CDPH projects NBS and PNS caseloads/specimens and multiplies them by their respective projected average cost, plus the baseline cost. They are then added to the Operational Support costs to calculate the total CDPH/GDSP Local Assistance cost.

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

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

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

Below, 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.

**Newborn Screening Expenditure Projections (See Appendices A1-A5)**

For FY 2018-19, CDPH/GDSP estimates NBS Local Assistance expenditures to total $41 million, which is no change compared to the 2018 Budget Act.

For FY 2019-20, CDPH/GDSP estimates that NBS Local Assistance expenditures will total $43 million, which is an increase of $2 million or 4.9 percent compared to the 2018 Budget Act amount of $41 million. The increase in the budget year funding is associated with the increase in contracted newborn screening rate costs, in addition to $523,000 in additional expenditures due to the screening of SMA. These costs include additional reagents, other consumables, and rental equipment.

Table 3 shows the 2018 Budget Act appropriation and the revised FY 2018-19 expenditures and proposed FY 2019-20 expenditures for the NBS Program costs by cost center type.
Prenatal Screening Expenditures Projections (See Appendices B1-B4)

For FY 2018-19, CDPH/GDSP estimates PNS Local Assistance expenditures total $35 million, which is no change compared to the 2018 Budget Act.

For FY 2019-20, CDPH/GDSP estimates that PNS Local Assistance expenditures will total $36.5 million, which is an increase of $1.4 million or 4.1 percent compared to the 2018 Budget Act appropriation of $35 million. The increase is due to higher contracted prenatal screening rate costs.

Table 4 shows the 2018 Budget Act appropriation and the revised FY 2018-19 expenditures and proposed FY 2018-19 expenditures for the PNS Program costs by client type.

Operational Support Expenditure Projections

For FY 2018-19, the CDPH/GDSP revised operational support expenditures total was $27.5 million, which is no change compared to the 2018 Budget Act.

In FY 2019-20, CDPH/GDSP projects operational support expenditures will total $30.3 million, which is an increase of $2.9 million or 10.5 percent compared to the 2018 Budget Act. The increase is associated with about $1.6 million in Screening Information Systems (SIS) upgrades for incorporating the new SMA disorder into the SIS database and another $1.3 million to address other SMA related software upgrades and maintenance.

Table 5 shows the difference between the 2018 Budget Act 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 revised estimate, CDPH/GDSP estimates that State Operations expenditures will total $30.6 million, which is an increase of $1.1 million or 3.9 percent compared to the 2018 Budget Act amount of $29.5 million. The increase is due to baseline adjustments for employee compensation and retirement costs.

In FY 2019-20, CDPH/GDSP estimates State Operations expenditures will total $31.4 million, which is an increase of $1.9 million or 6.5 percent from the 2018 Budget Act amount of $29.5 million. The increase is associated with additional positions needed for the implementation of SMA screening at $907,000 and baseline adjustments of $1.0 million.

Table 6 shows the difference between the 2018 Budget Act appropriation and the revised FY 2018-19 expenditures and proposed FY 2019-20 expenditures for the CDPH/GDSP State Operations costs.

E. Revenue Projections

Combined NBS and PNS Revenue

CDPH/GDSP has revised revenue estimates for FY 2018-19 totaling $132.2 million, which is an increase of $496,000 or 0.4 percent compared to the 2018 Budget Act amount of $131.7 million. The increase is due to the increase in collection rate from 83 percent to 90 percent for prenatal individuals with private insurances.

For FY 2019-20, CDPH/GDSP projects revenue will total $131.7 million, which is no change compared to the 2018 Budget Act amount of $131.7 million.

All other assumptions and calculations remain unchanged from the 2018 Budget Act.

Revenue Estimate 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).
CDPH/GDSP invoices and collects PNS payments from individual participants, private insurers and Medi-Cal. CDPH/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. CDPH/GDSP uses the following formula to estimate revenue generated from PNS fees:

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

Starting July 19, 2018, NBS participants are charged a fee of $142.25, an increase of $12. The increase was needed to support the increase in expenditures to perform the routine and ongoing workload for Mucopolysaccharidosis Type 1 (MPS-1) and Pompe disease screening. Unlike PNS, where CDPH/GDSP bills patients and collects fees from insurers, CDPH/GDSP collects the bulk of NBS revenue directly from hospitals. Only home births, where specimens are collected outside of the hospital, are billed to the newborns’ parents or their insurance company. As such, the billing for NBS screening services is much more streamlined resulting in a 98 percent collection rate. CDPH/GDSP uses the following formula to estimate revenue generated from NBS fees:

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

**NBS Revenue (See Appendix C-1)**

In FY 2018-19, NBS revenue is expected to total $65.4 million, which is a decrease of $1.3 million or -1.9 percent compared to the 2018-19 Budget Act amount of $66.7 million.

In FY 2019-20, CDPH/GDSP projects NBS revenue will total $65.3 million, which is a decrease of $1.3 million compared to the 2018-19 Budget Act amount of $66.7 million.

The decrease in revenue for both current year and budget year is due to the decrease in caseloads.

**PNS Revenue (See Appendix C2)**

In FY 2018-19, PNS revenue is expected to total $66.8 million, which is an increase of $1.8 million or 2.8 percent compared to the 2018-19 Budget Act amount of $65.0 million.

In FY 2019-20, CDPH/GDSP projects PNS revenue will total $66.3 million, which is an increase of $1.3 million or 2 percent compared to the 2018-19 Budget Act amount of $65.0 million.

The increase in current year and budget year is due to the change in collection rate from 83 percent to 90 percent for individuals with private insurances.

Table 7 shows the revised current year revenue projections for current year and budget year compared to 2018 Budget Act.
<table>
<thead>
<tr>
<th></th>
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<th></th>
<th></th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Total</td>
<td>$131,799,000</td>
<td>$132,205,000</td>
<td>$4,806,000</td>
<td>0.4%</td>
<td>$131,634,000</td>
<td>($3,000)</td>
<td>0.0%</td>
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<tr>
<td>NBS</td>
<td>$66,694,000</td>
<td>$65,402,000</td>
<td>($1,292,000)</td>
<td>-1.9%</td>
<td>$65,338,000</td>
<td>($1,366,000)</td>
<td>-2.0%</td>
</tr>
<tr>
<td>PNS</td>
<td>$65,105,000</td>
<td>$66,803,000</td>
<td>$1,788,000</td>
<td>2.8%</td>
<td>$66,313,000</td>
<td>$1,288,000</td>
<td>2.0%</td>
</tr>
</tbody>
</table>
II. Fund Condition Statement

**GENETIC DISEASE TESTING FUND**

**FUND CONDITION REPORT**

**Dollars in thousands**

<table>
<thead>
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<th></th>
<th>2017-18</th>
<th>2018-19</th>
<th>2019-20</th>
</tr>
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<tbody>
<tr>
<td><strong>RESOURCES</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Beginning Balance</td>
<td>$21,761</td>
<td>$26,468</td>
<td>$23,350</td>
</tr>
<tr>
<td>Prior Year Adjustment</td>
<td>9,914</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Adjusted Beginning Balance</td>
<td>31,675</td>
<td>26,468</td>
<td>23,350</td>
</tr>
<tr>
<td><strong>REVENUES</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>121100 Genetic Disease Testing Fees</td>
<td>124,586</td>
<td>132,205</td>
<td>131,651</td>
</tr>
<tr>
<td>150300 Income from Surplus Investments</td>
<td>217</td>
<td>45</td>
<td>45</td>
</tr>
<tr>
<td>181000 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>132,252</td>
<td>131,688</td>
</tr>
<tr>
<td><strong>TOTAL RESOURCES</strong></td>
<td>$156,414</td>
<td>$158,760</td>
<td>$155,048</td>
</tr>
</tbody>
</table>

| EXPENDITURES AND EXPENDITURE ADJUSTMENTS |         |         |         |
| 4265 Department of Public Health (State Operations) | 23,507 | 30,563 | 31,351 |
| 4265 Department of Public Health (Local Assistance) | 104,831 | 103,501 | 109,825 |
| 0840 State Controller (State Operations) | 0 | 0 | 0 |
| 8880 Financial Information System for California (State Operations) | 34 | 3 | -8 |
| 0692 Supplemental Pension Payments (State Operations) | 0 | 202 | 480 |
| 0600 Statewide General Admin Exp (ProRata) (State Operations) | 1,744 | 1,101 | 1,039 |
| **TOTAL EXPENDITURES AND EXPENDITURE ADJUSTMENTS** | $129,916 | $135,400 | $142,703 |

| FUND BALANCE |         |         |         |
| 2018-19      | 26,498  | 23,360  | 12,345  |
| 2019-20      | 20%     | 17%     | 9%      |

**REVENUE PROJECTIONS**

**2018-19**

- **2018-19 NBS FEES BASED ON**
  - 458,150 TESTS @ $142.20 AND 98% Provider 1/ = $65,402,000

- **2018-19 PNS FEES BASED ON**
  - 100,493 TESTS @ $211.00 AND 90% Non Medi-Cal 2/ = $22,001,300

- **2018-19 PNS FEES BASED ON**
  - 183,996 TESTS @ $211.00 AND 90% Medi-Cal 3/ = $38,142,000

**GDSP Total**

$132,205,000

**2019-20**

- **2019-20 NBS FEES BASED ON**
  - 408,093 TESTS @ $142.20 AND 98% Provider 1/ = $60,336,000

- **2019-20 PNS FEES BASED ON**
  - 149,391 TESTS @ $211.00 AND 90% Non Medi-Cal 2/ = $25,420,300

- **2019-20 PNS FEES BASED ON**
  - 182,549 TESTS @ $211.00 AND 90% Medi-Cal 3/ = $37,803,300

**GDSP Total**

$131,651,900

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1/ NBS Fees based on 98% hospital and other provider collection rate
2/ PNS Fees based on 60% of private payer / insurance collection rate
3/ PNS Fees based on 98% 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 California Department of Public Health (CDPH)/Genetic Disease Screening Program (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).

The Advisory Committee on Heritable Disorders in Newborns and Children (ACHDNC) has scheduled a public meeting will also discuss the nomination of cerebrotendinous xanthomatosis (CTX) to the RUSP and vote on whether to move the nomination forward to evidence review. If the nomination moves forward, the Committee is required to vote again within nine months (probably during the summer of our FY 2019-20) about whether to add CTX to the RUSP. This could potentially impact Budget Year expenditures and revenues if added. However, the timing of when a new disorder is added is not certain and this will remain as a future fiscal impact.

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

Discretionary: No

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

Fiscal Impact (Range) and Fund Source(s): Expenditures will 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 as it was based on costs for the last two additions to the Newborn Screening panel –MPS-I and Pompe disease. Furthermore, as additional diseases are added to the RUSP, there will be a need to request additional one time expenditure authority necessary to plan, prepare for, and implement the additional required screening (for any new diseases). If CDPH/GDSP is unable to absorb the additional spending authority within its current revenue, a fee increase may need to be implemented. The fund source is the Genetic Disease Testing Fund (Fund 0203).
New Assumptions/ Premises

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

**Background:** CDPH/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, CDPH/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, CDPH/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:** CDPH/GDSP needs to align its 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 CDPH/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 FY 2016-17, CDPH/GDSP fully transitioned its in-house patient billing process to an outsourced vendor, SHS. With the in-house process using call center staff, CDPH/GDSP had an approximate 83 percent collection rate from non-Medi-Cal insurers for prenatal screening. This has been the rate used in CDPH/GDSP’s estimates for revenue projection. CDPH/GDSP 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.

**Description of Change:** Since CDPH/GDSP contracted with Sutherland for the PNS billing and collection, the collection rate 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 Genetic Disease Testing Fund (Fund 0203).
Budget Change Proposal: Implementation of Newborn Screening for Spinal Muscular Atrophy (SMA) in California

Background: Senate Bill (SB) 1095 (Chapter 393, Statutes of 2016) established H&S Code section 125001(d) and required the CDPH 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). The Secretary of Health and Human Services added SMA to the federal RUSP on July 2, 2018; the 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 SIS, the follow-up systems, and the addition of new confirmatory testing.

Discretionary: No

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

Fiscal Impact (Range) and Fund Source(s): 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 positions. FY 2020-21 and ongoing expenditures increase to $2.6 million ($1.4 million in Local Assistance and $1.2 million in State Operations) annually. A fee increase in FY 2020-21 will be needed to support the additional expenditures. The fund source is the Genetic Disease Testing Fund (Fund 0203).

Existing (Significantly Changed) Assumptions/Premises

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

Unchanged Assumptions/Premises

There are no Existing Unchanged Assumptions/Premises.
Discontinued Assumptions/Premises

Budget Change Proposal: Routine Screening for Pompe and Mucopolysaccharidosis type I to Support Senate Bill (SB) 1095: expanding California’s Newborn Screening Program and Second-Tier Testing

The 2018 Budget Act included $2.23 million in ongoing State Operations expenditure authority and an increase of $1.5 million in ongoing Local Assistance expenditure authority in order to comply with SB 1095 (Chapter 393, Statutes of 2016) and perform the routine and ongoing workload for MPS-I and Pompe disease screening. The 2018 Budget Act also included a transfer of $460,000 in expenditure authority from Local Assistance to State Operations in order to perform the routine and ongoing workload for second-tier testing.

Birth Defects Surveillance Activities

The shift of surveillance activities from the Birth Defects Monitoring Fund (Fund 3114) to the Genetic Disease Testing Fund (Fund 0203) will result in reduced expenditures of $1.8 million from the Birth Defects Monitoring Fund. This change was included in the 2018 Budget Act.
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 – CDPH/GDSP estimates current year caseload will total 469,150, an increase of 3,787 or 0.8 percent compared to the FY 2017-18 actual total caseload of 465,363. Caseload in FY 2019-20 is estimated at 468,693, which is a decrease of 457 or 0.1 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.

<table>
<thead>
<tr>
<th>Fiscal Year</th>
<th>Actual/Projected Caseload</th>
</tr>
</thead>
<tbody>
<tr>
<td>FY 15-16</td>
<td>486,207</td>
</tr>
<tr>
<td>FY 16-17</td>
<td>485,740</td>
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<td>FY 17-18</td>
<td>465,363</td>
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<tr>
<td>FY 18-19</td>
<td>469,150</td>
</tr>
<tr>
<td>FY 19-20</td>
<td>468,693</td>
</tr>
</tbody>
</table>

Appendix A.1

Contract Laboratory Average Cost Projections - CDPH/GDSP estimates current year average laboratory cost per participant will be $14.82, which is an increase of $1.15 or 8 percent compared to the FY 2017-18 actual average laboratory cost per participant of $13.67. Average
laboratory cost per participant in FY 2019-20 is estimated at $15.04, which is an increase of $0.22 or 2 percent compared to the current year estimate. The increase is due to the increased rate of one of the contract labs.

Contract Laboratory Total Cost Projections – CDPH/GDSP estimates current year contract laboratory costs to total $7 million, which is an increase of $600,000 or 9 percent compared to FY 2017-18 actual contract laboratory costs of $6.4 million. FY 2019-20 contract laboratory costs are projected to be $7 million which is virtually no change 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** – CDPH/GDSP estimates current year average Technical and Scientific cost per participant will be $53.90, an increase of $1.68 or 3 percent compared to FY 2017-18 actual average Technical and Scientific cost per participant of $52.22. Average Technical and Scientific cost per participant in FY 2019-20 is estimated at $55.06, which is an increase of $1.16 or 2 percent compared to the current year estimate.

<table>
<thead>
<tr>
<th>NBS Tech &amp; Sci Average Cost</th>
</tr>
</thead>
<tbody>
<tr>
<td>FY 15-16</td>
</tr>
<tr>
<td>Average Cost</td>
</tr>
</tbody>
</table>

**Technical and Scientific Total Cost** – CDPH/GDSP estimates current year Technical and Scientific costs to total $25.3 million, which is an increase of $984,000 or 4 percent compared to FY 2017-18 actual technical and scientific costs of $24.3 million. For FY 2019-20 the Technical and Scientific costs are estimated to be $25.8 million, which is an increase of $523,000 or 2 percent compared to the current year. The current and budget year increases in cost are due to the additional costs associated with consumables, reagents, DNA sequencing and supplies needed for screening the new disorders Pompe and MPS-I.
3. **Case Management and Coordination Services:**

**Overview:** Services provided to infants who screen initial positive or have questionable screening test results for over 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** – CDPH/GDSP estimates current year CMCS caseload will total 14,811, which is an increase of 318 or 2 percent compared to FY 2017-18 actual CMCS caseload of 14,493. CMCS caseload in FY 2019-20 is estimated at 14,797 which is a decrease of 14 or 0.1 percent compared to the current year estimate. The increase in the current year is attributed to the newest disorders added to the screening panel.
Case Management and Coordination Services (CMCS) Average Cost - CDPH/GDSP estimates current year average CMCS cost per participant will be $165, which is a decrease of $30 or 15 percent compared to FY 2017-18 actual average CMCS cost per participant of $195. Average CMCS cost per participant in FY 2019-20 is estimated at $207, which is an increase of $42 or 26 percent compared to the current year estimate. Fluctuation in the Average Cost is tied directly to the Total Cost.

Case Management and Coordination Services (CMCS) Total Cost - CDPH/GDSP estimates current year CMCS costs to total $4.8 million, which is a decrease of $436,000 or 8 percent compared to FY 2017-18 actual CMCS total costs of $5.2 million. CMCS costs in FY 2019-20 are estimated to total $5.4 million, which is an increase of $645,000 or 14 percent compared to the current year estimate. The increase reflects the change to estimating costs based on projected caseload and actual contracts as opposed to projected expenditures. In addition
CDPH/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 MPS-I.

<table>
<thead>
<tr>
<th>NBS CCC (ASC) Total Cost</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>
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</thead>
<tbody>
<tr>
<td>Caseload Cost</td>
<td>$2,648,000</td>
<td>$3,067,000</td>
<td>$2,825,000</td>
<td>$2,447,000</td>
<td>$3,069,000</td>
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<tr>
<td>Fixed Cost</td>
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<td>$2,368,000</td>
<td>$2,384,000</td>
<td>$2,326,000</td>
<td>$2,349,000</td>
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<tr>
<td>Total Cost</td>
<td>$4,947,000</td>
<td>$5,435,000</td>
<td>$5,209,000</td>
<td>$4,773,000</td>
<td>$5,418,000</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, Phenylketonuria (PKU), beta thalassemia, alpha thalassemia, and various neurologic, metabolic, and endocrine disorders, etc. Services are provided through Special Care Centers, which are composed of highly specialized medical teams; cost is based on per case reimbursement and a small base allocation.

Diagnostic Services Caseload – CDPH/GDSP estimates current year Diagnostic caseload will total 5,654, based on projected new referral cases and annual patient summary cases, which is an increase of 23 or 0.4 percent compared to FY 2017-18 actual Diagnostic Services caseload of 5,631. Diagnostic caseload in FY 2019-20 is estimated at 5,648, which is a decrease of 6 or 0.1 percent compared to the current year estimate. Fluctuations are tied to overall DRU-based caseload.
Diagnostic Services Average Cost - CDPH/GDSP estimates current year average Diagnostic Services cost per participant will be $373, calculated based on projected new referral cases and annual patient summary cases, which is a decrease of $7 or 2 percent compared to FY 2017-18 actual average Diagnostic Services cost per participant of $380. The Average Diagnostic Services cost per participant in FY 2019-20 are estimated at $399, which is an increase of $26 or 7 percent compared to the current year average cost. The increase is tied to the increase in total cost.

Diagnostic Services Total Cost - CDPH/GDSP estimates current year Diagnostic Services costs to total $2.1 million, which virtually no change compared to FY 2017-18 actual Diagnostic Services total costs. Diagnostic Services costs in FY 2019-20 are estimated to total $2.3 million, which is an increase of $147,000 or 7 percent compared to the current year estimate. The increase in total cost is attributable to the contract increases.
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 – CDPH/GDSP estimates current year Reference Laboratory caseload will total 10,262, which is an increase of 83 or 0.8 percent compared to FY 2017-18 actual Reference Laboratory caseload of 10,179. Reference Laboratory caseload in FY 2019-20 is estimated at 10,252, which is virtually no change compared to the current year estimate.
Reference Laboratory Average Cost – CDPH/GDSP estimates current year Reference Laboratory average cost per participant will be $182, which is a decrease of $8 or 4.0 percent compared to FY 2017-18 Reference Laboratory actual average cost per participant of $190. Reference Laboratory average cost per participant in FY 2019-20 is estimated at $241, which is an increase of $59 or 32 percent compared to the current year estimate. Fluctuation is tied to total cost.

Reference Laboratory Total Cost – CDPH/GDSP estimates current year Reference Laboratory costs to total $1.9 million, which is virtually no change compared to FY 2017-18 actual Diagnostic Services total costs of $1.9 million. Reference Laboratory costs in FY 2019-20 are estimated to total $2.5 million which is an increase of $602,667 or 24.4 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 CDPH/GDSP estimated the number of 1st trimester and 2nd trimester screens performed separately in the estimate. This is because the average cost of the 1st trimester screen was substantially less than the cost of the 2nd trimester screens. Currently 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** – CDPH/GDSP estimates current year specimens will total 557,895, which is an increase of 14,217 or 3 percent compared to FY 2017-18, actual total specimens of 543,678. Specimens in FY 2019-20 is estimated at 552,031 which is a decrease of 5,864 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. CDPH/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 by year, along with our projected numbers for the remainder of the current year and budget year.
Contract Laboratory Average Cost Projections – CDPH/GDSP estimates current year average laboratory cost per participant will be $8.05, which is a decrease of $0.41 or 5 percent compared to FY 2017-18 actual average laboratory cost per participant of $8.46. Average laboratory cost per participant in FY 2019-20 is estimated at $8.63, which is an increase of $0.58 or 7 percent compared to current year estimate.

Contract Laboratory Total Cost Projections – CDPH/GDSP estimates current year contract laboratory cost to total $4.5 million, which is a decrease of $107,000 or 2 percent compared to FY 2017-18 actual contract laboratory costs of $4.6 million. Laboratory costs in FY 2019-20 are
estimated to total $4.8 million, which is an increase of $273,000 or 6 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 & Scientific costs, are purchased in lots based on anticipated specimens. Reagents vary in cost depending upon the type of screening performed.

Technical and Scientific Caseload: See appendix B 1

Technical and Scientific Average Cost – CDPH/GDSP estimates current year average Technical and Scientific cost per participant will be $23.69, which is an increase of $0.50 or 2 percent compared to FY 2017-18 actual average Technical and Scientific cost per specimen of $23.19. Average laboratory cost per specimen in FY 2019-20 is estimated at $23.69, which is no change compared to the current year estimate. The increase in the current year is attributed to the increase in total cost and is tied to contract increases.
Technical and Scientific Total Cost – CDPH/GDSP estimates current year Technical and Scientific costs to total $13.2 million, which is an increase of $609,000 or 4 percent compared to FY 2017-18 actual technical and scientific costs of $12.6 million. Technical and Scientific costs in FY 2019-20 are estimated to total $13 million which is a decrease of $141,000 or 1 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 – CDPH/GDSP estimates current year PDC caseload will total 12,563, which is an increase of 469 or 4 percent compared to the FY 2017-18 actual PDC caseload of 12,094. 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 12,390, which is a decrease of 173 or 1 percent compared to the current year estimate.

<table>
<thead>
<tr>
<th>Year</th>
<th>PDC Cases</th>
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<tbody>
<tr>
<td>FY 15-16</td>
<td>13,529</td>
</tr>
<tr>
<td>FY 16-17</td>
<td>12,892</td>
</tr>
<tr>
<td>FY 17-18</td>
<td>12,094</td>
</tr>
<tr>
<td>FY 18-19</td>
<td>12,563</td>
</tr>
<tr>
<td>FY 19-20</td>
<td>12,390</td>
</tr>
</tbody>
</table>

Prenatal Diagnostic Services Average Cost – CDPH/GDSP estimates current year average PDC cost per participant will be $894.66, which is a decrease of $87.41 or 10 percent compared to FY 2017-18 actual average PDC cost per participant of $982.06. Average laboratory cost per participant in FY 2019-20 is estimated at $982.07, which is an increase of $87.41 or 10 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 – CDPH/GDSP estimates current year PDC costs to total $11.2 million, which is a decrease of $226,000 or 2 percent compared to FY 2016-17 actual PDC total costs of $11.5 million. PDC costs in FY 2018-19 are estimated to total $11.2 million, which is virtually no change 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 PDCs 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 - CDPH/GDSP estimates current year CMCS caseload will total 148,400, which is an increase of 3,592 or 2 percent compared to FY 2017-18 actual CMCS caseload of 144,808. CMCS caseload in FY 2019-20 is estimated at 146,840, which is decrease of 1,560 or 1 percent compared to the current year estimate. This is due largely to changes in the DRU-based caseload, and CDPH/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 - CDPH/GDSP estimates current year average CMCS cost per participant will be $22.05, which is a decrease of $2.76 or 11 percent compared to FY 2017-18 actual average CMCS cost per participant of $24.81. The decrease in the current year is attributable to a slight increase in caseload causing a decrease in average cost. Average CMCS cost per participant in FY 2019-20 is estimated at $24.66, which is an increase of $2.61 or 12 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 - CDPH/GDSP estimates current year CMCS costs to total $6.1 million, which is a decrease of $321,000 or 5 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 $377,000 or 6 compared to the current year estimate.

Appendix C: Revenue Projections

1. NBS Revenue

Effective July 19, 2018, the NBS fee increased by $12 and the new fee is $142.25. In most cases the fee is paid to directly to CDPH/GDSP by hospitals. For births that occur outside of a hospital CDPH/GDSP does invoice the appropriate fee from the family of the infant or their
insurance company. Since the majority of births happen within a hospital billing and receiving payment for NBS services is greatly streamlined and efficient. Past actual collection amounts indicate that CDPH/GDSP collects approximately 98 percent of all revenue related to providing NBS services. The collection rate remains unchanged. As such NBS revenue is estimated using the following formula:

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

### 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>FY 2018-19</td>
<td>Fee $142.25</td>
<td>Case load 469,150.40</td>
<td>Collection Rate 98%</td>
<td>Total Revenue $65,402,000</td>
</tr>
<tr>
<td>FY 2019-20</td>
<td>Fee $142.25</td>
<td>Case load 468,693.16</td>
<td>Collection Rate 98%</td>
<td>Total Revenue $65,338,000</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 Defects 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:

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

### PNS Revenue Projections

<table>
<thead>
<tr>
<th></th>
<th>A=$221.60</th>
<th>B</th>
<th>C</th>
<th>D=I*C</th>
<th>E</th>
<th>F</th>
<th>G=I*B</th>
<th>H=I*B</th>
<th>I=G<em>A</em>I+H<em>A</em>I</th>
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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>
<td>Total Revenue</td>
</tr>
<tr>
<td>FY 2018-19</td>
<td>$221.60</td>
<td>334,430</td>
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<td>45%</td>
<td>98%</td>
<td>90%</td>
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<tr>
<td>FY 2019-20</td>
<td>$221.60</td>
<td>331,972</td>
<td>55%</td>
<td>45%</td>
<td>98%</td>
<td>90%</td>
<td>182,588.72</td>
<td>149,390.77</td>
<td>$66,313,037</td>
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