STATE OF CALIFORNIA

Budget Change Proposal - Cover Sheet

DF-46 (REV 03/25)

Fiscal Year	Business Unit Number	Department
2026-27	4265	California Department of Public Health

Hyperion Budget Request Name	Relevant Program or Subprogram
4265-093-BCP-2026-GB	4045068 – Laboratory Sciences

Budget Request Title

Augmentation to the BabyBIG® Infant Botulism Treatment and Prevention Program

Budget Request Summary

The California Department of Public Health (CDPH) requests $3.6 million in 2026-27 from the Infant Botulism Treatment and Prevention Fund to meet increased BabyBIG® manufacturing and stability testing.

Requires Legislation (submit required legislation with the BCP)	Code Section(s) to be Added/Amended/Repealed
☐ Trailer Bill Language ☐ Budget Bill Language ☒ N/A	N/A

Does this BCP contain information technology (IT) components? ☐ Yes ☒ No *If yes, departmental Chief Information Officer must sign.*	Department CIO	Date
	N/A	N/A

For IT requests, specify the project number, the most recent project approval document (FSR, SPR, S1BA, S2AA, S3SD, S4PRA), the approval date, and the total project cost.

Project No. N/A **Approval Date:** N/A

Project Approval Document: N/A **Total Project Cost:** N/A

If proposal affects another department, does other department concur with proposal? ☐ Yes ☒ No

Attach comments of affected department, signed and dated by the department director or designee.

Prepared By	Date	Reviewed By	Date
Anthony Tran, DrPH, MPH, D(ABMM)	7/21/2025	Phuong La	7/25/2025
Department Director	**Date**	**Agency Secretary**	**Date**
Susan Fanelli	8/4/2025	Julie Souliere	8/29/2025

Department of Finance Use Only

Additional Review: ☐ Capital Outlay ☐ ITCU ☐ FSCU ☐ OSAE ☐ Dept. of Technology

Principal Program Budget Analyst	Date submitted to the Legislature
Nina Hoang	1/9/2026

A. Problem Statement

The Infant Botulism Treatment and Prevention Program (IBTPP) within the California Department of Public Health (CDPH) is the only manufacturer of BabyBIG®, an orphan drug licensed by the U.S. Food and Drug Administration (FDA) used to treat infant botulism. Historically, CDPH has requested increases in expenditure authority to cover increased manufacturing and regulatory costs. The most recent increase in expenditure authority was approved in 2025-26 to produce Lot 8 of BabyBIG® and to cover increased BabyBIG® storage and distribution costs to treat critically ill infant botulism patients. However, due to the magnitude and speed of cost increases from lot to lot, and factors affecting availability of the investigational recombinant botulinum vaccine known as rBV A/B which is needed to produce BabyBIG®, IBTPP requires additional expenditure authority in 2026-27.

The rBV A/B vaccine is the only immunogen available to boost BabyBIG® plasma donors. The U.S. Department of Defense (DoD), Surgeon General, Department of the Army, which is the current sponsor of the investigational rBV A/B vaccine, has halted vaccine stability testing and only funded the testing through July 2025. Vaccine stability testing comprises a series of tests performed at defined time points to check how long the vaccine will maintain its quality and work effectively. Ensuring safety and effectiveness throughout the vaccine's lifespan is crucial. The DoD has indicated to CDPH that they plan to maintain the vaccine's Investigational New Drug (IND) application and its storage currently.

The DoD approved CDPH to support the rBV A/B vaccine stability program, which will be formalized through an amended agreement. Consequentially, IBTPP will have additional costs for stability testing of the vaccine to allow its continued availability to immunize BabyBIG® source plasma donors. In 2026-27, IBTPP will not be able to perform the necessary rBV A/B stability testing, scheduled to occur in Spring 2026, with existing expenditure authority. If the FDA approves, testing will need to be shifted forward to July 2026, resulting in two sets of stability testing in 2026-27 with an estimated cost of approximately $2.2 million.

To comply with the requirements in Health and Safety Code (HSC) Sections 123700-123709 and maintain continued production and distribution of BabyBIG® for the treatment of infant botulism, CDPH-IBTPP is requesting additional expenditure authority of $3.6 million in 2026-27 from the Infant Botulism Treatment and Prevention Fund.

Resource History – Infant Botulism Treatment and Prevention Fund
(Dollars in thousands)

Program Budget	2020-21	2021-22	2022-23	2023-24	2024-25	2025-26*
Authorized Expenditures	$10,309	$9,138	$6,642	$14,072	$17,789	$16,584
Actual Expenditures	$9,704	$7,587	$6,514	$10,385	TBD	TBD
Revenues	$11,766	$11,208	$14,119	$14,458	TBD	TBD
Authorized Positions	7	7	7	5	4	6
Filled Positions	6	5	5	3	4	TBD
Vacancies	1	2	2	2	0	TBD

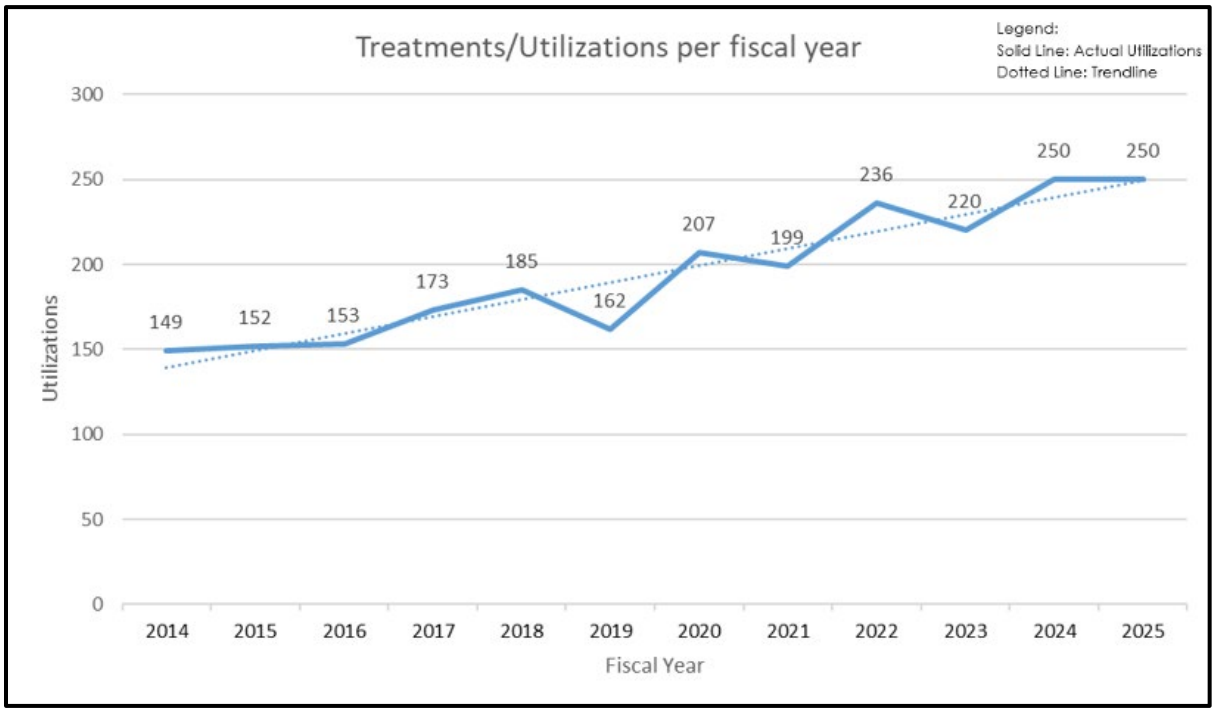
* Figures are estimates based on current projections

Workload History

Workload Measure	2020-21	2021-22	2022-23	2023-24	2024-25	2025-26
Number of BabyBIG® distributions*	209	202	241	227	259**	228-259
Number of treatments/utilizations*	207	199	236	220	250**	222-250***

*Distributions describe the number of BabyBIG® treatment doses leaving the distribution center. Utilization is defined as a full treatment dose administered to one patient. Distribution is not synonymous with utilization.
**FY 2024-25 was 20 percent higher than the previous 5-year moving average.
***N=222 (lower end of range) is the current 5-year moving average and 250, the higher end of the range is based on current FY 2024-25 actuals through June 30, 2025.

For the past decade, BabyBIG® distributions and treatments have been steadily on an upward trend and IBTPP has reached a large number of treatments in 2024-25, surpassing previous record set in 2022-23. Below is a scatter plot of BabyBIG® Treatments/Utilizations per fiscal year, showing linear regression trendline for future year projections.



B. Justification

BabyBIG® is the only licensed treatment in the United States for the rare, life-threatening disease infant botulism, and CDPH is the only source of BabyBIG® in the world. The FDA licensed BabyBIG® to CDPH in October 2003. BabyBIG® is distributed by CDPH nationwide for a fee to treat patients with infant botulism, as required by the Federal Orphan Drug Act and HSC Sections 123700-123709. BabyBIG® is also distributed on a case-by-case basis internationally at the request and approval of countries' medical regulatory authorities.

Approval of this proposal will provide CDPH the necessary expenditure authority to address increased costs associated with 1) stability testing of the booster immunogen for BabyBIG® production, the investigational recombinant botulinum vaccine, rBV A/B[1]; 2) increased rBV

[1] https://pubmed.ncbi.nlm.nih.gov/29475762/

A/B clinical study costs to boost BabyBIG® donors in 2026-27; and 3) increasing costs associated with maintenance of the rBV A/B vaccine program; and 4) BabyBIG post-production regulatory compliance activities. .

The DoD, the current sponsor of the rBV A/B vaccine, has notified CDPH they plan to stop stability testing of the vaccine after July 2025. In order to continue using the vaccine to boost BabyBIG® plasma donors, CDPH will need to assume the costs of the rBV A/B stability program. The estimated cost is $1.1 million per testing timepoint and testing usually occurs once per year. This figure is based on current costs with federally contracted vendors. CDPH must continue to have access to rBV A/B to boost BabyBIG® source plasma donors and collect high titer plasma for future BabyBIG® production. To meet FDA requirements, vaccines must be stored properly and have stability testing prior to use.

According to the Bureau of Labor Statistics Producer Price Index (PPI)[2], Pharmaceutical and Medicine Manufacturing costs have increased 4.5 percent per year since 1984. This indicates an approximate 20 to 25 percent rise in BabyBIG® manufacturing costs between the 5-year production cycles. Manufacturing costs for BabyBIG® Lot 9 include the IND clinical study to boost donors and collect their source plasma, fill and finish of BabyBIG® lots, stability testing, and FDA regulatory costs, which have increased more than 25 percent between Lot 7 and Lot 8 production. The increase in costs between BabyBIG® manufacturing lot cycles often surpasses PPI data.

Manufacturing and regulatory costs for BabyBIG® have increased over 50 percent for our FDA Biologics License Application (BLA) approved vendors between Lot 7 production, which occurred from 2018-19 through 2022-23, and Lot 8 production, which occurred or will occur from 2023-24 through 2027-28. Fill and finish costs, which include costs of filling the vial with the bulk product, freeze-drying it, then capping and sealing the vial, have increased over 200 percent from Lot 7 to Lot 8.

In addition, Takeda Pharmaceuticals, our BLA-approved manufacturing contractor, has experienced unforeseen delays in procuring the materials needed to complete the 2024-25 portion of Lot 8 manufacture of BabyBIG®. As a result, CDPH is amending the current manufacturing contract, shifting budget amounts across multiple years, and augmenting CDPH's need for increased expenditure authority.

For the past three clinical studies utilizing investigational rBV A/B to collect source plasma, IBTPP has used the same, limited number of BabyBIG® source plasma donors who have existing botulinum immunity and were previously boosted with rBV A/B. It is not guaranteed that IBTPP will have access to the same donors for future clinical studies. Therefore, the program aims to increase its pool of donors to maintain sufficient supply of high titer source plasma for future BabyBIG® lot production. IBTPP plans to amend its IND to recruit botulinum-naïve adult source plasma donors (individuals with no previous exposure to botulinum immunogens) which represents a vastly larger recruitment population. This would safeguard the program in case the existing group of donors elect not to participate in upcoming clinical studies and/or no longer qualify to participate in the study and source plasma collection.

Recruiting new source plasma donors adds costs to conducting the clinical study, including expanding the number of clinical study sites and plasma collection sites which may include multiple out-of-state locations (additional vendors); donor recruitment; and developing and implementing the clinical plan to accomplish primary vaccination (initial series of vaccinations), as well as booster vaccinations with rBV A/B. There will be additional costs to test the expanded pool of source plasma units to determine their anti-botulinum toxin types A

[2] https://fred.stlouisfed.org/series/PCU32543254

and B antibody titers. The larger pool of donors and source plasma units will result in increased plasma qualification, storage, quality assurance and regulatory costs.

A new lot of BabyBIG® is made approximately every five years and the lot size has been sufficient to provide treatment to the estimated number of infant botulism patients until the next lot is ready for release for commercial distribution. The five-year production cycle for BabyBIG® Lot 7 was completed in 2022-23, and the Lot 8 cycle started in 2023-24, providing an uninterrupted supply of BabyBIG® for critically ill patients with infant botulism. Lot 8 production activities will be completed in the next two fiscal years, overlapping the ramp up to Lot 9 production.

For the first time since 2004, CDPH implemented a BabyBIG® treatment fee increase in 2019. This fee increase was needed due to the expected increase in production, storage and distribution costs, new costs associated with additional FDA regulatory requirements and increases in state administrative and overhead expenses. To keep pace with the rising costs, IBTPP has implemented a second BabyBIG® treatment fee increase effective July 1, 2025, from $57,300 to $69,300, paid directly to CDPH by the ordering hospitals. Accounting for the fee increase, hospitals using BabyBIG® in 2025-26 are estimated to avoid average costs of over $118,000 per patient. IBTPP is closely monitoring its fund balance and may implement fee increases as needed to meet increased program costs.

These resources support future BabyBIG® production, post-production regulatory compliance activities, distribution of Lot 8 and rBV A/B maintenance.

C. Departmentwide and Statewide Considerations

The IBTPP was established in California statute in 1995 as a fee-supported program to produce and distribute BabyBIG® nationwide in accordance with the Federal Orphan Drug Act, and to accomplish additional requirements in HSC Sections 123700-123709. IBTPP necessitates the production and distribution of BabyBIG® nationwide, investigating all cases of infant botulism in California, providing laboratory diagnostic services statewide, improving the treatment and prevention of infant botulism, and collaborating scientifically with outside institutions to accomplish these mandates.

This proposal supports the CDPH strategic plan goals of 1) achieving health equities through public health policies and programs; 2) optimizing the role of public health in health care reform; 3) enhancing preparedness and response for emerging health threats; and 4) optimizing the use of science and technology to improve health.

D. Outcomes and Accountability

Approval of this proposal will provide CDPH resources to improve BabyBIG® operational efficiencies and assume the responsibilities for the investigational recombinant botulinum vaccine (rBV A/B). CDPH will remain in compliance with federal and state laws that require the production and distribution of BabyBIG® statewide and nationwide.

Projected Outcomes

Workload Measure	2025-26	2026-27	2027-28	2028-29	2029-30	2030-31
Number of Treatments/Utilizations*	222	222	222	222	222	222
Estimated Avoided Hospital Costs**	$27.1M	27.9M	$28.7M	$29.6M	$30.5M	$31.4M
Estimated Medi-Cal Savings	$1.03M	$1.06M	$1.09M	$1.12M	$1.16M	$1.19M

*****New 5-year utilization average represents increased revenue and increased workload/costs for program. This is Program's most conservative estimate in order to not overstate health care cost savings, although actual treatments and utilizations are expected to exceed the 5-year utilization average based on historical trendlines.

** Estimated avoided hospital costs based on FY 2024-25 cost savings of $118,627 plus conservative annual inflation of 3 percent. Per Bureau of Labor Statistics Inpatient Hospital Services inflation data, costs go up on average 5 percent a year since 1998. FY 2025-26 calculation: $118,627 * 1.03 * 222 = $27.1M

E. Implementation Plan

IBTPP is working closely with the DoD to select the contractors who meet federal requirements and to determine costs for storage, stability testing, potency, and manufacturing of the rBV A/B vaccine. As of now, the estimated cost specifically for ongoing stability testing of rBV A/B is $1.1 million per testing timepoint which is generally once per year. However, in FY 2026-27, there will be two testing timepoints with an estimated total cost for stability testing of $2.2 million.

Increased expenditure authority is needed to cover increased BabyBIG® manufacturing and rBV A/B stability testing costs in 2026-27. IBTPP is in the process of obtaining cost estimates from our contractors for FY 2027-28 (Lot 9 production cycle) to gauge Lot 9 manufacturing costs.

F. Supplemental Information

Attachment A: BCP Fiscal Detail Sheet

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BCP Fiscal Detail Sheet

(Dollars in Thousands)
BCP Title: Augmentation to the BabyBIG Infant Botulism Treatment and Prevention Program
BR Name: 4265-093-BCP-2026-GB
Budget Request Summary

Operating Expenses and Equipment

Operating Expenses and Equipment	FY26 Current Year	FY26 Budget Year	FY26 BY+1	FY26 BY+2	FY26 BY+3	FY26 BY+4
5301 - General Expense	0	3,640	0	0	0	0
Total Operating Expenses and Equipment	**$0**	**$3,640**	**$0**	**$0**	**$0**	**$0**

Total Budget Request

Total Budget Request	FY26 Current Year	FY26 Budget Year	FY26 BY+1	FY26 BY+2	FY26 BY+3	FY26 BY+4
Total Budget Request	**$0**	**$3,640**	**$0**	**$0**	**$0**	**$0**

Fund Summary

Fund Source

Fund Source	FY26 Current Year	FY26 Budget Year	FY26 BY+1	FY26 BY+2	FY26 BY+3	FY26 BY+4
State Operations - 0272 - Infant Botulism Treatment and Prevention Fund	0	3,640	0	0	0	0
Total State Operations Expenditures	**$0**	**$3,640**	**$0**	**$0**	**$0**	**$0**
Total All Funds	**$0**	**$3,640**	**$0**	**$0**	**$0**	**$0**

Program Summary

Program Funding

Program Funding	FY26 Current Year	FY26 Budget Year	FY26 BY+1	FY26 BY+2	FY26 BY+3	FY26 BY+4
4045068 - Laboratory Sciences	0	3,640	0	0	0	0
Total All Programs	**$0**	**$3,640**	**$0**	**$0**	**$0**	**$0**