

STATE OF CALIFORNIA
Budget Change Proposal - Cover Sheet
 DF-46 (REV 10/20)

Fiscal Year 2022	Business Unit 4140	Department Department of Health Care Access and Information	Priority No.
Budget Request Name 4140-079-BCP-2022-A1		Program 3831-Health Care Quality and Affordability	Subprogram

Budget Request Description
 Reducing the Cost of Insulin: CalRx Biosimilar Insulin Initiative

Budget Request Summary
 The Department of Health Care Access and Information (HCAI) requests one-time \$100 million General Fund, available until 2025-26, for the CalRx Biosimilar Insulin initiative. Through a contract partnership, the State would invest \$50 million towards the development of low-cost interchangeable biosimilar insulin products and an additional \$50 million towards a California-based insulin manufacturing facility. HCAI also requests \$2.8 million General Fund, over four years, for state operations to fulfill requirements of the partnership, including monitoring, oversight, and legal compliance.

Requires Legislation <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	Code Section(s) to be Added/Amended/Repealed Health and Safety Code Sections 127691-127692, 127694-127696	
Does this BCP contain information technology (IT) components? <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No <i>If yes, departmental Chief Information Officer must sign.</i>	Department CIO	Date

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

Project No. _____ **Project Approval Document:** _____

Approval Date: _____

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 David Toppelberg	Date 2/9/2022	Reviewed By Scott Christman	Date 2/9/2022
Department Director Elizabeth Landsberg	Date 2/9/2022	Agency Secretary Vishaal Pegany for Mark Ghaly, MD, MPH	Date 2/9/2022

Department of Finance Use Only

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

PPBA Sonal Patel	Date submitted to the Legislature 4/1/2022
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A. Budget Request Summary

HCAI requests one-time \$100 million General Fund, available until 2025-26, for the CalRx Biosimilar Insulin initiative. Through a contract partnership, the State would invest \$50 million towards the development of low-cost biosimilar insulin products, an additional \$50 million towards a California-based insulin manufacturing facility. HCAI also requests \$2.8 million General Fund, over four years, for state operations to fulfill requirements of the partnership, including monitoring, oversight, and legal compliance. The insulin products are expected to be widely available to Californians, through a variety of outlets.

B. Background/History

The insulin market has long epitomized the market failures that plague the pharmaceutical industry, such as excessively high barriers for new market entrants, exertion of market power, and leveraging of the legal-regulatory system to maintain market dominance. A recent bipartisan U.S. Senate Finance Committee investigation into insulin pricing found that insulin manufacturers and pharmacy benefits managers (PBMs) work in tandem and respond to incentives to keep insulin prices high and rising. The Committee's report described the dynamic between the two industries as follows:

“Higher list price increases the dollar value of rebates, discounts, and other fees that a manufacturer can offer to a PBM and health plans, which are based on a percentage of the list price... PBMs have an incentive for manufacturers to keep list prices high, since the rebates, discounts, and fees PBMs negotiate are based on a percentage of a drug's list price—and PBMs retain at least a portion of what they negotiate... [T]he investigation found instances in which insulin manufacturers were dissuaded from setting lower list prices for their products, which would have likely lowered out-of-pocket costs for patients, due to concerns that PBMs and health plans would react negatively.”¹

As the U.S. Senate Finance Committee's report found, hyper-consolidation along the insulin supply chain and dysfunctional incentive structures have essentially constrained the insulin market of any opportunity for true competition. As a result, both list (also known as wholesale acquisition cost or WAC) and net prices for insulin have risen dramatically over the last decade.²

The downstream impacts of the market failure for affordable insulins impacts California and its residents directly. Based on national data, as many as 1 in 4 diabetics cannot afford their insulin, and thus ration or have ceased taking insulin altogether. Affordable insulin is critical for black, brown, and lower income Americans as they are much more likely to have severe diabetes-related complications, such as renal disease and amputations.

Other efforts to reform insulin pricing have been limited in their effectiveness in addressing structural issues in the market for insulins. The federal Biologics Price Competition and Innovation Act (BCPIA), for instance, has not yet delivered on its promise of low-cost biosimilars for drugs like insulin. Under the framework, biosimilar insulins are treated like branded products, which has resulted in manufacturers engaging in the same tactics of charging of high list prices and rebates to lock-in market share. The only recently approved biosimilar insulin, Semglee, carries a list price of \$269.38 per vial, which is only \$14 cheaper than its chief competitor, Lantus (for a five-pen pack, the list price for Semglee is \$404.04 compared to \$425.31 for Lantus).³ The proposed federal Build Back Better legislation calls for a \$35 monthly cap on out-of-pocket (OOP) costs for Medicare Part D and commercially insured enrollees only. While the \$35 monthly cap provides predictability in consumer OOP costs for eligible enrollees, the federal proposal would not lower the actual price paid for insulin and would not benefit uninsured consumers.

¹ Senators Charles Grassley and Ron Wyden, “Insulin: Examining the Factors Driving the Rising Cost of a Century Old Drug,” United States Senate Finance Committee, [https://www.finance.senate.gov/imo/media/doc/Grassley-Wyden%20Insulin%20Report%20\(FINAL%201\).pdf](https://www.finance.senate.gov/imo/media/doc/Grassley-Wyden%20Insulin%20Report%20(FINAL%201).pdf)

² Ibid. Grassley and Wyden

³ Bob Herman, “the new generic insulin isn’t as cheap as you thought,” Axios (17 Nov. 2021).

C. State Level Consideration

This proposal will provide the resources necessary to advance implementation of the California Affordable Drug Manufacturing Act (Chapter 207, Statutes of 2020 [SB 852]). SB 852 authorizes California Health and Human Services Agency (CalHHS) to enter into generic drug manufacturing partnerships on behalf of the State, including the production of at least one form of insulin, provided that a viable pathway for manufacturing a more affordable form of insulin exists.⁴ In compliance with SB 852, CalRx has conducted market research examining several factors (including time for drug development, time to market entry, total partnership costs, distributional costs, minimum purchasing requirements, proven expertise in development and manufacturing, public health alignment, and economic development opportunities for the State) and has determined that a contract manufacturing partnership is the most viable pathway to accomplish the Legislature's mandate for producing biosimilar insulin at transparent, low prices without any rebates, other than those required by federal law.⁵ In assessing target medications for generic manufacturing, CalRx has also fully considered the SB 17 reports and spend/utilization data from Medi-Cal, DGS, CalPERS, and Covered California, as required by SB 852.⁶

The resources in this budget request would also address Executive Order N-01-19, which described the State's spending on prescription drugs as increasing at an "unsustainable rate, constituting a substantial fiscal drain" on government budgets, small businesses, families, and individuals who need lifesaving drugs. Bringing a low-cost insulin to market reflects the Governor's priorities to lower prescription drug and health care costs for all California families and move California closer to the goal of health care for all. Given the scale of the affordability crisis for insulin, state-led generic manufacturing of affordable insulins will provide relief for millions of diabetics and generate system wide savings and advance the State's ability to address the disparities in outcomes amongst those with diabetes.

D. Justification

CalRx enables California to manufacture generic drugs in highly concentrated, low competition drug markets. CalRx has the potential to become a "Producer of Last Resort," remedying drug shortages and addressing what researchers have described as oligopolistic market structures and other market failures that plague the pharmaceutical industry. Under this proposal, CalRx would identify a partner to bring to market low-cost interchangeable biosimilar insulins with the goal of providing Californians with access to insulin products that are a fraction of the \$300 per vial prices charged by insulin manufacturers in the United States. Injecting such steep price competition in the market would ease the financial burden for millions of diabetics in the State.

This proposal will use \$50 million in funding to enter into a partnership with a contract manufacturer to develop and bring to market interchangeable biosimilar insulin products in both vial and pen form. The potential market for these biosimilar insulin products will be substantial for consumers. CalRx biosimilar insulin products will likely be widely available through a variety of major outlets, generating significant system wide savings. Many Californians, such as the uninsured, underinsured, and those with high deductible plans, are exposed to high list prices, and would benefit enormously from broadly available low-cost insulin. In the long run, all consumers would also benefit if the branded insulin manufacturers lower their prices in response to the entry of a low-cost option.

While patients with good insurance coverage may pay very little cost-sharing for their insulin, many diabetics do not fall into this category, or are at risk of paying high out-of-pocket costs during coverage disruptions, such as unemployment or aging out of dependent coverage. Uninsured or underinsured diabetics (often due to enrollment in plans with high deductibles)

⁴ 127693(c)(2)

⁵ 127693(b)(4)

⁶ 127693(c)(1)

oftentimes must pay the list (WAC) price for their insulin, spending thousands of dollars per year to afford their lifesaving medications. Even diabetics with moderate deductible plans, such as individual market enrollees in Bronze level plans, still spend substantial sums for their insulin.

Some industry observers may point to Patient Assistance Programs (PAPs) as a solution for low-income uninsured or underinsured patients. PAPs are manufacturer-funded programs that pay all or nearly-all of the prescription cost for qualifying patients. Patients typically apply directly to the drug manufacturer for assistance. In practice, though, patients applying for PAPs face strict eligibility and qualification criteria, including, but not limited to, income limits, rules for qualification, application processes, and program duration, that can be opaque for patients.

Beyond their potential for inaccessibility and unreliability, PAPs are problematic for economic reasons. As one health economist described it, "Assistance programs are a triple boon for manufacturers: they increase demand, allow companies to charge higher [list and net] prices [for non-PAP patients], and provide public-relations benefits."⁷ Importantly, PAPs are not charitable programs by drug manufacturers; the final price of a drug actually "bakes in" the operating costs of PAPs. Many manufacturers strategically use these programs as part of their negotiations with PBMs and insurers.⁸ The federal government has even warned manufacturers that PAPs may violate the Anti-Kickback Statute.⁹ These ongoing issues have led some industry observers to label patient assistance programs as "shams" that only worsen the crisis of drug affordability.¹⁰ Due to these issues, PAPs are unlikely to be a scalable solution for the financial burden of prescription drugs.

This proposal also includes an additional \$50 million for the construction of an insulin manufacturing facility based in California. CalHHS will partner with the Governor's Office of Business and Economic Development (GO-Biz), leveraging its expertise in business investment services such as site review, permit assistance, and other related activities. CalHHS will lean on GO-Biz's expertise to mitigate risk and properly execute the proposed manufacturing facility, if CalRx proceeds with this component of the project.

Development of this facility may spur economic development and create highly technical positions for Californians, thus expanding skilled employment in the State. Furthermore, it will support and strengthen insulin supply chains within the State. The location of the California-based insulin manufacturing facility would be jointly determined by the State and the contract manufacturer.

In addition to the consumer savings associated with low-priced CalRx biosimilar insulins, the State seeks the following benefits as part of a potential biosimilar insulin partnership:

- **Priority Access:** California will have priority of supply, so that the state's volume needs are met. However, no minimum volume commitment would apply to the state.
- **Branding:** CalRx insulin products sold within California will be labeled with California-related branding, such as the logo with a California Golden Bear, or verbiage, such as "CalRx Insulin" or "CalRx Insulin – Brought to you by the State of California." As a highly utilized drug, this labeling will create brand awareness among stakeholder and grassroots supporters, as well as demonstrate the State's commitment to providing low-cost prescription drugs.

⁷ David Howard, "Drug Companies' Patient-Assistance Programs — Helping Patients or Profits?" *New England Journal of Medicine*, Perspective, July 2014. <https://www.nejm.org/doi/pdf/10.1056/NEJMp1401658>; and Curis Haas et. Al, "Patient Assistance Programs: The good, the bad, and the ugly," *Pharmacy Times/American Journal of Pharmacy Benefits*, 2020. <https://www.pharmacytimes.com/view/patient-assistance-programs-the-good-the-bad-and-the-ugly>

⁹ <https://www.modernhealthcare.com/article/20150307/MAGAZINE/303079980/lifesavers-or-kickbacks-critics-say-patient-assistance-programs-help-keep-drug-prices-high>

¹⁰ Michael Hiltzik, "Why Big Pharma's patient-assistance programs are a sham," *LA Times* 2015.

<https://www.latimes.com/business/hiltzik/la-fi-mh-pharma-s-sham-patient-assistance-programs-20150925-column.html>

- **Low-Cost Implementation:** Compared to direct manufacturing, partnerships in contract manufacturing are likely the lowest cost and most feasible option for the State to bring affordable biosimilar insulin products to market. The contract manufacturer will be responsible for product roll-out and distribution, so that the products are widely available to Californians, through a variety of retailers, pharmacies, and other outlets, as well as mail order pharmacy.

The total funds the State is providing for drug development, manufacturing and distribution is fair and reasonable because it is consistent with independent estimates for biosimilar insulin product development. A U.S. Federal Trade Commission report on the emerging biosimilar insulin market estimated that the cost of bringing a biosimilar product to market (development, capital expenditure and regulatory costs) at \$100–200 million in markets such as the U.S.¹¹

To quickly effectuate an agreement with the contract manufacturer, statutory changes are also proposed that would provide contract exemption authority for HCAI, the implementing department for CalRx.

State Operations Administrative Resources

The resource requirements are new business functions and require state operations resources as well as expert consultation and technical assistance for planning, implementation, and ongoing operations. The request of \$700,000 each year, for four fiscal years, will support the following resources:

- Staff Services Manager I (Specialist) to perform all contract support activities including but not limited to drafting the contract, contract negotiation functions, and compliance with contract deliverables.
- Attorney IV to serve as the legal expert and monitor corporate governance, advise on contractual compliance, and review and advise on contract amendments.
- Pharmacy Program Consultant to serve as the subject matter expert to advise the CalRx program; assess and analyze pharmaceutical data and information necessary for oversight of contract deliverables; research, analyze, and prepare various reports to inform ongoing program priorities and feasibility of prescription drug development considerations.

E. Outcomes and Accountability

CalRx has developed a number of tools to maintain accountability for this project. Contracting language will allow the State to monitor its investment and provide transparency for effective monitoring and oversight of this partnership. The State will also mitigate risk through gated payments contract milestones are achieved.

¹¹ Federal Trade Commission Report. 2009. Emerging health care issues: follow-on biologic drug competition. Available at <https://www.ftc.gov/reports/emerging-health-care-issues-follow-biologic-drug-competition-federal-trade-commission-report>. Note: these estimates for follow-on biologics (i.e., biosimilars) costs are likely to be somewhat dated due to inflation since 2009. Costs for biosimilar development have also decreased somewhat in the last decade due to clarifying guidelines from the FDA and the BCPIA legislation.

Projected Outcomes

F. Analysis of All Feasible Alternatives

CalRx has examined all three options below for development and manufacturing of biosimilar insulin products and recommends the first alternative.

Alternative 1: Contract Manufacturing for Biosimilar Insulin Development

As described in the proposal, CalRx would partner with a contract manufacturer to develop biosimilar products in both vial and pen form. \$50 million would fund drug development and an additional \$50 million fund the construction of an insulin manufacturing facility in California.

Pros:

- Savings to the uninsured, underinsured, and those with high deductible plans, as these consumers are exposed to high list prices, as well as to health plans who can obtain a lower price than net prices after pharmacy rebates. Additional savings to the broader market if over time the branded insulin makers lower their prices in response.
- Increased patient adherence to insulin regimens, thereby improving the health outcomes of diabetics and eliminating adverse events from rationing, such as diabetes ketoacidosis.
- In addition to low, transparent pricing, the State would receive substantial benefits including priority supply, CalRx/California-related labeling, and low-cost implementation.
- Relatively low design and implementation costs for CalRx as the contract manufacturer would take responsibility for roll-out, distribution, and leveraging networks to make their products widely and easily available.

Cons:

- Increased General Fund costs, which are offset by long-term savings to consumers.

Alternative 2: Directly Manufacture Biosimilar Insulin

This option would have the State directly develop its own insulin product(s) using state resources without an industry partner.

Pros:

- The State would have maximum control over insulin pricing.
- The State would develop the manufacturing infrastructure to develop any off-patent drug in the future it wishes.
- The State would greatly expand employment within California.

Cons:

- Extremely costly and complex; the State would essentially be building its own pharmaceutical firm.
- This option would be the riskiest and costliest in the short- and medium-term, as the State would have to develop active drug substances and products, build and manage factories, navigate the legal-regulatory system, distribute products, and etc.
- CalRx currently does not have the expertise, knowledge, or bandwidth for such an undertaking and would require significant staffing and consulting services. As a new entrant, CalRx would have high startup costs to effectively compete with existing players in the pharmaceutical industry.
- This approach would likely take several years to develop the necessary infrastructure, while patients and budgets desperately need relief in the immediate and near term.

Option 3: Maintain the Status Quo

Pros:

- No direct General Fund expenditures

Cons:

- Continuation of high rebate, high list price tactics between insulin manufacturers, PBMs, and health plans that result in uninsured and underinsured consumers bearing the brunt of high-cost insulins. These tactics perpetuate disparities in health care access and outcomes as patients with good insurance coverage pay low cost-shares, while the uninsured and underinsured are exposed to ever increasing list prices for insulin.
- Indirect costs for unmanaged diabetes due to non-adherence to insulin, leading to unsustainable costs for health budgets at the local, county, and state level as insulin prices continue to escalate.
- One in four diabetics cannot afford their insulin, and thus ration or have ceased taking their medicine altogether. The status quo has led to the deaths of numerous diabetics in California and across the nation.
- Patients will continue utilizing PAPs to afford their lifesaving medication, even if those programs raise system-wide costs and are largely unreliable.

G. Implementation Plan

Upon appropriation of funds, HCAI would implement the California Biosimilar Insulin Initiative, including obtaining consulting services for monitoring and oversight and disbursing funds according to the milestone/gated payment schedule.

H. Supplemental Information

Attachment A: Fiscal Detail Sheet

Attachment B: Proposed Provisional Language

I. Recommendation

HCAI recommends approval of this request, per Alternative 1, which would allow CalRx to begin funding its biosimilar insulin development and manufacturing initiative, in accordance with the California Affordable Drug Manufacturing Act of 2020 (Chapter 207, Statutes of 2020 [SB 852]) and Executive Order N-01-19. Doing so would bring low-cost interchangeable biosimilar insulin products to Californians needing insulin. These products will be widely and easily available, bringing substantial financial relief to diabetics and budgets at the local, county, and state level.

BCP Fiscal Detail Sheet

BCP Title: Reducing the Cost of Insulin: CalRx Biosimilar Insulin Development

BR Name: 4140-079-BCP-2022-A1

Budget Request Summary

Personal Services

Personal Services	FY22 Current Year	FY22 Budget Year	FY22 BY+1	FY22 BY+2	FY22 BY+3	FY22 BY+4
Salaries and Wages	0	406	406	406	406	0
Earnings - Temporary Help						
Total Salaries and Wages	\$0	\$406	\$406	\$406	\$406	\$0
Total Personal Services	\$0	\$406	\$406	\$406	\$406	\$0

Operating Expenses and Equipment

Operating Expenses and Equipment	FY22 Current Year	FY22 Budget Year	FY22 BY+1	FY22 BY+2	FY22 BY+3	FY22 BY+4
5301 - General Expense	0	6	6	6	6	0
5302 - Printing	0	2	2	2	2	0
5304 - Communications	0	2	2	2	2	0
5306 - Postage	0	2	2	2	2	0
5320 - Travel: In-State	0	8	8	8	8	0
5324 - Facilities Operation	0	30	30	30	30	0
5340 - Consulting and Professional Services - External	0	230	240	240	240	0
5346 - Information Technology	0	14	4	4	4	0
54XX - Special Items of Expense	0	100,000	0	0	0	0
Total Operating Expenses and Equipment	\$0	\$100,294	\$294	\$294	\$294	\$0

Total Budget Request

Total Budget Request	FY22 Current Year	FY22 Budget Year	FY22 BY+1	FY22 BY+2	FY22 BY+3	FY22 BY+4
Total Budget Request	\$0	\$100,700	\$700	\$700	\$700	\$0

Fund Summary

Fund Source

Fund Source	FY22 Current Year	FY22 Budget Year	FY22 BY+1	FY22 BY+2	FY22 BY+3	FY22 BY+4
State Operations - 0001 - General Fund	0	700	700	700	700	0
Total State Operations Expenditures	\$0	\$700	\$700	\$700	\$700	\$0
Local Assistance - 0001 - General Fund	0	100,000	0	0	0	0
Total Local Assistance Expenditures	\$0	\$100,000	\$0	\$0	\$0	\$0
Total All Funds	\$0	\$100,700	\$700	\$700	\$700	\$0

Program Summary

Program Funding

Program Funding	FY22 Current Year	FY22 Budget Year	FY22 BY+1	FY22 BY+2	FY22 BY+3	FY22 BY+4
3831 - Health Care Quality and Affordability	0	100,700	700	700	700	0
Total All Programs	\$0	\$100,700	\$700	\$700	\$700	\$0

Provisional Language

This proposal includes the following corresponding provisional language.

Item 4140-001-0001:

6. Of the funds appropriated in Schedule (1), \$700,000 is available to implement the CalRx Biosimilar Insulin Initiative.

Item 4140-101-0001:

8. Of the funds appropriated in Schedule (1), \$100,000,000 is available for encumbrance or expenditure until June 30, 2026, and for liquidation until June 30, 2028, to support the development of three low-cost interchangeable biosimilar insulin products and a California-based insulin manufacturing facility.