Request for Information (RFI)
RFI No. CBII-001

CalRx Biosimilar Insulin Initiative

DATE: August 1, 2022

TO: All Interested Entities

FROM: California Department of Health Care Access and Information (HCAI)

SUBJECT: Phase 1 of the CalRx Biosimilar Insulin Initiative

A. Purpose of the Request for Information

The State of California appropriated fifty million dollars ($50,000,000) to the California Department of Health Care Access and Information (HCAI) to support the development of three low-cost interchangeable biosimilar insulin products[1] with one or more partners under the California Affordable Drug Manufacturing Act of 2020[2]. This is the first phase of the CalRx Biosimilar Insulin Initiative (Initiative).

Phase 1 may include HCAI providing funding or other assistance to one or more partners for the development, production/procurement, and/or distribution of three biosimilars for insulin drugs (such as aspart, lispro, and glargine). The goal of Phase 1 is for the State to secure a consistent source of insulin products for several years so a significant portion of California residents needing insulin may obtain it at a much lower price compared to today.

Through this Request for Information (RFI), HCAI hopes to find a partner or partners to implement Phase 1 of the Initiative. HCAI seeks information about best practices for Phase 1 and the capabilities of potential partners.

HCAI understands that the information provided in this RFI is not sufficient to enable detailed analysis and costing by respondents. Respondents should provide responses based on knowledge and experience with other organizations and initiatives of this kind.

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[1] Assembly Bill No. 178, 2021-2022 Reg. Sess. (Cal. 2022), Section 130, Provision 8.
[2] Cal. Health & Safety Code sections 127690-127696 (2022).

Respondents should read this RFI document thoroughly and adhere to the response submission guidelines.

B. Key Action Dates

Listed below are the RFI Key Action Dates and Times by which actions should be taken or completed.

Event	Date
Release of RFI.	August 1, 2022
Respondents may submit questions for clarification.	August 12, 2022, by 3:00 p.m. PDT
RFI Responses due.	August 22, 2022

C. Background

1. Market Failure for Insulin

Far too many Californians today experience the pain of unaffordable, skyrocketing drug prices while drug companies post record profits, and patients struggle to afford their lifesaving medications while seeing their health insurance premiums increase year after year.

Unsurprisingly, CalRx's first and top drug priority is insulin. The insulin market has long epitomized the worst 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. 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 and net prices for insulin have risen dramatically over the last decade.

The downstream impacts of the market failure for affordable insulins impacts California and its residents directly. Insulin inaccessibility affects the 10.7% of Californians who have been diagnosed with diabetes—roughly 200,000 of whom are uninsured or underinsured—and disproportionately harms low-income, Black, and Latino Californians. Based on national data, as many as 1 in 4 diabetics cannot afford their insulin, and thus ration or have ceased taking insulin altogether. Over time, utilizing insulin less than prescribed by physicians leads to poorly regulated blood sugars and

contributes to severe disease such as diabetic ketoacidosis, renal failure and neuropathies that lead to limb loss.

2. The CalRx Biosimilar Insulin Initiative

The California Affordable Drug Manufacturing Act of 2020[3] codified the CalRx initiative, a State of California program intended to address the market failures for pharmaceutical drugs by having the State partner with others for the production or distribution of lower-cost generic drugs or biosimilars, including insulin.

The Budget Act of 2022 recently appropriated one hundred million dollars ($100,000,000) to HCAI for the Initiative "to support the development of three low-cost interchangeable biosimilar insulin products and a California-based insulin manufacturing facility."[4]

HCAI is required to utilize funds to enter into "partnerships" with others that result in the production and distribution of insulin biosimilars "at a price that results in savings, targets failures in the market for generic drugs, and improves patient access to affordable medications."[5] The intent is "that these drugs be made widely available to" to those who provide or sell drugs to patients (e.g., pharmacies, doctors, hospitals).[6] Statute requires that the biosimilar insulin products "be produced or distributed by a drug company or generic drug manufacturer that is registered with the United States Food and Drug Administration."[7] Further, statute requires that each drug be available at a transparent price and without rebates, other than federally required rebates.[8]

D. Response Instructions

To respond to this RFI, please review and respond to **Attachment A** of this RFI. Respondents are free to include multiple entities in joint submissions.

Responses must be submitted as follows:

- The response is sent by email to the HCAI contact person listed below on or before **August 22, 2022**.
    - Indicate the RFI title in the subject line.

[3] Cal. Health & Safety Code sections 127690 to 127696 (2022).
[4] Assembly Bill No. 178, 2021-2022 Reg. Sess. (Cal. 2022), Section 130, Provision 8.
[5] Cal. Health & Safety Code section 127693(b).
[6] Cal. Health & Safety Code section 127693(a).
[7] Cal. Health & Safety Code section 127693(a).
[8] Cal. Health & Safety Code section 127693(b)(4).

- A signed cover letter on company letterhead that includes the following:
    - Information about Respondent's primary contact for this RFI including their name, title, address, telephone number, and e-mail address; and
    - Why Respondent is interested in CalRx or the Initiative.
- The response to **Attachment A**.
    - Respondents should feel free to add or reply differently to Attachment A as they see fit based on their own expertise and experience. Respondents do not have to answer all the questions in Attachment A and Attachment A may be used to frame or provide guidance to the response. HCAI is interested in different perspectives and views on how Phase 1 should be implemented and is open to new ideas.

E. RFI Responses Assumed to be Public Records

Please be aware that all documents submitted to HCAI in response to this RFI will become the property of the State of California and will be assumed to be public records subject to public review under the California Public Records Act[9] *unless* HCAI has agreed in advance to keep the information confidential.

If you believe that disclosure of non-public or proprietary information is necessary to respond to this RFI, please contact HCAI at the contact below before submitting your response.

F. RFI Disclaimers and General Information

Not a Solicitation: This RFI is issued for information and planning purposes only and does not constitute a solicitation. A response to this RFI is not an offer and cannot be accepted by HCAI to form a binding contract. Respondents are solely responsible for all expenses associated with responding to this RFI.

Effect of Submitting an RFI Response: HCAI may follow up with any respondents that submit an RFI for the purposes of entering into an agreement. However, submitting a response to this RFI will not enhance the review of that respondent's proposal(s) to any future opportunities. Not submitting a response to this RFI will not prohibit a response to any future opportunities, nor disadvantage the evaluation of a response to any future opportunities.

[9] Cal. Government Code sections 6250, et seq.

Budget Information: HCAI asks willing respondents to share non-binding budgetary pricing information. Pricing is only for planning purposes. Any pricing provided in a response to this RFI will not be considered a proposal/bid on the part of the respondent.

G. Questions for Clarification

Respondents may submit questions for clarification of this RFI, via e-mail, by the specified date and time stated in the Key Action Dates.

H. Contact Information

Respondents must submit their written response, via e-mail, to the HCAI contact listed below:

James Yi
(916) 326-3614
insulin@hcai.ca.gov

Attachment A

A. Instructions

HCAI seeks an understanding of the potential entities available to partner with HCAI for the three potential subphases of Phase 1 (development, production/procurement, and distribution), and their ideas on the best business model(s) to execute Phase 1. For partnerships, HCAI is looking at contracting or providing grants to one or more entities. HCAI, currently, would prefer to partner with one entity for all of Phase 1.

Respondents should feel free to add or reply differently to Attachment A as they see fit based on their unique circumstances, expertise, and experiences. Respondents do not have to answer all the questions in this attachment and the questions may be used to frame or provide guidance to a response. HCAI is interested in different perspectives and views on how Phase 1 should be implemented and is open to new ideas and innovations.

B. RFI Questions

1) Provide a brief overview of your company including number of years in business, number of employees, nature of business, description of services, company vision, and description of clients.

    a) Identify any relevant parent corporation and/or subsidiaries, if applicable.

    b) Include a brief description of Respondent's experience in the pharmaceutical industry, especially regarding biologics or biosimilars and/or insulin products.

    c) Provide a brief overview of Respondent's experience doing business with the State of California.

    d) State whether the State of California is taking or has taken any administrative, civil, or criminal action against Respondent.

2) Generally, what are some of the key issues that HCAI should consider for Phase 1?

    a) What services or products can Respondent provide regarding these issues?

3) What is Respondent's plan to partner with HCAI to execute Phase 1 fully or partially, and why should HCAI consider this option?

    a) Generally, describe the business model; services/products provided; the form of partnership; Respondent's role; other partners, contractors, or suppliers required; and the potential challenges and significant risks for Respondent;

b) Describe how Respondent would like the partnership with HCAI to be structured (e.g., contract, grant, or other), including the desired length of time for the partnership;

c) Describe the estimated amount of funding and/or non-monetary assistance Respondent would require from HCAI and/or the State of California;

d) Estimate the overall costs, and how Respondent plans to obtain funding to cover the costs, including funding from HCAI and other sources. Itemize costs for each part of Respondent's plan, including startup costs and ongoing costs;

e) State how Respondent would perform each service it is proposing, or obtain supplies it requires for its plan;

f) Include Respondent's experience regarding each service/product that can be provided and whether Respondent is engaged in these activities now;

g) If applicable, whether Respondent plans to develop the insulin biosimilar(s) and obtain FDA approval, or whether Respondent will access a biologics license to manufacture such product;

h) If Respondent's plan includes development of insulin biosimilar(s), the following:
   i) Estimated time to develop the insulin biosimilar(s);
   ii) How Respondent will handle regulatory issues;
   iii) How Respondent will achieve interchangeability status for its biosimilar insulin products;
   iv) Description of delivery devices, such as pens or needles to inject insulin; and
   v) Description of ownership of intellectual property or any other barrier that may affect the product's development (including delivery devices);

i) If Respondent's plan includes leveraging an existing biologic license, the following:
   i) Estimated time to obtain use of the license; and
   ii) The entity that currently holds the license and Respondent's strategy to use the license, including any payments or ongoing obligations;

j) If Respondent's plan includes the production or procurement of insulin biosimilars, the following:
   i) Estimated volume of product that would be available to California consumers and how long this capability would be available;
   ii) Respondent's plan for ramping up production to meet increased demand;
   iii) Whether HCAI will be guaranteed priority access to the product; and
   iv) Estimated time of first delivery and delivery periods;

k) If Respondent's plan includes product roll-out and/or distribution of insulin biosimilars, the following:
   i) How Respondent will engage existing supply chain entities, such as pharmacy benefit managers, distributors, wholesalers, and pharmacies, so products are widely available to Californians;
   ii) Alternatives to working within the existing supply chain, such as mail order pharmacy services;
   iii) Estimated amount that can be distributed;
   iv) When distribution would start; and
   v) Geographic areas in California that can be served.

l) If governmental approval, licensure, or registration is needed for any part of Respondent's plan; Respondent's expertise, experience, and history in obtaining those with the United States Food and Drug Administration (FDA) or other regulatory agencies;
   i) This includes whether Respondent is currently registered with the FDA and is in good standing.

4) Respondent's estimate of the final cost to California customers for the insulin biosimilar products created from Respondent's plan.

5) Current law[10] requires that the insulin biosimilar products be made available for purchasers "at a transparent price and without rebates, other than federally required rebates.

   a) If applicable, can Respondent do this?

   b) What concerns, if any, does Respondent have about this?

[10] Cal. Health & Safety Code section 127693(b)(4) (2022).

6) To make sure state funds are being used appropriately, HCAI expects to fund its partners in stages based on the achievement of certain metrics or milestones. Pending legislation may also make this a requirement.[11]

    a) State whether this would be acceptable for Respondent, and if not, why not;

    b) Under Respondent's plan, how would Respondent structure the stages for payment and what milestones or metrics would be reasonable for Respondent?

    c) What remedies would be reasonable for the failure of Respondent to meet required metrics or milestones?

7) HCAI is currently planning to brand the insulin biosimilar products provided under the Initiative with the "CalRx" name.

    a) State whether this would be reasonable for Respondent, and if not, why not;

    b) What concerns or issues, if any, Respondent has about this?

    c) What, if any, assistance Respondent can give HCAI in creating a state branded insulin product.

8) Current legislation[12] may require partnership agreements to have provisions giving HCAI representation and involvement with the governance of the partner.

    a) If this becomes a requirement, what options, if any, can Respondent provide for this?

    b) What concerns or issues, if any, does Respondent have about this?

9) During the partnership with HCAI, can Respondent help the State of California build expertise for CalRx to produce, procure, or distribute pharmaceutical drugs? If so, how can Respondent do this?

[11] Senate Bill No. 838, 2021-2022 Reg. Sess. (Cal. 2022), Section 2.
[12] Senate Bill No. 838, 2021-2022 Reg. Sess. (Cal. 2022), Section 3.