



## CalRx Biosimilar Insulin Initiative Patient Advisory Council Charter

### Background

Diabetes is a significant health burden impacting roughly 4 million California adults, as of 2019.<sup>1</sup> Additionally, the estimated prevalence of prediabetes and diabetes among California adults has significantly increased since 2013, with higher rates among racial and ethnic minorities and older adults.<sup>2</sup> Every year 272,814 people in California are newly diagnosed with diabetes.<sup>1</sup>

It is estimated that approximately 31% of people with diabetes use insulin.<sup>3</sup> Insulin prices in the U.S. are, on average, five to ten times higher than in other industrialized countries.<sup>4</sup> Newer versions of insulin retail between \$90 and \$300 per 10 mL vial.<sup>5</sup> Most patients with diabetes need two to three vials per month, and some patients require more. Current prices are especially challenging for uninsured patients or patients with high deductible plans, who often pay cash for their insulin.

While patients with more generous health coverage may pay very little for their insulin due to their relatively low out-of-pocket cost sharing responsibilities, many people with diabetes 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 people with diabetes typically must pay the list price for their insulin, spending thousands of dollars per year to afford their lifesaving medications.<sup>6</sup> Even people with diabetes with moderate deductible plans still spend substantial sums for their insulin. Based on national data, as many as 1 in 4 people with diabetes cannot afford their insulin and, thus, ration or cease taking insulin altogether.<sup>7</sup> Those not adhering to insulin therapy have worse diabetes control and are at higher risk for diabetes exacerbations, long-term complications, and death.

To address the market failure of insulin and the skyrocketing costs of other generic drugs, in January 2019, Governor Newsom's first executive order (Executive Order N-01-19) focused on drug affordability in the State's Medicaid program, Medi-Cal, and the private sector. Building on the Executive Order, Governor Newsom announced, in the 2020 proposed budget, the CalRx Program which called for state-led manufacturing of generic drugs in highly concentrated,

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<sup>1</sup> American Diabetes Association, [The Burden of Diabetes in California Fact Sheet](#), January 2022 5 Centers for Disease

<sup>2</sup> Taylor CW, Downie C, Mercado V. (2019). [Burden of Diabetes in California](#). California Department of Public Health. Sacramento, California, June 2019

<sup>3</sup> Centers for Disease Control and Prevention [Age-adjusted percentage of adults with diabetes using diabetes medication, by type of medication](#), U.S., 1997–2011. May 5, 2015.

<sup>4</sup> [Cost of Insulin by Country 2023](#), World Population Review, January 2023

<sup>5</sup> Benita Lee, Diane Li, [How Much Does Insulin Cost? Here's How 28 Brands and Generics Compare](#), GoodRx Health, January 2022

<sup>6</sup> Underinsured are those who spend more than ten percent of their income on health insurance coverage or five percent when their income is less than two hundred percent of the federal poverty level of \$13,590 for an individual or \$27,750 for a family of 4., Source: HealthWellFoundation.org, [Underinsured Americans Need a Financial Lifeline](#), July 2015

<sup>7</sup> Darby Herkert, Pavithra Vijayakumar, Jing Luo, MD., [Cost-Related Insulin Underuse Among Patients with Diabetes](#), JAMA Intern Med. 2019;179(1):112-114. doi:10.1001/jamainternmed.2018.5008



## CalRx Biosimilar Insulin Initiative Patient Advisory Council Charter

low competition drug markets. Legislation was signed into law to codify the CalRx Program through the California Affordable Drug Manufacturing Act of 2020 (Pan, SB 852, Chapter 207, Statutes of 2020), and the program is administered by the Department of Health Care Access and Information (HCAI).

CalRx has the following aims:

- Empowering the State of California to develop, produce, and distribute generic drugs and sell them at a low cost.
- Targeting prescription drugs where the pharmaceutical market has failed to lower drug costs, even when a generic or biosimilar medication is available.
- Transparent pricing based on development, production, and distribution costs. CalRx prescription drugs will not use rebates or discounts (other than those federally mandated).
- Seeking deep, mutually beneficial partnerships with companies that share the State's goal of increasing access to affordable medications.

California's first drug project, called the CalRx Biosimilar Insulin Initiative, is a partnership with Civica Rx and focuses on supporting the development of three insulins – glargine, lispro and aspart (biologics corresponding to, and expected to be interchangeable with, Lantus, Humalog and Novolog, respectively) – each of which will be available both in vials and prefilled pens under the CalRx label. Civica and CalRx have the mutual goal of ensuring access to affordable insulins that have single, low transparent prices. Although the major brand-name insulin manufacturers have reduced their prices<sup>8</sup>, overall implementation and patient experience has been uneven and insulin remains unaffordable for many.

As such, CalRx insulins manufactured by Civica are expected to have a manufacturer suggested retail price of no more than \$30 per 10 mL vial and no more than \$55 for a box of five 3 mL pre-filled pens, a significant discount to prices charged to uninsured individuals today. At these prices, insured Californians who currently pay cost sharing amounts for their insulin will also experience overall savings.

### Purpose

The CalRx Insulin Patient Advisory Council serves as an important bridge between the CalRx Program and the diabetes patient community, providing input and guidance to advance awareness, education, and advocacy for CalRx low cost, biosimilar insulin products. A core focus of the Council is to aid efforts to build sustainable access to CalRx insulin products for all

<sup>8</sup>Feldman WB, Rome BN. [The Rise and Fall of the Insulin Pricing Bubble](https://doi.org/10.1001/jamanetworkopen.2023.18074). JAMA Netw Open. 2023;6(6):e2318074. doi:10.1001/jamanetworkopen.2023.18074



## CalRx Biosimilar Insulin Initiative Patient Advisory Council Charter

patients throughout California, particularly uninsured and underinsured communities. While the intent is for CalRx-branded insulin products to be readily available via pharmacies, retail stores, and mail order, the CalRx Program may require access through non-traditional outlets if standard pharmaceutical distribution options are not available or are insufficient.

The Council provides critical insights and expertise as the CalRx Biosimilar Insulin Initiative evaluates alternative distribution models, addresses barriers in the current market, and ensures equitable access to insulin for diverse communities.

<b>The Advisory Council will:</b>	<b>The Advisory Council will not:</b>
<ul style="list-style-type: none"><li>• Share insights and feedback as consumers of insulin products</li><li>• Advocate for inclusion of CalRx-branded insulin in traditional outlets</li><li>• Offer guidance on how to reach patients through non-traditional outlets</li><li>• Increase awareness of CalRx-branded insulin products</li><li>• Provide input on patient education materials</li></ul>	<ul style="list-style-type: none"><li>• Have decision-making authority</li><li>• Have access to non-public and confidential information</li></ul>

### Council Composition

#### Authority

The Council serves the CalRx Biosimilar Insulin Initiative in an advisory capacity to HCAI. HCAI provides quarterly updates to the Civica Joint Steering Committee on the Council's activities and recommendations.

#### Membership Composition & Selection Criteria

The Council includes up to 12 members from across the diabetes and health care community and representing the key populations whom the CalRx Program is trying to serve. Members are highly knowledgeable of the challenges facing low-income Californians in accessing insulin products. Council members may be recognized leaders or key participants in national or California-focused programs and organizations seeking to raise awareness of diabetes issues, address disparities in access to diabetes services, and/or support diabetes education initiatives. To avoid conflicts of interest, members of the Council cannot be employed or represent organizations which receive funding from the pharmaceutical industry.



## CalRx Biosimilar Insulin Initiative Patient Advisory Council Charter

### Roles & Responsibilities

- **Council Members** will provide input to support the success of the CalRx Biosimilar Insulin Initiative through their regular participation in Council meetings. Members will also help define the annual goals for the Council and may provide input to HCAI on various activities such as evaluating options to distribute CalRx insulin products broadly, including to rural communities with limited retail pharmacy access; implementing social media campaigns; or collaborating with professional organizations to disseminate accurate information about CalRx insulin quality, safety, and cost-effectiveness.
- **HCAI** serves as the main point of contact between the Council and the Civica Joint Steering Committee. HCAI manages the Council work overall, leads and facilitates all Council meetings, and ensures Council input and recommendations are shared with Civica.
- **Civica Members** attend Council meetings to provide expertise to support discussions and to receive input from the Council.
- **Council Coordinator** assists with administrative responsibilities such as meeting scheduling, meeting material and agenda preparation, meeting minutes and note-taking, and other logistical needs. The Council Coordinator is an HCAI staff member.

### Council Member Commitments

- Serve at least a one-year term. The term begins January 1<sup>st</sup> each year. Unless extended by HCAI, the Council will terminate one year after the launch of CalRx insulin products.
- Attend at least two of the quarterly Council meetings in a term year. Members cannot send a designee or substitute. Failure to meet this requirement will be treated as a resignation unless previous arrangements have been made.
- Prepare for and actively participate in Council meetings.
- Notify the Council Coordinator when unable to attend a meeting.
- Share opinions and experiences constructively.

### Communication with the Public and Media

- Members of the Council may speak to the media in a personal capacity about their views.
- Media inquiries regarding official CalRx information should be directed to HCAI's Public Relations Officer, Andrew DiLuccia, and cc'd to [info@calrx.ca.gov](mailto:info@calrx.ca.gov).



## CalRx Biosimilar Insulin Initiative Patient Advisory Council Charter

### Meeting Operating Principles

- Communicate clearly and concisely.
- Ensure all participants who wish to speak, have the chance to do so.
- Respectively listen to the perspective of others.
- Ask questions if clarification is needed.
- Avoid jargon whenever possible.
- Keep discussion and comments relevant to the issues being discussed.

### Council Member Selection Process

Council members may be nominated by HCAI, Civica, members of the diabetes community, or by self-referral. Interested individuals should complete a Submission of Interest form and attest that they do not have any conflict-of-interests. Membership recruitment is continuous. HCAI may remove any member of the Council at any time if such removal is in the best interest of the Council. If a Council member is removed, steps down, or requests a leave of absence from the Council, HCAI may elect to fill the vacancy from the recruitment list available or leave the position open until the next term begins.

### Compensation

Council members do not receive compensation or a stipend for their participation.

## Council Logistics

### Meeting Schedule and Process

The Council will meet at least quarterly, and meetings are scheduled in advance for the term year. Meetings will be held via video conference. Meetings are not subject to the Bagley-Keene Open Meeting Act and will not be open to the public; however, HCAI and the Council may work together to plan public-facing events.

### Meeting Agenda

The agenda for each meeting will be sent out no later than one week prior to the meeting. Written minutes will be taken at each meeting and sent out with the agenda for the upcoming meeting.



## CalRx Biosimilar Insulin Initiative Patient Advisory Council Charter

### Recordkeeping

Records of the Council are maintained on the HCAI file repository. Council meetings are not confidential and all records including agendas, minutes, materials, and recordings, if any, are public record. For more information, visit: <https://hcai.ca.gov/home/public-transparency/public-records/>

### Council Charter Approval

#### Filing Date

September 23, 2024

#### Approved By

September 19, 2024

Vishaal Pegany, MPH, MPP

Deputy Director, Office of Health Care Affordability