



**Insulin Patient  
Advisory Council  
Kickoff**

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April 29, 2025

# Virtual Meeting Etiquette



1

**Mute your microphone when you are not speaking to avoid background noise**



2

**Use of your camera is encouraged**



3

**Raise your virtual hand or use the chat feature for questions/comments**



# Agenda



- |    |  |         |
|----|--|---------|
| 1. | Welcome & Introductions                                | 2:30 PM |
|    | HCAI Director's Welcome                                |         |
|    | Civica Rx CEO's Welcome & Overview                     |         |
|    | Council Member Introductions                           |         |
| 2. | CalRx® Program Overview                                | 3:00 PM |
| 3. | CalRx® Biosimilar Insulin Initiative Accomplishments   | 3:15 PM |
| 4. | Insulin PAC Role & Responsibilities                    | 3:25 PM |
|    | Review charter & roadmap of anticipated meeting topics |         |
| 5. | Insulin Market Discussion Questions                    | 3:35 PM |
| 6. | Next Steps & Adjournment                               | 4:30 PM |

# HCAI Director's Welcome

# Civica Rx CEO's Welcome & Overview

# Civica, Inc. (Civica Rx) is a Nonprofit Generic Drug Company



- Created by hospitals in 2018 to address drug shortages
- 97 million patients served (215 million vials of medicine)
- CivicaScript created with health plans to lower drug costs for consumers
- Civica Foundation raising funds to develop affordable insulin





# Civica and CalRx: Partnering for Affordable Insulin

- Civica, Inc. (Civica Rx) – a mission-driven, nonprofit generic company created to ensure reliable and affordable access to medicines
- Civica is developing and will manufacture and distribute insulins at significantly lower prices than insulins currently on the market
- 3 interchangeable insulins:
  1. Glargine (Lantus®)
  2. Aspart (Novolog®)
  3. Lispro (Humalog®)
- Each will be available in vials & prefilled pens
- One-price model – no hidden rebates or price concessions





- Insulins are sterile injectable medications requiring special manufacturing expertise and equipment
- Civica has built a new state-of-the-art manufacturing facility in Virginia







## Civica Petersburg

- 140,000 square feet
- 350 employees at full staffing
- 90 million vials/year
- 50 million syringes/year
- 120 million prefilled pens/year

# Civica Insulin Embedded in Big Pharma Price-Cut Story



Eli Lilly also faces the threat of competition from outside the industry, said Larry Levitt, the executive vice president for health policy at KFF...Civica Rx, a nonprofit company in Lehi, Utah, said last year that it plans to make and sell generic versions of insulin to consumers at no more than \$30 a vial and no more than \$55 for a box of five pen cartridges.



Eli Lilly's announcement that it will cut the list price of its most commonly prescribed insulin product, Humulin, by 70 percent before year's end was heralded by President Joe Biden.... But drug policy experts say the truth is more nuanced and this week's announcement reflects a variety of factors, including market pressure from emerging biosimilar manufacturers and generic efforts by generic drugmaker Civica Rx...



...Pressure is growing on drugmakers to slow the increases. The state of California has said it plans to explore making its own cheaper insulin. Drugmakers also may face competition from companies like the nonprofit Civica, which plans to produce three insulins at a recommended price of no more than \$30 a vial...

# Supported by leading advocates to reduce cost of insulin



Blue Cross and Blue Shield of Alabama

Arkansas Blue Cross and Blue Shield

Blue Shield of California

CareFirst BlueCross BlueShield

Excellus BlueCross BlueShield

Blue Cross and Blue Shield of Hawaii

Highmark Blue Cross Blue Shield

Horizon Blue Cross Blue Shield of New Jersey

Blue Cross of Idaho

Independence Blue Cross

Blue Cross Blue Shield of Vermont

Florida Blue



**Glen Tullman  
Family Foundation**



# Council Member Introductions



# 12 Members Appointed



- **Albert Bach, Pharm.D.**  
Providence Medical Foundation
- **Allison Hardt**  
Community Development Director  
T1International
- **Christopher Noble**  
Organizing Director, Health Access CA
- **Craig Stubing**  
CEO, Beta Cell Foundation
- **Diana Wyenn**  
Director and Creative Producer
- **Joe L. Garbanzos**  
State President (volunteer), AARP-CA
- **Joseph Wotawa**  
Teacher, Former T1International Chapter Lead
- **Kathryn Topalis, M.D.**  
Diabetes Lead, Ambulatory Care Network  
Los Angeles Department of Health Services
- **Laura Feeney, Pharm.D.**  
Care Plus Program, Kaiser Permanente
- **Luz Gallegos**  
Executive Director, TODEC Legal Center
- **Michelle Chu, Pharm.D.**  
Primary Care Clinic  
Los Angeles General Medical Center
- **Samantha Lappin**  
T1International Chapter Member  
Talent Acquisition Recruiter, DAP Health

# Meeting Operating Principles



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

# CalRx<sup>®</sup> Program Overview

# California Department of Health Care Access & Information (HCAI)



## HCAI's Mission:

HCAI expands equitable access to quality, affordable health care for all Californians through resilient facilities, actionable information, and the health workforce each community needs.



# HCAI's Program Areas

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**Facilities:** Monitor the construction, renovation, and seismic safety of California's hospitals and skilled nursing facilities.

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**Financing:** Provide loan insurance for nonprofit healthcare facilities to develop or expand services.

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**Workforce:** Promote a culturally competent and linguistically diverse health workforce.

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**Data:** Collect, manage, analyze and report information about California's healthcare landscape.

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**Affordability:** Improve health care affordability through data analysis, spending targets, and measures to advance value. Enforce hospital billing protections, and **provide generic drugs at a low, transparent price.**

# CalRx®: State-powered market intervention for better drug affordability and access



- The California Affordable Drug Manufacturing Act of 2020 (Senate Bill 852, Statutes of 2020) empowered California to enter into partnerships resulting in the production, procurement, or distribution of generic drugs and sell them at a low cost.
- Target areas are drugs where the U.S. health care system has failed to lower drug costs, even when a generic or biosimilar medication is available.
- All CalRx® pricing is based on development, production, and distribution costs without rebates or other discounts (other than federally mandated ones).
- The CalRx® program is administered by the Pharmaceutical Policy & Programs Branch (P3B) within HCAI's Office of Health Care Affordability (OHCA).

**Our Vision: An equitable, transparently priced pharmaceutical market where all Californians can afford and access the medications they need for healthy lives.**

# Our Purpose & Intervention Models



- CalRx's purpose is to **improve equitable access and affordability of medications** in California by developing strategic partnerships and innovative solutions in the pharmaceutical market.
- To date, there are 3 major initiatives under our program:

## CalRx Models for Intervention

1. Invest in development (insulin model)
2. Stockpiling (misoprostol model)
3. Leverage state volume for white labels<sup>1</sup> (naloxone model)



**CalRx® Biosimilar Insulin Initiative**



**Reproductive Health Stockpile**



**CalRx® Naloxone Access Initiative**



# **CalRx® Biosimilar Insulin Initiative Timelines & News Updates**



# CalRx<sup>®</sup> Biosimilar Insulin Initiative Accomplishments

# Extensive distribution for CalRx<sup>®</sup> insulins is imperative

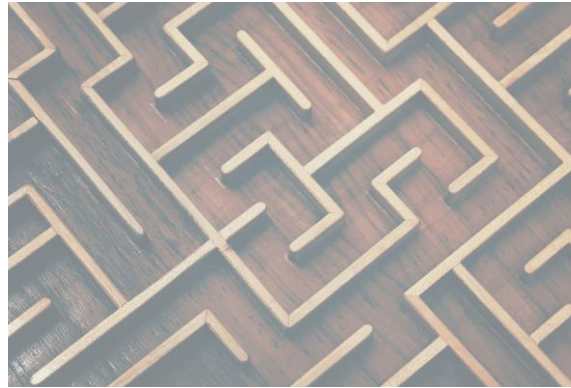


The success of this program hinges on reaching diverse communities



This includes vulnerable populations grappling with affordability challenges in accessing insulin

Certain traditional supply chain models for drug distribution might present formidable barriers



Breaking into these established systems and ensuring equitable access for all can be a daunting task, but one that is crucial for the program's overall effectiveness

We recognize the significance of collaboration



By identifying the areas where HCAI's expertise can be most impactful, we can work in tandem with Civica to bridge gaps and overcome distribution challenges

# A collaborative distribution approach will complement Civica's commercialization efforts



## Market Analysis

### *HCAI-led*

Gather diabetes, income, and census data in HCAI's centralized data warehouse to identify target geographical regions. Overlay with pharmacy, retail, and federally qualified health center location data.



## Education & Advocacy

### *HCAI-led*

Utilize educational programs, marketing campaigns, and social media platforms to raise awareness of CalRx insulins, particularly in target segments



## Traditional Supply Channels

### *Civica-led*

Contract with wholesalers, pharmacy benefit managers, health plans, and pharmacies to include CalRx insulins



## Formulary Inclusion

### *Civica-led*

Engage in conversations with health plans, pharmacy benefit managers, and retail pharmacies to encourage the inclusion of CalRx products in their formularies & implement legislation



## Explore Non-Traditional Supply Channels

### *Co-led*

As feasible, collaborate with non-traditional distribution partners such as safety-net providers, community clinics, and federally qualified health centers to facilitate distribution



## Monitoring & Support

### *Co-led*

Establish a customer support system to address inquiries on "where to find CalRx products". Implement a monitoring system to measure the effectiveness of the distribution strategy.

# Equitable insulin distribution will develop in phases



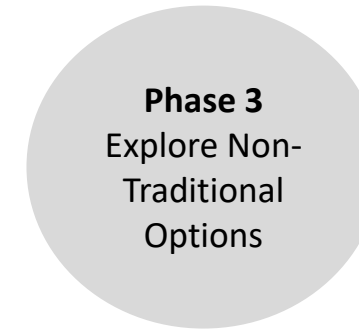
 Civica-led  
 Co-led



*Use the traditional supply model to establish broad access for both the insured and uninsured population*



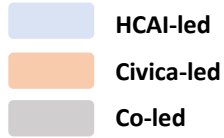
*Add additional retail pharmacy options in low-income communities with high diabetes prevalence*



*As feasible, develop alternative distribution methods to close access gaps for consumers that lack a fixed address or live in pharmacy deserts*



# CalRx<sup>®</sup> Insulin Distribution Strategy Roadmap: 2023



Summer 2023

Fall 2023

Winter 2023

## Market Analysis

### Metrics Project Planning (Sprint 0)

- Develop CalRx Metrics charter
- Identify data gaps & create report mock-ups
- Develop CalRx data repository

### Market Analysis (Sprint 1)

- Collect pharmacy, healthcare facility, disease prevalence, and grocery store data
- Develop reports analyzing diabetes prevalence & low retail pharmacy access

## Education & Advocacy

### Patient Advisory Council Planning

- Define CalRx Insulin Patient Advisory Council scope
- Draft charter
- Develop submission of interest form

## Traditional Supply Channels

### Create Roadmap to Wholesale Distribution

- Goal is traditional wholesale model and broad pharmacy network
- Conduct market research with 16 large national and regional pharmacies on willingness to stock & dispense CalRx/Civica insulin. All 16 respondents said they would.

## Formulary Inclusion

### Created Civica Affordable Insulin Pledge

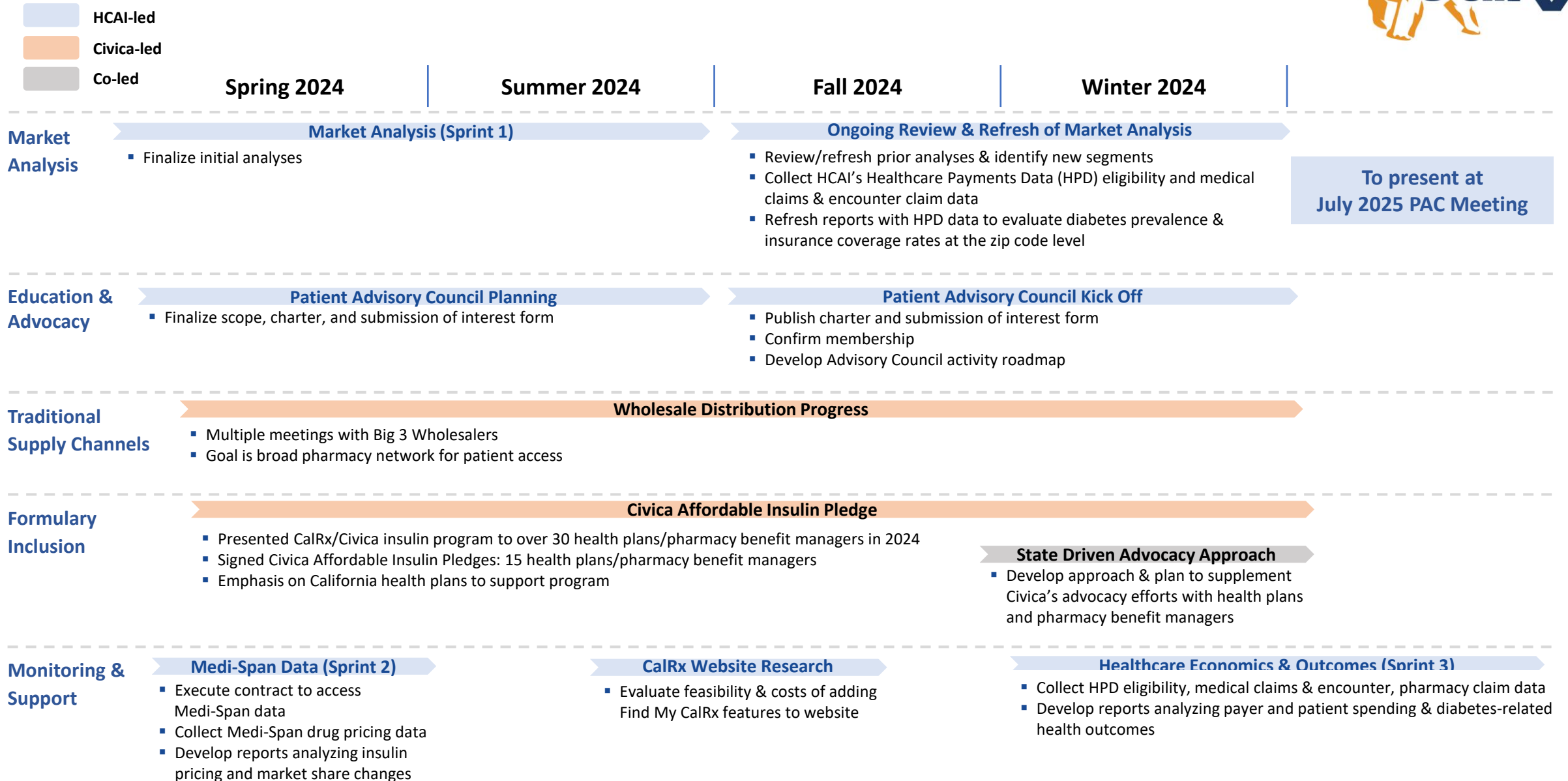
- Create pledge form for health plans & pharmacy benefit managers to agree to create formulary access for CalRx/Civica insulin & allow Civica to use their name as a show of support
- Eight health plans signed by end of 2023

## Explore Non-Traditional Supply Channels

### Channel Partner Research

- Identify non-traditional channel partner options
- Develop profiles of non-traditional partner options

# CalRx® Insulin Distribution Strategy Roadmap: 2024



# Council's Role & Responsibilities

# Council's Purpose



- Serve the CalRx® Biosimilar Insulin Initiative in an advisory capacity
- Provide input and guidance to advance awareness, education, and advocacy for CalRx® low-cost biosimilar insulin products for all patients throughout California
- Provide insights and expertise on alternative distribution models, barriers in the insulin market, and ensuring equitable access to insulin for diverse communities

## The Council will...

- Share insights and feedback as consumers of insulin products
- Advocate for inclusion of CalRx® insulin in traditional outlets
- Offer guidance on how to reach patients through non-traditional outlets
- Increase awareness of CalRx® insulin products
- Provide input on patient education materials

## The Council will not...

- Have decision-making authority
- Have access to non-public and confidential information
- Receive compensation or a stipend for meeting participation

# Council Member's Role



- Support the success of the CalRx® Biosimilar Insulin Initiative through regular participation in Council meetings
- Help define the Council's annual goals and provide input on various activities, such as:
  - Evaluating options to distribute CalRx® insulin products broadly
  - Disseminating accurate information about CalRx® insulin quality, safety, and cost-effectiveness
  - Implementing social media campaigns
- Refer to the commitments listed on your **Appointment Acceptance Form**



# Council Meeting Logistics



- The Council will meet quarterly via video conference
- Meetings are scheduled in advance for the term year
- Agendas will be sent out no later than one week prior to the meeting
- Minutes will be sent out with the agenda for the upcoming meeting
- Meetings are not subject to the Bagley-Keene Open Meeting Act and are not open to the public
- Meetings are not confidential and all records including agendas, minutes, and materials are public record
- Public-facing events may be planned

# Communication with the Public & Media



- Council members may speak to the media in a personal capacity about their views
- Direct media inquiries regarding official CalRx<sup>®</sup> information to:  
[info@calrx.ca.gov](mailto:info@calrx.ca.gov)

# Council Resources



## **CalRx Statute**

[https://leginfo.legislature.ca.gov/faces/billCompareClient.xhtml?bill\\_id=202120220SB838](https://leginfo.legislature.ca.gov/faces/billCompareClient.xhtml?bill_id=202120220SB838)

## **CalRx Website**

<https://calrx.ca.gov/downloads/>  
(Meeting Materials Archive)

## **Council Coordinator**

Sarah Turner  
[info@calrx.ca.gov](mailto:info@calrx.ca.gov)

## **Council Charter**

<https://calrx.ca.gov/uploads/2024/09/CalRx-Insulin-Patient-Advisory-Council-Charter.pdf>

# 2025 Council Meeting Roadmap\*

\*This is subject to change.



April

- Council kickoff & orientation
- Insulin market discussion questions

July

- Overview of biosimilar drug development process by Civica
- Insulin market analysis presentation by HCAI
- Market data discussion questions

October

- Presentation of 2024 out-of-pocket expenses survey results by T1I
- CalRx<sup>®</sup> insulin distribution strategy planning
- Communications & outreach discussion questions



# Questions



# Insulin Market Discussion Questions



# Thank you.

**Next Council Meeting:  
Tuesday, July 29, 2025  
2:30 – 4:30 p.m. (PST)**