



**Insulin Patient
Advisory Council
Kickoff**

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
HCAI Director's Welcome
Civica Rx CEO's Welcome & Overview
Council Member Introductions | 2:30 PM |
| 2. | CalRx® Program Overview | 3:00 PM |
| 3. | CalRx® Biosimilar Insulin Initiative Accomplishments | 3:15 PM |
| 4. | Insulin PAC Role & Responsibilities
Review charter & roadmap of anticipated meeting topics | 3:25 PM |
| 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[®] 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

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

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

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

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

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® Biosimilar Insulin Initiative



Reproductive Health Stockpile



CalRx® Naloxone Access Initiative

CalRx Models for Intervention

1. Invest in development (insulin model)
2. Stockpiling (misoprostol model)
3. Leverage state volume for white labels¹ (naloxone model)



CalRx® Biosimilar Insulin Initiative Timelines & News Updates

CalRx[®] Biosimilar Insulin Initiative Accomplishments

Extensive distribution for CalRx[®] insulins is imperative

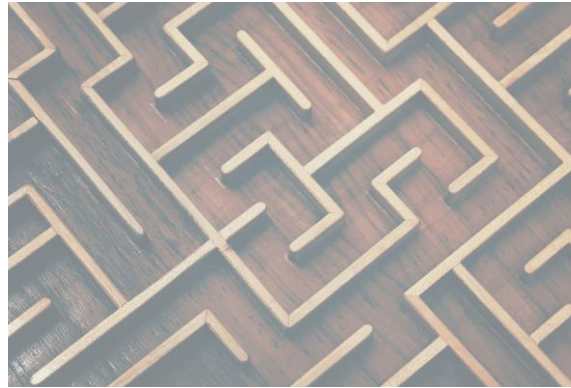


The success of this program hinges on reaching diverse communities



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



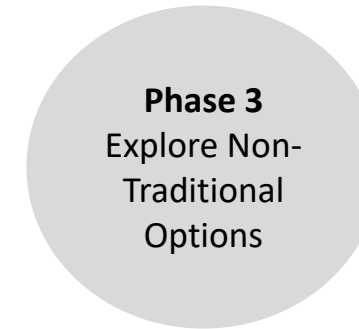
Phase 1
Large Health Plans
& Retail Pharmacy
Chains

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



Phase 2
Online,
Independent,
Govt Retail
Pharmacies

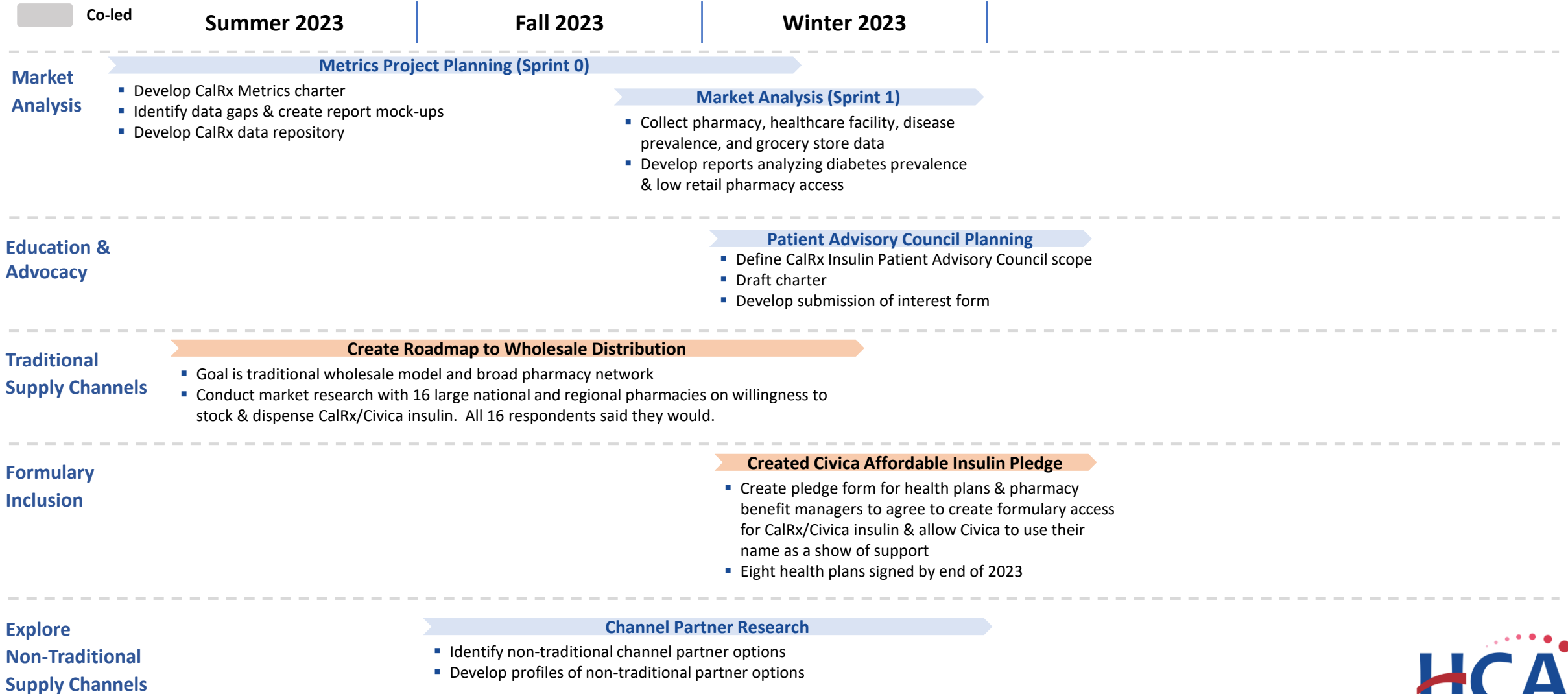
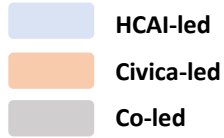
Add additional retail pharmacy options in low-income communities with high diabetes prevalence



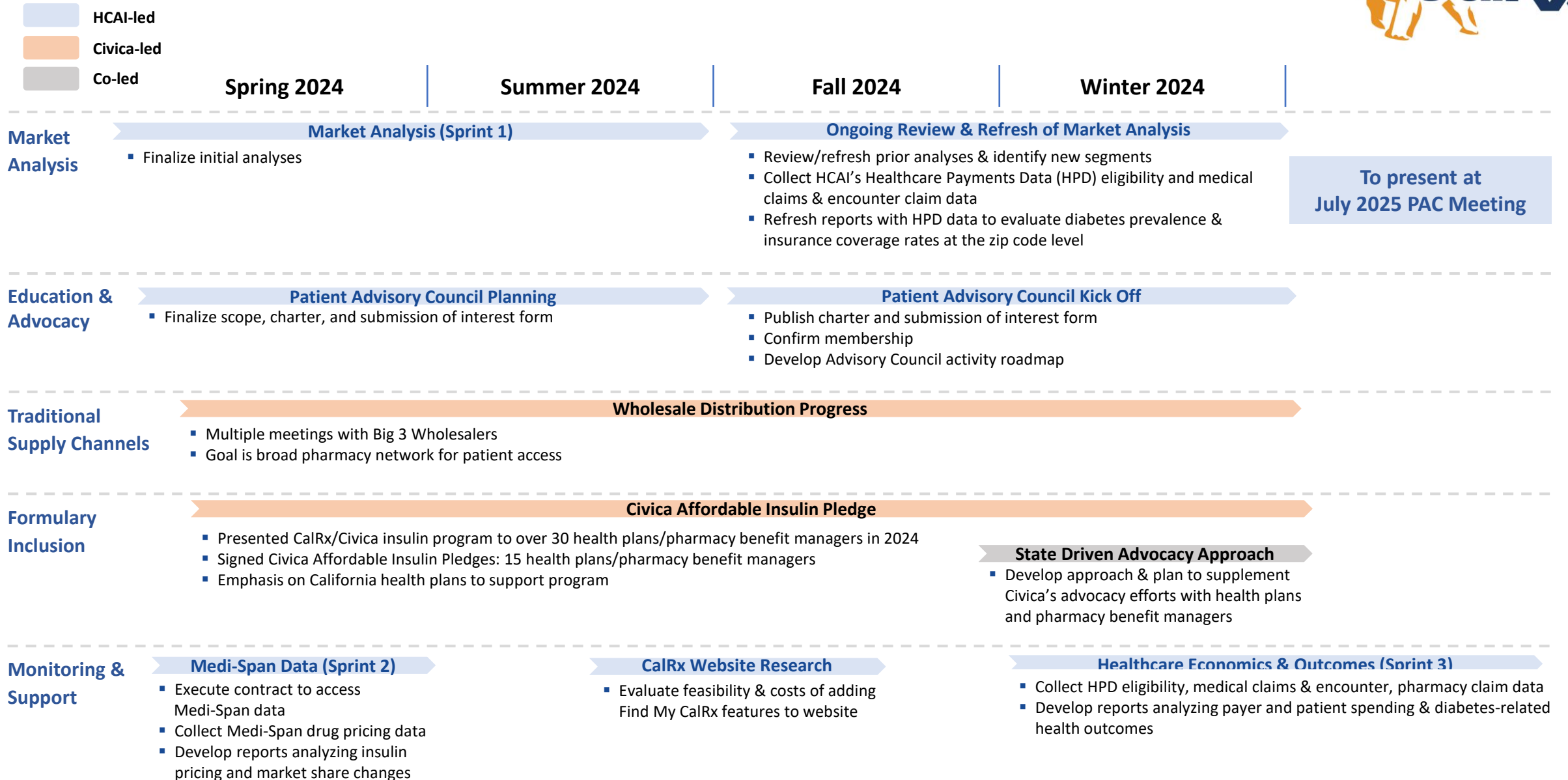
Phase 3
Explore Non-
Traditional
Options

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

CalRx[®] Insulin Distribution Strategy Roadmap: 2023



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[®] information to:
info@calrx.ca.gov

Council Resources



- [CalRx Statute](#)
- [CalRx Website \(Meeting Materials Archive\)](#)
- Council Coordinator, Sarah Turner info@calrx.ca.gov
- [Council Charter](#)

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[®] 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)**