



CalRx® Biosimilar Insulin Initiative Patient Advisory Council Meeting Minutes

Meeting Details:

Title: CalRx Insulin Patient Advisory Council (PAC) Kickoff
Date: Tuesday, April 29, 2025
Time: 2:30 – 4:30 PM (PST)
Location: Virtual

Attendees:

Council Members: Albert Bach, Pharm.D.
Allison Hardt
Christopher Noble
Craig Stubing
Diana Wyenn
Joe Garbanzos
Joseph Wotawa
Kathryn Topalis, M.D.
Laura Feeney, Pharm.D.
Luz Gallegos
Michelle Chu, Pharm.D.
Samantha Lappin

HCAI Staff: Sarah Turner, CalRx Project Manager
Robin Figueroa, Sr. CalRx Program Advisor
Nitisha Patel, Pharmaceutical Data Specialist
Ryvonna Hanson, Pharmaceutical Policy Analyst
Emily Estus, Chief, Pharmaceutical Policy & Programs Branch
Vishaal Pegany, Deputy Director, Office of Health Care Affordability
Helen Lee, Pharm.D., Chief Pharmacy Officer
James Yi, Attorney
Scott Christman, Chief Deputy Director
Elizabeth Landsberg, Director

Civica Rx Staff: Greg Ferguson, Vice President, Market Access & Distribution
Liz Power, Vice President, Communications
Allan Coukell, Chief Government Affairs & Public Policy Officer
Ned McCoy, President & Chief Executive Officer (CEO)

Key Takeaways:

1. **Access Barriers:** Insurance restrictions, prior authorizations, and limited medication formularies delay and/or limit insulin access, especially for underserved populations.
2. **Patient Needs & Continuity:** Insulin use varies widely; flexible supply options and coordinated care are essential for safety and equity.



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3. **Biosimilar Hesitancy:** Biosimilar uptake is hindered by formulary restrictions, brand loyalty, and lack of patient-provider communication. Many PAC members noted that they did not have a brand vs. biosimilar preference.
4. **Formulary Changes and Switching:** Sudden coverage changes cause confusion and disrupt care, with little communication to patients or providers. Patients find having to switch insulins confusing and destabilizing without proper provider communication.
5. **Discount Program Issues:** Manufacturer discount programs are difficult to navigate and often ineffective; direct-to-consumer (DTC) models raise concerns about care fragmentation and industry control.

Civica Rx Overview:

Ned McCoy, President and CEO of Civica, described the nonprofit, non-stock pharmaceutical company's mission to address drug shortages and affordability by prioritizing patient needs over profit. Civica has built a sterile injectable manufacturing facility in Petersburg, Virginia which can supply 90 million vials/year, 50 million syringes/year, and 120 million prefilled pens/year. CivicaScript is their retail arm and the Civica Foundation raises funds for their initiatives and oversees the insulin program.

In partnership with CalRx, Civica is developing three biosimilar insulins (glargine, aspart, and lispro) with transparent pricing—no more than \$30 per vial or \$55 for five pens. Their clinical development of insulin glargine is in progress and availability is largely dependent on successful clinical trials and approval by the U.S. Food and Drug Administration (FDA). Insulin aspart will soon follow and Civica expects this project will progress more quickly as they now have the infrastructure, resources, and agreements in place with companies such as Profil (clinical research organization) and Ypsomed (pen supplier).

CalRx® Program Overview:

The CalRx program is administered by the California Department of Health Care Access and Information (HCAI) and aims to disrupt the pharmaceutical market by making medications more affordable and accessible, with a focus on transparency and equity. Under the [California Affordable Drug Manufacturing Act of 2020](#) (California Health & Safety Code Sections 127690 to 127697), CalRx is empowered to produce, procure, or distribute generic drugs at prices based on actual production and distribution costs, excluding rebates. Its initiatives include the biosimilar insulin program (in partnership with Civica), a 2023 reproductive health stockpile of misoprostol, and the 2024 Naloxone Access Initiative which reduced naloxone pricing by 40% and has saved the state \$17 million to date. While insulin development has taken longer than anticipated, it remains on track with industry norms and CalRx continues to collaborate with Civica to ensure the delivery of high-quality biosimilar insulins for Californians.



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CalRx® Biosimilar Insulin Initiative Accomplishments:

HCAI and Civica are collaborating to ensure equitable access to CalRx insulins with a focus on reaching vulnerable populations and overcoming barriers in traditional drug distribution. Their multi-phase strategy includes market analysis, education and advocacy (including the creation of this Council), traditional supply channels and formulary inclusion, exploring non-traditional supply channels, and monitoring and support. In 2023, HCAI began collecting data to identify high-need areas, while Civica led efforts to build partnerships and prepare for broad insulin distribution.

Greg Ferguson, Civica's VP of Market Access and Distribution, shared that since 2023, Civica has focused on building a broad pharmacy distribution network for CalRx insulin in California and nationwide. They began early engagement with wholesalers and surveyed the 18 largest U.S. pharmacy chains—16 of which confirmed their willingness to stock and dispense CalRx insulin. Additionally, Civica has worked to secure formulary placement with California health plans and launched the Civica Affordable Insulin Pledge, with eight plans committed to ensuring future access and promoting insulin affordability. Mr. Ferguson hopes to reach 25 pledges nationwide by the end of 2025.

Insulin PAC Role & Responsibilities:

The CalRx Insulin Patient Advisory Council (PAC) serves in an advisory role to support the CalRx Biosimilar Insulin Initiative by offering consumer insights, promoting inclusion in traditional and non-traditional outlets, guiding patient education and outreach, and informing social media and communication strategies. While the Council does not have decision-making authority nor access to confidential information, members are expected to participate in quarterly meetings, contribute constructively, and serve a one-year term. Meetings are not public but are transparent, with materials posted online. Future topics include biosimilar development, market analysis, and distribution strategy planning.

Insulin Market Discussion:

Ensuring Equitable Insulin Access & Affordability

1. What is top of mind for you in ensuring equitable access to insulin?
2. What is top of mind for you regarding insulin affordability?
3. What other challenges do consumers face regarding insulin availability and managing their treatment regimen?

The discussion highlighted several key barriers and considerations for ensuring equitable insulin access and affordability. Council members emphasized systemic challenges such as insurance restrictions, prior authorizations, and limited formulary options which can delay or prevent access to appropriate insulin types. Many members raised concerns about patients who reside in pharmacy deserts, those who lack stable housing, those who experience food insecurity affecting insulin effectiveness, and those with limited digital or language access—particularly non-English language



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speakers—underscoring the need for culturally and linguistically appropriate outreach. Others stressed the importance of addressing gaps in affordability for people who fall between public assistance and commercial coverage and often face high out-of-pocket costs or rely on informal support networks. Additionally, disruptions in access due to changes in Medi-Cal managed care contracts or health insurance lapses and inconsistent communication between doctors, pharmacies, and insurers can leave patients without access to insulin for weeks.

Several members also emphasized the diversity of insulin needs among patients, noting that some require much higher volumes than others and that pricing and distribution models must account for that variability. A “one-size-fits-all” approach with rigid packaging (e.g., pens in packs of 5 or 10) often fails to meet patients’ real-world dosing needs. Concerns were also raised about the disconnect between advertised insulin prices and what patients pay at the pharmacy counter with calls for clarity, transparency, and reliability at the point of sale. Another key issue is the affordability and accessibility of diabetes testing supplies which are critical for safe insulin use but often prohibitively expensive. Finally, members reinforced the importance of patient-centered approaches; individualized care; coordinated communication between providers, pharmacists, and patients; and the need for education to combat stigma and misinformation about diabetes—highlighting that affordability must be paired with consistent, patient-centered support to achieve equitable insulin access and affordability.

Biosimilar vs. Brand Insulin Preference

To better understand the potential barriers to accessing more affordable, FDA-approved biosimilar insulins, such as formulary coverage by pharmacy benefit managers (PBMs) and consumer concerns about efficacy, CalRx asked the Council members:

1. What are the key barriers to uptake of biosimilar insulins?
2. How do consumers perceive the effectiveness of biosimilar insulins?
3. Are there patient education models, frameworks, or resources that you’ve found useful in alleviating consumer concerns about biosimilar insulins?
4. What do insured patients experience when their health plan changes the formulary, and their current insulin is now listed as “not covered”?

Council members identified structural, cultural, and linguistic barriers to the uptake of biosimilar insulins. Formulary restrictions, lack of product choice, and pharmacy-level substitutions without provider consultation create confusion and erode patient trust. One member highlighted the significant disruption caused when health plans change formularies and stop covering a patient’s current insulin—patients are informed at the pharmacy counter and providers are notified after the fact, limiting their ability to intervene or provide guidance. In under-resourced systems, such as county healthcare settings, cost-driven decisions dictate formulary options and leave many patients—particularly those with limited English proficiency—without clear information about biosimilars or alternative options. Consumer and provider perceptions of lower-cost biosimilars are



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mixed due to brand loyalty and limited education. Several members emphasized that patients often first encounter biosimilars without explanation, leading to hesitancy and anxiety. Community-shared experiences through social media and online forums were noted as powerful sources of informal education and support, suggesting the need for community-based, ambassador-led communications to build biosimilar trust. Throughout the discussion, members called for clearer, more consistent education from trusted providers and acknowledged that fear of change and lack of transparent communication are major barriers to biosimilar adoption.

Feedback on Existing Insulin Discount & Access Programs

To better understand the potential barriers to participating in insulin discount and access programs, such as discount cards or copay programs, CalRx asked the Council members:

1. What do consumers experience when navigating participation in these programs?
2. For those of you that work in advocacy, how are insulin manufacturers responding to concerns about barriers to accessing these programs?
3. How do consumers perceive the use of direct-to-consumer models being offered by insulin manufacturers (e.g., Lilly Direct)?

Council members expressed widespread frustration with current insulin discount and access programs, citing them as difficult to navigate, inconsistently accepted, and often ineffective—particularly for insured patients or those using integrated systems such as Kaiser. Many members described these programs as more symbolic than impactful, with some members likening them to public relations efforts that fail to address systemic affordability issues. Patient assistance programs were noted as occasionally helpful for uninsured individuals but often limited by restrictive eligibility requirements, logistical barriers (e.g., medications sent only to prescribers' offices) and shifting rules. Concerns were also raised about DTC models, such as LillyDirect. While potentially convenient, DTC models may fragment care, limit patient choice, and further consolidate control within pharmaceutical manufacturers—raising red flags around transparency, equity, and continuity of care. Overall, members urged caution when designing DTC programs to ensure they genuinely center patients rather than expanding manufacturer influence.

Mail Order vs. Community Pharmacy Preference

These discussion questions were tabled for the next Council meeting.

Next Meeting: July 29, 2025, at 2:30 – 4:30 p.m. PST