# Making prescription drugs more affordable for Californians



#### People should not go into debt to receive lifesaving medication.

The State of California launched the <u>CalRx Initiative (CalRx)</u> to make medications more affordable for all Californians.

Far too many Californians struggle with skyrocketing drug prices while pharmaceutical companies and others in the drug supply chain report record profits. Even those with health insurance often find it increasingly difficult to afford lifesaving medications as premiums continue to rise year after year.

When markets work well, generic drugs reduce costs by driving competition. However, not all generic drugs result in an automatic price reduction. Drug markets are susceptible to failures, such as consolidation and incentives that keep prices high. For uninsured or underinsured Californians, the high cost of prescription drugs can often mean choosing between paying rent or purchasing their lifesaving medications.

#### How does CalRx work?

CalRx represents a groundbreaking solution for addressing drug affordability. Originally announced in January 2019 in Governor Newsom's first <a href="Executive Order">Executive Order</a> and later signed into law in the <a href="California Affordable Drug Manufacturing Act of 2020">California Affordable Drug Manufacturing Act of 2020</a> (Pan, SB 852, Chapter 207, Statutes of 2020), CalRx empowers the State of California to develop, produce, and distribute generic drugs and sell them at low cost.

The State will target prescription drugs where the market competition has failed to lower drug costs, even when a generic or biosimilar medication exist.

Compared to traditional procurement of prescription drugs, CalRx seeks deep, mutually beneficial partnerships with companies that share the State's goals.

#### How does CalRx help make prescription drugs more affordable?

CalRx aims to increase competition in the market where there is low competition, drug shortages or fragile supply chains.

- Medications sold under the CalRx label reflect the true cost of manufacturing and distribution
- CalRx products will not use rebates, except where federally required.

This transparent approach will offer consumers one low, honest price, especially benefiting uninsured individuals and those in high-deductible health plans who currently pay the highest out-of-pocket costs.

Low-cost, Transparent Prices

Make Prescription
Drugs Affordable for
all Californians

No Rebates or Coupons

## Low-cost, biosimilar insulin for all Californians who need it.

#### What is CalRx's first project?

CalRx's first drug initiative, the CalRx Biosimilar Insulin Initiative, aims to develop affordable biosimilar versions of the three most commonly used insulin medications—glargine (longacting), aspart, and lispro (both rapid-acting). These will be available in both vial and pen forms at a fraction of current cash prices.

To achieve this, the State is investing \$50 million to produce three interchangeable biosimilar insulin products in partnership with a U.S.-based nonprofit pharmaceutical company.

The initiative has already established a foundation for new CalRx programs, including the <u>CalRx Naloxone Initiative</u> and the <u>CalRx School Albuterol Initiative</u>, both designed to reduce the cost of essential medications. CalRx Naloxone is already available online through the <u>CalRx website</u>, while the biosimilar insulins and future CalRx products are expected to reach pharmacies, retailers, and mail-order channels soon.

#### What does biosimilar insulin mean?

When talking about biosimilars, it is helpful to understand 3 different terms: Biologic, biosimilar and interchangeable.

**Biologics** generally come from living organisms, such as animal cells or microorganisms such as bacteria and yeast. Biologics include a wide range of products such as vaccines, blood and blood components, hormones, and antibodies. In addition to insulin, a common example of a biologic drug is the flu vaccine.

**Biosimilars** are biologics that are highly similar to a biologic that has already been approved by the U.S. Food & Drug Administration (FDA). A biosimilar must have no clinically meaningful differences from their reference product in terms of safety, purity, and potency. If not designated "interchangeable," patients typically need a new prescription to receive a biosimilar.

An **interchangeable biosimilar** drug is a product that may be substituted for the reference product without the need for a new prescription, much like what pharmacies routinely do for conventional generic drugs. The FDA grants this designation after reviewing a comprehensive body of analytical and clinical evidence.

For more information on biosimilar drugs, please refer to the FDA website, here.

#### Who will make the CalRx Biosimilar Insulins?

California partnered with Civica Rx (Civica), a U.S.-based nonprofit pharmaceutical company, to develop and manufacture the three most commonly used long-acting and rapid-acting types of insulin. With the State's \$50 million investment, Civica can expand ongoing efforts to bring affordable, interchangeable biosimilar insulins to market (corresponding to Lantus®, Humalog®, and Novolog®).

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## Low-cost, biosimilar insulin for all Californians who need it.

Civica was selected as CalRx's first manufacturing partner because of its commitment to transparent pricing that aligns with California's vision for accessible, affordable insulin.

Civica has also partnered with Biocon Biologics Ltd., which manufactures an FDA-approved insulin glargine that is interchangeable with Lantus®. Through a white-label agreement, Civica Rx will begin distributing this product starting in January 2026 under the CalRx® brand, offering it to pharmacies at \$45 and recommending a maximum retail price of \$55 for a five-pack of 3mL pens.

Meanwhile, Civica continues to advance independent production of CalRx-labeled insulin glargine vials and pens, working closely with the FDA and conducting rigorous quality testing. The State of California remains steadfast in its commitment to ensuring the success and long-term sustainability of this initiative.

#### How much will CalRx Biosimilar Insulin cost?

Civica has announced a manufacturer's suggested retail price of no more than \$30 for a 10mL vial and \$55 for a five-pack of 3mL pens, including distribution and pharmacy dispensing costs—just a fraction of the prices typically paid today.

#### How much can consumers save by using CalRx Biosimilar Insulins?

According to an analysis published in the <u>Annals of Internal Medicine</u>, CalRx insulin prices are estimated to be about 90 percent lower than the list price of branded products. This could save patients between \$2,000 and \$4,000 annually, offering much needed financial relief for Californians who depend on insulin for their health and quality of life.

#### Where will I be able to purchase CalRx Biosimilar Insulin?

The intent is for CalRx-branded insulin products to be available in pharmacies throughout California, as well as through mail order pharmacies.

#### Will I need a prescription for CalRx-branded insulin products?

The goal is for all three CalRx-branded insulins—glargine, lispro, and aspart—to be designated as interchangeable with their respective reference products: Lantus®, Humalog®, and Novolog®. This allows patients to request CalRx substitutes directly from their pharmacist without needing a new prescription.

CalRx-branded insulin glargine pens are already approved as interchangeable with Lantus®. Patients can ask their pharmacist to substitute their current Lantus—or any interchangeable insulin glargine product—with CalRx insulin glargine without requiring a new doctor's prescription.

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### Low-cost, biosimilar insulin for all Californians who need it.

#### Where will the CalRx Biosimilar Insulins be manufactured?

There are two major steps when making insulin:

- 1) Manufacturing the drug substance, which is the active ingredient used to make the drug product, and
- 2) Finishing and filling it into vials or pens

Civica is working with overseas manufacturers to co-develop the drug substance for the three CalRx biosimilar insulins. Final filling and packaging will take place at Civica's state-of-the-art, 140,000-square-foot facility in Petersburg, Virginia.

## If other insulin manufacturers drop the price of their insulin products, will CalRx stop the CalRx Biosimilar Insulin Initiative?

No. Even if other manufacturers reduce their prices, California will continue the CalRx Biosimilar Insulin Initiative. The program's purpose is to disrupt the insulin market by offering insulin at a transparent, fair price that reflects the true cost of production. The State remains committed to fostering real market competition and ensuring insulin remains affordable for everyone who needs it.

#### **About Civica**

Civica Inc. (Civica Rx, or Civica) is a 501(c)(4) social welfare organization founded in 2018 by a coalition of health systems and philanthropic partners to strengthen the reliability of the U.S. drug supply chain and address drug shortages and rising prices. The organization is guided by a team of seasoned healthcare and pharmaceutical industry leaders.

Today, more than 60 health systems, hospitals, and philanthropic organizations are part of Civica's network. The organization now supplies more than 70 essential medicines to over 1,400 hospitals, serving the needs of more than 90 million patients nationwide. Civica's core mission is to ensure that high-quality generic medications remain accessible and affordable for everyone—driven by its founding principle to "Do what is in the best interest of patients."

To further that mission, Civica has built a state-of-the-art manufacturing facility in Petersburg, Virginia, dedicated to producing sterile injectable medicines used in hospitals for surgeries, emergency and intensive care treatments, and other critical conditions, including COVID-19.

For questions or comments about the CalRx initiative, please email: info@calrx.ca.gov

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