

Making prescription drugs more affordable for Californians



People should not go into debt to receive lifesaving medication.
The State of California is officially launching the [CalRx Initiative \(CalRx\)](#) to make medications more affordable for all Californians.

Far too many Californians feel the pain of skyrocketing drug prices while drug companies and other supply chain actors post record profits. Even those with health insurance struggle to afford their lifesaving medications while seeing their health insurance premiums increase year after year.

When markets work well, generic drugs provide relief by driving down drug prices to a fraction of the brand name drug. 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 taking lifesaving medication.

How does CalRx work?

CalRx represents a groundbreaking solution for addressing drug affordability. Originally announced in January 2019 in Governor Newsom's first [Executive Order](#) and later signed into law in the [California Affordable Drug Manufacturing Act of 2020](#) (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 pharmaceutical market has failed to lower drug costs, even when a generic or biosimilar medication is available.

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?

The intent of CalRx is to increase competition in the pharmaceutical market where there is low competition, drug shortages or fragile supply chains. First, medications sold under the CalRx label will be as close as possible to the actual cost to manufacture and distribute the prescription drug. Second, CalRx prescription drugs will not use rebates, other than where federally mandated. Taken together, this will result in consumers having access to products that have a single, low transparent price. This will be most helpful to uninsured patients or insured patients in the deductible phases, who often pay higher cash prices for their medications today.

**Low-cost,
Transparent Prices**

**Make Prescription
Drugs Affordable for
all Californians**

**No Rebates or
Coupons**
(other than federally mandated)

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

What is CalRx's first project?

CalRx's first drug project, called the CalRx Biosimilar Insulin Initiative, will focus on supporting the development of a biosimilar version of the three most popular insulin medications; one long-acting and two rapid-acting products – glargine, aspart, and lispro, respectively, in both vial and pen form at a fraction of existing cash prices for insulin.

To make this happen, the State is investing \$50 million into developing three interchangeable biosimilar insulins, and an additional \$50 million will be used to support the construction of an insulin manufacturing facility based in California.

The CalRx Biosimilar Insulin Initiative will lay the groundwork for future drug projects addressing a number of medications that have become a financial burden for Californians. These products could reach pharmacies, retailers, and other channels, such as mail order pharmacy, in the next few years.

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, including 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 a biosimilar has not been determined to be interchangeable with the reference product (see below), a pharmacy may require a new prescription in order to dispense the 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 evaluates the totality of analytical and clinical evidence in order to determine whether a product is designated interchangeable.

For more information on biosimilar drugs, please refer to the FDA website, [here](#).

Who will make the CalRx Biosimilar Insulins?

California will partner with Civica Rx (Civica), a nonprofit generic drug and 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 will be able to enhance

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

efforts already underway to bring to market biosimilar versions of insulin glargine, lispro, and aspart in both vial and pen forms (expected to be interchangeable with reference products Lantus, Humalog, and Novolog respectively), with the process for FDA approval occurring sometime in 2024 and public availability shortly thereafter.

Civica was chosen to be CalRx's first manufacturing partner due to their commitment to sell its insulins to all consumers at single, low transparent prices, which aligns with the State's goals to ensure affordable insulins exist in the market.

How much will CalRx Biosimilar Insulin Cost?

Civica has announced that the manufacturer suggested retail price for a 10mL vial of insulin will be no more than \$30, and a 5-pack of 3 mL pens will be no more than \$55, including the cost of distribution and pharmacy dispensing. That price is a fraction of the cash prices of \$300 per vial, or more than \$500 for a 5-pack of pens people often pay today.

Why aren't the CalRx Biosimilar Insulins free?

There are significant costs to manufacture and dispense insulin products. Civica and CalRx insulin prices will be close to the actual cost of making and distributing the product. We will continue to look for efficiencies that will allow further price reductions.

How much can consumers save by using CalRx Biosimilar Insulins?

According to a recent analysis published in the [Annals of Internal Medicine](#), CalRx insulin prices are estimated to be about 90 percent lower than list prices for branded products, saving patients between \$2,000 and \$4,000 annually. This will provide much needed financial relief for insulin-dependent Californians, especially those who are uninsured or underinsured and need insulin to maintain their health and quality of life.

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

Our work was intended to disrupt the market and offer insulin as close to the cost of production and at a low, transparent price. The State of California is committed to continuing our efforts on the CalRx Biosimilar Insulin Initiative to make sure that true competition in the market does exist, so the price of insulin remains affordable for everyone who needs this lifesaving drug.

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 to have all three of the CalRx-branded insulin products of insulin glargine, lispro, and aspart to be interchangeable with the corresponding brand-name products (Lantus,

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

Humalog, and Novolog, respectively). This means that you can ask your pharmacist if they can substitute your current insulin product for CalRx-branded insulin, and if you have a current insulin prescription for Lantus, Humalog or Novolog respectively, you would not need a new doctor's prescription to make the substitution to the respective CalRx-branded insulin.

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 GeneSys Biologics to co-develop the drug substance for the three CalRx biosimilar insulins. The filling and finishing of the three insulins will be done at Civica's state-of-the-art 140,000 square-foot manufacturing plant, being built in Petersburg, Virginia. It is also planned that Civica will work with the State to also identify a future California-based manufacturing facility.

About Civica

Civica Inc. (Civica Rx, Civica) is a 501(c)(4) social welfare organization established in 2018 by health systems and philanthropies to increase the reliability of the drug supply chain, reduce drug shortages and related high prices in the United States. Civica is led by an experienced team of healthcare and pharmaceutical industry leaders.

Today, more than 55 health systems have joined Civica. They represent more than 1,550 hospitals and one-third of all U.S. hospital beds.

Civica's mission is to ensure that quality generic medications are accessible and affordable to everyone. From the beginning, the number 1 policy for the Civica team has been "Do What Is in the Best Interest of Patients."

Civica is building an essential medicines manufacturing facility in Petersburg, Virginia, to produce sterile injectable medications used in hospitals for patient care, emergency room and intensive-care unit treatments, surgeries, and to treat other serious conditions, including COVID-19. This facility will manufacture insulin vials and prefilled pens, with manufacturing test runs expected to begin in late 2023.

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