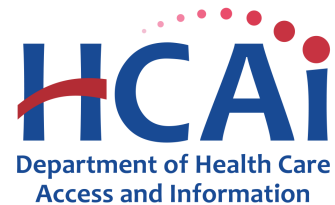


# Agenda

- » California's Naloxone Distribution Project
- » CalRx Naloxone Access Initiative
- » Amneal Pharmaceuticals



# California's Naloxone Distribution Project

SANDI SNELGROVE  
DHCS  
Community Services Division

# What is Naloxone?

- » Naloxone is a medication approved by the Food and Drug Administration (FDA) designed to rapidly reverse opioid overdoses ([Source](#))
- » Naloxone binds to opioid receptors in the brain and blocks the effects of other opioids
- » Naloxone is administered when a patient is showing signs of an [opioid overdose](#)
- » Naloxone and its effects are temporary but allows time for first responders to arrive and provide additional medical intervention
- » Naloxone is regarded as safe to administer to someone even if opioids are not present in their system

# The Naloxone Distribution Project (NDP)

- » DHCS created the NDP in 2018 to combat fatal opioid overdoses throughout California
- » The NDP aims to address the opioid crisis by reducing opioid overdose deaths through the provision of free naloxone
- » Eligible organizations apply through an online application to request naloxone and have it shipped directly to their address

# NDP Eligible Organizations

First Responders, EMS, Fire	Law Enforcement & Criminal Justice	Hospitals & Emergency Departments	Community Organizations
Unhoused Services Organizations	Harm Reduction Organizations	Veteran Organizations	Faith-Based Organizations
Tribal Organizations	Schools, Universities, & Libraries	Substance Use Recovery Facilities	County Public & Behavioral Health Agencies

# Naloxone Formulations Available through the NDP

**4mg INTRANASAL NALOXONE (Narcan and generic)**

**INTRAMUSCULAR NALOXONE (generic)**



# Fentanyl Test Strips

- » While funding is available, eligible organizations can receive free fentanyl test strip kits through the [online application form](#).
- » The all-in-one kits streamline testing a drug for the presence of fentanyl by packaging together a measuring scoop, the test strip, a water pouch, and instructions.



Instruction 1

Decide on the number of scoops for your test and add them to the water reservoir.



Instruction 2

Dip the strip into the water and hold it steady for a moment



Instruction 3

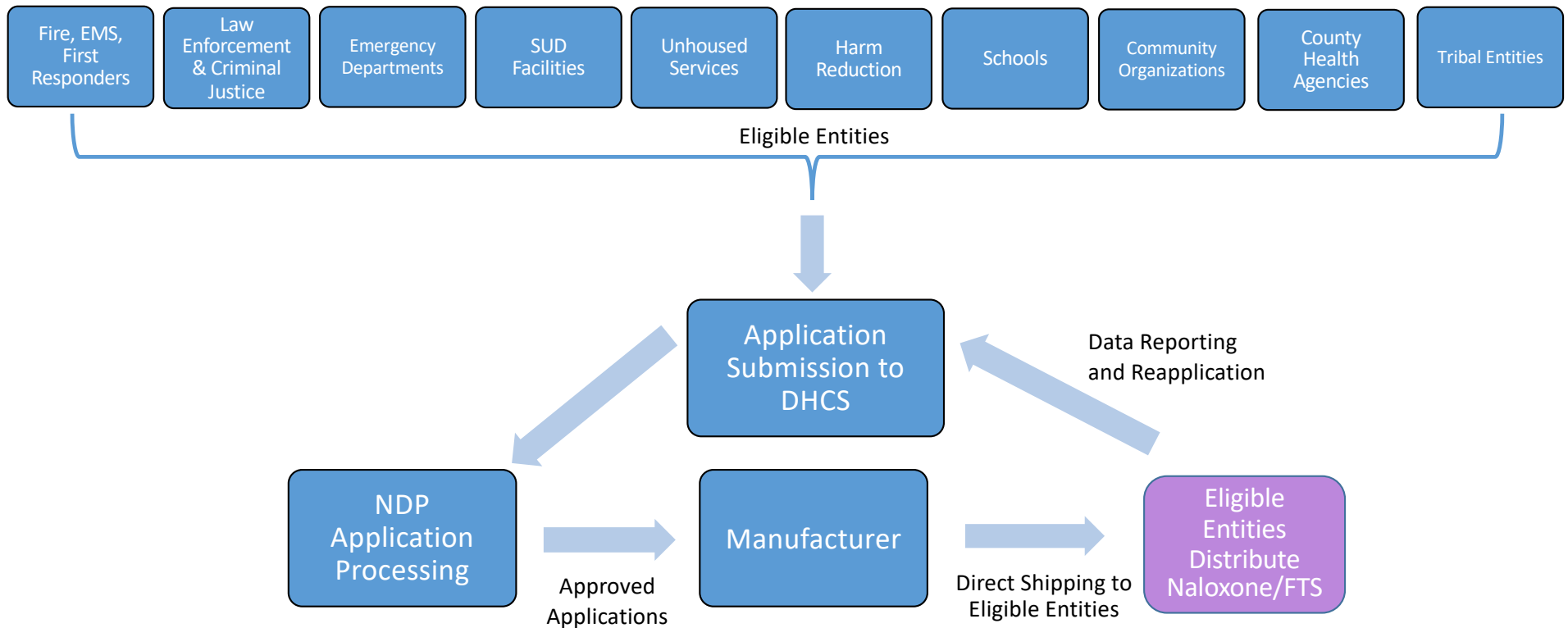
After five minutes, compare the strip to the result guide on the pouch.

# How to Apply for Naloxone and/or Fentanyl Test Strips

- » Eligible organizations can request up to 2,400 units of nasal naloxone spray, 1,000 units of IM naloxone, and 25,000 fentanyl test strip kits per application.
- » To apply for naloxone and/or fentanyl test strips through the NDP:
  - Gather the [required supplemental materials](#)
  - Complete the [NDP online application form](#)
  - Submit the application and supplemental materials
- » Manufacturer ships the naloxone and/or fentanyl test strips directly to applicants.



# NDP Process Flow

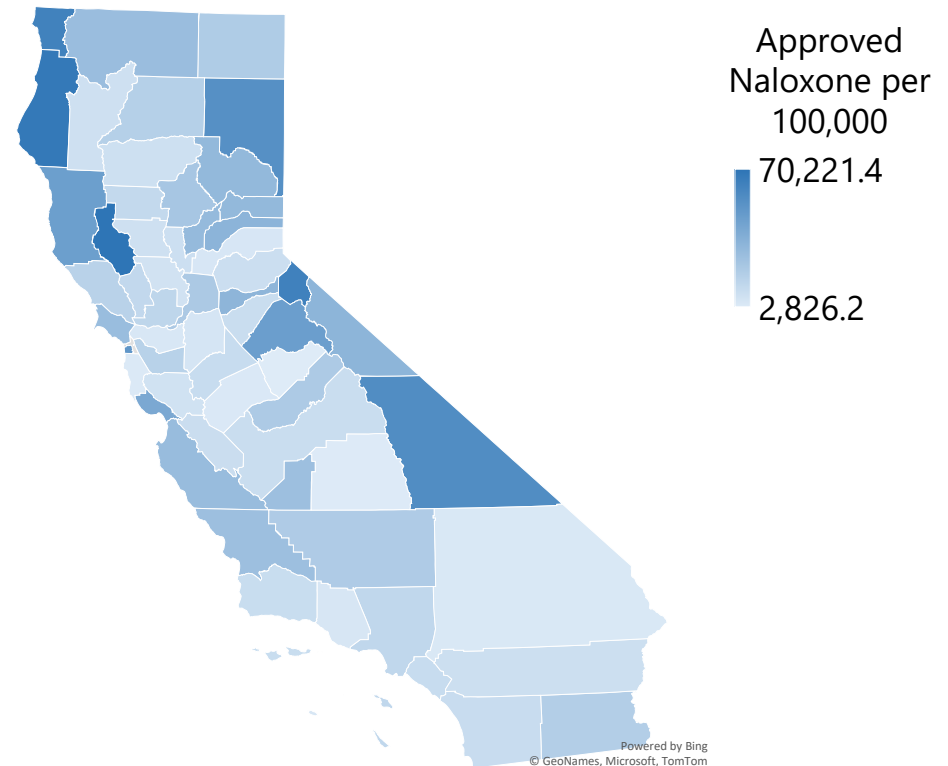


# NDP Outcomes

Since 2018:

- » Distributed more than **5,400,000 naloxone kits** to
- » More than **6,000 unique organizations**
- » In all **58 California counties** resulting in
- » Over **324,000 reported opioid overdose reversals**

Approved Naloxone Kits per 100,000 Residents, 2018-2024



**Questions?**

**Email [naloxone@dhcs.ca.gov](mailto:naloxone@dhcs.ca.gov)**





# CalRx Naloxone Access Initiative

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Emily Estus  
CalRx Program Manager

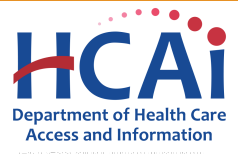
January 2025

## CalRx<sup>®</sup>: State-powered market intervention for better drug affordability



- California Affordable Drug Manufacturing Act of 2020 (Senate Bill 852, Statutes of 2020) empowered CA 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<sup>®</sup> pricing is based on development, production, and distribution costs without rebates or other discounts (other than federally mandated ones).
- Program is housed within HCAI.

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



# CalRx<sup>®</sup> Purpose: To improve equitable access and affordability of medications in California



- To date, there have been 3 major initiatives under our program:



**CalRx<sup>®</sup> Biosimilar  
Insulin Initiative**



**Reproductive  
Health Stockpile**



**CalRx<sup>®</sup> Naloxone  
Access Initiative**

# Why naloxone?



- This initiative is part of [Governor Newsom's Master Plan for Tackling the Fentanyl and Opioid Crisis](#) to address the opioid crisis, which has had a devastating impact on individuals, families, and communities across the U.S. and in California.

70.6K

Opioid-related overdose deaths nationwide in 2021<sup>1</sup>

7.2K

Opioid-related overdose deaths in CA in 2021<sup>2</sup>

87%

Opioid deaths are related to fentanyl<sup>3</sup>

19

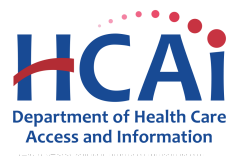
Californians die per day

Sources:

1 – CDC, <https://www.cdc.gov/nchs/nvss/vsrr/drug-overdose-data.htm>

2 – California Overdose Surveillance Dashboard, California Quick Stats 2021, <https://skylab.cdph.ca.gov/ODdash/?tab=Home>

3 – California's Opioid Response Website: <https://www.cdph.ca.gov/Programs/CCDPPH/opioids/Pages/landingpage.aspx>



# \$24 CalRx<sup>®</sup> over-the-counter (OTC) naloxone



- Through a competitive process, CalRx<sup>®</sup> selected Amneal Pharmaceuticals as our naloxone partner
- DHCS began ordering CalRx<sup>®</sup>/ Amneal OTC naloxone nasal spray for the Naloxone Distribution Project (NDP) in May 2024
- The \$24 price per twin pack is currently available to all CA businesses and government entities that meet certain requirements (for example, not reselling the product)

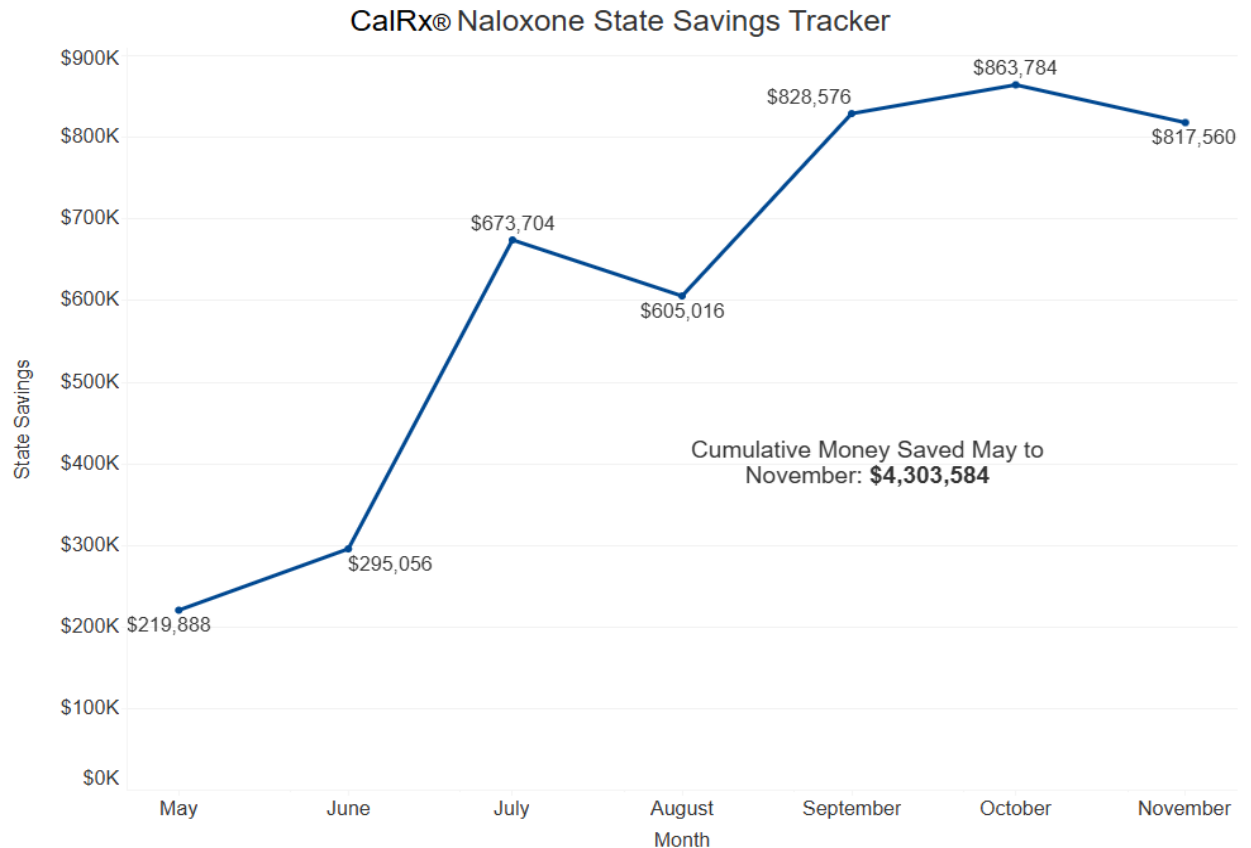




# CalRx<sup>®</sup> naloxone delivers significant costs savings to CA



- CalRx<sup>®</sup> naloxone is now the primary supplier for the NDP
- At the time of launch, CalRx<sup>®</sup> naloxone was a 40% savings off the state's previous contracted rate
- From May – Nov 2024, CalRx<sup>®</sup> naloxone **saved California over \$4.3 million**, which can be used to purchase additional units of naloxone to provide to communities
  - This information will continue to be tracked monthly on the [CalRx<sup>®</sup> Naloxone State Savings Tracker](#)



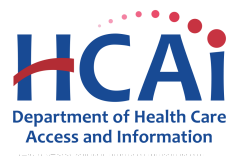
Notes: CalRx Naloxone nasal 4mg became available in California's market in May 2024. Sales data obtained from Amneal Pharmaceuticals. Money saved was calculated by identifying the amount of money saved by purchasing CalRx Naloxone nasal 4mg units at \$24/unit versus previous supplier of nasal 4mg naloxone.



## What's next for CalRx®?

- CalRx® will continue to monitor the naloxone market to ensure access to affordable naloxone
- We will also continue to evaluate the pharmaceutical market to identify other target drugs that could be included under our program
- We will launch an Insulin Patient Advisory Council in Spring 2025 to provide input and guidance to advance public awareness of CalRx® biosimilar insulin products

For more information, visit: <http://calrx.ca.gov> or contact us at [info@calrx.ca.gov](mailto:info@calrx.ca.gov)





# Amneal Pharmaceuticals CalRx Partnership

January 22, 2025



**AMRX**  
LISTED  
**NYSE**

# Amneal Is a Leading Affordable Medicines Company

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- Amneal is a purpose-driven company providing affordability and accessibility for patients
- Founded in 2002 in Paterson, N.J. by our current co-CEOs, our people and company culture are our greatest assets
- We make healthy possible® through our:
  - Unwavering commitment to the highest standards of quality and good manufacturing practices, with manufacturing in the U.S., Ireland, and India
  - Diversified portfolio and pipeline of generic products, growing biosimilar presence, and movement disorder specialty products
  - Industry-leading investment in science and innovation providing access to the most complex products
  - Robust partnerships with U.S. Government ensuring affordable medicines to Department of Defense and Veterans Affairs
  - Prioritization, always, of the patients who trust us



# Naloxone Hydrochloride (Naloxone HCl) Nasal Spray

- Amneal's Naloxone HCl Nasal Spray is manufactured in New Jersey and distributed from our Glasgow, Kentucky facility.
- Amneal is committed to partnering with states and municipalities to ensure communities have access to this life-saving medicine.
- This is the type of medicine that underscores Amneal's commitment to public health. Naloxone is lifesaving. Ensuring convenient, affordable access is critical. Manufacturing requires sophisticated technologies and expertise as well as substantial capabilities to produce at a scale that can be meaningful. Amneal excels in each of these areas. It's how we make healthy possible.



