

## Frequently Asked Questions

Below is a list of frequently asked questions about naloxone and the Naloxone Distribution Project (NDP).

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# Frequently Asked Questions (FAQ)

## Naloxone Overview

### 1. What is the Naloxone Distribution Project?

The Naloxone Distribution Project (NDP) is administered by the Department of Health Care Services (DHCS) to combat opioid overdose-related deaths throughout California. The NDP aims to reduce opioid overdose deaths through the provision of free naloxone. Through the NDP, qualified entities can request free naloxone from DHCS and have it directly shipped to their address.

The NDP's funding comes from various sources including state, federal, and opioid settlement funds. This project is subject to normal state legislative appropriation and budgetary processes and is subject to available funding for naloxone distribution.

To learn more about ordering naloxone through the NDP, please visit the [Naloxone Distribution Project website](#).

To access data on NDP outcomes, please visit the [DHCS Opioid Response](#) website.

### 2. What is naloxone?

Naloxone is a life-saving medication that reverses an opioid overdose while having little to no effect on an individual if opioids are not present in their system. Naloxone works by blocking the opioid receptor sites and reversing the toxic effects of the overdose. It has few known adverse effects and no potential for abuse.

Naloxone is administered when a patient is showing signs of opioid overdose. The medication can be given by intranasal spray, intramuscular (into the muscle), subcutaneous (under the skin), or by intravenous injection.

### 3. Can naloxone be used for a fentanyl overdose?

Yes. Fentanyl is a synthetic opioid, so naloxone can be used to reverse a fentanyl overdose.

### 4. Can naloxone be used for a xylazine overdose?

No. Xylazine is not an opioid. Xylazine is a central nervous system depressant that can cause drowsiness and amnesia and can also slow breathing, heart rate, and blood pressure to dangerously low levels. However, if a xylazine overdose is suspected, experts still recommend giving the opioid reversal agent naloxone. This is because xylazine is frequently mixed with fentanyl, which is an opioid.

### 5. What formulations of naloxone are available through the NDP?

The NDP currently distributes 4mg naloxone nasal spray from two manufacturers – generic naloxone nasal spray and Narcan naloxone nasal spray. The NDP also distributes 0.4mg/mL intramuscular naloxone from a third manufacturer.

## **6. How will entities know which naloxone nasal spray they will receive?**

After an application is approved, the entity will receive an approval letter from [naloxone@dhcs.ca.gov](mailto:naloxone@dhcs.ca.gov). The approval letter will indicate whether the entity's order will be fulfilled by generic naloxone nasal spray or Narcan naloxone nasal spray. The email will include contact information for the manufacturer fulfilling the order.

Generic naloxone nasal spray will be labeled either as "CalRx" or "Amneal" and is manufactured by Amneal Pharmaceuticals. Narcan naloxone nasal spray will be labeled as "Narcan" and is manufactured by Emergent BioSolutions.

## **7. What is Narcan naloxone nasal spray?**

Narcan (naloxone HCl) nasal spray is a medication used for the treatment of an opioid emergency such as an overdose or a possible opioid overdose, indicated by signs of breathing problems and severe sleepiness or not being able to respond.

Narcan naloxone nasal spray is to be given right away and does not take the place of emergency medical care. You can get additional information at the [Narcan manufacturer's website](#).

## **8. What is generic naloxone nasal spray?**

Generic naloxone nasal spray contains the exact same active ingredients as brand-name naloxone nasal spray, is taken the same way, and has the same effect. The NDP also distributes the generic formulation of Narcan naloxone nasal spray.

## **9. What is the shelf life of naloxone nasal spray?**

The shelf life of Narcan naloxone nasal spray is four years. The shelf life of generic naloxone nasal spray is two years. Please follow the expiration date as printed on the package you receive.

## **10. Are there training resources available for naloxone administration?**

Online training resources can be found at <https://getnaloxonenow.org> or the [Harm Reduction Coalition's Overdose Prevention and Naloxone Manual](#). Training materials and other resources focusing on youth can be found at [SongforCharlie.org](http://SongforCharlie.org).

As part of the NDP application, organizations must certify that they have received training on overdose prevention and treatment to respond effectively in an opioid emergency, and that they will provide overdose prevention and treatment training to all individuals receiving naloxone from the organization.

## **11. In the State of California, can individuals over the age of 12 receive naloxone without the consent of a parent or guardian?**

California has no statute requiring minors to obtain parental or guardian consent prior to receiving naloxone.

## **12. What is the purpose of the naloxone standing order?**

The standing order was issued by the state Public Health Officer (authorized by California Civil Code Section §1714.22) to: 1) allow community organizations and other entities in California that are not currently working with a physician, to distribute prescription naloxone to a person at risk of an opioid-related overdose or to a family member, friend, or other person in a position to assist; and 2) allow for the administration of naloxone by a family member, friend, or other person to a person experiencing or reasonably suspected of experiencing an opioid overdose.

For more information about naloxone standing orders, review this [FAQ document issued by the California Department of Public Health](#). A standing order is no longer required for either of the two 4mg naloxone nasal sprays that the NDP distributes due to the over-the-counter status. The 0.4mg/mL intramuscular naloxone that the NDP distributes will remain available by prescription only and requires a standing order to distribute and administer.

## **13. What is the Good Samaritan Law?**

[California's Good Samaritan law](#) protects those giving emergency medical care at the scene of a medical emergency, including giving naloxone. Under this law, a person cannot be liable for any civil damages that result from his or her providing of emergency care, such as giving naloxone, if: 1) The person acted in good faith, and not for compensation; 2) The person provided either emergency medical care or nonmedical care; and 3) The care was provided at the scene of an emergency.

## **14. Are there protections against liabilities for naloxone administration and distribution?**

According to the [California Department of Public Health](#), while the [Statewide Standing Order for Naloxone](#) is not required for over-the-counter products and no longer required for participation in the Naloxone Distribution Project, it can provide additional liability protections, see: [CA Civil Code Section 1714.22](#).

The NDP team is unable to advise recipients on their organization's liabilities. We recommend that you consult with your organization's legal team for further questions.

## **Applying to the NDP**

### **1. How can entities in California apply to the NDP for naloxone nasal spray?**

To request free naloxone nasal spray, complete the [online NDP application](#) located on the [DHCS website](#). The application includes instructions, as well as terms and conditions of participating in the NDP. In addition to filling out the application form and agreeing to the terms and conditions, organizations must also provide:

- a. A copy of a valid and active business license, FEIN number or tax-exempt letter.
- b. If the naloxone request is for more than 240 units, the entity must provide

a comprehensive summary explaining why the quantity was requested and a document of policies and procedures for naloxone distribution including: inventory and tracking of naloxone received through the program and a distribution plan for naloxone received through the program.

- c. Any additional supplemental documents required for your organization type (refer to the NDP homepage, or the Eligibility for the NDP section of the FAQ document, for any additional required documentation).

Submit the application and supplemental information via the online application form. Applications that fail to submit all required documentation will be deemed incomplete and may result in application denial.

## **2. How do entities apply for intramuscular naloxone through the NDP?**

The NDP offers free intramuscular (injectable) naloxone in addition to 4mg naloxone nasal spray. Please submit separate applications for intramuscular naloxone and naloxone nasal spray.

Before applying for intramuscular naloxone, please email [naloxone@dhcs.ca.gov](mailto:naloxone@dhcs.ca.gov) to be added to the list of entities able to receive intramuscular naloxone. This list is updated quarterly, and your organization's name must be on it before the application can be approved.

Once you have received a confirmation that your organization has been approved to receive intramuscular naloxone, you may apply by submitting the online application form and include the following information:

- a. Check intramuscular (injectable) naloxone as the requested formulation. The minimum order is 1000 vials and orders must be made in multiples of 1000. Currently there is no maximum order.
- b. Standing order or physician's prescription for naloxone.
- c. FEIN, business license, or tax-exempt letter.
- d. Comprehensive summary justifying your need, and
- e. Distribution plan including policies and procedures for distribution, tracking, and inventory.
  - a. Entities receiving intramuscular naloxone must store, track, and report reversal information for NDP intramuscular naloxone **separately** from all other naloxone, including naloxone nasal spray received through NDP. Include how you will meet this requirement in your distribution and tracking plan.

## **3. Can I apply on behalf of another program?**

No. Eligible entities must apply directly to DHCS for their program.

#### **4. Can organizations apply for additional supplies of naloxone?**

Yes. You may request more naloxone by submitting a new application to DHCS via the online form. Prior approval does not guarantee automatic approval of the secondary request for additional naloxone.

### **Eligibility for the NDP**

#### **1. What types of organizations are eligible to apply for the NDP?**

DHCS provides free naloxone to entities eligible including:

- Community organizations
- County health agencies
- Community clinics or federally qualified health centers
- Emergency departments or hospitals
- Emergency medical services
- Fire authorities
- First responders
- Law enforcement, courts, and criminal justice partners
- Libraries
- Local city agencies
- Organizations that provide services to unhoused individuals/community
- Religious organizations
- Schools and universities
- Substance use recovery facilities
- Veteran organizations
- Tribal entities

If you have a question about whether or not your organization is eligible to receive naloxone through the NDP, please contact [naloxone@dhcs.ca.gov](mailto:naloxone@dhcs.ca.gov). The NDP is not intended to distribute directly to individuals. Individuals in California can purchase CalRx® 4 mg nasal spray naloxone for \$24 per two-pack plus taxes and shipping through the [CalRx Naloxone Access Initiative](#) direct-to-consumer option at <https://calrxnaloxone.com/>. Some community organizations and other entities listed above may also offer naloxone at low or no cost to individuals. Naloxone received through the NDP may not be resold.

#### **2. Can Federal agencies apply for the NDP?**

No. Only state, local, and tribal agencies in the state of California are eligible to apply for the NDP.

#### **3. Can county public health and behavioral health agencies apply to the NDP to receive naloxone?**

Yes, county public health and behavioral health agencies may apply to the NDP to

receive naloxone.

County agency applications that include eligible sub-recipients (e.g. law enforcement, homeless shelters, or community clinics) are typically not approved. DHCS recommends sub-recipients directly apply to the NDP for their naloxone needs. This is so that DHCS can collect accurate data regarding naloxone distribution and overdose reversals. If your agency has a need to apply to the NDP with sub-recipients, please include a detailed distribution plan that includes naloxone allotments to each entity and overdose reversal tracking policies with your application to the NDP.

#### **4. Can hospital emergency departments apply for the program?**

Yes. Hospital emergency departments are eligible entities for the NDP and may provide take-home doses of naloxone to patients and visitors. Emergency departments should provide the following supplemental documentation with the application:

- a. FEIN, business license, or a tax-exempt letter.
- b. Policies and procedures for naloxone distribution. Example policies and procedures are located here: <https://cabridge.org/resource/guide-to-naloxone-distribution/>.

The California Department of Public Health and the California Board of Pharmacy clarified regulations pertinent to the distribution of naloxone in hospitals. Essential requirements of compliance are:

- The naloxone must be acquired and stored separately from the hospital's pharmacy inventory. The emergency department is required to keep a log to track the distribution of the naloxone doses distributed through this program.
- The hospital emergency department is required to have policies and procedures, which will dictate how the hospital emergency department will distribute the naloxone, including storage locations and whether the naloxone will be labeled or not labeled. The Board of Pharmacy has clarified that naloxone obtained through the NDP and stored separately from the hospital's pharmacy inventory for distribution under a standing order pursuant to Civil Code §1714.22 is not a pharmaceutical that will be used in the healthcare setting and is exempt from California Code of Regulations, Title 22 §70265, Business and Professions Code §4068, and Business and Professions Code §4076. As the inventory is considered separate from the pharmacy inventory, it does not need to be maintained, stored, or labeled in compliance with Business and Professions Code §4068.

#### **5. Can substance use disorder recovery facilities apply for the NDP?**

Yes. Substance use disorder recovery facilities (outpatient, residential, and sober living homes) are eligible entities for the NDP and may have naloxone onsite in case of overdoses or provide take-home naloxone to clients leaving the facility.

SUD recovery facilities should provide the following supplemental documentation with the application:

- a. Copy of the program's DHCS license (if applicable).
- b. Policies and procedures for naloxone distribution, including:
  - i. Separate storage of naloxone received through the program from other medications that may be billed to patient insurance.
  - ii. Inventory and tracking of naloxone received through the program.
  - iii. Distribution plan for naloxone received through the program.

## **6. What if I operate a harm reduction or community outreach program out of an FQHC or clinic?**

If you operate a harm reduction or community outreach program out of a health care site, please provide supplemental documentation to your application that explains the program, and how naloxone provided through the NDP will be stored separately from naloxone used in the health care site.

## **Cost & Ordering from the NDP**

### **1. How much does it cost to obtain naloxone through the NDP?**

The product is free and is shipped directly to approved applicants.

### **2. What is the minimum order that I can request through the NDP?**

There is a minimum order of 24 naloxone nasal spray units (two 4mg devices per unit) per application.

There is a minimum of 1000 vials of intramuscular naloxone per application. Orders for intramuscular naloxone must be placed in increments of 1000.

### **3. Do I have to order naloxone nasal spray in multiples of 24 units?**

Yes.

### **4. Can I split the two 4mg devices per unit?**

As noted above, one unit of naloxone nasal spray includes two 4mg spray devices. DHCS does not recommend splitting or separating the 4mg devices.

### **5. What is the maximum order that I can request through the NDP?**

The maximum that an entity can request is currently 2,400 naloxone nasal spray units per application. The maximum request is determined by the ability of the NDP to meet projected demand with available funding and is subject to change. There is no maximum request for intramuscular naloxone.

For any order requesting over 240 units of naloxone nasal spray you must provide a comprehensive summary that justifies your request.

## Naloxone Shipment from the NDP

### 1. Is it acceptable to include a P.O. box as the mailing address?

No. FedEx (one of the shipping services utilized under this project) will not deliver the product to P.O. boxes.

### 2. Once an application is approved, how long does the applicant have to wait to receive the shipment?

DHCS will contact the applicant via email within 2-4 weeks of the date of application submission and confirm if the request has been approved or denied. The shipment will be mailed within 1-2 weeks of the date of approval of the application.

### 3. What should I do if there are issues with my naloxone shipment?

Please direct all questions regarding the product or shipment of Narcan naloxone nasal spray to [narcancustomerservice@ebsi.com](mailto:narcancustomerservice@ebsi.com).

Please direct all questions regarding the product or shipment of generic naloxone nasal spray to [CA\\_AmnealOrders@amneal.com](mailto:CA_AmnealOrders@amneal.com).

Please direct all questions regarding the product or shipment of intramuscular naloxone to [GMB-SPS-Hikma@cordlogistics.com](mailto:GMB-SPS-Hikma@cordlogistics.com).

Please direct any questions regarding the application process to DHCS at [naloxone@dhcs.ca.gov](mailto:naloxone@dhcs.ca.gov).

## Guidelines for Naloxone from the NDP

### 1. Can recipients of NDP naloxone ship the naloxone out of state?

No. Naloxone received through the NDP must be distributed to individuals within the state of California.

### 2. Are entities that receive free naloxone through the NDP permitted to sell naloxone?

No. The NDP was established to allow community organizations and other entities that are in possession of naloxone to distribute it, and to allow individuals that receive naloxone to administer it.

The product may only be used by the applicant and may not be submitted for reimbursement of any type, including and not limited to, private pay, commercial, government authority, agency, or otherwise.

### 3. Can I return the product?

No. The product is not returnable or refundable.

### 4. What can I do with naloxone that is expiring soon?

NDP recipients that have soon-to-expire naloxone can connect with local syringe service programs or other harm reduction groups for redistribution. These organizations can quickly distribute naloxone to meet the need for naloxone in high-risk communities, while preventing waste of medication due to expiration.

Please note that this is an exception to the terms and conditions of the NDP that requires any subrecipients to directly apply to the NDP.

Please track the number of units redistributed to external organizations and include this number in any subsequent applications to the NDP.

If you have any questions or would like to be connected with syringe service programs (SSP) or harm reduction groups in your community, please [visit California Department of Public Health's directory of SSPs](#).

## Data Reporting Requirements

### 1. What are data reporting requirements for entities receiving naloxone through the NDP?

Entities participating in the program agree to maintain and report information regarding the number of reversals that occurred using the naloxone provided by the NDP. Please report reversals to [naloxone@dhcs.ca.gov](mailto:naloxone@dhcs.ca.gov) with each incident, or submit the total number of reversals using the previous shipment of naloxone with subsequent applications to the NDP via the online form. Entities that are re-applying for the program are required to submit information about overdose reversals using naloxone received through the NDP.

## Alternative Sources for Naloxone

### 1. What are some alternate sources for naloxone?

DHCS's NDP is not the sole or primary source for naloxone in California. Individuals can purchase naloxone nasal spray over the counter.

4mg naloxone nasal spray is the only formulation of naloxone currently available over the counter. Due to the over-the-counter status, organizations do not need to obtain a standing order or letter of authorization to acquire or distribute 4mg naloxone nasal spray. CalRx negotiated a price for generic naloxone nasal spray of \$24 per twin-pack. Entities that would like to supplement their order of no-cost generic naloxone through the NDP or purchase outside of the NDP can choose to purchase additional naloxone at this \$24/twin pack price directly through Amneal. For more information on how to obtain this price, please visit [CalRx's website](#).

Eligible organizations can also purchase Narcan naloxone nasal spray directly from the manufacturer at the public interest price by creating an online ordering account at

[narcandirect.com](http://narcandirect.com). Counties may have funding available, such as Substance Use Prevention and Treatment Block Grants (SUBG) or Opioid Settlement Funds, to purchase naloxone from these and other sources.

Emergent BioSolutions provides two free units of Narcan naloxone nasal spray to non-profits, schools, universities and colleges, public libraries, and YMCAs in the United States. Information regarding Emergent's Free Goods Program can be found by emailing [EmergentGives@ebsi.com](mailto:EmergentGives@ebsi.com).

Other formulations of naloxone are available to all Medi-Cal beneficiaries with a prescription. Additionally, many other third-party payers (e.g., Medicaid, Medicare Part D, and private insurance) cover naloxone, however, costs and coverage vary by plan. Individuals should contact their plan to understand how it covers naloxone.

Individuals in California can purchase CalRx® 4 mg nasal spray naloxone for \$24 per two-pack plus taxes and shipping through the [CalRx Naloxone Access Initiative](https://calrxnaloxone.com/) direct-to-consumer option at <https://calrxnaloxone.com/>.

Naloxone can also be dispensed by participating community pharmacists to individuals if applicable requirements are met.

## **2. Where else can entities find harm reduction materials?**

Hospitals and emergency departments looking to participate in Physician Lead Syringe Exchange should reach out to the California Department of Public Health at [SSPinfo@cdph.ca.gov](mailto:SSPinfo@cdph.ca.gov). The Harm Reduction Supply Clearinghouse provides materials to SSPs, including fentanyl test strips, needles and syringes, containers for mixing injectable drugs (cookers), glass pipes, tourniquets, and condoms. For more information on supplies currently offered by the Clearinghouse, contact [SSPinfo@cdph.ca.gov](mailto:SSPinfo@cdph.ca.gov).

## **3. Is naloxone available over the counter?**

Yes. The [U.S. Food and Drug Administration](https://www.fda.gov) approved Narcan, 4 milligram (mg) naloxone hydrochloride nasal spray for over-the-counter (OTC), nonprescription, use on March 29, 2023, and approved generic OTC naloxone hydrochloride nasal spray manufactured by Amneal Pharmaceuticals on April 24, 2024.

Generic naloxone is available through the [CalRx website](https://calrx.com). Narcan naloxone nasal spray is available at local pharmacies and retailers, both online and in stores. Visit [Where to Buy Narcan Nasal Spray Near Me](#) to locate a retailer in your area. Other formulations and dosages of naloxone will remain available by prescription only.