

Naloxone Distribution Project

Frequently Asked Questions

December 2022

1. What is the Naloxone Distribution Project (NDP)?

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.

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. What is NARCAN (naloxone HCI) Nasal Spray?

NARCAN[®] Nasal Spray is a prescription medicine 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[®] 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.

4. What is the shelf life of NARCAN®?

The U.S. Food and Drug Administration (FDA) has approved an extended shelf-life for the nasal spray formulation of naloxone (Narcan) from two years to three years.

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

Both nasal spray naloxone and intramuscular naloxone is available to all eligible entities through the NDP.

6. How can entities in California apply to the NDP?

To request free naloxone, 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 send:

- a. A copy of a valid and active business license, FEIN number or taxexempt letter.
- b. A copy of a naloxone standing order or physician's prescription.
- c. If the naloxone request is for more than 48 units, the organization/entity must provide a brief and comprehensive summary explaining why the quantity was requested and the plan for distribution.
- d. Any additional supplemental documents required for your organization type (refer to the NDP homepage, or this FAQ document, for any additional required documentation).

Send the application and supporting documents to Naloxone@dhcs.ca.gov. Applications that fail to submit all required documentation will be deemed incomplete and will result in application denial.

7. What are some alternate sources for Naloxone?

DHCS's NDP is not the sole or primary source for naloxone in California. Naloxone is 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. Naloxone can also be furnished by participating community pharmacists to individuals if applicable requirements are met.

In addition, counties have SAMHSA grant funding available, such as Substance Abuse Prevention and Treatment Block Grants (SABG), to provide naloxone. Counties and cities also have opioid settlement funding that can be used to provide naloxone to local communities.

Emergent provides two free units of NARCAN® (naloxone HCI) 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.

8. Can naloxone be used for a fentanyl overdose?

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

9. 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. Additionally, Civil Code §1714.22 indicates that naloxone may be distributed to a family member, friend, or other person in a position to assist a person at risk of a suspected opioid-related overdose.

10. 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.

11. Can I apply on behalf of another program?

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

12. What types of organizations are eligible to apply for the NDP?

DHCS will provide free naloxone to entities eligible to administer or distribute naloxone through a California Public Health standing order. Examples include:

- a. First responders
- b. Emergency medical services
- c. Fire authorities
- d. Law enforcement, courts, & criminal justice partners
- e. Veteran organizations

- f. Homeless programs
- a. Schools & universities
- h. Libraries
- i. Religious entities
- j. Community organizations

The NDP is not intended to distribute directly to individuals. Some community organizations and other entities listed above may offer naloxone at low or no cost to individuals. However, naloxone received through the NDP may not be resold.

13. How do entities apply for IM through the NDP?

NDP is now offering free intramuscular (injectable) naloxone **in addition** to Narcan nasal spray. The application process for intramuscular naloxone is the same as for previous NDP orders.

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

To apply, please email the following documents to naloxone@dhcs.ca.gov:

- a) NDP application
- b) Please check intramuscular (injectable) naloxone on the second page of the application under "formulation". The minimum order is 1000 vials and orders must be made in multiples of 1000. Currently there is no maximum order.
- c) Standing order or physician's prescription for naloxone
- d) FEIN, license, or tax exempt letter
- e) Comprehensive summary justifying your need, and
- f) Distribution Plan including policies and procedures for distribution, tracking, and inventory.

DHCS is requesting the above supplemental information even if an entity has applied to NDP in the past 12 months. After this initial application, supplemental application information will be valid for one year. DHCS only requires the NDP application and reversal reporting to apply for more naloxone.

Please store, track, and report reversal information for NDP intramuscular naloxone **separately** from all other naloxone, including Narcan received through NDP. Include how you will meet this requirement in your distribution and tracking plan.

This request is just for intramuscular naloxone. Nasal naloxone (NARCAN) orders should be placed separately. Approval may take several weeks and DHCS will contact you when the process has been completed and we are able to ship

intramuscular naloxone to your organization.

14. Can county public health and behavioral health agencies apply to NDP to receive naloxone?

Yes, county public health and behavioral health agencies may apply to 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. This is so that DHCS can collect accurate data regarding naloxone distribution and overdose reversals. DHCS recommends sub-recipients directly apply to NDP for their naloxone needs. If your agency has a need to apply to 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 NDP.

15. 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. Copy of a standing order for naloxone.
- 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.

16. 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 a naloxone standing order or physician's prescription
- b. Copy of the program's DHCS license (if applicable)
- c. 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.

17. 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 program will be kept separate from naloxone used in the health care site.

18. 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 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 <u>FAQ document</u> issued by the California Department of Public Health.

If your organization does not have a standing order, you may apply for one at the California Department of Public Health's standing order application page.

19. Is training required to distribute naloxone?

Yes. Staff of community organizations and other entities distributing naloxone under the NDP are required to receive opioid overdose prevention and treatment training and are required to train individuals who receive naloxone from them. Minimum training requirements, and an example training resource, are included on the NDP application. For additional training resources, please visit the website getnaloxonenow.org or the <a href="Harm Reduction Coalition's Overdose Prevention and Naloxone Manual.

20. How much does it cost to obtain naloxone through the NDP?

The product is free and is shipped directly to the qualified applicant.

21. What is the minimum order that I can request through the NDP?

There is a minimum of 12 Narcan units (two 4mg devices per unit) per application; 12 units in one case. Order in increments of 12 – for example, if you want three cases of Narcan, please fill in "36" under the "units order" box in the NDP application.

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

22. Do I have to order Narcan in multiples of 12 units?

Yes. Each shipping case contains 12 units of naloxone.

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

DHCS does not recommend splitting or separating the 4mg devices.

24. What is the maximum order that I can request through the NDP?

The maximum that an entity can order is 2,100 Narcan units. Currently DHCS is providing intramuscular naloxone without caps.

For an order over 48 units of Narcan, you must provide a brief yet comprehensive summary that justifies your request.

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

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

26. If DHCS denies an application, can the entity reapply?

Yes. If your application is denied, you may submit another application.

27. If DHCS approves an application for a specific quantity of naloxone, can another application be submitted to request more naloxone?

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

As of July 1, 2021, supplemental application documents (standing order, license, and any other materials) are valid for one year from application. If your organization has applied within the last 12 months, you only need to send in the NDP application pdf and report the number of opioid overdose reversals to reapply for more naloxone. Please reference the date of your last full application in your email.

If you have not applied to the program within the last 12 months, please resend the full application package.

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

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

29. Can recipients of NDP naloxone ship the naloxone out of state?

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

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

No. The NDP program 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.

31. Can I return the product?

No. The product is not returnable or refundable.

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

NDP recipients that have soon-to-expire naloxone shall connect with local syringe service programs or other harm reduction groups for redistribution. These organizations can quickly distribute naloxone and can assist local organizations to meet the need for reducing opioid overdose deaths, while preventing waste of medication due to expiration.

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

Please track the number of units redistributed to external organizations and include this number in any subsequent applications to 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 <u>visit</u> California Department of Public Health's directory of SSPs.

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

Please direct all questions regarding the product or shipment of Narcan nasal spray to customerservice@adaptpharma.com.

Please direct all questions regarding the product or shipment of intramuscular naloxone to GMB-SPS-Hikma@cordlogistics.com.

Please direct any questions regarding the application process to DHCS at Naloxone@dhcs.ca.gov.

34. 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 to Naloxone@dhcs.ca.gov. Entities that are re-applying for the program are required to submit information about overdose reversals using naloxone received through NDP.