

Naloxone Distribution Project

Frequently Asked Questions December 2020

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

The Naloxone Distribution Project (NDP) is funded by the Substance Abuse and Mental Health Services Administration (SAMHSA) and 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, in its nasal spray formulation.

Through the NDP, qualified organizations and entities are able to 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, reversing the toxic effects of the overdose. Naloxone requires a prescription but is not a controlled substance. 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 <u>Narcan manufacturer's website</u>.

4. Can naloxone be used for a fentanyl overdose?

Yes. Fentanyl is an opioid therefore naloxone can be used to reverse a fentanyl overdose.

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

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

- First responders
- Emergency medical services
- Fire authorities
- Law enforcement, courts, & criminal justice partners
- Veteran organizations
- Homeless programs
- Schools & universities
- Libraries
- Religious entities
- Community organizations

The program 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.

6. 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.

However, counties are recommended to request only for their specific agency needs. The distribution plan should justify the volume requested and provide details of the recipients. If the distribution plan includes eligible sub-recipients (e.g. law enforcement, homeless shelters or community clinics) the volume of naloxone requested may be reduced or denied. DHCS strongly recommends sub-recipients to directly apply to NDP for their naloxone needs. This is so that DHCS can collect accurate data regarding naloxone distribution, use and reversals to report to the State Opioid Response grantor, the Substance Abuse and Mental Health Services Administration (SAMHSA).

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

If you would like to request free naloxone, complete the online NDP application 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 copy of a valid and active business license, FEIN number or tax-exempt letter.
- A copy of a naloxone standing order or physician's prescription.
- 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.

Send the application and supporting documents to <u>Naloxone@dhcs.ca.gov</u>.

Applications that fail to submit all required documentation will be deemed incomplete and will result in application denial.

8. 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. Emergency departments should provide the following supplemental documentation with the application:

- Copy of a standing order for naloxone or pharmacy license for the facility
- Signed Naloxone Terms & Conditions Form for Emergency Departments (<u>Terms and Conditions form</u>) is available on the website.
- Policies and procedures for naloxone distribution

Dr. Kelly Pfeifer, Deputy Director, and James Gasper, Psychiatric and Substance Use Disorder Pharmacist, at DHCS and Anne Sodergren, Interim Executive Officer of the California Board of Pharmacy have 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 and track the distribution of the naloxone doses distributed through this program
- The hospital emergency room are required to have policies and procedures, which will dictate how the hospital emergency will distribute the naloxone, including 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 <u>does not need to be labeled</u> as stated in Business and Professions Code 4068.

9. Can substance use disorder treatment programs apply for the NDP?

Yes. Substance use disorder treatment programs 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 treatment programs should provide the following supplemental documentation with the application:

- Copy of a naloxone standing order or physician's prescription
- Copy of the program's DHCS license (if applicable)
- Policies and procedures for naloxone distribution, including:
 - Separate storage of naloxone received through the program from other medications that may be billed to patient insurance;
 - Inventory and tracking of naloxone received through the program;
 - Distribution plan for naloxone received through the program

10. 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.

11. 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.

12. Can I apply on behalf of another program?

No. Please have any eligible entities apply separately for the program.

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

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

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

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

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

Yes. Each shipping case contains 12 units of naloxone.

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

The maximum that an entity or organization can order is 2,400 units. For an order over 48 units, you must provide a brief and comprehensive summary that justifies your request.

If DHCS has additional questions about the quantity of naloxone requested, they may reach out to the applicant and request additional information to substantiate the request.

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

Yes. If your application is denied, you may submit another application. Follow the application instructions, and the terms and conditions to qualify to receive the free shipment of naloxone. Applicants will be required to report on overdose reversals when re-applying for more naloxone.

18. 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.

19. 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.

20. 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 <u>getnaloxonenow.org</u> or the Harm Reduction Coalition's <u>Overdose Prevention and Naloxone Manual</u>.

21. 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.

22. 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 <u>Naloxone@dhcs.ca.gov</u>. Entities requesting re-applying for the program be required to submit information about overdose reversals using naloxone received through the project.

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

DHCS will contact you via email within 8-10 weeks of the date of receipt of application and confirm if your request has been approved or denied. The shipment will be mailed within four weeks of the date of approval of application.

24. Can I return the product?

No. The product is not returnable or refundable.

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

Please direct all questions regarding the product or shipment to <u>customerservice@adaptpharma.com</u>

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