

California Department of Public Health  
Safe and Active Communities Branch  
Naloxone Grant Program

REQUEST FOR APPLICATIONS (RFA #16-10967)  
Naloxone Distribution Projects

Question and Answers

Q: Is there any way to get a copy of the webinar presentation? And how do we find the RFA?

A: Both can be obtained by going to the Safe and Active Communities (SAC) Branch's [Naloxone Grant Program website](#).

Q: I was curious - if we submit our application by the end of this week, how soon could we expect a grant agreement? We're trying to time our request to our Board of Supervisors, and are trying to determine whether to ask for permission to *apply* or permission to *accept* the award.

A: We will make every effort to process the applications as soon as possible, but cannot guarantee when the grant agreements will be finalized.

Q: If our county applies for this grant, how would we proceed if we are unable to identify local entities that have a naloxone distribution system established, or decline to participate?

A: If this is the case after conducting outreach activities, CDPH will work with a local health department to develop alternatives for distributing the naloxone for the benefit of high risk individuals in your jurisdiction.

Q: The question has arisen during the rollout of the Behavioral Health Naloxone distribution program whether local physicians could obtain kits from this grant-funded supply to be provided to their patients who are on chronic opioid Rx, and meet the risk criteria for overdose and provision of rescue Naloxone Rx. Have any restrictions been placed on who is eligible to receive a kit (e.g., insurance status)?

A: The Narcan products made available from this grant should be distributed to those local naloxone distribution systems that need it the most, serve the highest risk clients, and that would otherwise have difficulty obtaining naloxone. Since physicians and their patients may have access to naloxone through other means, such as local pharmacies, they would be considered a lower priority for receiving this naloxone.

Q: Regarding the person we list on the application as the “Person to Direct Inquiries to”, do you recommend this be the same person identified as the “contact person” in the Letter of Interest we submitted, or can it be someone else in the agency?

A: It does not have to be the same person. It is up to the grantee to determine who is the best contact for inquiries related to the grant application.

Q: If we do not have a program up and running yet, are we eligible if it is in the works, or if we can get one up and running in a certain amount of time?

A: Yes.

Q: To clarify our position on what we can do, if we accept these supplies of naloxone, we would only be able to re-distribute to the recognized local overdose prevention programs. We do not have the staff or funding to operate the overdose prevention program directly out of public health. Therefore I would not be issuing the standing order myself.

A: You are required to distribute the naloxone to local entities that have a naloxone distribution system in place, as defined in the RFA, page 2. These entities must have access to a standing order which does not have to be issued by the health officer.

Q: I am wondering about the role of the Principal Investigator as we are unsure who that would be in connection with this grant. Can you say more about what this person does?

A: The Principle Investigator should be the person who is responsible for the grant and most importantly, is authorized to sign the grant agreement on behalf of the grantee.

Q: Concerning criteria #2 for local entities receiving naloxone, would a Buprenorphine MAT clinic be considered in lieu of a syringe exchange program for jurisdictions without SEPs?

A: Yes.

Q: Will the reporting requirements actually require names of individuals to be reported, rather than numbers? Is this compliant with HIPAA?

A: No names or other personal information will be collected.

Q: What about the intermediary entity for distribution of the naloxone, e.g., drug and alcohol treatment programs, jail medical programs? Would an MOU be needed for accountability for the naloxone given to the intermediary distributing entity? The standing order would not apply to the intermediary entity.

A: An MOU is not required between the receiving entity and the local health department.

Q: Can we add distributors who aren't named in the original RFA if new providers emerge in the future?

A: Yes. In the application we ask that you indicate who you intend to distribute naloxone to, understanding that this may change after you conduct community outreach. Any changes to the distribution plan will be documented in the final report.

Q: Do you expect ongoing funding for this program after the two years to sustain continued operation?

A: At this time, we have no expectations of continued funding.

Q: Can the County Dashboard data page be formatted to print as a fact sheet?

A: Yes.

Q: Do you have a ballpark on the county numbers used in the formula to determine allocations?

A: An average of the last three years of deaths and emergency department visits for each county was used in the formula. If you are interested in obtaining data specific to your county, please visit the [California Opioid Overdose Surveillance Dashboard](#).

Q: Regarding the administrative portion of the allocation, there will be a one-time invoice? What level of detail/allowable expenses will be required?

A: Grantees will be allowed to submit a single invoice for administrative costs. A sample invoice will be prepared and disseminated to grantees which will require minimal detail.

Q: Regarding the distribution plan, is there a training log template that can be shared?

A: The distribution plan, submitted on-line, will include the names of selected local entities, the type(s) of services they provide, a description of the target population(s) they serve, and the number of naloxone product they will receive from you. CDPH will provide a standardized distribution plan template.

Q: Our jurisdiction has a distribution program but it is not listed on Attachment C. Does that mean I should answer "NO" for question #13 in the application?

A: Please answer "yes" if you have a harm reduction/syringe exchange program in your jurisdiction. Attachment C lists those harm reduction/syringe exchange programs that have existing naloxone distribution system in place (that we were aware of) at the time the RFA was released.

Q: What is your input on our idea to distribute naloxone product to AED stations? Are other programs considering this option? What might be the challenges?

A: We are not aware of other programs considering this option. It would be acceptable as long as after conducting community outreach it was determined to be of benefit to the highest risk individuals and training for use of naloxone was included.

Q: Is distribution to pharmacies acceptable in areas where other partnerships have not been established?

A: Pharmacies would generally be considered a lower priority for receiving naloxone from this grant since they usually have the means to obtain naloxone from other sources. We encourage grantees to explore all options for ensuring that naloxone is given to entities that serve those at highest risk and are in the most need of naloxone.

Q: Can narcotic treatment programs be considered as partners?

A: Yes. Treatment programs serve high risk individuals and would be excellent partners.

Q: If we have Partnership in our County, can we use Partnership Health plan as one our local entities. Can we have an agreement with them to distribute and train their providers under this grant?

A: We are asking that you conduct outreach in your jurisdiction to identify community distribution systems that serve high risk individuals and are in most need of naloxone. Often times health plans can obtain naloxone by other means.

Q: Can a non-listed distribution program operate under the health officer's standing order?

A: The local health officer would determine which entities are eligible to participate under the health officer's standing order.

Q: What type of training is required? Does the training need to be completed by the new distributors prior to receiving the Naloxone?

A: Local entities chosen to receive naloxone must have a naloxone distribution system in place at the time they receive naloxone from the health department grantee. They must 1) have access to a standing order from a licensed clinician/medical director; 2) have staff that are trained (or are trained to provide education to others) on naloxone storage and administration, overdose prevention techniques, how to recognize an opioid overdose (signs and symptoms), how to respond by calling 911 and provide rescue breathing, and post-overdose care; 3) dispense naloxone products; and 4) document distribution efforts.

Q. Due to the financial constraints of this grant, is there a standard training for staff of local entities wanting to establish a naloxone distribution system? Will there be information on where we can have new distributors trained? When can we expect training opportunities to be available?

A: Please see the [Naloxone Grant Program's](#) website for a list of training resources. CDPH will include additional information about on-line trainings, conduct training webinars, and in-person trainings as these resources are identified.

Q: Will there be a network set up to share best practices and resources? Will more be added to the webpage?

A: Yes. We will host a series of web conferences for grantees to share best practices, experiences, and resources. Additional resources and information will be added to the web page as identified.

Q: What is DEA #?

A: The DEA # is the license from the Drug Enforcement Administration (DEA) that authorizes medical professionals to prescribe controlled substances.

Q: Our local health department does not have an organizational DEA license—we do not prescribe narcotics in our clinics. The application asks for our DEA number. Do we need to obtain one before we can apply? Also, while we are prepared to apply for one, given that naloxone is not a controlled substance, is it required that we obtain a DEA license?

A: The manufacturer is asking for a DEA license and address for the purposes of shipping the naloxone.

Q: The application calls for a clinic DEA #. To my knowledge we don't have one and I'm not sure the relevance, since the project does not involve controlled substances. I do have a personal DEA# on my own license.

A: The manufacturer is asking for a DEA license and address for the purposes of shipping the naloxone.

Q: The Health Officer we would like on the grant and whose DEA # we would like to use for the standing order is the Director of EMS, but he has a different address from where we would like the naloxone shipment sent. My department is going to be overseeing the distribution system, and we will also be storing the product at our location, which is where some of our other distributing departments are housed. Is it possible to use our address for the shipment but still use our EMS Director's DEA #?

A: Our understanding is that the naloxone needs to be shipped to the address associated with the DEA number provided.

Q: Naloxone is a prescription-only product and DEA has restrictions on transfer of prescription medications. Is a documentation process included that meets DEA requirements for transfer to another entity? Is an MOU needed with recipient partners regarding receipt and management of the medication?

A: Your DEA number will be used to receive the naloxone. CDPH does not require an MOU between your local health department and the local entity receiving the naloxone.

Q: Are there DEA restrictions on the local health department giving the naloxone product to an agency where it will be distributed under a CBO physician's standing orders, not the Health Officers?

A: No DEA restrictions. Naloxone can be distributed under a standing order from a physician or pharmacist associated with a naloxone distribution system.

Q: Do you mean the DEA of the health officer or DEA of the naloxone program health department will be distributing naloxone to?

A: Please include the DEA number that is associated with your health department.

Q: My question is not about the legality of dispensing without a prescription, but the transfer of “dangerous drugs”, i.e., non-controlled prescription medication, from a prescriber who received the medications on their DEA # and transferring it to another entity, who may or may not have a health professions license, to dispense under a standing order/protocol to a lay person to administer at another time and place.

I am asking this question on the basis of the procedures used for receipt of H1N1 vaccine by local health officers/department and passing on to providers to administer to their patients.

A: Please visit the [Naloxone Grant Program's](#) website for more information about naloxone distribution.

Q: The larger question has to do with how this project complies with pharmacy laws. To my knowledge, redistribution of prescription medication stock requires a pharmacy license. Our health department does not operate a pharmacy, so I'm wondering if there is a special exemption for this redistribution project under the Board of Pharmacy and can I get documentation for that?

A: Please visit the [Naloxone Grant Program's](#) website for more information about naloxone distribution.

Q: Can you also talk to liability please and who would be responsible if an event occurred? Is there legal exposure for the local health department to receive and distribute naloxone? Is there an emergency waiver to hold the local health department and/or distributor harmless?

A: Please see page 2 of the RFA and the [Naloxone Grant Program's website](#) for a reference to laws that eliminate liability for the distribution of naloxone.

Q: The application asks if we would like to receive two separate shipments, and we were wondering if it would be possible to split them unevenly.

A: Yes. Please indicate how you'd like the shipment split in your application.

Q: Our jurisdiction has been rolling out a Naloxone distribution program using kits purchased by the Behavioral Health Department last fall using their grant funding. It would be ideal to use this new funding stream to expand that existing program as that supply becomes exhausted. That means we may not need to actually get our first distribution of product until sometime in 2018. Will we be required to take a first distribution by 7/16/2017? If so, is there a minimum number of kits required to order on the first pass?

A: You are not required to take the first shipment according to the timelines in the RFA and could wait until the second shipment scheduled for June, 2018. Please base this decision on the needs of naloxone distribution systems in your jurisdiction.

Q: Is the second distribution date also flexible?

A: We will consider alternatives if justified.

Q: Do we need to accept the full allocation, or can we choose to take less than our allocation?

A: Grantees can choose to take less than their allocated amount of naloxone if after conducting outreach in their jurisdiction it is determined that accepting the full amount is unnecessary.

Q: What is the unit packaging, e.g, a case of XX individual units? What are the dimensions of the individual packages that will be shipped? What are the storage specs needed for an organization that might be interested in participating?

A: An individual unit (one box) of Narcan Nasal Spray contains two blister packed Narcan Nasal sprays and the box dimensions are 2.5" X 3" X 3.75". They are shipped in case quantities of 12 units each and are combined depending on how many are being shipped. The 12 unit case dimensions are 10" X 9" X 3 7/8". The product can be kept at

room temperature does not need to be locked up (not a controlled substance). Please visit the [Naloxone Grant Program's](#) website for more product information.

Q: Regarding the 2-dose package, can they be easily separated? We were planning on practitioners handing out one dose at a time, because we were under the assumption that one dose is adequate to revive a person from overdose.

A: Yes, they can be split into two single doses.

Q: Is Narcan Nasal Spray the only option?

A: Yes.

Q: Can you provide an estimated expiration date for the Narcan? What is the shelf life? If we choose to only take half, will meds distributed in 2018 have a longer shelf life?

A: Narcan is manufactured with a 24-month expiration date. We are working with the manufacturer to ensure the products will have the latest expiration date possible when shipped to local health departments.