

THE NALOXONE APP COMPETITION



Frequently Asked Questions

- 1. Purpose of the App.** We received several questions asking how the app is meant to be used. Examples of such questions included:

- **Is the goal of the app to get people who are overdosing to treatment centers, or for treatment personnel to get to the people who are overdosing?**
- **Is the app meant to be used by an individual onsite at an overdose to request help?**
- **Is this app intended to function as a means to track the location of naloxone carriers and allow police or EMS to contact those individuals closest to the overdose?**

Answer: The goal of the Competition is to develop an app that increases the likelihood of timely naloxone administration by connecting opioid users experiencing an overdose with nearby naloxone carriers.

The Rules for the Competition indicate that the minimum requirements for a submission are:

- Use of crowd-sourcing technology to identify one or more individuals in close proximity to the overdose who could administer naloxone;
- Minimize the time required to identify one or more individuals in close proximity to the overdose that could deliver naloxone to an individual experiencing an opioid overdose; and
- Compatibility with multiple platforms, including Android and iOS.

Any submission that meets these requirements will be considered, so you may otherwise be creative in the design of your app.

- 2. Requirements for the App.** We also received several questions related to what requirements an app may have to meet.

Are there any guidelines for building the app using a wearable device such as FitBit?

Answer: The Federal Register Notice indicates that the competition is seeking submissions for an “app that increases the likelihood of timely naloxone administration”. Therefore, it does not preclude building an app that leverages a wearable device like Fitbit. If the wearable device manufacturer does not provide an open source api then the team should take this constraint into consideration before moving forward.

Are you only going to consider full iPhone and Android apps? If there is a web-based or alternate solution, would it be considered?

Answer: Any submission that meets the minimum requirements will be considered. As listed above, however, one of the minimum requirements is “compatibility with multiple platforms, including Android and iOS.”

Is integration with 911 or EMS systems expected?

Answer: There is no requirement that the app interface with EMS or the 911 system, though we would note that the FDA labeling instructs users to call for emergency medical assistance immediately after administration of naloxone. There are resources available that may be relevant to designing an app that interfaces with 911, including: Next Generation 911 Standards: <http://www.911.gov/standardsfornextgen.html>.

Is the app required to be publicly available in an app store or on the internet to be considered for the Competition?

Answer: No, the app is not required to be publicly available at the time you submit your solution for the Competition.

3. Testing of the App.

Can we generate real-world or live-usage data to help test our app?

Answer: The Rules document states that entrants may not test or evaluate their app using real people, including opioid users and naloxone carriers, during the competition. It also notes that drug use and abuse are sensitive topics that require careful consideration of privacy and confidentiality issues. The submissions must not contain any data about real people, and entrants may not use data from or about actual people in development of the app.

4. Data Sources. Several participants had questions on the availability of specific data sources beyond what was provided in our [Resources Document](#).

Does FDA have a database of naloxone carriers that can be downloaded or accessed using an api?

Answer: No, FDA does not maintain such a database and is not aware that such a database exists elsewhere.

Does FDA have a national database of all locations where naloxone can be obtained?

Answer: No, FDA does not maintain such a database and is not aware that such a database exists elsewhere.

Are there data on the breakdown of annual household incomes for fatal heroin overdoses versus fatal prescription opioid overdoses?

Answer: To our knowledge, these specific data have not been collected. There is evidence that some populations are switching from prescription opioid abuse to heroin use, so it is likely that the socioeconomic data for these populations are at least somewhat overlapping. This resource may be of further help: <https://www.drugabuse.gov/about-nida/legislative-activities/testimony-to-congress/2016/americas-addiction-to-opioids-heroin-prescription-drug-abuse>

5. Submission Requirements.

How do we make our app testable for the judges or is the video demonstration sufficient?

Answer: A submission must consist of the video demonstration and a summary document, as described in the Rules of the Competition. The app does not need to be made available for testing.

Can a single team submit multiple solutions?

Answer: Yes, a team may submit multiple solutions, each of which will be judged independently.

How “functional” does the app prototype need to be? How do we demonstrate that it is functional?

Answer: As stated in the rules, the submission video “must demonstrate a functional prototype of the application, including any planned interfaces between the app and existing systems or datasets.” We recognize that there may be some elements of functionality that cannot be demonstrated by video. Where app functionality can be demonstrated by video, all entrants should include such a demonstration in their submission video. If certain elements of app functionality cannot be demonstrated by video, entrants should describe in detail the planned approach to developing such functionality in the summary document. For example, if the functionality of an app relies on databases that have not yet been built, on novel mechanisms for distributing, procuring or delivering naloxone, or on untested linkages to outside networks or systems, the entrant should describe with specificity how such elements would be developed.

Are there font, size or spacing requirements for the summary document?

Answer: FDA would prefer that participants submit a double-spaced document with text in a standard size and font, but these are not requirements. A PDF is acceptable, and images may be included in the summary document. The only requirements for the summary document are that it is in English, is submitted on <http://www.challenge.gov>, does not exceed three pages, and includes:

1. A description of the entrant(s), including relevant fields of expertise;
2. A summary of the concept for the app, including identification of the target audience;
3. A general description of the proposed technical design, including an explanation of any planned interfaces between the app and existing systems or datasets; and
4. The URL for the uploaded YouTube video

6. Naloxone Use by First Responders.**Are there any mechanisms to interface with EMS directly without routing through 911?**

Answer: With very few exceptions, the public interfaces with EMS by calling 9-1-1. This allows the jurisdiction to utilize its EMS assets in the most efficient and effective manner possible, by following pre-established protocols and standard operating procedures.

7. How is the cost for naloxone procurement borne by EMS/first responders? Do localities buy naloxone directly?

Naloxone, like other medications, is generally purchased in bulk by EMS agencies or by local hospitals. When a patient is transported to a hospital, the hospital will often resupply the ambulance with medications that were administered to the patient. These practices do vary by state and locality. The supply and purchase of medications by EMS agencies is generally overseen by the agency medical director.