Naloxone for Administration by Service Entity Personnel

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Ohio law permits naloxone to be available for administration at locations, known as Service Entities, that serve individuals who may be at risk of experiencing an opioid-related overdose. It also exempts the site be licensed as a terminal distributor of dangerous drugs (TDDD) for the purposes of storing naloxone for administration only.

For questions regarding this law, please review the following frequently asked questions. If you need additional information, the most expedient way to have your questions answered will be to e-mail the Board office by visiting: http://www.pharmacy.ohio.gov/contact.aspx.

Q1) What kind of locations (i.e. Service Entities) can procure naloxone for emergency administration?

The law permits entities, referred to as "Service Entities," that serve individuals who may be at risk of experiencing an opioid-related overdose to procure naloxone for use in emergency situations.

It defines "Service Entity" as a public or private entity that provides services to individuals who there is reason to believe may be at risk of experiencing an opioid-related overdose. The law includes the following as Service Entities: a college or university, school, local health department, community addiction services provider, court, probation department, halfway house, prison, jail, community residential center, homeless shelter, or similar entity.

Q2) Are Service Entities required to obtain a terminal distributor of dangerous drugs (TDDD) license to purchase, possess and administer naloxone?

No. Ohio law exempts Service Entities that possess naloxone for emergency administration from having to obtain licensure as terminal distributors of dangerous drugs.

Q3) How does a Service Entity become authorized to administer naloxone?

To be eligible to administer naloxone at a Service Entity, a physician or board of health must establish a written protocol for administering naloxone. In the case of a board of health, the
The protocol must be established through a physician acting as the board’s health commissioner or medical director. The protocol must include the following:

1. A description of the clinical pharmacology of naloxone;
2. Precautions and contraindications concerning the administration of naloxone;
3. Any limitations concerning the individuals to whom naloxone may be administered;
4. The naloxone dosage that may be administered and any variation in the dosage based on circumstances specified in the protocol;
5. Labeling, storage, record-keeping, and administrative requirements;
6. Training requirements that must be met before an individual can be authorized to administer naloxone.

The law permits an employee, volunteer, contractor of a Service Entity to administer naloxone pursuant to the physician-approved protocol. A sample protocol is available here: www.pharmacy.ohio.gov/serviceprotocol

**IMPORTANT:** The law requires an authorized Service Entity employee, volunteer, or contractor to obtain the naloxone from the Service Entity, comply with the protocol, and summon emergency services as soon as practicable.

**Q4) How often does the protocol have to be renewed or reviewed?**

There is no requirement in the law indicating when the protocol for naloxone administration must be renewed or reviewed.

**Q5) I am a Service Entity that also personally furnishes (i.e. provides take home doses) of naloxone. Do I need to obtain a terminal distributor license?**

Yes. The law still requires a Service Entity or any other location that is providing take-home doses of naloxone to obtain a terminal distributor of dangerous drugs license.

NOTE: If a Service Entity is associated with a location that is licensed as a terminal distributor, it may not require a license in order to personally furnish. For more information, visit: www.pharmacy.ohio.gov/TDDDoffsite

**Q6) Does the law include any legal protections for Service Entities?**

Section 4729.514 of the Ohio Revised Code states: A Service Entity or an employee, volunteer, or contractor of a Service Entity is not liable for or subject to any of the following for injury, death, or loss to person or property that allegedly arises from an act or omission associated with procuring, maintaining, accessing, or using naloxone under this section, unless the act or omission constitutes willful or wanton misconduct: damages in any civil action, prosecution in any criminal proceeding, or professional disciplinary action.
In addition, the following apply to Boards of Health and physicians as it relates to Service Entities:

**Boards of Health & Medical Director (ORC 3707.562):**

A board that in good faith authorizes an individual to administer naloxone under this section is not liable for damages in any civil action for any act or omission of the authorized individual.

A physician serving as a board's health commissioner or medical director who in good faith authorizes an individual to administer naloxone under this section is not liable for or subject to any of the following for any act or omission of the authorized individual: damages in any civil action, prosecution in any criminal proceeding, or professional disciplinary action.

**Physicians (ORC 4731.943):**

A physician who in good faith authorizes an individual to administer naloxone under this section is not liable for or subject to any of the following for any act or omission of the authorized individual: damages in any civil action, prosecution in any criminal proceeding, or professional disciplinary action.

**Q7) How do I obtain naloxone for my Service Entity?**

Naloxone can be obtained using any of the following methods:

**Wholesale Purchase:** Naloxone can be obtained from a wholesaler that is licensed by the State of Ohio Board of Pharmacy. To verify a wholesale drug distributor is licensed in Ohio, visit: [www.pharmacy.ohio.gov/licenselookup](http://www.pharmacy.ohio.gov/licenselookup)

**Purchase from a Pharmacy:** The State of Ohio Board of Pharmacy permits a pharmacy licensed as a terminal distributor dangerous drugs to conduct an occasional sale of drugs at wholesale. There are no restrictions on the amount that can be provided by a pharmacy pursuant to rule 4729:5-3-09 of the Administrative Code.

The Ohio Department of Mental Health and Addiction Services operates Ohio Pharmacy Services, which sells naloxone kits. To contact Ohio Pharmacy Services, please call: 1-888-471-5632

**Purchase from another TDDD:** The State of Ohio Board of Pharmacy permits any entity licensed as a terminal distributor dangerous drugs to provide naloxone at wholesale. Please be advised that the terminal distributor must properly document the transaction (even if the health department is donating the naloxone). There are no restrictions on the amount that can be provided/sold by a terminal distributor.