



Naloxone for Administration by Service Entity Personnel

Updated 4/30/2018

On January 4, 2017, SB 319 was signed by Governor Kasich. This law (effective 4/6/2017) 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 removes the requirement that the site be licensed as a terminal distributor of dangerous drugs (TDDD) for the purposes of storing naloxone **for administration only**.

These changes are set to take effect on **April 6, 2017**.

For questions regarding these changes, 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>.

For a summary of SB 319, please visit:

<https://www.legislature.ohio.gov/download?key=6079&format=pdf>

(1) 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.

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

No. The law exempts Service Entities that possess naloxone for emergency administration from



having to obtain licensure as terminal distributors of dangerous drugs.

(3) 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 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

NOTE: 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.

(4) 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.

(5) 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.

(6) I am a Service Entity that currently has a terminal distributor license to administer naloxone on-site. How do I go about cancelling my license?

As the effective date of the law and the end of the terminal distributor renewal cycle (March 31) are so close, the Board advises you to let your license lapse (i.e. do not renew). Please be advised that this is **ONLY** if you are planning to keep naloxone on-site for emergency administration. If you are planning to personally furnish from your location or have other dangerous drugs (prescription drugs) on-site you still need your terminal distributor license.

(7) 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.

(8) How do I obtain naloxone for my Service Entity?

Naloxone can be obtained by two methods.

Wholesale purchase: A Service Entity is permitted to order naloxone 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

Please indicate to the wholesaler that, effective 4.6.2017, your organization is exempt from licensure as a terminal distributor of dangerous drugs pursuant to ORC 4729.541.

Wholesale purchase from any licensed terminal distributor of dangerous drugs: The State of Ohio Board of Pharmacy permits any entity licensed as a terminal distributor dangerous drugs to conduct sales of naloxone at wholesale. There are no restrictions on the amount that can be provided by a terminal distributor pursuant to rule 4729-9-10. These sites include hospitals, [Project DAWN locations](#), pharmacies ([particularly those offering naloxone without a prescription](#)), health departments and any other location licensed as a terminal distributor of dangerous drugs.

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

Please note: Per ORC 5119.44, Ohio Pharmacy Services is only permitted to sell to state facilities, county health departments, community mental health agencies, free clinics, county jails, non-profits, etc.

The State of Ohio Board of Pharmacy strongly supports efforts to reduce opioid overdose death through expanded use of naloxone. If you have any questions regarding the purchase, storage or use of naloxone, please call us at 614-466-4143 or email us by visiting <http://www.pharmacy.ohio.gov/Contact.aspx> and we will do everything we can to assist you.