



## Personally Furnishing Naloxone Pursuant to a Protocol

**Updated 9/23/2020**

**IMPORTANT:** [HB 341](#) (133<sup>rd</sup> General Assembly) was signed into law by Governor Mike DeWine on September 16, 2020. This act exempts locations, known as “service entities,” who personally furnish naloxone to at-risk individuals from licensure as a terminal distributor of dangerous drugs. For more information on these changes related to licensure, visit [www.pharmacy.ohio.gov/Service](http://www.pharmacy.ohio.gov/Service).

Section 4731.941 of the Ohio Revised Code permits a physician to authorize one or more individuals to personally furnish a supply of naloxone pursuant to a protocol to either of the following:

- (1) An individual who there is reason to believe is experiencing or at risk of experiencing an opioid-related overdose; or
- (2) A family member, friend, or other person in a position to assist an individual who there is reason to believe is at risk of experiencing an opioid-related overdose.

**NOTE:** Effective 12/16/2020, [HB 341](#) (ORC 4723.485, 4723.486, 4730.435, and 4730.436) authorizes clinical nurse specialists, certified nurse-midwives, certified nurse practitioners (collectively “APRNs”) and physician assistants to develop and authorize protocols to personally furnish naloxone.

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 are the requirements for the protocol?

According to the section [4731.941](#) of the Ohio Revised Code, a physician established protocol for personally furnishing naloxone must include all the following in writing:

- (1) A description of the clinical pharmacology of naloxone;
- (2) Precautions and contraindications concerning furnishing naloxone;
- (3) Any limitations the physician specifies concerning the individuals to whom naloxone may be furnished;



- (4) The naloxone dosage that may be furnished 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 will be authorized to furnish naloxone;
- (7) Any instructions or training that the authorized individual must provide to an individual to whom naloxone is furnished.

Please be advised that the law also permits a health department to issue a protocol. See ORC [3707.561](#) for more information.

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## **Q2) Is there a sample protocol available?**

The Ohio Department of Health, in collaboration with the State Board of Pharmacy, have developed the following sample protocol for personally furnishing naloxone that can be accessed [here](#).

## **Q3) What type of naloxone can be personally furnished pursuant to the physician approved protocol?**

The law does not specify or limit the type of naloxone that can be personally furnished pursuant to a physician approved protocol. However, the type of naloxone that may be personally furnished is subject to the formulations specified within the protocol. If new formulations are developed, they may be added to the protocol.

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## **Q4) Where do I obtain naloxone?**

Naloxone can be obtained using any of the following methods:

**Wholesale Purchase:** Naloxone can be obtained from a wholesaler or other drug distributor that is licensed by the State of Ohio Board of Pharmacy. To verify a wholesaler or 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 or limitation 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. There are no restrictions on the amount that can be provided/sold by a terminal distributor. Please be advised that the terminal distributor must properly document the transaction (even if the health department is donating the naloxone).

**IMPORTANT:**

Per Board of Pharmacy rules, a service entity that is exempted from licensure may purchase naloxone from a wholesaler or terminal distributor if the service entity attests in writing, which may include an electronic signature, that the person meets the licensing exemptions in section [4729.541](#) of the Revised Code on an annual basis.

To assist service entities in providing this documentation, the Board has developed a [Service Entity Attestation Form](#). Please be advised that this a suggested form and that the service entity may have to submit different or additional documentation based upon the policies of the seller.

**Q5) Does the Board of Pharmacy have specific requirements for personally furnishing naloxone?**

Effective 9/16/2020, service entities that personally furnish naloxone are exempted from licensure by the Board of Pharmacy. Please be advised that there are some limitations to this exemption. For more information, visit: [www.pharmacy.ohio.gov/Service](http://www.pharmacy.ohio.gov/Service).

**IMPORANT:** Please be advised that if a facility maintains a terminal distributor of dangerous drugs license it is subject to all applicable record keeping, labeling, and other requirements associated with licensure. For more information on these requirements, licensees should review their applicable inspection guide available on the Board's terminal distributor licensing page: <https://www.pharmacy.ohio.gov/Licensing/TDDD.aspx>

**Q6) My organization is already licensed as a terminal distributor of dangerous drugs; do I need to do anything else to begin ordering naloxone?**

**IMPORTANT:** *Effective 9/16/2020, service entities that personally furnish naloxone are exempted from licensure by the Board of Pharmacy. Please be advised that there are some limitations to this exemption. For more information, visit: [www.pharmacy.ohio.gov/Service](http://www.pharmacy.ohio.gov/Service). The following answer to this question only applies to facilities that are not exempted from licensure.*

If your organization has an unlimited category II or category III TDDD license, you are not required to do anything to order naloxone.

If your agency has a limited TDDD category II or III license, you will need to update your drug list to reflect the addition of naloxone. The new drug list must contain the following information:

- a) the brand name (Narcan®)
- b) the generic name (Naloxone)
- c) strength to be stocked (Naloxone 2 mg / 2 mL)
- d) dosage form (*intranasal solution*)

Your drug list must be submitted electronically in .PDF format by visiting:

[www.pharmacy.ohio.gov/upload](http://www.pharmacy.ohio.gov/upload). A [sample drug list](#) can be found on the Board's terminal distributor licensing page: <https://www.pharmacy.ohio.gov/Licensing/TDDD.aspx>.

**BE ADVISED:** Each time you revise your drug list you must upload your **ENTIRE** list. Previous versions of your drug list will not be displayed on the website; they will be replaced with your most current submissions once approved.

To check to see if your agency has a terminal distributor of dangerous drugs, please visit:

[www.pharmacy.ohio.gov/licenselookup](http://www.pharmacy.ohio.gov/licenselookup)

#### **Q7) Is there written information available to assist with the training of patients?**

Yes. The Board has developed a brochure that covers many of the typical training requirements for providing naloxone to laypersons. The brochure is available electronically by visiting:

[www.pharmacy.ohio.gov/naloxone](http://www.pharmacy.ohio.gov/naloxone)

Additional training materials can also be accessed here:

**Ohio Department of Health - Project DAWN (Deaths Avoided with Naloxone):**

<https://odh.ohio.gov/wps/portal/gov/odh/know-our-programs/violence-injury-prevention-program/projectdawn/>

**Prescribe to Prevent:** <http://prescribetoprevent.org/>

#### **Q8) The law allows me to personally furnish naloxone to “a person in a position to assist an individual who there is reason to believe is at risk of experiencing an opioid-related overdose”. How do I make this determination?**

Many individuals work in environments where they may assist an individual experiencing an overdose including, but not limited to, the following:

- Colleges (residence life staff) and schools (school nurses, administrators, teachers, etc.)
- Substance abuse treatment programs (residential and nonresidential)
- Halfway houses
- Homeless shelters

- Home healthcare agencies

**NOTE: The naloxone must be personally furnished in the name of the person who requests it.**

**Q9) What type of prescribers can authorize a protocol to personally furnish naloxone?**

Currently, Ohio licensed physicians (including those employed by [local health departments](#)) must authorize a protocol. The law does not limit the number of protocols a physician may authorize therefore a physician may authorize a protocol for several locations.

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**Q10) Are there any protections for physicians and individuals authorized to personally furnish naloxone on behalf of the physician pursuant to a protocol?**

Yes. A physician and a person authorized by the physician to personally furnish naloxone, acting in good faith, are not liable for or subject to any of the following for any action or omission of the individual to whom the naloxone is furnished: damages in any civil action, prosecution in any criminal proceeding, or professional disciplinary action.

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**Q11) When does the protocol expire?**

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

**Q12) Can I bill a patient’s insurance for the naloxone?**

Medicaid, Medicare, and many private insurance companies may cover the cost of naloxone.

**NOTE: The naloxone must be dispensed in the name of the person who is requesting it at the pharmacy. Therefore, it must also be billed in the name of that person (if billing insurance).**

**Q13) Is there a limit to the amount of naloxone that can be personally furnished pursuant to a protocol?**

The authorized individual personally furnishing the naloxone should refer to their protocol to determine if there are any established limits.

**Q14) Are there any substance abuse treatment resources available to patients and their families?**

For anyone seeking substance abuse treatment, you may refer them to the Ohio Department of Mental Health and Addiction Services' treatment referral line at 1.877.275.6364.