



Guidance Document – Personally Furnishing Naloxone Pursuant to a Protocol

Updated 10-16-2016

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.

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>.

More information about these recent law changes can also be accessed here: <https://www.legislature.ohio.gov/legislation/legislation-documents?id=GA131-HB-4>

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 of 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.

Q2) Is there a sample protocol available?

Currently a sample protocol does not exist. However, the Board has created a sample protocol for dispensing pharmacies that may be helpful, as it has some overlapping requirements. This sample protocol can be accessed here: www.pharmacy.ohio.gov/naloxone.

Please note: The pharmacy protocol does differ in its requirements from what is listed in Q1.



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

The law has also been changed to allow any formulation of naloxone to be personally furnished via a protocol (or directly by a prescriber). The type of naloxone that may be dispensed may include all of the following formulations:

Intramuscular naloxone:

- *Naloxone 0.4 mg/ml single dose vial, 2 vials (NDC No. 0409-1215-01)*
- *SIG: Inject 1 ml IM upon signs of opioid overdose. Call 911. May repeat ×1.*
- *Syringe 3 ml 25G ×1 inch No. 2*
- *SIG: Use as directed for naloxone administration*

Intranasal naloxone (Narcan Nasal Spray):

- *Naloxone 4mg/0.1mL FDA approved nasal spray device, 2 doses per unit (NDC No. 69547-353-02)*
- *SIG: Administer a single spray intranasally into one nostril. Call 911. May repeat ×1.*

Intranasal naloxone:

- *Naloxone 2 mg/2 ml prefilled syringe, 2 syringes (NDC No. 76329-3469-01)*
- *SIG: Spray one-half of syringe into each nostril upon signs of opioid overdose. Call 911. May repeat ×1.*
- *Two mucosal atomization devices (MAD300)*
- *SIG: Use as directed for naloxone administration*

Auto-injector (Evzio intramuscular naloxone):

- *Naloxone 0.4 mg/0.4 ml (NDC No. 60842-030-01)*
- *No. 1 twin pack*
- *SIG: Use one auto-injector upon signs of opioid overdose. Call 911. May repeat ×1.*

Please note: The type of naloxone that may be personally furnished is subject to the formulations approved within the physician protocol. If new formulations are developed, they may be added to the protocol.

Q4) Where do I obtain the naloxone and the required delivery devices?

The single-dose vial, naloxone nasal spray, prefilled syringe, auto-injector and IM syringes are available from Ohio licensed wholesale distributors. The atomizers ([MAD300](#)) for nasal administration via the prefilled syringe are available from medical supply vendors and, in some cases, can be purchased directly from a wholesaler.

Q5) Does the Board of Pharmacy have specific requirements for personally furnishing prescription drugs such as naloxone?

Unless specifically exempted by law, all sites that possess prescription drugs (such as naloxone) are required to be licensed as terminal distributors of dangerous drugs. Such licensure requires any drug that is personally furnished to meet all of the following requirements:

- Labeling and Personally Furnishing: <http://codes.ohio.gov/oac/4729-5-17> **(The naloxone must be personally furnished in the name of the person who requests it.)**
- Storage/Security Requirements: <http://codes.ohio.gov/oac/4729-9-11>
- Recordkeeping: <http://codes.ohio.gov/oac/4729-9-22>

These requirements (labeling for example) will be delegated in the protocol to an authorized individual to perform on behalf of the physician pursuant to rule 4729-5-17. Board staff is available to answer any questions you may have regarding these requirements and our inspectors can assist should you need on-site assistance.

To see if your location is licensed as a terminal distributor, please visit:
<https://license.ohio.gov/lookup/default.asp?division=96>

The following entities are exempt from obtaining a terminal distributor of dangerous drugs:

- **Law enforcement (for naloxone only):** A guidance document for law enforcement is available by visiting: www.pharmacy.ohio.gov/naloxone
- **Certain prescriber practices:** For more information, please visit: www.pharmacy.ohio.gov/prescribertddd

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

If your organization has an unlimited TDDD category II or III license with the State of Ohio Board of Pharmacy, you can order, store and personally furnish naloxone to third parties (family, friends, etc.) and individuals who are at-risk for an opioid overdose.

For those organizations that have a limited TDDD category II or III license with the Board, you will need to update your drug list and protocols to reflect the addition of naloxone. To update these documents please use the following link: <http://pharmacy.ohio.gov/TDDD/DrugList.aspx>

IMPORTANT: BOTH your Drug List and Protocols must be signed by the medical director and notarized.

IMPORTANT: When uploading new documents, the old documents are OVERWRITTEN. Be sure to upload the ENTIRE Drug List and Protocols, NOT just the changes.

We ask that you allow for a 7-10 day approval period for these documents.

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

Additional training materials can also be accessed here:

Ohio Department of Health - Project DAWN (Deaths Avoided with Naloxone):
<http://www.healthy.ohio.gov/vipp/drug/ProjectDAWN.aspx>

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 go about making 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

Please note: The authorizing physician should indicate in their protocol the individuals that meet this requirement or should be directly consulted if there are any questions. The naloxone must be personally furnished in the name of the person who requests it. Therefore, it must also be billed in the name of that person (if billing insurance).

Q9) What type of prescribers are able to authorize the protocol?

Ohio licensed physicians must authorize the protocol. The law does not limit the number of protocols a physician may authorize therefore a physician may authorize a protocol for a number of locations (or individuals).

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.

Q11) When does the protocol expire?

The law does not stipulate when the protocol expires. However, the authorizing physician may include an expiration date if they so choose.

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

Medicaid, Medicare, and many private insurance companies may cover the cost of naloxone. To assist with billing, the law permits a pharmacist to document the dispensing of naloxone by the pharmacist or a pharmacy intern on a prescription form. The form may be assigned a number for record-keeping purposes.

According to the Ohio Department of Medicaid, all plans, except Buckeye Health Plan, pay for all formulations of naloxone (intranasal, intramuscular and auto-injector) when dispensed to a plan member. Buckeye Health Plan will cover the intranasal formulation as part of their pharmacy benefit.

Please be advised that the auto-injector for all plans requires prior authorization.

Please 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) Can I bill a patient's insurance for the atomizer needed for intranasal use?

It may be difficult securing reimbursement for the atomizer needed for intranasal use via the prefilled syringe. Currently, the atomizer lacks a National Drug Code or UPN, which are universal product identifiers typically used in insurance billing systems.

Please note: There is an FDA-approved intranasal formulation that is now available that does not require a nasal atomizer (See Q3).

Q14) Is there a limit to the amount of naloxone that can be dispensed pursuant to a protocol?

The authorized individual personally furnishing the naloxone should refer back to their protocol to determine if there are any established limits. If no such limitations exist, they should consult with the authorizing physician to determine if additional doses may be supplied.

Q15) Are there any substance abuse resources available to patients and their families?

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