



## **Dispensing of Naloxone by Pharmacists and Pharmacy Interns without a Prescription**

**Updated 6/13/2019**

[Section 4729.44 of the Ohio Revised Code](#) and [rule 4729-5-39 of the Ohio Administrative Code](#) authorizes a pharmacist or pharmacy intern under the direct supervision of a pharmacist to dispense naloxone without a prescription to the following in accordance with a physician-approved protocol:

- (1) An individual who there is reason to believe is experiencing or at risk of experiencing an opioid-related overdose;
- (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; or
- (3) A peace officer as defined in section 2921.51 of the Revised Code.

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 a physician-approved protocol in rule 4729-5-39?**

According to [the rule](#), a physician approved protocol for dispensing naloxone without a prescription must include all of the following:

- (1) A description of the clinical pharmacology of naloxone.
- (2) Indications for use of naloxone as rescue therapy, including criteria for identifying persons eligible to receive naloxone under the protocol.
- (3) Precautions and contraindications concerning dispensing naloxone.
- (4) Assessment and follow-up actions by the pharmacist or pharmacy intern.
- (5) Naloxone products authorized to be dispensed, including name of product, dose, route of administration, required delivery device and directions for use.
- (6) Any patient instructions in addition to the counseling requirements in the rule.

Full text of the rule can also be accessed here: <http://codes.ohio.gov/oac/4729-5-39>

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

Yes. The Board has developed a sample protocol that can be used by pharmacies. The sample protocol



can be accessed here: [www.pharmacy.ohio.gov/naloxone](http://www.pharmacy.ohio.gov/naloxone)

**Q3) What type of naloxone can be dispensed pursuant to a physician-approved protocol?**

The law does not specify or limit the type of naloxone that can be dispensed pursuant to a physician approved protocol. However, the type of naloxone that may be dispensed is subject to the formulations specified 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 wholesale distributors with a valid Ohio license. 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 the pharmacy wholesaler, or obtained from point persons within the pharmacy corporation.

**Q5) 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.

**IMPORTANT:** The naloxone must be dispensed in the name of the person who is requesting it at the pharmacy.

**Q6) Why do I need to submit notification to the Board if my pharmacy dispenses naloxone pursuant to a protocol?**

Rule 4729-5-39 of the Ohio Administrative Code requires a pharmacy to submit notification to the Board within 30 days of establishing an approved protocol. The Board will use this documentation to create a list on its web site of all pharmacies that offer naloxone pursuant to a physician protocol in an effort to facilitate access to the medication. Please be advised, that a pharmacy that discontinues their protocol will also be required to notify the Board. The Naloxone Notification Form, including submission instructions, can be accessed here: [www.pharmacy.ohio.gov/naloxone](http://www.pharmacy.ohio.gov/naloxone).

**NOTE:** If you are a chain pharmacy that is planning to offer this service in a particular region or state-wide, please submit a spreadsheet of all participating pharmacies to: [contact@pharmacy.ohio.gov](mailto:contact@pharmacy.ohio.gov).

**Q7) Rule 4729-5-39 requires notification to the Board if dispensing naloxone pursuant to a physician authorized protocol. Does this apply if dispensing only to individuals being treated by a hospital or institutional facility?**

No. If the institutional pharmacy is only engaged in dispensing to patients upon discharge, then notification is not required pursuant to paragraph (I) of rule 4729-5-39.

**Q8) Can a pharmacist designate a trainee (such as a technician) to conduct the patient training?**

Yes. The terminal distributor and the pharmacy's responsible person are required to ensure that all pharmacist designees are appropriately trained on the use of naloxone and can meet the training requirements required in rule 4729-5-39.

**Q9) What are the patient training requirements prior to dispensing naloxone pursuant to a protocol?**

In addition to requirements specified in the protocol, rule 4729-5-39 requires a pharmacist, pharmacy intern under the direct supervision of a pharmacist, or a pharmacist's designee that is appropriately trained to provide the following in-person training and written educational materials to the individual to whom naloxone is dispensed:

- (1) Instructing the individual to whom naloxone is dispensed to summon emergency services as soon as practicable either before or after administering naloxone;
- (2) Risk factors of opioid overdose;
- (3) Strategies to prevent opioid overdose;
- (4) Signs of opioid overdose;
- (5) Steps in responding to an overdose;
- (6) Information on naloxone;
- (7) Procedures for administering naloxone;
- (8) Proper storage and expiration of naloxone product dispensed; and
- (9) Information on where to obtain a referral for substance abuse treatment.

All patient training shall be documented in accordance with rule [4729-5-27 of the Ohio Administrative Code](#).

**Q10) Is an offer to counsel the patient required if dispensing pursuant to a protocol?**

Yes. An offer to counsel is still required. However, the pharmacist or intern shall not be required to counsel a patient or caregiver, pursuant to rule 4729-5-22 of the Administrative Code, if the patient or caregiver refuses the offer of counseling or does not respond to the written offer to counsel.

**Q10) Is there written information available to assist pharmacists, pharmacy interns and pharmacist designees with meeting the training requirements?**

Yes. The Board has developed a [brochure](#) that covers all of the required training listed in OAC 4729-5-39. The Board has a printed supply of these brochures that can be requested by a pharmacy free-of-charge by sending a request with all of the following information to [contact@pharmacy.ohio.gov](mailto:contact@pharmacy.ohio.gov):

- Name of Requestor
- Pharmacy Name
- Mailing Address
- Phone Number
- Quantity Requested (there is a 250-brochure limit, but additional requests can be made if the pharmacy is running low)

*Please allow 7-10 days for delivery from the date of the request.*

The brochure is also available electronically (in English and Spanish) by visiting: [www.pharmacy.ohio.gov/naloxone](http://www.pharmacy.ohio.gov/naloxone)

**Q11) The law allows me to dispense 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

The pharmacist or pharmacy intern should use their professional judgement to determine if the person meets the requirement of the law.

**NOTE:** The naloxone must be dispensed in the name of the person who is requesting it at the pharmacy.

**Q12) What type of prescribers can authorize the protocol?**

Ohio licensed physicians must authorize the protocol. The law does not limit the number of protocols a physician may authorize, allowing a single physician to authorize a protocol for multiple pharmacy locations.

[Section 3707.56 of the Revised Code](#) also permits a local board of health, through a physician serving as the board's health commissioner or medical director, to authorize the protocol for pharmacists and pharmacy interns working in a county that includes all or part of the health district represented by the board

**Q13) Are there any protections for pharmacists, interns, physicians and boards of health in the law?**

Yes. A pharmacist, intern, physician or board of health, acting in good faith, is not liable for or subject to any of the following for any action or omission of the individual to whom the naloxone is dispensed: damages in any civil action, prosecution in any criminal proceeding, or professional disciplinary action.

**Q14) When does a protocol expire?**

The protocol should be reviewed and updated as necessary but does not expire. A pharmacy may discontinue a protocol at any time as long as proper notice is provided to the Board within 30 days (see Q6).

**Q15) Is there a limit to the amount of naloxone that can be dispensed pursuant to a protocol?**

A pharmacist or pharmacy intern should refer back to their protocol to determine if there are any established limits. If no such limits exist, they should exercise their professional judgement to determine if additional doses should be supplied.

**Q16) Are there record keeping and other requirements for pharmacists and pharmacy interns dispensing naloxone pursuant to a protocol?**

All laws and rules regarding the dispensing of drugs by a pharmacy would apply to naloxone dispensed pursuant to a protocol.

**Q17) 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.

**Q18) Are there any training resources available for pharmacists that dispense naloxone?**

Yes. A no-cost ACPE approved pharmacist continuing education course is available from Prescribe to Prevent and Boston University. It can be accessed here:  
<https://www.scopeofpain.org/supplemental-training/overdose-prevention-and-naloxone-rescue-kits-for-prescribers-and-pharmacists/>

**Q19) I am a pharmacy dispensing naloxone pursuant to a prescription? Do I need to comply with the requirements of rule 4729-5-39?**

No. The requirements in rule 4729-5-39 are only required for pharmacies that dispense naloxone pursuant to a physician approved protocol. It does not apply to pharmacies that provide naloxone pursuant to a prescription or an order by a licensed prescriber.

**Q20) Are there any age restrictions for dispensing naloxone pursuant to a protocol?**

Unless specified in the signed protocol, there are no restrictions on age for dispensing naloxone. A pharmacist must use their professional judgement to determine if a minor is sufficiently mature with respect to intellect and emotions to carry out all the responsibilities to effectively respond to a suspected overdose, including the administration of naloxone.

**Q21) I am a physician that will be authorizing several pharmacies to dispense naloxone pursuant to a protocol. Do I need to have a signed protocol for every pharmacy?**

No. The protocol issued by the physician can be signed once and include a list of all the authorized pharmacies. That protocol should then be copied and provided to all the participating pharmacies.