



Dispensing of Naloxone by Pharmacists and Pharmacy Interns without a Prescription

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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.

Section 3707.56 of the Ohio Revised Code 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 that board of health's jurisdiction.

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 an 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 physicians and pharmacies as their official protocol. The sample protocol can be accessed here: www.pharmacy.ohio.gov/naloxone

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

The type of naloxone that may be dispensed includes 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 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.

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.

Q6) Can I bill a patient's insurance for the atomizer needed for one of the intranasal formulas?

It may be difficult securing reimbursement for the atomizer needed for intranasal use. Currently, the atomizer lacks a National Drug Code or UPN, which are universal product identifiers typically used in insurance billing systems. Most likely, the pharmacy will have to charge the patient the cost of the atomizer if not covered by insurance.

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

Q7) Why do I need to submit notification to the Board if my pharmacy initiates a protocol to dispense naloxone without a prescription?

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 can be accessed here: 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 signed notification on company letterhead that includes a spreadsheet of all participating pharmacies to: contact@pharmacy.ohio.gov.

Q7.5) 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) How do I submit this required documentation?

Step 1: The pharmacy's responsible person completes the notification form, which can be accessed here: www.pharmacy.ohio.gov/naloxone

Step 2: Go to the general document submission page:
<http://www.pharmacy.ohio.gov/Licensing/GeneralDocumentUpload.aspx>

Step 3: When at the page, enter the following information:

- The pharmacy's TDDD license number.
- Select "Naloxone Notification Form" from the drop down menu.
- Include your e-mail address or addresses for confirmation of your submission.
- Indicate whether you are dispensing naloxone pursuant to OAC 4729-5-39 or you are no longer dispensing naloxone in accordance with the rule.
- Upload the form (.PDF only).

Step 4: Once all the information is entered and the Click the submit button.

This process is also used for notifying the Board that your pharmacy has discontinued the protocol.

NOTE: If you are a chain pharmacy that is planning to offer this service in a particular region or state-wide, please submit a signed notification on company letterhead that includes a spreadsheet of all participating pharmacies to: contact@pharmacy.ohio.gov.

Q8.5) 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 training requirements for a pharmacist, pharmacy intern or pharmacist's designee prior to dispensing naloxone pursuant to a protocol?

In addition to requirements specified in the protocol, OAC 4729-5-39 requires a pharmacist or pharmacy intern to provide written and verbal training on the following topics:

- (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](#).

Q9.5) 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.

In this situation, when counseling is refused, the pharmacist, intern or their designee shall ensure that such refusal is documented in the presence of the patient or the patient's caregiver.

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:

- Name of Requestor
- Pharmacy Name
- Mailing Address
- Phone Number
- Quantity Requested (there is a 250 pamphlet 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 pamphlet is also available electronically by visiting: 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.

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

Q12) 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 pharmacy locations.

The law 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 that board of health's jurisdiction.

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 the 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 Q7).

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

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

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

All laws and regulations 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:

http://www.opioidprescribing.com/naloxone_module_1-landing

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

No. The requirements for [OAC 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 a number of 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 of the participating pharmacies to be signed by the responsible person.