



Hospitals Providing Naloxone Upon Discharge

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Hospitals treating individuals who suffer from non-fatal opioid-related overdoses have an important opportunity to provide naloxone upon discharge. Providing naloxone can be an effective tool to prevent a fatal overdose, as data indicates that a [risk factor](#) for a fatal overdose includes individuals discharged from emergency medical care following opioid intoxication or poisoning.

This document provides guidance to hospitals seeking to provide naloxone to at-risk individuals upon discharge utilizing a physician approved protocol. The options presented in this document can be used in addition to, or in place of, prescribing or personally furnishing of naloxone by licensed Ohio prescribers.

For questions on this topic, please review the following guidance document. 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>.

This document is intended to serve as guidance and should not be construed as legal advice or legal opinion on specific facts or circumstances. You should contact your organization's legal department with respect to any particular issue or concern.

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Option 1: Personally Furnishing Pursuant to a Physician Approved Protocol

[Ohio law](#) (ORC 4731.941) permits a physician to authorize one or more individuals to personally furnish a supply of naloxone pursuant to a protocol to an individual who there is reason to believe is experiencing or at risk of experiencing an opioid-related overdose.

This allows any appropriately trained hospital staff (nurse, social worker, etc.) to personally furnish the drug to at-risk individuals prior to discharge. The following FAQ provides additional information regarding the use of a physician approved protocol to personally furnish naloxone.

What are the requirements of the protocol?

The protocol must include all of the following:

- (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.

Is the authorizing physician required to name specific individuals permitted to personally furnish naloxone?

The authorizing physician can identify specific individuals or may use broader categories that include reference to hospital staff (for example, appropriately trained social workers or use of internal hospital credentialing). Regardless of how "authorized individuals" are identified in the protocol, the hospital should have policies in place to ensure all of the following:

- (1) The authorized individual complies with the protocol established by the authorizing physician, including having completed the training required by the protocol.
- (2) The authorized individual instructs the individual to whom naloxone is furnished to summon emergency services as soon as practicable either before or after administering naloxone.

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/naloxoneprotocol.

Note: While the sample protocol includes a number of indications for the provision of naloxone, it is up to the authorizing physician to determine which of these categories is appropriate for individuals discharged from the hospital.

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.

Should the provision of naloxone be reserved only for individuals who are discharged following opioid intoxication or poisoning?

Such a determination is the responsibility of the physician authorizing the protocol. However, treatment or identification of other conditions that may be associated with opioid abuse (i.e. abscesses, HIV, endocarditis or hepatitis) may warrant the provision of naloxone upon discharge.

How do I store naloxone?

There are a number of options for storing naloxone that is personally furnished by hospital staff. It can be maintained in an automated medication dispensing system that is used by nurses and other individuals authorized by law to administer medications.

For individuals that do not have access to a dispensing system or where no such system is available, the naloxone can be stored a locked cabinet or drawer accessible to individuals authorized under the physician's protocol.

What are the record keeping requirements for personally furnishing naloxone pursuant to a protocol?

[Rule 4729-9-22](#) requires all records related to personally furnishing to contain a description of the kind and quantity of the drug provided, the name and address of the person to whom or for whose use the drug was personally furnished. These records can be kept in as separate log or can be entered as part of the patient's medical record. The rule also requires the positive identification of the person who personally furnished the

drug to the patient (this can easily be achieved through a manual wet-ink signature on the log).

What are the labeling requirements for personally furnishing naloxone pursuant to a protocol?

[Rule 4729-5-17](#) requires the following to be affixed to naloxone prior to personally furnishing the drug to the patient:

- (1) The name and address of the physician. This should be the name of the physician authorizing the protocol and the hospital address.
- (2) The name of the patient for whom the naloxone is intended.
- (3) Name and strength of the naloxone.
- (4) Directions for use; and
- (5) Date furnished.

These labels can be preprinted with the name and strength of the drug, name and address of the physician and directions for use. The staff personally furnishing the drug would be responsible for filling in the remainder of the information on the labels.

If personally furnishing naloxone pursuant to a protocol, is the physician required to conduct the final check of the drug?

No. [Rule 4729-5-17](#) permits the authorized individual personally furnishing naloxone pursuant to the protocol to do all of the following:

- Prepare, package and appropriately label the naloxone.
- Conduct the final check of the naloxone prior to personally furnishing on behalf of the physician.
- Keep and maintain all records in accordance with rule [4729-9-22](#) of the Administrative Code. The rule requires the positive identification of the person who personally furnished the drug to the patient (this can easily be achieved through a manual wet-ink signature on the log).
- Conduct patient counseling, including training on the use of naloxone, as specified in the physician protocol.

Do I need a patient-specific prescriber order to personally furnish naloxone?

No. While an order may be required to bill the patient's insurance for the naloxone, it is not necessary to personally furnish naloxone pursuant to a protocol. For the purposes of

compliance with Board of Pharmacy regulations, a protocol authorized pursuant to 4731.941 is considered a valid order.

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

It may be possible to bill a patient's insurance for the naloxone. It is recommended you contact your hospital's billing department for more information.

Is there written information available to assist with the training of patients?

Yes. The Board has developed a brochure (available in English and Spanish) 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

Copies of the patient counseling brochure are available free-of-charge from the Board by sending a request with all of the following information to contact@pharmacy.ohio.gov:

- Name of Requestor
- Hospital Name
- Mailing Address
- Phone Number
- Quantity Requested (there is a 250 pamphlet limit but additional requests can be made if the hospital is running low)

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

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/>

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

[ORC 4731.941](#) states that 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.

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

The type of naloxone that may be dispensed may include any or 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 \(Evizo intramuscular naloxone\)](#):

- 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.

Are there any substance abuse resources available?

It is recommended that the hospital provide substance abuse treatment resources and/or referrals to patients. You can get more information about such resources by [contacting your local treatment board](#).

The Ohio Department of Mental Health and Addiction Services (MHAS) has a listing of treatment resources that can be accessed here:
<http://mha.ohio.gov/Default.aspx?tabid=347>

MHAS also has a toll-free treatment referral line: 1-877-275-6364.

Option 2: Dispensing Naloxone from the Hospital Pharmacy Pursuant to a Protocol

Naloxone may also be dispensed by a hospital pharmacy for outpatient use [pursuant to a physician approved protocol](#). For example, if a patient is identified as meeting the criteria specified in the pharmacy's protocol, a hospital employee (nurse, social worker, etc.) can request naloxone be dispensed from the pharmacy in the patient's name.

Pursuant to [rule 4729-5-39](#), a pharmacist, pharmacist intern or a pharmacist's designee (which can be any appropriately trained hospital employee) can provide the required training to the patient. The pharmacist, intern or pharmacist's designee can provide the naloxone once dispensed by the hospital pharmacy. The following FAQ provides additional information regarding the use of a physician approved protocol to dispense naloxone.

NOTE: *This section does apply to the prescribing and dispensing of naloxone by a pharmacist acting pursuant to a [consult agreement](#). Nor does it apply to dispensing pursuant to a patient-specific prescriber order.*

What are the requirements for an approved protocol?

Unlike personally furnishing, the requirements for a pharmacy protocol are specified in [rule 4729-5-39](#).

According to the rule, a physician approved protocol for dispensing naloxone 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.

Is the authorizing physician required to name specific pharmacists or interns who are authorized to dispense naloxone pursuant to a protocol?

The authorizing physician can identify specific individuals or may use broader categories that include reference to hospital staff (for example, appropriately trained pharmacists and interns). Regardless of how “authorized individuals” are identified in the protocol, the hospital should have policies in place to ensure all of the following:

- (1) The authorized pharmacist/intern or pharmacist designee complies with the protocol established by the authorizing physician, including having completed the training required by the protocol.
- (2) The authorized pharmacist/intern or designee instructs the individual to whom naloxone is dispensed to summon emergency services as soon as practicable either before or after administering naloxone.

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/naloxoneprotocol.

Note: While the sample protocol includes a number of indications for the provision of naloxone, it is up to the authorizing physician to determine which of these categories is appropriate for individuals discharged from the hospital.

What training is required prior to the provision of naloxone pursuant to a physician protocol?

A pharmacist, pharmacy intern under the direct supervision of a pharmacist, or a pharmacist's designee that is appropriately trained shall personally provide in-person training and written educational materials to the individual to whom naloxone is dispensed, appropriate to the dosage form of naloxone dispensed, including, but not limited to, all of the following:

- (1) Risk factors of opioid overdose;
- (2) Strategies to prevent opioid overdose;
- (3) Signs of opioid overdose;
- (4) Steps in responding to an overdose;
- (5) Information on naloxone;
- (6) Procedures for administering naloxone;
- (7) Proper storage and expiration of naloxone product dispensed; and

(8) Information on where to obtain a referral for substance abuse treatment.

The hospital and the pharmacy's responsible person on their terminal distributor license shall ensure that all pharmacist designees are appropriately trained on the use of naloxone and can meet the training requirements listed above.

NOTE: A designee can be any hospital employee (nurse, social worker, etc.) and does not have to be limited to a pharmacy employee.

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.

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.

Should the provision of naloxone be reserved only for individuals who are discharged following opioid intoxication or poisoning?

Such a determination is the responsibility of the physician authorizing the protocol. However, treatment or identification of other conditions that may be associated with opioid abuse (i.e. abscesses, HIV, endocarditis or hepatitis) may warrant the provision of naloxone upon discharge.

What are the recordkeeping and other requirements for 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.

Note: All drugs dispensed for use by outpatients of an institutional facility shall be labeled in accordance with paragraphs (A), (B), and (C) of rule [4729-5-16](#) of the Administrative Code

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.

Rule 4729-5-39 requires notification to the Board of Pharmacy if dispensing naloxone pursuant to a physician authorized protocol. Does this apply if dispensing only to individuals being treated at a hospital?

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

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

It may be possible to bill a patient's insurance for the naloxone dispensed. It is recommended you contact your hospital's billing department for more information.

Please note: Pursuant to Ohio law, a pharmacist may document the dispensing of naloxone by the pharmacist or a pharmacy intern supervised by the pharmacist on a prescription form. The form may be assigned a number for record-keeping purposes.

Is there written information available to assist with the training of patients?

Yes. The Board has developed a brochure (in English and Spanish) that covers many of the typical training requirements for providing naloxone. The brochure is available electronically by visiting: www.pharmacy.ohio.gov/naloxone

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

Are there any protections in the law for physicians and pharmacists/interns authorized to dispense naloxone pursuant to a protocol?

Yes. A pharmacist, pharmacy intern, or physician, 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.

What type of naloxone can be dispensed pursuant to the physician approved protocol?

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[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.

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

Unless specified in the 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.

Are there any substance abuse resources available?

It is recommended that the hospital provide substance abuse treatment resources and/or referrals to patients. You can get more information about such resources by [contacting your local treatment board](#).

The Ohio Department of Mental Health and Addiction Services (MHAS) has a listing of treatment resources that can be accessed here:

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