Distribution of Overdose Reversal Drugs in Ohio

Updated 10/23/2023

To assist Ohioans in understanding laws governing the distribution of overdose reversal drugs (ORDs), the State of Ohio Board of Pharmacy developed this comprehensive guide. The guide is divided into sections based upon the type of entity engaged in the distribution of ORDs.

If you need additional information, the most expedient way to have your questions answered will be to e-mail the Board office by visiting: www.pharmacy.ohio.gov/contact.

IMPORTANT: The requirements listed in this guide DO NOT APPLY to overdose reversal drugs that have been approved for over-the-counter use. Rather, the requirements apply to ORDs that have not been approved for over-the-counter use by the FDA (e.g., usually requires a prescription).

REMINDER: The State of Ohio developed a dedicated website to order naloxone for personal and organizational use. For more information, please visit: www.naloxone.ohio.gov.

Section 1 – What is an Overdose Reversal Drug?

An overdose reversal drug (ORD) is defined in ORC 4729.01 as both of the following:

> (1) Naloxone;
>
> (2) Any other drug that the state board of pharmacy, through rules adopted in accordance with Chapter 119. of the Revised Code, designates as a drug that is approved by the U.S. Food and Drug administration for the reversal of a known or suspected opioid-related overdose.

Effective 10/31/23: Nalmefene (OPVEE®) was added as an overdose reversal drug per OAC 4729-8-01.

Manufacturers of FDA-approved overdose reversal drugs may submit a request for consideration to the Board by sending an email to: contact@pharmacy.ohio.gov.

IMPORTANT: The naloxone and nalfemene approved for distribution in Ohio are not limited to a specific formulation, brand, or method of delivery.

Section 2 – Liability Protections for Administration of an Overdose Reversal Drug

The liability protections for those administering an overdose reversal drug are now found in ORC 3715.504. This section specifically states:

> *(B) An individual who administers an overdose reversal drug under the authority conferred by division (A) of this section is not liable for damages in a civil action for injury, death, or loss to person or property for an act or omission that arises from administering the drug, and not subject to administrative action or criminal prosecution for an act or omission that arises from administering the drug, if the individual, acting in good faith, does all of the following:*
>
> *(1) Obtains the overdose reversal drug under section 3715.50, 3715.501, 3715.502, or 3715.503 or the Revised Code;*
>
> *(2) Administers the overdose reversal drug to an individual who is apparently experiencing an opioid-related overdose;*
>
> *(3) Attempts to summon emergency services as soon as practicable either before or after administering the overdose reversal drug, except that making such an attempt is not required if the individual administering the drug knows that emergency services already have been summoned or are present.*

Section 3 – Distributing Overdose Reversal Drugs without a Protocol

Ohio law (ORC 3715.50) permits **any** person or government entity to purchase, possess, personally furnish, and distribute an overdose reversal drug (ORD) without a prescriber-authorized protocol if all the following conditions are met:

(1) The overdose reversal drug is in its original manufacturer's packaging.

(2) The overdose reversal drug's packaging contains the manufacturer's instructions for use.

(3) The overdose reversal drug is stored in accordance with the manufacturer's or distributor's instructions.

To assist in the implementation of this law, the Board developed the following frequently asked questions:

Frequently Asked Questions - Distributing Overdose Reversal Drugs without a Protocol	
How does the law define a person?	The law permits a person or government entity to distribute an ORD without a prescriber approved protocol. A person is defined in ORC 3715.01 as follows: *"Person" means an individual, partnership, corporation, or association.*
Are there any legal protections for persons and government entities distributing ORDs?	Yes. ORC 3715.50 (D) states: *The person or government entity exercising the authority is not subject to administrative action or criminal prosecution and is not liable for damages in a civil action for injury, death, or loss to person or property for an act or omission that arises from exercising that authority.* *After an overdose reversal drug has been dispensed or personally furnished, the person or government entity is not liable for or subject to any of the following for any act or omission of the individual to whom the drug is dispensed or personally furnished: damages in any civil action, prosecution in any criminal proceeding, or professional disciplinary action.*
Does this law now permit me to treat an overdose reversal drug like an over-the-counter medication?	Yes, if the person, company, or government entity distributing overdose reversal drug meets the three requirements listed above. For example, pharmacies can now offer overdose reversal drug on store shelves rather than having it behind the pharmacy counter. However,

	pharmacies that are dispensing overdose reversal drug pursuant to a prescriber authorized protocol for insurance reimbursement should consult **Section 4** of this guide.
What type of overdose reversal drug can be distributed?	The law does not specify or limit the type of overdose reversal drug that can be distributed.
I am licensed as a terminal distributor of dangerous drugs. Is there a patient-specific record keeping requirement or labeling requirement for the distribution of overdose reversal drug in accordance with this section?	No. In February 2023, the Board adopted the following resolution: *The Board hereby suspends all patient-specific record keeping requirements of division 4729:5 of the Administrative Code for personally furnishing or selling overdose reversal drug from a site licensed as a terminal distributor of dangerous drugs.* Therefore, a terminal distributor engaged in the distribution of overdose reversal drug in accordance with this section is not required to maintain patient logs or apply patient-specific labels to the drug.
How does this law change impact Service Entities?	The law authorizing Service Entities is repealed effective 4/6/23. The service entity law was replaced with ORC 3715.50, which provides more expansive authority for overdose reversal drug distribution (and no longer requires a prescriber protocol). A previous Service Entity that still wishes to distribute via a prescriber protocol (for example, for insurance billing) may still do so if they comply with the requirements in **Section 5** of this guide.

Section 4 – Dispensing Overdose Reversal Drugs in a Pharmacy

Effective April 6, 2023, section 4729.44 will be officially renumbered to section 3715.502 of the Revised Code. This new section governs the ability of pharmacist and pharmacy interns to dispense overdose reversal drugs (ORDs) pursuant to a prescriber-authorized protocol.

IMPORTANT: If you are a pharmacy that was dispensing overdose reversal drugs pursuant to a prescriber-authorized protocol prior to 4/6/23, you will not have to modify your current processes.

NOTE: This section applies to the dispensing of ORDs pursuant to a prescriber-authorized protocol. Nothing in Ohio law prohibits the dispensing of an ORD pursuant to a patient-specific prescription.

The Board has developed a sample protocol that can be used by pharmacies. The sample protocol can be accessed here: www.pharmacy.ohio.gov/sample.

Additionally, pharmacies may distribute overdose reversal drug without meeting the requirements for dispensing (see **Section 3** of this guide). The ability to dispense pursuant to a prescriber-authorized protocol is maintained in the law to allow for insurance reimbursement by the pharmacy.

To assist pharmacists and pharmacy personnel, the Board developed the following frequently asked questions:

Frequently Asked Questions - Dispensing Overdose Reversal Drugs in a Pharmacy	
Who may authorize a pharmacy dispensing protocol?	Physician (MD/DO), Physician Assistant, Advance Practice Registered Nurse **NOTE:** Prior to April 6, 2023, only a physician was permitted to authorize a dispensing protocol.
Who is eligible to receive an overdose reversal drug pursuant to a pharmacy dispensing 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 individual in a position to assist an individual who there is reason to believe is at risk of experiencing an opioid-related overdose.
What are the requirements for the dispensing protocol?	(1) A description of the clinical pharmacology of the overdose reversal drug.

See: OAC 4729:1-3-04 (B)	(2) Indications for use of the overdose reversal drug as rescue therapy, including criteria for identifying persons eligible to receive overdose reversal drug under the protocol. (3) Precautions and contraindications concerning dispensing an overdose reversal drug. (4) Overdose reversal drugs authorized to be dispensed, including all of the following information: (a) Name of product; (b) Dose; (c) Route of administration and required delivery device; and (d) Directions for use. (5) Any patient instructions in addition to the required patient training.
Is there a requirement to instruct individuals receiving an ORD to summon emergency services?	Yes. A pharmacist or pharmacy intern who dispenses an overdose reversal drug under this section shall instruct the individual to whom the drug is dispensed to summon emergency services as soon as practicable either before or after administering the drug.
What type of overdose reversal drug can be dispensed pursuant to a prescriber-approved protocol?	The law does not specify or limit the type of overdose reversal drug that can be dispensed pursuant to an approved protocol. However, the type of overdose reversal drug that may be dispensed is subject to the formulations specified within the protocol. If new formulations are developed, they may be added to the protocol.
If I dispense overdose reversal drug, am I required to notify the Board?	Yes. OAC 4729:1-3-04 requires a pharmacy to submit notification to the Board within 30 days of establishing an approved protocol. The Board uses this documentation to create a list on its web site 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 Notification Form, including submission instructions, can be accessed here. **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.

	REMINDER: The notification requirement does not apply to institutional facilities that only provide ORDs upon discharge.
Can a pharmacist delegate the required training to a designee (such as a technician)?	Yes. The pharmacy is required to ensure that all pharmacist designees are appropriately trained on the use of overdose reversal drugs and can meet the training requirements.
What are the patient training requirements prior to dispensing an overdose reversal drug pursuant to a protocol? ***See: OAC 4729:1-3-04(D)***	In addition to requirements specified in the protocol, rule 4729:1-3-04 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 an overdose reversal drug is dispensed: (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 the overdose reversal drug dispensed; (6) Procedures for administering the overdose reversal drug dispensed; (7) Proper storage and expiration of the overdose reversal drug dispensed; and (8) Information on where to obtain a referral for substance abuse treatment. ***Additionally, the patient receiving overdose reversal drug must be instructed, either verbally or in writing, that emergency services must be summoned as soon as practicable before or after administering overdose reversal drug.***
When does a prescriber authorized protocol expire? ***See: OAC 4729:1-3-04(J)***	The protocols shall be renewed by on a biennial basis.
Is an offer to counsel the patient required if dispensing pursuant to a protocol?	Yes. An offer to counsel if still required. However, the pharmacist shall not be required to counsel a patient or caregiver pursuant to rule 4729:5-5-09 of the Administrative Code if the patient or caregiver refuses the offer of counseling or does not respond to the written offer to counsel.

Is there a limit to the amount of an overdose reversal drug that can be dispensed pursuant to a protocol?	A pharmacist or pharmacy intern should refer to their protocol to determine if there are any established limits. If no such limits exist, they should exercise their professional judgement.
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. The Board has a printed supply of these brochures that can be requested by a pharmacy free-of-charge by visiting: www.pharmacy.ohio.gov/NalBrochure The brochure is also available electronically (in the following languages: Nepali, Spanish, Somali, Arabic, and Simplified Chinese) by visiting: www.pharmacy.ohio.gov/naloxone
Are there any legal protections for pharmacists, interns, and authorizing prescribers?	Yes. ORC 3715.502 (E) states: *A physician, physician assistant, or advanced practice registered nurse who in good faith authorizes a pharmacist or pharmacy intern to dispense overdose reversal drugs without a prescription, as provided in this section, is not liable for or subject to any of the following for any act or omission of the individual to whom the drugs are dispensed: damages in any civil action, prosecution in any criminal proceeding, or professional disciplinary action.* *A pharmacist or pharmacy intern authorized under this section to dispense overdose reversal drugs without a prescription who does so in good faith is not liable for or subject to any of the following for any act or omission of the individual to whom the drugs are dispensed: damages in any civil action, prosecution in any criminal proceeding, or professional disciplinary action.*
Are there record keeping requirements for pharmacists and pharmacy interns dispensing an overdose reversal drug pursuant to a protocol?	All laws and rules regarding the dispensing of drugs by a pharmacy would apply to an ORD dispensed pursuant to a protocol.
Are there any age restrictions for dispensing an overdose reversal drug pursuant to a protocol?	Unless specified in the signed protocol, there are no restrictions on the age for dispensing an overdose reversal drug. 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 an ORD.
I am a prescriber that will be authorizing several pharmacies to dispense ORDs pursuant to a protocol. Do I need to have a signed protocol for every pharmacy?	No. The protocol issued by the prescriber can be signed once and include a list of all the authorized pharmacies. That protocol should then made available to all participating pharmacies.
Are there any substance abuse resources available to patients and their families?	The Ohio CareLine (1-800-720-9616) is a toll-free emotional support call service created by the Ohio Department of Mental Health and Addiction Services and administered in community settings. Behavioral health professionals staff the CareLine 24 hours a day, 7 days/week. They offer confidential support in times of personal or family crisis when individuals may be struggling to cope with challenges in their lives. When callers need additional services, they will receive assistance and connection to local providers.
I am a pharmacy dispensing overdose reversal drugs pursuant to a prescription. Do I need to comply with the requirements of OAC 4729:1-3-04?	No. The requirements in OAC 4729:1-3-04 are only for pharmacies that dispense overdose reversal drugs pursuant to a prescriber approved protocol. It does not apply to pharmacies that provide overdose reversal drug pursuant to a prescription or an order by a licensed prescriber.
Are there any additional training requirements for pharmacies that offer overdose reversal drugs without a prescription?	Yes. A pharmacy that has submitted notification of overdose reversal drug dispensing shall provide initial training to all new employees and annual training to existing employees on the availability of overdose reversal drugs dispensing pursuant to a protocol. Employees requiring training in accordance with this paragraph shall include pharmacists, pharmacy interns, certified pharmacy technicians, registered pharmacy technicians, pharmacy technician trainees, and support personnel, as defined in rule 4729:3-1-01 of the Administrative Code, that have direct contact with the public. Training documentation records shall be maintained for a period of three years and shall be made readily retrievable.

Does my pharmacy need to keep overdose reversal drugs on-site?	Yes. Except in the event of a drug shortage, a pharmacy that has submitted notification of overdose reversal drug dispensing shall ensure the drug is made available for patients who request it.
Do I need to comply with the standard record keeping requirements for dispensing a dangerous drug?	Yes. Any drug that is dispensed (even if dispensed via protocol) must comply with the Board's record keeping requirements for the dispensing of dangerous drugs.

Section 5 – Personally Furnishing Overdose Reversal Drugs via Prescriber Protocol

Previous sections of the Ohio Revised Code that governed the distribution of overdose reversal drug via a prescriber protocol have been consolidated into section 3715.503 of the Revised Code. This section governs the ability of lay persons to dispense ORDs pursuant to a prescriber-authorized protocol.

Please be advised that a protocol IS NOT REQUIRED for the distribution of naloxone and other ORDs (see Section 3). However, the ability to distribute via a prescriber protocol was retained in the law to allow for the billing of an overdose reversal drug via a patient's insurance. Facilities that previously considered themselves "Service Entities" are no longer required to distribute via a prescriber issued protocol (see Section 3).

To assist those seeking to distribute overdose reversal drugs in accordance with a prescriber protocol, the Board developed the following frequently asked questions:

Frequently Asked Questions - Personally Furnishing Overdose Reversal Drugs via Prescriber Protocol	
Who may authorize a protocol to personally furnish an ORD?	Physician (MD/DO), Physician Assistant, Advance Practice Registered Nurse
Who is eligible to receive an ORD pursuant to a prescribe authorized protocol?	The law provides no specifics. The eligibility criteria should be established in the protocol.
What are the requirements for a protocol to personally furnish an ORD? ***See: ORC 3715.503 (B)***	A protocol established by a physician, physician assistant, or advanced practice registered nurse for purposes of this section shall include all of the following: (1) Any limitations to be applied concerning the individuals to whom the overdose reversal drug may be personally furnished; (2) The overdose reversal drug dosage that may be personally furnished and any variation in the dosage based on circumstances specified in the protocol; (3) Any labeling, storage, recordkeeping, and administrative requirements;

	(4) Training requirements that must be met before a person will be authorized to personally furnish overdose reversal drugs; (5) Any instructions or training that the authorized person must provide to an individual to whom an overdose reversal drug is personally furnished.
Is there a requirement to instruct individuals receiving an ORD to summon emergency services?	Not specifically. However, the immunity protections in ORC 3715.504 for those administering an ORD are contingent on the summoning of emergency services. Therefore, it is strongly recommended. (See **Section 2** for Liability Protections)
What type of overdose reversal drugs can be personally furnished pursuant to a prescriber-approved protocol?	The law does not specify or limit the type of overdose reversal drug that can be personally furnished pursuant to an approved protocol. However, the type of overdose reversal drug that may be dispensed is subject to the formulations specified within the protocol. If new formulations are developed, they may be added to the protocol.
What are the patient training requirements prior to personally furnishing overdose reversal drugs pursuant to a protocol?	There are no specific training requirements. Rather, the law requires the authorizing prescriber to establish those requirements in the protocol.
When does a prescriber authorized protocol expire?	The law does not require the protocols to be renewed once they have been authorized.
Are there any legal protections for authorizing prescribers?	Yes. ORC 3715.503 (C) states: *A physician, physician assistant, or advanced practice registered nurse who in good faith authorizes an individual to personally furnish a supply of an overdose reversal drug in accordance with a protocol established under this section, and an individual who in good faith personally furnishes a supply under that authority, is not liable for or subject to any of the following for any act or omission of the individual to whom the overdose reversal drug is personally furnished: damages in any civil action, prosecution in any criminal proceeding, or professional disciplinary action.*

Is there a patient-specific record keeping requirement or labeling requirement for lay distributors personally furnishing pursuant to a protocol?	No. There is no requirement in the law. Additionally, the Board issued the following resolution for licensed terminal distributors of dangerous drugs that are personally furnishing overdose reversal drugs in accordance with a prescriber protocol: *The Board hereby suspends all patient-specific record keeping requirements of division 4729:5 of the Administrative Code for personally furnishing or selling an overdose reversal drug from a site licensed as a terminal distributor of dangerous drugs.* Therefore, a terminal distributor distributing an ORD in accordance with this section is not required to maintain patient logs or apply patient-specific labels to the drug.
Are there any age restrictions for dispensing an overdose reversal drug pursuant to a protocol?	Unless specified in the signed protocol, there are no age restrictions.
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 an overdose reversal drug to laypersons. The brochure is available electronically by visiting: www.pharmacy.ohio.gov/naloxone. Additionally, the Ohio Department of Health's Project DAWN Program has several training resources available.
Are there any substance abuse resources available to patients and their families?	The Ohio CareLine (1-800-720-9616) is a toll-free emotional support call service created by the Ohio Department of Mental Health and Addiction Services and administered in community settings. Behavioral health professionals staff the CareLine 24 hours a day, 7 days/week. They offer confidential support in times of personal or family crisis when individuals may be struggling to cope with challenges in their lives. When callers need additional services, they will receive assistance and connection to local providers.

Section 6 – Overdose Reversal Drugs for Emergency Use (Naloxboxes)

Section 3715.50 of the Revised Code permits any person or government entity to obtain and maintain a supply of an overdose reversal drug for use in an emergency. Prior to April 6, 2023, only a licensed terminal distributor of dangerous drugs could obtain and maintain a supply of an overdose reversal drug for use in an emergency.

To assist in the implementation of this law, the Board developed the following frequently asked questions:

Frequently Asked Questions - Overdose Reversal Drugs for Emergency Use	
How does the law define a person?	The law permits a person or government entity to obtain and maintain a supply of an overdose reversal drug for use in an emergency. A person is defined in ORC 3715.01 as follows: *"Person" means an individual, partnership, corporation, or association.*
What are the requirements for obtaining and maintaining an ORD for emergency use? ***See: ORC 3715.50 (C)***	In the case of a supply of an overdose reversal drug obtained and maintained for use in an emergency situation, a person or government entity shall do all of the following: (1) Provide to any individual who accesses the drug instructions regarding emergency administration of the drug, including a specific instruction to summon emergency services as necessary; (2) Establish a process for replacing within a reasonable time period any overdose reversal drug that has been accessed; (3) Store the overdose reversal drug in accordance with the manufacturer's or distributor's instructions. **NOTE:** It is up to the person or government entity to determine a reasonable time period for replacing an ORD that has been accessed.
Are there any legal protections for persons and government entities maintaining ORDs for emergency use?	Yes. ORC 3715.50 (D) states: *The person or government entity exercising the authority is not subject to administrative action or criminal prosecution and is not liable for damages in a civil action for injury, death, or loss to person or property for an act or omission that arises from exercising that authority.*

	After an overdose reversal drug has been dispensed or personally furnished, the person or government entity is not liable for or subject to any of the following for any act or omission of the individual to whom the drug is dispensed or personally furnished: damages in any civil action, prosecution in any criminal proceeding, or professional disciplinary action.
What type of overdose reversal drug can be maintained for emergency use?	The law does not specify or limit the type of overdose reversal drug that can be distributed.
Do I need a prescriber protocol or prescription to access and use the emergency overdose reversal drug?	No. Section 3715.50 of the Revised Code does not require a prescriber protocol or prescription to access and use the emergency overdose reversal drug.
I obtained a terminal distributor of dangerous drugs license from the Board of Pharmacy to maintain overdose reversal drugs for emergency use. Do I need to maintain my license?	If you obtained a terminal distributor of dangerous drugs license for the **sole purpose** of maintaining overdose reversal drugs for emergency use, then you may discontinue your license. To do so, please following the instructions on this form: www.pharmacy.ohio.gov/DCB.

Section 7 – Vending Machines for Overdose Reversal Drugs

Section 3715.50 of the Revised Code permits any person or government entity to obtain and maintain a supply of an overdose reversal drug for distribution through an automated mechanism (e.g., a vending machine). Prior to April 6, 2023, only a licensed terminal distributor of dangerous drugs could distribute an overdose reversal drug through an automated mechanism.

To assist in the implementation of this law, the Board developed the following frequently asked questions:

Frequently Asked Questions - Vending Machines for Overdose Reversal Drugs	
How does the law define a person?	The law permits a person or government entity to obtain and maintain a supply of an overdose reversal drug for distribution through an automated mechanism. A person is defined in ORC 3715.01 as follows: *"Person" means an individual, partnership, corporation, or association.*
What are the requirements for distribution of an ORD through an automated mechanism? ***See: ORC 3715.50 (C)***	In the case of a supply of an overdose reversal drug obtained and maintained for distribution through an automated mechanism, a person or government entity shall do all of the following: (1) Ensure that the mechanism is securely fastened to a permanent structure or is of an appropriate size and weight to reasonably prevent it from being removed from its intended location; (2) Provide to any individual who accesses the drug instructions regarding emergency administration of the drug, including a specific instruction to summon emergency services as necessary; (3) Develop a process for monitoring and replenishing the supply maintained in the automated mechanism; (4) Store the overdose reversal drug in accordance with the manufacturer's or distributor's instructions.
Are there any legal protections for persons and government entities distributing	Yes. ORC 3715.50 (D) states: *The person or government entity exercising the authority is not subject to administrative action or criminal prosecution and is not liable for damages in a civil action for injury,*

ORDs through an automated mechanism?	*death, or loss to person or property for an act or omission that arises from exercising that authority.* *After an overdose reversal drug has been dispensed or personally furnished, the person or government entity is not liable for or subject to any of the following for any act or omission of the individual to whom the drug is dispensed or personally furnished: damages in any civil action, prosecution in any criminal proceeding, or professional disciplinary action.*
What type of overdose reversal drug can be provided via automated mechanism?	The law does not specify or limit the type of overdose reversal drug that can be distributed.
Do I need a prescriber protocol or prescription to access an overdose reversal drug via an automated mechanism?	No. Section 3715.50 of the Revised Code does not require a prescriber protocol or prescription to distribute an overdose reversal drug through an automated mechanism.
I obtained a terminal distributor of dangerous drugs license from the Board of Pharmacy to install an automated mechanism. Do I need to maintain my license?	If you obtained a terminal distributor of dangerous drugs license for the **sole purpose** of distributing overdose reversal drugs, then you may discontinue your license. To do so, please following the instructions on this form: www.pharmacy.ohio.gov/DCB.