



Administration and Community Distribution of Naloxone by Service Entity Personnel

Updated 9/23/2020

On September 16, 2020, Governor Mike DeWine signed [HB 341](#) (133rd General Assembly) into law. This act exempts specific locations, known as “service entities,” that personally furnish naloxone (i.e. engage in community distribution) pursuant to a valid protocol from Board of Pharmacy licensure requirements.

To reduce any potential barriers to service entities obtaining naloxone between the signing of the law and its effective date (12/16/2020), the Board of Pharmacy has issued the following resolution:

To promote expanded access to naloxone, the State of Ohio Board of Pharmacy hereby waives the terminal distributor of dangerous drug licensure requirements for service entities that personally furnish naloxone in accordance with a valid physician-approved protocol. This resolution shall go into effect upon the Governor's signature of HB 341 (133rd General Assembly) and will expire upon the effective date of the act. This resolution does not waive any other licensure requirements to possess dangerous drugs in accordance with Chapter 4729. of the Revised Code. This resolution is being issued in accordance with a Board resolution adopted on May 4, 2020.

[Ohio law](#) and Board of Pharmacy resolution now permit naloxone to be available for administration and personally furnishing at service entities without requiring licensure as a terminal distributor of dangerous drugs (TDDD). [**NOTE:** Prior to this change, service entities were only exempted from Board of Pharmacy licensure if they stored naloxone for emergency administration.]

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>.



Q1) How is a service entity defined?

[Ohio law](#) and Board of Pharmacy resolution now permit naloxone to be available for administration and personally furnishing at service entities without requiring licensure as a terminal distributor of dangerous drugs (TDDD). [**NOTE:** Prior to this change, service entities were only exempted from Board of Pharmacy licensure if they stored naloxone for emergency administration.]

"Service entity" is defined in law as a public or private entity that may provide services to or interact with individuals who there is reason to believe may be at risk of experiencing an opioid-related overdose. "Service entity" includes a church or other place of worship, college or university, school, library, health department operated by the board of health of a city or general health district, community addiction services provider, court, probation department, halfway house, prison, jail, community residential center, homeless shelter, or similar entity.

IMPORTANT: Any location providing community distribution of naloxone (i.e. engaged in personally furnishing – such as a [Project DAWN site](#)) pursuant to a valid protocol (see [guidance](#)) is considered a service entity.

Q2) Are service entities required to obtain a terminal distributor of dangerous drugs license to purchase, possess, administer, or personally furnish naloxone?

No. [Ohio law](#) and Board of Pharmacy resolution exempts service entities from having to obtain licensure by the Board as a terminal distributors of dangerous drugs.

Please note that this exemption does not apply in any of the following scenarios:

1. A service entity that maintains a stock of prescription drugs, other than naloxone, on-site for distribution or administration.
2. Additionally, [HB 341](#) authorizes a terminal distributor, subject to Board rules, to acquire a supply of naloxone and to maintain the supply at an alternative location to use in emergency situations and/or to distribute through an automated mechanism. Locations interested in distributing via automated mechanisms or maintaining an off-site supply for emergency administration (like an AED) will still be required to hold a license as a terminal distributor of dangerous drugs. In the coming weeks, the Board will be issuing draft rules on this topic for public comment. It is the Board's intention to have the rules final close to the effective date of the legislation (12/16/2020). [Click here](#) to subscribe to Board of Pharmacy rule updates.

Q3) How does a service entity become authorized to administer naloxone?

To be eligible to administer naloxone at a service entity, a physician or board of health must establish a written protocol for administering naloxone. In the case of a board of health, the protocol must be established through a physician acting as the board's health commissioner or medical director. The protocol must include the following:

1. A description of the clinical pharmacology of naloxone;
2. Precautions and contraindications concerning the administration of naloxone;
3. Any limitations concerning the individuals to whom naloxone may be administered;
4. The naloxone dosage that may be administered 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 can be authorized to administer naloxone.

The law permits an employee, volunteer, or contractor of a service entity to administer naloxone pursuant to a physician-approved protocol. A sample administration protocol is available here: www.pharmacy.ohio.gov/serviceprotocol

IMPORTANT: [The law](#) requires an authorized service entity employee, volunteer, or contractor to obtain the naloxone from the service entity, comply with the protocol, and summon emergency services as soon as practicable.

NOTE: Effective 12/16/2020, [HB 341](#) (ORC 4723.485, 4723.486, 4730.435, and 4730.436) authorizes clinical nurse specialists, certified nurse-midwives, certified nurse practitioners (collectively “APRNs”) and physician assistants to develop and authorize protocols to both administer and personally furnish naloxone.

Q4) How does a service entity become authorized to personally furnish naloxone (i.e. engage in community distribution)?

To be eligible to personally furnish naloxone at a service entity, a prescriber or board of health must establish a written protocol for personally furnishing naloxone. For more information on personally furnishing naloxone in accordance with a prescriber protocol visit: www.pharmacy.ohio.gov/naloxonePF.

Q5) How often does the protocol have to be renewed or reviewed?

There is no requirement in the law indicating when the protocol for naloxone administration or personally furnishing must be renewed or reviewed.

Q6) I am a service entity that also personally furnishes (i.e. engaged in community distribution) of naloxone. Is there any reason to keep my current terminal distributor license?

This answer depends. [Ohio law](#) and Board of Pharmacy resolution no longer require a service entity that personally furnishes naloxone to obtain a terminal distributor of dangerous drugs license. **However, this exemption does not apply in any of the following scenarios:**

1. A service entity that stores other prescription drugs (referred to in Ohio law as “dangerous drugs”).
2. Additionally, [HB 341](#) authorizes a terminal distributor, subject to Board rules, to acquire a supply of naloxone, and to maintain the supply at an alternative location, to use in emergency situations and to distribute through an automated mechanism. Locations interested in distributing via automated mechanisms will still be required to maintain licensure as a terminal distributor of dangerous drugs. In the coming weeks, the Board will be issuing draft rules on naloxone automated mechanisms for public comment.

Q7) I am a service entity that obtained a terminal distributor license to personally furnish naloxone prior to the recent law change. Should I discontinue my license with the Board of Pharmacy?

Service entities that no longer require a terminal distributor of dangerous drugs license can either:

- A service entity may discontinue their license by submitting a [discontinuation of business form](#); or
- A service entity may opt to not renew the entity’s license during the next renewal period that will begin in January 2021 and end on March 31, 2021.

As a reminder, exemptions for service entities do not apply for any of the following:

1. A service entity that stores other prescription drugs (referred to in Ohio law as “dangerous drugs”).
3. Additionally, [HB 341](#) authorizes a terminal distributor, subject to Board rules, to acquire a supply of naloxone and to maintain the supply at an alternative location to use in emergency situations and/or to distribute through an automated mechanism. Locations interested in distributing via automated mechanisms or maintaining an off-site supply for emergency administration (like an AED) will still be required to hold a license as a terminal distributor of dangerous drugs. In the coming weeks, the Board will be issuing draft rules on this topic for public comment. It is the Board’s intention to have the rules final close to the effective date of the legislation (12/16/2020). [Click here](#) to subscribe to Board of Pharmacy rule updates.

IMPORANT: Please be advised that if a facility maintains a terminal distributor of dangerous drugs license it is subject to all applicable record keeping, labeling, and other requirements associated with licensure. For more information on these requirements, licensees should review their applicable inspection guide available on the Board’s terminal distributor licensing page: <https://www.pharmacy.ohio.gov/Licensing/TDDD.aspx>

Q8) How do I obtain naloxone for my service entity?

Naloxone can be obtained using any of the following methods:

Wholesale Purchase: Naloxone can be obtained from a wholesaler or other drug distributor that is licensed by the State of Ohio Board of Pharmacy. To verify a wholesaler or drug distributor is licensed in Ohio, visit: www.pharmacy.ohio.gov/licenselookup

Purchase from a Pharmacy: The State of Ohio Board of Pharmacy permits a pharmacy licensed as a terminal distributor dangerous drugs to conduct an occasional sale of drugs at wholesale. There are no restrictions or limitations on the amount that can be provided by a pharmacy pursuant to rule [4729:5-3-09](#) of the Administrative Code.

The Ohio Department of Mental Health and Addiction Services operates Ohio Pharmacy Services, which sells naloxone kits. To contact Ohio Pharmacy Services, please call: 1-888-471-5632

Purchase from another TDDD: The State of Ohio Board of Pharmacy permits any entity licensed as a terminal distributor dangerous drugs to provide naloxone at wholesale. There are no restrictions on the amount that can be provided/sold by a terminal distributor. Please be advised that the terminal distributor must properly document the transaction (even if the health department is donating the naloxone).

IMPORTANT:

Per Board of Pharmacy rules, a service entity that is exempted from licensure may purchase naloxone from a wholesaler, drug distributor, or terminal distributor if the service entity attests in writing, which may include an electronic signature, that the person meets the licensing exemptions in section [4729.541](#) of the Revised Code on an annual basis.

To assist service entities in providing this documentation, the Board has developed a [Service Entity Attestation Form](#). Please be advised that this a suggested form and that the service entity may have to submit different or additional documentation based upon the policies of the seller.