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H.B. 341*
133rd General Assembly

Bill Analysis

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Version: As Reported by Senate Health, Human Services and Medicaid

Primary Sponsor: Rep. Ginter

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SUMMARY

- Authorizes a pharmacist to administer by injection any long-acting or extended-release addiction treatment drug prescribed by a physician, instead of limiting the pharmacist's authority to the administration of opioid antagonists as under current law.
- Exempts from State Board of Pharmacy office-based opioid treatment licensure requirements those facilities in which addiction treatment drugs are administered only on-site and directly by prescribers, rather than off-site by patients.
- Provides that a patient whose addiction treatment drugs are administered on-site directly by a prescriber is not to be counted when determining whether a facility offering office-based opioid treatment is required to be licensed by the Board.
- Authorizes the Board to provide information from its Ohio Automated Rx Reporting System (OARRS) to a prescriber or pharmacist participating in a prescription monitoring program operated by a federal agency if certain conditions are met.
- Expands and clarifies the Board's exemption from the open meetings requirement as related to certain actions the Board may take without a prior hearing.
- Exempts from licensure as a terminal distributor of dangerous drugs a service entity that possess naloxone in order to permit an employee, volunteer, or contractor to personally furnish a supply of naloxone pursuant to a protocol established by a prescriber or board of health.

* This analysis was prepared before the report of the Senate Health, Human Services and Medicaid Committee appeared in the Senate Journal. Note that the legislative history may be incomplete.

- Authorizes a terminal distributor 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.
- Authorizes any person to access naloxone maintained by a terminal distributor and to administer it to an individual who appears to be experiencing an opioid-related overdose.
- Authorizes certain advanced practice registered nurses and physician assistants to develop protocols to permit individuals and employees of service entities to personally furnish or administer naloxone.
- Specifies that a family member, friend, or other individual who assists an individual who is experiencing an opioid-related overdose is not liable for damages in a civil action related to providing that assistance.

DETAILED ANALYSIS

Pharmacist authority to administer addiction treatment drugs by injection

Current law permits a pharmacist meeting specified conditions to administer by injection certain drugs, including long-acting or extended-release opioid antagonists used to treat drug addiction. The bill extends to the pharmacist authority to administer any injectable long-acting or extended-release addiction treatment drug, not just opioid antagonists as under existing law.[1]

Types of drugs prescribed to treat opioid addiction

According to the National Institute on Drug Abuse, there are effective medications to treat opioid use disorders.[2] These include opioid antagonists and agonists. An opioid antagonist is a drug, like naltrexone, that blocks the activation of opioid receptors in the brain. It treats opioid use disorder by preventing any opioid drug from producing rewarding effects such as euphoria.

Opioid agonists occupy and activate the brain's opioid receptors, eliminating withdrawal symptoms and relieving drug cravings. There are two types of agonists – full and partial. Methadone is an example of a full agonist, a slow-acting opioid that binds fully to the opioid

[1] R.C. 4729.45(B)(1)(a).

[2] *See* https://www.drugabuse.gov/publications/research-reports/medications-to-treat-opioid-addiction/overview.

receptor, while buprenorphine is a partial agonist, meaning it binds to the same receptors but activates them less strongly than full agonists do.[3]

At present, the only addiction treatment drugs available for administration by injection are Vivitrol, a long-acting form of naltrexone (an opioid antagonist)[4] and Sublocade, an injectable form of buprenorphine (a partial agonist) which was approved by the United States Food and Drug Administration in 2017.[5]

Conditions on pharmacist administration by injection generally

Under existing law maintained by the bill, a pharmacist may administer to an individual a drug by injection if it is prescribed by a physician and the physician has an ongoing physician-patient relationship with the individual.

The bill retains other current law requirements governing injections by a pharmacist, including that the pharmacist follow a protocol established by a physician, complete certain education in the administration of drugs, obtain the individual's permission before administering a drug, observe the individual for any adverse reactions, and notify the prescribing physician of the administration.[6] With respect to an addiction treatment drug administered by injection, the pharmacist also may order blood or urine testing to determine whether it is appropriate to administer the drug.[7]

Office-based opioid treatment

Current law defines "office-based opioid treatment" as the treatment of opioid dependence or addiction using a controlled substance.[8] Subject to several exemptions, a facility, clinic, or other location where a prescriber provides office-based opioid treatment to more than 30 patients must hold a category III terminal distributor of dangerous drugs license with an office-based opioid treatment classification issued by the State Board of Pharmacy.[9]

The bill exempts from this licensure requirement a facility in which both of the following apply:

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[3] *See* https://www.drugabuse.gov/publications/research-reports/medications-to-treat-opioid-addiction/how-do-medications-to-treat-opioid-addiction-work.

[4] *See* https://www.vivitrol.com/opioid-dependence/what-is-vivitrol.

[5] *FDA approves first once-monthly buprenorphine injection, a medication-assisted treatment option for opioid use disorder*, United States Food and Drug Administration, November 30, 2017, available at https://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm587312.htm.

[6] R.C. 4729.45(C), (D), and (F).

[7] R.C. 4729.45(D) and (E).

[8] R.C. 4729.553(A)(4).

[9] R.C. 4729.553(B)(1).

1. Patients are treated on-site for opioid dependence or addiction exclusively through direct administration of addiction treatment drugs by the following prescribers – physicians, physician assistants, or advanced practice registered nurses; and
2. Addiction treatment drugs are neither dispensed nor personally furnished to patients for self-administration off-site.[10]

The bill also specifies that patients who receive treatment on-site for opioid dependence or addiction by this direct administration of drugs are not to be included when determining whether a prescriber is providing office-based opioid treatment to more than 30 patients at a particular location.[11]

Locations currently exempt from office-based opioid treatment licensure include (1) hospitals and hospital-operated facilities and practices, (2) clinical research facilities, (3) federally regulated opioid treatment programs, and (4) programs and facilities licensed or certified by the Department of Mental Health and Addiction Services.[12] The bill maintains these exemptions.

OARRS access and federal monitoring programs

Existing law authorizes the Board of Pharmacy to establish a drug database to monitor the misuse and diversion of medical marijuana, controlled substances, naltrexone, and other prescription drugs.[13] The Board's database, known as OARRS, provides information about drug use to prescribers, pharmacists, and others.

In addition to the OARRS information the Board is authorized or required under current law to provide, the bill authorizes the Board to provide information requested by a prescriber or pharmacist from, or participating in, a prescription drug monitoring program operated by a federal agency. The Board may provide this information only if both of the following apply:

- The Board has approved the federal agency's prescription drug monitoring program;
- There is a written agreement between the Board and agency under which the information is to be used and disseminated according to Ohio law.[14]

Note that H.B. 166, the biennial budget bill enacted by the 133rd General Assembly, included this authority, but the Governor vetoed those provisions.[15]

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[10] R.C. 4729.553(B)(2)(i).

[11] R.C. 4729.553(B)(3).

[12] R.C. 4729.553(B)(2).

[13] R.C. 4729.75.

[14] R.C. 4729.80.

[15] *See* https://www.legislature.ohio.gov/download?key=12387&format=pdf.

Open meetings exemption

The bill expands and clarifies the Board's current exemption from open meetings requirements. Under current law, open meetings requirements do not apply to the Board when utilizing a telephone conference call to determine whether to suspend a license, certificate, or evidence of registration without a prior hearing because a person's professional practice or use of controlled substances or other dangerous drugs presents a danger of immediate and serious harm to others.[16] The bill instead specifies that the exemption applies when the Board is determining whether to suspend a license, certification, or registration without a prior hearing, including through a telephone conference, under any provision in the laws governing controlled substances, the practice of pharmacy, medical marijuana, or home medical services. It also makes the exemption applicable when the Board determines whether to restrict a person from obtaining further information from OARRS without a prior hearing.

Naloxone access

Service entities

The bill modifies current law related to a service entity's procurement of naloxone. A "service entity," as defined in current law, is a public or private entity that may provide services to individuals at risk of experiencing an opioid-related overdose, including churches, schools, prisons, homeless shelters, and similar entities. The bill specifies that a service entity may also interact with individuals at risk of overdosing (it does not have to provide services as stated under current law). It further specifies that libraries are service entities.[17]

Under current law, service entities are exempt from licensure as a terminal distributor of dangerous drugs when naloxone is possessed for use in an emergency, but not with respect to personally furnishing a supply. The bill expressly specifies that a service entity may maintain a supply of naloxone and permit its employees, volunteers, and contractors to personally furnish a supply of naloxone pursuant to a protocol (see "**APRN and PA naloxone protocol**" below).[18] It also exempts service entities from licensure as a terminal distributor when personally furnishing supplies of naloxone.[19]

The bill extends existing qualified immunities for service entities to personally furnishing naloxone.[20]

[16] R.C. 121.22(D)(8); see also R.C. 4729.16 and 3719.121, not in the bill.

[17] R.C. 4729.514(A).

[18] R.C. 4729.514(B).

[19] R.C. 4729.541(A)(12).

[20] R.C. 4729.514(C).

Terminal distributor maintenance of naloxone supply

The bill authorizes a terminal distributor to acquire and maintain, including at a location other than the location licensed as a terminal distributor, a supply of naloxone for use in emergency situations and for distribution through an automated mechanism.[21] Individuals may access emergency naloxone supplies, or receive naloxone through an automated system, and administer it to an individual at risk of experiencing an opioid-related overdose.[22] An individual who does so must make a good faith effort to activate emergency medical services as soon as possible unless the individual who administers the naloxone is part of an emergency medical services system or is at a hospital.[23]

Naloxone for use in emergency situations

A terminal distributor that maintains naloxone for use in emergency situations is required by the bill to do all of the following:[24]

1. Provide instructions regarding emergency administration to any individual who accesses the naloxone, including an instruction to summon emergency services;
2. Specify a process to be used to notify the terminal distributor that the naloxone has been accessed within a reasonable time of it being accessed;
3. Maintain the naloxone in accordance with manufacturer or distributor instructions.

Naloxone for distribution through an automated mechanism

The bill requires that in the case of naloxone for distribution through an automated mechanism, a terminal distributor must comply with standards and procedures specified in rules that the bill requires the Board to adopt. The rules must be adopted in accordance with the Administrative Procedure Act.[25]

Qualified immunity

The bill specifies that an individual is not liable for or subject to damages in a civil action, prosecution in a criminal proceeding, or professional disciplinary action related to injury, death, or loss to person or property allegedly arising from any action associated with accessing emergency naloxone supplies, receiving naloxone through an automated system, or administering it to an individual at risk of experiencing an opioid-related overdose.[26]

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[21] R.C. 4729.515(A).

[22] R.C. 4729.515(D)(1).

[23] R.C. 4729.515(D)(2).

[24] R.C. 4729.515(B).

[25] R.C. 4729.515(C) and (F).

[26] R.C. 4729.515(E).

APRN and PA naloxone protocol

The bill permits, subject to the same conditions as in current law for physicians,[27] clinical nurse specialists, certified nurse-midwives, certified nurse practitioners (collectively "APRNs") and physician assistants to develop protocols to permit individuals and employees, volunteers, and contractors of service entities to personally furnish or administer naloxone to individuals at risk of experiencing opioid-related overdoses, and to family and friends of such individuals. As under current law for physicians, the protocol must be in writing and include various provisions such as the naloxone dosage and training requirements.

APRNs, physician assistants, and individuals authorized to personally furnish naloxone pursuant to a protocol have qualified immunity from civil liability, criminal prosecution, and professional disciplinary action related to the provisions described above.[28]

Civil liability protection for layperson naloxone administration

The bill specifies that a family member, friend, or other individual who, as authorized by current law, assists an individual who is experiencing an opioid-related overdose is not liable for damages in a civil action related to providing that assistance. Under current law, such individuals are not subject to criminal prosecution, but immunity from civil liability is not expressly provided. As conditions to immunity, both for the existing criminal prosecution immunity and the bill's civil liability immunity, the individual must act in good faith and obtain the naloxone through a channel authorized by Ohio law, administer it to an individual who is apparently experiencing an opioid-related overdose, and attempt to summon emergency services as soon as practicable.[29]

HISTORY

Action	Date
Introduced	09-23-19
Reported, H. Health	01-15-20
Passed House (96-0)	02-12-20
Reported, S. Health, Human Services & Medicaid	---

H0341-RS-133/ts

[27] R.C. 4731.941 and 4731.943, not in the bill.

[28] R.C. 4723.485, 4723.486, 4730.435, and 4730.436; technical renumbering of other sections and related conforming changes.

[29] R.C. 2925.61(B).