OHIO LEGISLATIVE SERVICE COMMISSION

Bill Analysis Elizabeth Molnar

Sub. S.B. 119*

132nd General Assembly
(As Reported by H. Health)

Sens. Hackett and Hottinger, Beagle, Balderson, Brown, Burke, Dolan, Eklund, Gardner, Hoagland, Kunze, LaRose, Lehner, Manning, O'Brien, Oelslager, Peterson, Schiavoni, Terhar, Uecker, Wilson

BILL SUMMARY

- Authorizes a pharmacist to dispense or, in some cases, administer an emergency refill of naltrexone if certain conditions are met.
- Generally grants immunity to each of the following for administering naltrexone by injection under specified circumstances: the person who administers the drug, the person's employer, and the facility at which the drug is administered.
- Requires the dispensing or furnishing of naltrexone to be reported to the State Board of Pharmacy's Ohio Automated Rx Reporting System.
- Maintains current law requiring a physician, advanced practice registered nurse, or physician assistant to provide information about all drugs approved by the U.S. Food and Drug Administration for medication-assisted treatment before initiating a patient's medication-assisted treatment.
- Requires the Ohio Department of Public Safety, if it collects certain information concerning the administration of naloxone by emergency medical service personnel, to report that information to the Ohio Department of Health on a monthly basis.
- Names the act "Daniel's Law" and the "Opioid Data and Communication Expansion Act."

* This analysis was prepared before the report of the House Health Committee appeared in the House Journal. Note that the list of co-sponsors and the legislative history may be incomplete.

CONTENT AND OPERATION

Naltrexone – background

Naltrexone, also known as Vivitrol, is a drug approved by the U.S. Food and Drug Administration to treat both opioid and alcohol use disorders. It belongs in a class of medications called opiate antagonists and is available as an injectable or in pill form. Naltrexone may be prescribed by any licensed health professional authorized to prescribe drugs. It is reported to reduce opioid cravings and may prevent the feeling of getting high if a person relapses and uses the problem drug. According to the federal Substance Abuse and Mental Health Services Administration (SAMHSA), there is no abuse or diversion potential with naltrexone.[1]

Emergency refills of naltrexone

The bill authorizes a pharmacist to dispense naltrexone without a prescription if all of the following conditions are satisfied:

- The pharmacist is able to verify a record of a prescription for the injectable long-acting or extended release form of naltrexone in the name of the patient who is requesting it, but the prescription does not provide for a refill or the time for providing refills has lapsed;

- The pharmacist is unable to obtain authorization to refill the prescription from the prescriber who issued it or another prescriber responsible for the patient's care;

- In the exercise of the pharmacist's professional judgment, the drug is necessary to continue the patient's therapy for substance use disorder and failure to dispense naltrexone could result in harm to the patient's health.[2]

This authority is in addition to that granted under current law whereby a pharmacist may dispense a three-day supply of any prescription drug, other than a schedule II controlled substance, under certain circumstances.[3]

---

[1] *See* Substance Abuse and Mental Health Services Administration, *Medication-Assisted Treatment, Medication and Counseling Treatment, Naltrexone*, available at https://www.samhsa.gov/medication-assisted-treatment/treatment/naltrexone. *See also* National Institutes of Health, U.S. National Library of Medicine, *Naltrexone*, available at https://medlineplus.gov/druginfo/meds/a685041.html.

[2] R.C. 4729.283(A).

[3] R.C. 4729.283(F); R.C. 4729.281, not in the bill.

Form to be dispensed

Before dispensing naltrexone under the bill, the pharmacist must offer the patient the choice of receiving either the oral form or injectable long-acting or extended-release form of the drug. This requirement applies only if both forms are available for dispensing at the time of the patient's request or within one day after the request.[4]

Amount dispensed

If the patient chooses the oral form of naltrexone, the pharmacist cannot dispense an amount that exceeds a five-day supply.[5] Should the patient choose the injectable form, the pharmacist must exercise professional judgment in determining the amount to be dispensed.[6]

Administration by injection

If the patient chooses the injectable form of the drug, the bill authorizes the pharmacist to administer the naltrexone by injection. But, the pharmacist also must comply with current law that permits a pharmacist to administer by injection certain drugs, including naltrexone, only after completing specified training and pursuant to a protocol developed by a physician.[7]

Frequency of dispensing

The bill does not establish an explicit limit on the number of times an emergency refill of naltrexone may be dispensed to the same patient, but it does require the pharmacist to exercise professional judgment in determining that number.[8]

Additional pharmacist duties

After dispensing naltrexone under the bill, a pharmacist must do each of the following:

- Maintain for one year a record of the drug dispensed, including the amount and form dispensed, original prescription number, and the name

[4] R.C. 4729.283(B).

[5] R.C. 4729.283(C)(1).

[6] R.C. 4729.283(C)(2).

[7] R.C. 4729.45, not in the bill.

[8] R.C. 4729.283(E).

and address of the patient or the individual receiving the drug (if the individual is not the patient);

- Notify the prescriber who issued the prescription or another prescriber responsible for the patient's care of the refill not later than five days after dispensing the drug;

- If applicable, obtain from the prescriber authorization for additional dispensing.[9]

Immunity – administration of naltrexone by injection

S.B. 119 grants each of the following immunity from civil liability, criminal prosecution, or professional discipline for administering naltrexone by injection: the person who administers the drug by injection, the person's employer, and the facility at which the drug is administered.[10] To be eligible for immunity, the following conditions must be met:

- The individual to whom the drug is administered is unable to have it administered by a person who routinely does so, at the facility at which it is routinely administered, and under the prescriber's direction;

- The person who administers the naltrexone must be legally authorized to do so but cannot be the prescriber or someone who routinely administers it to the patient;

- The drug is provided to the person who administers it either by the individual to whom it is administered or the pharmacy that has a record of the individual's prescription;

- The person who administers the naltrexone is authorized to do so by the person's employer or the facility at which the drug is administered.

The immunity provided for under the bill does not apply in cases of gross negligence or intentional misconduct.

Naltrexone and OARRS

The bill revises the law governing the Ohio Automated Rx Reporting System (OARRS), the State Board of Pharmacy's database for monitoring controlled substances,

[9] R.C. 4729.283(D).

[10] R.C. 3719.063.

by adding naltrexone to the list of drugs monitored by the Board.[11] It requires a pharmacist or licensed health professional authorized to prescribe drugs – after dispensing or personally furnishing naltrexone – to report this information to OARRS.[12]

The bill also directs the Board of Pharmacy to include an aggregate of the information submitted about naltrexone in the semiannual reports the Board must prepare under existing law.[13] The aggregated information includes all of the following:

(1) The number of prescribers who issued the prescriptions for or personally furnished naltrexone;

(2) The number of patients to whom naltrexone was dispensed or personally furnished;

(3) The average quantity of the naltrexone dispensed per prescription or furnished at one time.[14]

Current law unchanged by the bill requires these semiannual reports to be submitted to various government officials and entities, including the Governor, Senate President, Speaker of the House of Representatives, and chairpersons of the standing legislative committees primarily responsible for considering health issues.[15]

Medication-assisted treatment

Medication-assisted treatment is the use of medication, often in combination with counseling and behavioral therapy, to treat substance use disorders and prevent overdose. It is used primarily to treat addiction to opioids such as heroin or prescription pain relievers. According to SAMHSA, the medication prescribed as part of this treatment operates to normalize brain chemistry, block the euphoric effects of opioids, relieve physiological cravings, and regulate bodily functions without the negative effects of the abused drug.[16]

---

[11] R.C. 4729.75.

[12] R.C. 4729.77, not in the bill; R.C. 4729.79.

[13] R.C. 4729.85(B).

[14] R.C. 4729.85(B)(4).

[15] R.C. 4729.85(B).

[16] *See* Substance Abuse and Mental Health Services Administration, *Medication-Assisted Treatment, Medication and Counseling Treatment,* available at https://www.samhsa.gov/medication-assisted-treatment/treatment.

Methadone, buprenorphine, and naltrexone are all drugs approved by the federal Food and Drug Administration (FDA) to treat opioid dependence and addiction. In general, methadone is dispensed from SAMHSA-certified opioid treatment programs, while buprenorphine is prescribed or furnished by a physician practicing in such a program or by a prescriber holding a SAMHSA-issued waiver authorizing office-based treatment. Naltrexone may be prescribed outside of an opioid treatment program and without the prescriber having to obtain a SAMHSA waiver.

The bill maintains current law requiring a physician, advanced practice registered nurse, or physician assistant to give a patient or patient's representative information about all drugs approved by the U.S. Food and Drug Administration for use in medication-assisted treatment.[17] This information must be provided both orally and in writing before initiating the patient's medication-assisted treatment and must be noted in the patient's medical record. In the event the physician, nurse, or physician assistant is not authorized to prescribe the drug chosen by the patient for medication-assisted treatment, the physician, nurse, or physician assistant must refer the patient to a provider able to prescribe it.

Naloxone administration – Department of Public Safety reports

Under the bill, if the Ohio Department of Public Safety (DPS) collects any of the following information regarding the administration of naloxone by emergency medical service personnel or firefighters, it must report the information for the previous month to Ohio Department of Health (ODH):

(1) The five digit postal zip code plus four-digit add-on where naloxone was administered;

(2) The date the naloxone was administered;

(3) The number of doses administered;

(4) The name of the emergency medical service organization or fire department that administered the naloxone;

(5) Whether or not an overdose was reversed;

(6) Whether the individual receiving the naloxone was taken to a hospital;

(7) If known, the individual's age;

[17] R.C. 3719.064 (renumbered from R.C. 3715.08).

(8) If known, the postal zip code in which the individual resides.

DPS must report to ODH in a manner prescribed by ODH. When submitting reports, DPS is prohibited from including any information that identifies or tends to identify specific individuals to whom naloxone was administered. Each month, ODH must compile the information received, organize it by county, and forward it to each local board of alcohol, drug addiction, and mental health services. The bill authorizes ODH to adopt rules as necessary to implement the bill's provisions.[18]

Naloxone background

The drug naloxone, commonly known by the brand name Narcan, can reverse the effects of an opioid overdose.[19] It counteracts the respiratory depression caused by the overdose, allowing the victim to breathe normally.[20] In enacting Am. Sub. H.B. 4, the 131st General Assembly increased access to naloxone by permitting authorized pharmacists and pharmacy interns to dispense the drug without a prescription in accordance with a protocol established by the Board of Pharmacy.[21] The bill includes language clarifying the definition of "prescription" for purposes of that law.[22]

HISTORY

ACTION	DATE
Introduced	03-28-17
Reported, S. Health, Human Services & Medicaid	06-06-18
Passed Senate (32-0)	06-27-18
Reported, H. Health	---

S0119-RH-132.docx/ks

[18] R.C. 4765.45.

[19] U.S. National Library of Medicine, National Institutes of Health, *Naloxone Injection*, available at <https://medlineplus.gov/druginfo/meds/a612022.html>.

[20] United Nations Office on Drugs and Crime and World Health Organization, *Opioid overdose: preventing and reducing opioid overdose mortality*, available at <http://www.who.int/substance_abuse/publications/opioid_overdose.pdf?ua=1>.

[21] R.C. 4729.44.

[22] R.C. 4729.01(H).