OHIO LEGISLATIVE SERVICE COMMISSION

Bill Analysis

Elizabeth Molnar

Sub. H.B. 167

132nd General Assembly
(As Passed by the House)

Reps. Edwards, Householder, Anielski, Antani, Antonio, Arndt, Blessing, Brenner, Brown, Butler, Carfagna, Clyde, Craig, Cupp, Dever, Gavarone, Ginter, Gonzales, Green, Hagan, Hambley, Henne, Hoops, Hughes, Ingram, Johnson, Keller, Kick, Landis, Lanese, Lang, Leland, Manning, McClain, Merrin, Miller, O'Brien, Patterson, Patton, Pelanda, Perales, Reineke, Riedel, Roegner, Rogers, Romanchuk, Ryan, Scherer, Schuring, Seitz, Sheehy, T. Smith, Stein, Thompson, West, Wiggam, Wilkin, Young, R. Smith

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.
- 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.
- Names the act "Daniel's Law."

CONTENT AND OPERATION

Naltrexone – background

Naltrexone 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]

Sub. H.B. 167 addresses the dispensing, administration, and prescribing of naltrexone. It is the companion to Sub. S.B. 119, a bill reported by Senate Health, Human Services and Medicaid on June 6, 2018 and passed by the Senate on June 27, 2018.[2]

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.[3]

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.[4]

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[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] *See* https://www.legislature.ohio.gov/legislation/legislation-documents?id=GA132-SB-119.

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

[4] R.C. 4729.283(F) and 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.[5]

Amount dispensed

If the patient chooses the oral form of naltrexone, the pharmacist cannot dispense an amount that exceeds a five-day supply.[6] Should the patient choose the injectable form, the pharmacist must exercise professional judgment in determining the amount to be dispensed.[7]

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.[8]

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.[9]

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

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

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

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

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

[9] 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.[10]

Immunity – administration of naltrexone by injection

The bill 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.[11] 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.

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

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

[11] R.C. 3719.063.

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.[12]

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.[13] 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.

HISTORY

ACTION	DATE
Introduced	03-28-17
Reported, H. Health	07-02-18
Passed House (94-0)	11-14-18

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[12] *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.

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