



# OHIO LEGISLATIVE SERVICE COMMISSION

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## Final Analysis

Elizabeth Molnar

### Sub. S.B. 119

132nd General Assembly  
(As Passed by the General Assembly)

- Sens.** Hackett and Hottinger, Beagle, Balderson, Brown, Burke, Dolan, Eklund, Gardner, Hoagland, Kunze, LaRose, Lehner, Manning, O'Brien, Oelslager, Peterson, Schiavoni, Terhar, Uecker, Wilson
- Reps.** Gavarone, Antani, Butler, Duffey, Edwards, Ginter, T. Johnson, Lepore-Hagan, Anielski, Arndt, Barnes, Blessing, Brenner, Brown, Carfagna, Craig, Cupp, Dean, Dever, DeVitis, Faber, Fedor, Galonski, Green, Greenspan, Hagan, Hambley, Hill, Holmes, Householder, Howse, Hughes, Kent, Kick, Landis, Lanese, Leland, Manning, McClain, Merrin, Miller, Patterson, Patton, Pelanda, Ramos, Reece, Riedel, Roegner, Rogers, Romanchuk, Ryan, Schaffer, Scherer, Schuring, Seitz, Sheehy, Slaby, K. Smith, T. Smith, Sprague, Stein, Strahorn, B. Sweeney, Sykes, Thompson, West, Wilkin, Young, Zeltwanger, R. Smith

**Effective date:** March 20, 2019

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## ACT SUMMARY

- Authorizes a pharmacist to dispense or, in some cases, administer by injection an emergency refill of naltrexone if certain conditions are met.
- 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.
- 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 monthly.
- Names the act "Daniel's Law" and the "Opioid Data and Communication Expansion Act."

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## CONTENT AND OPERATION

As enacted, S.B. 119 addresses several topics related to the treatment of overdoses and opioid use disorders, including the administration of naloxone by emergency medical service personnel, the dispensing of emergency refills of naltrexone, the administration of naltrexone by injection, and the inclusion of naltrexone in the State Board of Pharmacy's Ohio Automated Rx Reporting System.

### Emergency refills of naltrexone

Naltrexone (also known as Vivitrol, Depade, or ReVia) is a drug approved by the U.S. Food and Drug Administration to treat both opioid and alcohol use disorders. It is available as an injectable or in pill form.<sup>1</sup> Under the act, a pharmacist may 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, 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.<sup>2</sup>

The authority to dispense an emergency refill of naltrexone is in addition to that granted under continuing law whereby a pharmacist may dispense a three-day supply of any prescription drug, other than a schedule II controlled substance, under certain circumstances.<sup>3</sup>

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<sup>1</sup> 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>.

<sup>2</sup> R.C. 4729.283(A).

<sup>3</sup> R.C. 4729.283(F); R.C. 4729.281, not in the act.



## **Form to be dispensed**

Before dispensing naltrexone under the act, 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 within one day of the patient's request.<sup>4</sup>

## **Amount dispensed**

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

## **Administration by injection**

If the patient chooses the injectable, the pharmacist may administer the naltrexone by injection.<sup>6</sup> But, the pharmacist must comply with continuing law that permits a pharmacist to administer certain drugs by injection only after completing specified training and pursuant to a protocol developed by a physician.<sup>7</sup>

## **Frequency of dispensing**

The act does not limit 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.<sup>8</sup>

## **Additional pharmacist duties**

After dispensing naltrexone under the act, a pharmacist must

- Maintain for one year a record of the drug dispensed, including the amount and form dispensed, the original prescription number, and the name and address of the patient or individual receiving the drug (if the individual is not the patient);

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<sup>4</sup> R.C. 4729.283(B).

<sup>5</sup> R.C. 4729.283(C)(1) and (2).

<sup>6</sup> R.C. 4729.283(C)(2).

<sup>7</sup> R.C. 4729.45, not in the act.

<sup>8</sup> R.C. 4729.283(E).



- 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.<sup>9</sup>

### **Immunity – administration of naltrexone by injection**

The act 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.<sup>10</sup> 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 act does not apply in cases of gross negligence or intentional misconduct.

### **Naltrexone and OARRS**

The act adds naltrexone to the list of drugs monitored by the State Board of Pharmacy in its database, the Ohio Automated Rx Reporting System (OARRS).<sup>11</sup> It requires a pharmacist or licensed health professional authorized to prescribe drugs –

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<sup>9</sup> R.C. 4729.283(D).

<sup>10</sup> R.C. 3719.063.

<sup>11</sup> R.C. 4729.75.



after dispensing or personally furnishing naltrexone – to report this information to OARRS.<sup>12</sup>

The act also directs the Board to include an aggregate of the information submitted about naltrexone in the semiannual reports it must prepare under continuing law.<sup>13</sup> That information includes:

(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.<sup>14</sup>

Current law unchanged by the act requires these semiannual reports to be submitted to various government officials and entities.

### **Naloxone administration – Department of Public Safety reports**

The drug naloxone, commonly referred to by the brand name Narcan, can reverse the effects of an opioid overdose.<sup>15</sup> Under the act, 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;

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<sup>12</sup> R.C. 4729.77, not in the act; R.C. 4729.79.

<sup>13</sup> R.C. 4729.85(B).

<sup>14</sup> R.C. 4729.85(B)(4).

<sup>15</sup> U.S. National Library of Medicine, National Institutes of Health, *Naloxone Injection*, available at <https://medlineplus.gov/druginfo/meds/a612022.html>.



(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;

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

DPS must report to ODH monthly 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 act authorizes ODH to adopt rules as necessary to implement its provisions.<sup>16</sup>

The act also includes language clarifying the definition of "prescription" for purposes of the law governing dispensing naloxone without a prescription.<sup>17</sup>

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## 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	12-06-18
Passed House (86-0)	12-06-18
Senate concurred in House amendments (28-4)	12-12-18

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<sup>16</sup> R.C. 4765.45.

<sup>17</sup> R.C. 4729.01(H) and 4729.44.

