



Ohio Legislative Service Commission

Final Analysis

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Am. Sub. H.B. 4

131st General Assembly
(As Passed by the General Assembly)

- Reps.** Sprague and Rezabek, Gonzales, Huffman, Antonio, Barnes, Bishoff, Brown, Butler, Ginter, T. Johnson, LaTourette, Lepore-Hagan, Ramos, Sears, Schuring, Sykes, Amstutz, Anielski, Antani, Baker, Blessing, Boose, Brenner, Buchy, Burkley, Celebrezze, Cera, Conditt, Craig, Curtin, Derickson, Dever, Dovilla, Driehaus, Duffey, Fedor, Gerberry, Green, Grossman, Hackett, Hall, Hayes, Henne, Howse, G. Johnson, Koehler, Kraus, Kunze, Landis, Leland, Manning, McClain, M. O'Brien, S. O'Brien, Patmon, Patterson, Pelanda, Perales, Phillips, Rogers, Ruhl, Scherer, Sheehy, Slaby, K. Smith, R. Smith, Stinziano, Strahorn, Sweeney, Terhar, Thompson, Vitale, Zeltwanger, Rosenberger
- Sens.** Hottinger, Jones, Tavares, Brown, Hite, Beagle, Bacon, Balderson, Burke, Cafaro, Coley, Eklund, Gardner, LaRose, Lehner, Manning, Obhof, Oelslager, Patton, Peterson, Sawyer, Schiavoni, Seitz, Skindell, Thomas, Uecker, Widener, Williams, Yuko

Effective date: Emergency, July 16, 2015

ACT SUMMARY

NALOXONE

- Allows a physician to authorize one or more individuals to personally furnish naloxone, pursuant to the physician's protocol, to an individual at risk of an opioid-related overdose or to another in a position to assist that individual.
- Permits a physician or board of health to authorize a pharmacist or pharmacy intern to dispense naloxone without a prescription, in accordance with a protocol developed by the State Board of Pharmacy, to an individual at risk of an opioid-related overdose or to another in a position to assist that individual.
- Requires the Pharmacy Board, after consulting with the State Medical Board and Ohio Department of Health, to adopt rules regarding the authority of pharmacists and pharmacy interns to dispense naloxone without a prescription, including rules specifying the applicable protocol.

- Grants each of the following who acts in good faith immunity from civil liability, criminal prosecution, or professional discipline for the actions or omissions of the person to whom naloxone is furnished or dispensed under a physician or Pharmacy Board protocol: a physician, authorized individual, pharmacist, pharmacy intern, or board of health.
- Allows a board of health that is licensed by the Pharmacy Board as a terminal distributor of dangerous drugs to make occasional sales of naloxone at wholesale to a state or local law enforcement agency.

OPIOID TREATMENT PROGRAMS

- Excepts a physician who personally furnishes buprenorphine, as part of an opioid treatment program where buprenorphine (but not methadone) is distributed, from law that limits the amount of controlled substances a physician may personally furnish, if the program meets specified requirements.
- Requires that the Pharmacy Board and the Director of the Department of Mental Health and Addiction Services annually inspect or review certain opioid treatment programs.

CONTENT AND OPERATION

NALOXONE

The drug naloxone, commonly known by the brand name Narcan, can reverse the effects of an opioid overdose.¹ It counteracts the respiratory depression caused by the overdose, allowing the victim to breathe normally.²

Continuing law establishes for naloxone a limited exception to the requirement that a licensed health professional personally examine the intended recipient of a prescribed drug. A physician (including a podiatrist) or an advanced practice registered nurse (APRN) or physician assistant (PA) authorized to prescribe drugs may personally furnish a supply of naloxone or issue a prescription for the drug to a family member, friend, or another in a position to assist an individual who there is reason to believe is at

¹ U.S. National Library of Medicine, National Institutes of Health, *Naloxone Injection*, available at www.nlm.nih.gov/medlineplus/druginfo/meds/a612022.html.

² United Nations Office on Drugs and Crime and World Health Organization, *Opioid overdose: preventing and reducing opioid overdose mortality*, available at www.who.int/substance_abuse/publications/opioid_overdose.pdf?ua=1.



risk of experiencing an opioid-related overdose.³ Physicians, APRNs, PAs, and others who act in good faith in accordance with this law are not subject to criminal prosecution. Physicians, APRNs, and PAs acting in good faith are also immune from civil liability and professional discipline for the actions or omissions of the individual to whom the naloxone is furnished or the prescription is issued.⁴

Naloxone access

The act permits a physician to authorize one or more individuals to personally furnish naloxone in accordance with a protocol the physician establishes. It also allows a physician or a local board of health to authorize one or more pharmacists and pharmacy interns to dispense naloxone without a prescription in accordance with a protocol established by the State Board of Pharmacy.⁵

Physician-authorized individuals

The act permits a physician who establishes a protocol that meets specified requirements to authorize one or more individuals to personally furnish a supply of naloxone to either of the following:⁶

(1) An individual who there is reason to believe is experiencing or at risk of experiencing an opioid-related overdose;

(2) A family member, friend, or other person in a position to assist such an individual.

The authorized individual must comply with the physician's protocol and must instruct the individual to whom the naloxone is furnished to summon emergency services as soon as practicable either before or after administering the drug.⁷

The act specifies that the actions of an authorized individual in personally furnishing naloxone in accordance with a physician protocol do not fall within the legal definition of pharmacy or constitute the unauthorized practice of pharmacy.⁸

³ R.C. 4723.488, 4730.431, and 4731.94.

⁴ R.C. 2925.61, 4723.488, 4730.431, and 4731.94.

⁵ R.C. 4729.44(B) and 4731.941.

⁶ R.C. 4731.941(A)(1).

⁷ R.C. 4731.941(B).

⁸ R.C. 4729.29.



Physician protocol

A protocol established by a physician must be in writing and include the following:⁹

- (1) A description of the clinical pharmacology of naloxone;
- (2) Precautions and contraindications concerning the furnishing of naloxone;
- (3) Any limitations the physician specifies concerning the individuals to whom naloxone may be furnished;
- (4) The naloxone dosage that may be furnished 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 will be authorized to furnish naloxone;
- (7) Any instructions or training that the authorized individual must provide to an individual to whom naloxone is furnished.

Pharmacists and pharmacy interns

The act permits a pharmacist, or a pharmacy intern supervised by a pharmacist, to dispense naloxone without a prescription.¹⁰ For this to occur, a physician or a local board of health must have authorized the use of a protocol established by the Pharmacy Board.¹¹ In accordance with the protocol, the pharmacist or pharmacy intern may dispense naloxone without a prescription to either of the following:¹²

- (1) An individual who there is reason to believe is experiencing or at risk of experiencing an opioid-related overdose;
- (2) A family member, friend, or other person in a position to assist such an individual.

⁹ R.C. 4731.941(C).

¹⁰ R.C. 4729.44(B).

¹¹ R.C. 3707.56, 4729.44(G), and 4731.942.

¹² R.C. 4729.44(B).



A pharmacist or pharmacy intern who dispenses naloxone must instruct the individual to whom it is dispensed to summon emergency services as soon as practicable either before or after administering the drug.¹³ A pharmacist may document the dispensing of naloxone by the pharmacist or pharmacy intern on a prescription form. The form may be assigned a number for record-keeping purposes.¹⁴

The act specifies that it does not affect the authority of a pharmacist or pharmacy intern to fill or refill a prescription for naloxone.¹⁵

Pharmacy Board rules and protocol

The act requires the Pharmacy Board to adopt rules implementing its provisions authorizing the dispensing of naloxone without a prescription. The rules must specify a protocol under which pharmacists and pharmacy interns may dispense naloxone without a prescription. Before adopting these rules, the Board must consult with the State Medical Board and the Ohio Department of Health. The rules must be adopted in accordance with the Administrative Procedure Act.¹⁶

Conditions for authorization by boards of health

Under the act, a board of health may authorize pharmacists and pharmacy interns to dispense naloxone without a prescription in accordance with the Pharmacy Board's protocol, if both of the following conditions are met: (1) the authorization is through a physician serving as the board's health commissioner or medical director and (2) the pharmacists and pharmacy interns work in the board's jurisdiction.¹⁷

The act applies to a board of health of a city or general health district and to an authority having the duties of a board of health in a city that has not established a board.¹⁸

Immunity

Each of the following who acts in good faith and in accordance with the act is not liable for or subject to damages in any civil action, prosecution in any criminal

¹³ R.C. 4729.44(C).

¹⁴ R.C. 4729.44(D).

¹⁵ R.C. 4729.44(E).

¹⁶ R.C. 4729.44(G) and Chapter 119.

¹⁷ R.C. 3707.56(B).

¹⁸ R.C. 3707.56(A).



proceeding, or professional discipline for any action or omission of the person to whom the naloxone is furnished or dispensed without a prescription:

- (1) A physician;
- (2) A physician-authorized individual;
- (3) A pharmacist or pharmacy intern;
- (4) A board of health.¹⁹

The act makes two changes to the law governing immunity from criminal prosecution for those in a position to assist an individual at risk of an overdose. It allows a family member, friend, or other person to also obtain naloxone from (1) an individual authorized by a physician to personally furnish the drug or (2) a pharmacist or pharmacy intern authorized by a physician or board of health to dispense it without a prescription. With respect to summoning emergency services, it specifies that the individual attempt to do so as soon as practicable before or after administering naloxone.²⁰

Naloxone administration

Continuing law authorizes a physician or an APRN or PA with prescriptive authority to personally furnish a supply of naloxone or issue a prescription for the drug to a family member, friend, or other individual in a position to assist a person who there is reason to believe is at risk of experiencing an opioid-related overdose. Under prior law, this authorization applied only to naloxone administered intranasally or through an autoinjector. The act eliminates the intranasal and autoinjector limitations; as a result, the foregoing prescribers may furnish or prescribe to the individual any form of naloxone.²¹

Sales of naloxone to law enforcement agencies

The act allows a licensed terminal distributor of dangerous drugs to make occasional sales of naloxone at wholesale to a state or local law enforcement agency if the terminal distributor is any of the following:

- (1) A board of health of a city or general health district;

¹⁹ R.C. 4729.44 and 4731.941.

²⁰ R.C. 4723.488, 4730.341, and 4731.94.

²¹ R.C. 4723.488, 4730.431, and 4731.94.



- (2) An authority having the duties of a board of health;
- (3) A health department of such board or authority.²²

It also clarifies that when a registered wholesale distributor of dangerous drugs sells naloxone at wholesale to a law enforcement agency or its peace officers, the registered wholesaler does not need to obtain from the agency or officer a certificate indicating that the purchaser is licensed as a terminal distributor of dangerous drugs.²³ Under continuing law not modified by the act, a registered wholesaler may sell naloxone at wholesale to law enforcement agencies and their peace officers.²⁴

Definition of "prescription"

Ohio law defines "prescription" as a written, electronic, or oral order for drugs or combinations of drugs to be used by a particular individual, issued by a prescriber. For purposes of the act, "prescription" also includes a written, electronic, or oral order for naloxone issued to and in the name of a family member, friend, or other individual in a position to assist an individual who there is reason to believe is at risk of experiencing an opioid-related overdose.²⁵

OPIOID TREATMENT PROGRAMS

Limits on personally furnishing controlled substances

Continuing law limits the amount of controlled substances a prescriber may personally furnish to the following:²⁶

- In any 30-day period, 2,500 dosage units for all of the prescriber's patients taken as a whole;
- In any 72-hour period, the amount an individual patient needs for that period.

²² R.C. 4729.51.

²³ R.C. 4729.60(A).

²⁴ R.C. 4729.51(B)(1)(n).

²⁵ R.C. 4729.01(H).

²⁶ R.C. 4729.291(C).



Buprenorphine exceptions

Buprenorphine furnished to patients to treat drug dependence or addiction as part of an opioid treatment program is not counted in determining whether a prescriber has exceeded the limits on personally furnished controlled substances if the opioid treatment program (1) is certified by the U.S. Substance Abuse and Mental Health Services Administration (SAMSHA) and (2) distributes both buprenorphine and methadone.²⁷

The act modifies the foregoing exception by requiring that the opioid treatment program not only be SAMSHA-certified, but also be licensed as a terminal distributor of dangerous drugs by the Pharmacy Board.²⁸

The act also establishes a new exception from the controlled substances limits for an opioid treatment program that has physicians who personally furnish buprenorphine but not methadone. For this exception to apply, the program must meet all of the following conditions:

(1) Be accredited by a national accrediting organization approved by SAMHSA;

(2) Maintain a copy of the physician's signed and dated written order for buprenorphine in the record of each patient to whom the drug was administered or personally furnished;

(3) Be certified by the Ohio Department of Mental Health and Addiction Services (ODMHAS) regarding personally furnishing buprenorphine.²⁹

ODMHAS review

The act requires that the ODMHAS Director conduct annual on-site reviews of opioid treatment programs whose physicians (1) personally furnish buprenorphine but not methadone and (2) are excepted from the law that limits the amount of controlled substances a physician may personally furnish.³⁰

The act authorizes the ODMHAS Director to inspect both pharmacy and patient treatment records as part of the annual review. If the Director has reason to believe that

²⁷ R.C. 4729.291(D).

²⁸ R.C. 4729.291(D)(2).

²⁹ R.C. 4729.291(D)(2)(b).

³⁰ R.C. 5119.372.



a violation of local, state, or federal drug law has occurred, the act requires the Director to report that information to the Pharmacy Board.³¹

Associated with authorizing the Director to inspect pharmacy records, the act requires that persons who must keep files or records under Ohio's controlled substances law³² make them available for inspection and copying by an employee designated by the Director, upon that employee's written request. The documents must be made available at all reasonable hours and the ODMHAS employee must be given an opportunity to check the documents' accuracy.³³

The act specifies that the Director's authority to conduct an on-site review of a community mental health services provider or community addiction and mental health services provider for cause does not affect the Director's duty to also conduct the annual review of a community mental health services provider or community addiction and mental health services provider that is an opioid treatment program.³⁴

The act authorizes the ODMHAS Director to adopt rules, in accordance with the Administrative Procedure Act, implementing its provisions regarding on-site reviews.³⁵

Pharmacy Board inspection

The act requires that the Pharmacy Board also conduct annual on-site inspections of opioid treatment programs whose physicians (1) personally furnish buprenorphine but not methadone and (2) are excepted from the law that limits the amount of controlled substances that a physician may personally furnish.³⁶ Continuing law authorizes the Pharmacy Board to inspect pharmacy and other drug-related records.³⁷

³¹ R.C. 3719.13 and 5119.372.

³² R.C. Chapter 3719.

³³ R.C. 3719.27(B).

³⁴ R.C. 5119.371(C)(2).

³⁵ R.C. 5119.372 and Chapter 119.

³⁶ R.C. 4729.292.

³⁷ R.C. 3719.13 and 3719.27.



HISTORY

ACTION	DATE
Introduced	01-28-15
Reported, H. Health & Aging	02-25-15
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Reported, S. Health & Human Services	05-27-15
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