



Ohio Legislative Service Commission

Bill Analysis

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Sub. H.B. 4

131st General Assembly

(As Reported by S. Health and Human Services)

Reps. Sprague, 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. Jones, Tavares, Beagle, Brown, Hite, Hottinger

BILL SUMMARY

NALOXONE

- Allows a physician to authorize one or more other individuals to personally furnish a supply of naloxone pursuant to the physician's protocol to a person at risk of an opioid-related overdose or to another person in a position to assist that person.
- Authorizes a pharmacist or pharmacy intern to dispense naloxone without a prescription to a person at risk of an opioid-related overdose or to another person in a position to assist that person if the dispensing action is authorized by a physician or board of health and performed in accordance with a protocol developed by the State Board of Pharmacy.
- Requires the Pharmacy Board, after consulting with the State Medical Board and Ohio Department of Health, to adopt rules to implement the bill's provisions authorizing pharmacists and pharmacy interns to dispense naloxone without a prescription, including rules specifying the applicable protocol.
- Grants a family member, friend, or another person in a position to assist a person at risk of an opioid-related overdose immunity from criminal prosecution if he or she obtains and administers naloxone in accordance with the bill.

- Grants the following who act 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's protocol or the Pharmacy Board's protocol: a physician, authorized individual, pharmacist, pharmacy intern, or board of health.
- Provides that the authority to prescribe or personally furnish naloxone or dispense it without a prescription under circumstances specified in existing law and the bill applies to all forms of the drug, rather than only to intranasal and autoinjector forms.
- 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.
- Clarifies that a wholesale distributor of dangerous drugs does not need proof of terminal distributor of dangerous drugs licensure from a law enforcement agency or its peace officers before selling naloxone to them.
- Specifies that, for purposes of law governing when naloxone is prescribed or dispensed to persons other than the ultimate user, the definition of "prescription" 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.

OPIOID TREATMENT PROGRAMS

- Specifies that a physician who personally furnishes buprenorphine to patients participating in an opioid treatment program where buprenorphine (but not methadone) is personally furnished to patients may be excluded from current law limits on the amount of controlled substances the physician may personally furnish if the program meets certain requirements.
- Requires the Pharmacy Board and the Ohio Department of Mental Health and Addiction Services (ODMHAS) to conduct annual on-site inspections of such opioid treatment programs.
- Requires such opioid treatment programs to make their records available to ODMHAS staff during annual inspections.

EMERGENCY CLAUSE

- Declares an emergency.



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CONTENT AND OPERATION

NALOXONE

Background

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 an overdose, allowing the overdose victim to breathe normally.²

Current law regarding naloxone

Current law, as enacted by Sub. H.B. 170 of the 130th General Assembly, establishes for naloxone a limited exception to the requirement that a licensed health professional personally examine the intended recipient of a prescribed drug. A licensed health professional who is a physician (including a podiatrist), or who is an advanced practice registered nurse or physician assistant authorized to prescribe drugs, may

¹ U.S. National Library of Medicine, National Institutes of Health, *Naloxone Injection* (last visited June 15, 2015), available at <<http://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* (last visited June 15, 2015), available at <http://www.who.int/substance_abuse/publications/opioid_overdose.pdf?ua=1>.



personally furnish a supply of naloxone or issue a prescription for naloxone to a family member, friend, or another individual in a position to assist a person who there is reason to believe is at risk of an opioid-related overdose.³ This authority to personally furnish or prescribe without examining the person at risk applies only to naloxone that can be administered intranasally or through an autoinjector (similar to an EpiPen®) in a manufactured dosage form.

Licensed health professionals and others who act in good faith in accordance with the naloxone law are not subject to criminal prosecution.⁴ Licensed health professionals acting in good faith are also immune from civil liability and professional disciplinary action for the actions or omissions of the individual to whom the naloxone is furnished or the prescription is issued.⁵

Naloxone access under the bill

The bill extends to nonprescribers the authority to personally furnish naloxone or to dispense it without a prescription. Authorization may be granted under the bill to (1) one or more individuals authorized by a physician to personally furnish naloxone in accordance with a protocol the physician establishes and (2) one or more pharmacists and pharmacy interns authorized by a local board of health or physician to dispense naloxone without a prescription in accordance with a State Board of Pharmacy protocol.⁶ This authority to furnish or dispense without a prescription is not limited to naloxone administered intranasally or through an autoinjector (see "**Naloxone administration**," below).

Physician-authorized individuals

The bill permits a physician who establishes a protocol that meets the bill's requirements to authorize one or more other individuals to personally furnish a supply of naloxone to either of the following:⁷

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

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

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. 4723.488, 4730.431, and 4731.94.

⁶ R.C. 4729.44(B) and 4731.941.

⁷ R.C. 4731.941(A)(1).



The authorized individual may personally furnish naloxone without having examined the person to whom it may be administered; however, the authorized individual must comply with the physician's protocol and must instruct the person to whom naloxone is furnished to summon emergency services as soon as practicable either before or after administering it.⁸

The bill specifies that the actions of an authorized individual in personally furnishing naloxone in accordance with a physician protocol do not fit within the legal definition of pharmacy or constitute the unauthorized practice of pharmacy.⁹

Physician protocol

Under the bill, a protocol established by a physician under which naloxone may be personally furnished by one or more authorized individuals must be in writing and include the following:¹⁰

- (1) A description of the clinical pharmacology of naloxone;
- (2) Precautions and contraindications concerning the dispensing or furnishing of naloxone;
- (3) Any limitations the physician specifies concerning the persons to whom naloxone is dispensed or furnished;
- (4) The naloxone dosage that may be dispensed or 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.

⁸ R.C. 4731.941(B).

⁹ R.C. 4729.29.

¹⁰ R.C. 4731.941(C).



Pharmacists and pharmacy interns

The bill also authorizes a pharmacist, or a pharmacy intern supervised by a pharmacist, to dispense naloxone without a prescription.¹¹ To do so, a physician or a local board of health must have authorized the use of a protocol that is to be established under the bill by the Pharmacy Board.¹² In accordance with the protocol, the pharmacist or pharmacy intern may dispense naloxone without a prescription to either of the following:¹³

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

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

A pharmacist or pharmacy intern who dispenses naloxone must instruct the person to whom it is dispensed to summon emergency services as soon as practicable either before or after administering the drug.¹⁴ 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.¹⁵

The bill specifies that it does not affect the authority of a pharmacist or pharmacy intern to fill or refill a prescription for naloxone.¹⁶

Pharmacy Board rules and protocol

The bill requires the Pharmacy Board to adopt rules to implement the bill's provisions for dispensing naloxone without a prescription, including rules that specify a protocol under which pharmacists and pharmacy interns may dispense the naloxone. Before adopting the 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 (R.C. Chapter 119.).¹⁷

¹¹ R.C. 4729.44(B).

¹² R.C. 3707.56, 4729.44(G), and 4731.942.

¹³ R.C. 4729.44(B).

¹⁴ R.C. 4729.44(C).

¹⁵ R.C. 4729.44(D).

¹⁶ R.C. 4729.44(E).

¹⁷ R.C. 4729.44(G).



Conditions for authorization by boards of health

Under the bill, the authority of a board of health to authorize pharmacists and pharmacy interns to dispense naloxone as described above is subject to the following specifications: (1) the action is to be taken through a physician serving as the board's health commissioner or medical director and (2) the authorization applies to pharmacists and pharmacy interns working in the board's jurisdiction.¹⁸

The bill specifies that its provisions regarding authorization from boards of health apply to the board of health of a city or general health district, as well as the authority having the duties of a board of health in a city that has not established a board of health.¹⁹

Immunity

Under the bill, each of the following who acts in good faith is not liable for or subject to damages in any civil action, prosecution in any criminal proceeding, or professional disciplinary action 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.²⁰

The bill also specifies that a family member, friend, or another in a position to assist a person at risk of an opioid-related overdose is not subject to criminal prosecution for the unauthorized practice of medicine or certain drug offenses if he or she obtains and administers the naloxone in good faith and in accordance with the bill.²¹

Naloxone administration

Current law authorizes a physician, or an advanced practice registered nurse or physician assistant with prescriptive authority, to personally furnish a supply of naloxone or issue a prescription for naloxone to a person in a position to assist an

¹⁸ R.C. 3707.56(B).

¹⁹ R.C. 3707.56(A).

²⁰ R.C. 4729.44 and 4731.941.

²¹ R.C. 2925.61.



individual at risk of an opioid overdose. This authorization applies only to naloxone that can be administered intranasally or through an autoinjector. The bill eliminates the intranasal and autoinjector limitations; as a result, the specified prescribers may furnish or prescribe to the person any form of naloxone.²²

Notification of emergency services

A person in a position to assist an individual at risk of an opioid overdose who administers naloxone under current law must attempt to summon emergency services immediately before or immediately after administering the drug. Under the bill, the person must attempt to summon emergency services as soon as practicable before or after administering naloxone, rather than immediately before or after doing so.²³

Sales of naloxone to law enforcement agencies

The bill 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;
- (2) An authority having the duties of a board of health;
- (3) A health department of such board or authority.²⁴

The bill 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.²⁵ Under current law not modified by the bill, a registered wholesaler may sell naloxone at wholesale to law enforcement agencies and their peace officers.²⁶

Definition of "prescription"

The bill specifies that, for purposes of the law governing the dispensing, personally furnishing, and administering of naloxone, the definition of "prescription"

²² R.C. 4723.488, 4730.431, and 4731.94.

²³ R.C. 4723.488, 4730.341, and 4731.94.

²⁴ R.C. 4729.51.

²⁵ R.C. 4729.60(A).

²⁶ R.C. 4729.51(B)(1)(n).



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. Under current law, a prescription includes only a written, electronic, or oral order for drugs or combinations of drugs, issued by a prescriber, to be used by a particular individual or for treating a particular animal.²⁷

OPIOID TREATMENT PROGRAMS

Limits on personally furnishing controlled substances

Background

Law not modified by the bill establishes limits on the amount of controlled substances a prescriber may personally furnish to or for patients. Under the limits, a prescriber (other than a veterinarian) generally cannot personally furnish more than either of the following:²⁸

- 2,500 dosage units in a 30-day period to all patients taken as a whole; or
- A 72-hour supply for a patient's use in that period.

Buprenorphine

Under certain conditions, buprenorphine provided to treat drug dependence or addiction as part of an opioid treatment program is not included in determining whether a prescriber has exceeded the limits on personally furnishing controlled substances. For the exclusion to apply, an opioid treatment program must (1) be certified by the U.S. Substance Abuse and Mental Health Services Administration (SAMSHA) and (2) distribute both buprenorphine and methadone.²⁹

The bill modifies the first condition of the exclusion by requiring that the opioid treatment program not only be SAMSHA-certified, but also possess a terminal distributor of dangerous drugs license issued by the Pharmacy Board.³⁰

²⁷ R.C. 4729.01(H).

²⁸ R.C. 4729.291(C).

²⁹ R.C. 4729.291(D).

³⁰ R.C. 4729.291(D)(2).



The bill also creates a new exclusion for opioid treatment programs that have physicians who personally furnish buprenorphine but not methadone. For the new exclusion to apply, the following conditions must be met:

(1) The program must be accredited by a national accrediting organization approved by SAMHSA;

(2) The service of personally furnishing buprenorphine must be certified by the Ohio Department of Mental Health and Addiction Services (ODMHAS); and

(3) The program must 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.³¹

The bill specifies that the criterion for ODMHAS certification described in (2), above, applies despite a current law provision that requires the ODMHAS Director to accept a community addiction services provider's or community mental health services provider's national accreditation in lieu of undergoing a determination by the Director that ODMHAS's certification standards have been met.³²

On-site inspections and reviews

The bill requires the Pharmacy Board and ODMHAS Director to conduct annual on-site inspections and reviews, respectively, of opioid treatment programs where physicians personally furnish buprenorphine, but not methadone, and that meet the bill's conditions for exclusion from limits on personally furnishing controlled substances.³³ If the ODMHAS Director has reason to believe that a local, Ohio, or federal drug law, or provision of Ohio law governing controlled substances, other drugs, or pharmacies, has been violated, the bill requires the Director to report that information to the Pharmacy Board.³⁴

The bill authorizes the ODMHAS Director to inspect pharmacy records as part of the annual review of an opioid treatment program.³⁵ The Pharmacy Board already has the authority to inspect pharmacy and other drug-related records. The bill also

³¹ R.C. 4729.291(D)(2)(b).

³² R.C. 5119.371.

³³ R.C. 4729.292 and 5119.372.

³⁴ R.C. 5119.372.

³⁵ R.C. 3719.13 and 5119.372.



authorizes the Director to inspect patient treatment records as part of the review of the program.³⁶

Associated with granting the ODMHAS Director authority to review pharmacy records, the bill requires persons who must keep files or records under Ohio's controlled substances law³⁷ to make those documents available to ODMHAS employees on written request. The documents must be made available for inspection and copying at all reasonable hours and the ODMHAS employee must be given an opportunity to check the document's accuracy. A person is prohibited from failing to comply with this requirement.³⁸

The bill specifies that the ODMHAS Director's existing authority to conduct an on-site review of a community addiction and mental health services provider for cause, including complaints or alleged deficiencies, does not affect the Director's duty to conduct the annual inspection of an opioid treatment program.³⁹

The bill authorizes the ODMHAS Director to adopt rules to implement the provisions regarding on-site reviews.⁴⁰ The rules must be adopted in accordance with the Administrative Procedure Act.⁴¹

Conforming changes

In other provisions of existing law that establish exclusions from the limits on personally furnishing supplies of controlled substances, the bill replaces the term "provide" with "personally furnish" for consistency.⁴²

³⁶ R.C. 3719.13 and 3719.27.

³⁷ R.C. Chapter 3719.

³⁸ R.C. 3719.27(B).

³⁹ R.C. 5119.371(C)(2).

⁴⁰ R.C. 5119.372.

⁴¹ R.C. Chapter 119.

⁴² R.C. 4729.291(D).



HISTORY

ACTION	DATE
Introduced	01-28-15
Reported, H. Health & Aging	02-25-15
Passed House (98-0)	03-04-15
Reported, S. Health & Human Services	05-27-15

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