



Ohio Legislative Service Commission

Bill Analysis

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Sub. H.B. 4

131st General Assembly
(As Passed by the House)

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

BILL SUMMARY

- Allows a physician to authorize one or more other individuals to furnish 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 drug is dispensed in accordance with a board of health or physician protocol.
- Requires the Ohio Department of Health to develop a model protocol regarding the dispensing of naloxone without a prescription by one or more pharmacists or pharmacy interns and authorizes a local board of health to establish a naloxone protocol not less stringent than the model.
- Specifies what must be included in a naloxone 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 liability if he or she obtains and administers naloxone in accordance with the bill.
- Grants the following who act in good faith immunity from civil or criminal liability or professional discipline for the actions or omissions of the person to whom

naloxone is furnished or dispensed without a prescription: 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 the bill and existing law applies to all forms of the drug, rather than only to intranasal and autoinjector forms.
- Allows a local board of health that is licensed by the State Board of Pharmacy as a terminal distributor of dangerous drugs to make occasional sales of naloxone at wholesale to a state or local law enforcement agency.

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

Current law regarding naloxone

Current law, as enacted by Substitute H.B. 170 of the 130th General Assembly, established 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 an advanced practice registered nurse or physician assistant authorized to prescribe drugs may personally furnish or prescribe 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.

¹ U.S. National Library of Medicine, National Institutes of Health, *Naloxone Injection* (last visited March 8, 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 March 8, 2015), available at <http://www.who.int/substance_abuse/publications/opioid_overdose.pdf?ua=1>.

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



Licensed health professionals and others who act in good faith in accordance with the naloxone law are immune from criminal liability.⁴ Licensed health professionals 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.⁵

Naloxone access under the bill

The bill extends to individuals who are not authorized to prescribe drugs the authority to personally furnish naloxone or dispense it without a prescription. Authorization may be granted under the bill to one or more individuals authorized by a physician to personally furnish naloxone and to one or more pharmacists and pharmacy interns dispensing naloxone without a prescription in accordance with a board of health or physician protocol.⁶ This authority to furnish or dispense without a prescription is not limited to naloxone administered intranasally or through an autoinjector.

Authorized individual

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 naloxone to either of the following:

- (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.

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.

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.⁷

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, 4731.941, and 4731.942.

⁷ R.C. 4729.29.



Pharmacist or pharmacy intern

The bill also authorizes a pharmacist or a pharmacy intern supervised by a pharmacist to dispense naloxone without a prescription. Naloxone may be dispensed in accordance with a protocol established by a board of health or physician under the bill to either of the following:

- (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. A pharmacist may document the dispensing of naloxone by the pharmacist or a pharmacy intern on a prescription form. The form may be assigned a number for record-keeping purposes.

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

Physician protocol

The bill authorizes a physician to establish a protocol under which naloxone may be personally furnished by one or more authorized individuals or dispensed by one or more pharmacists specified by the physician and any of the pharmacy interns under the supervision of the pharmacist or pharmacists. A physician protocol must be in writing and include the following:

- (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) Any instructions or training that a pharmacist, pharmacy intern, or authorized individual must provide to the person to whom naloxone is dispensed or furnished;



(6) In the case of a pharmacist or pharmacy intern, procedures for dispensing subsequent supplies of naloxone to the same person;

(7) In the case of a pharmacist or pharmacy intern, training in preventing, recognizing, and responding to opioid overdose that must be completed before being authorized to dispense naloxone;

(8) In the case of an authorized individual, labeling, storage, record-keeping, and administrative requirements;

(9) In the case of an authorized individual, training requirements that must be met before an individual will be authorized to furnish naloxone.⁸

ODH protocol

The bill requires that the Department of Health (ODH) develop a model protocol under which one or more pharmacists and any of the pharmacy interns supervised by the pharmacist or pharmacists may dispense naloxone without a prescription.⁹ The model protocol must include all of the following:

(1) A description of the clinical pharmacology of naloxone;

(2) Precautions and contraindications concerning dispensing naloxone;

(3) Any limitations concerning the individuals to whom naloxone is dispensed;

(4) The naloxone dosage that may be dispensed and any variation in the dosage based on circumstances specified in the protocol;

(5) Procedures for dispensing subsequent supplies of naloxone to the same individual;

(6) Training in preventing, recognizing, and responding to opioid overdose that must be completed by a pharmacist or pharmacy intern before the pharmacist or pharmacy intern will be authorized to dispense naloxone;

(7) A requirement that a pharmacist or pharmacy intern who dispenses naloxone pursuant to a protocol instruct the individual to whom the naloxone is dispensed to summon emergency services as soon as practicable either before or after administering naloxone;

⁸ R.C. 4731.942.

⁹ R.C. 3707.56.



(8) Any instructions or training that a pharmacist or pharmacy intern must provide to an individual to whom naloxone is dispensed.

The bill requires ODH to provide a copy of the model protocol to each board of health and to assist any board of health that establishes its own naloxone protocol under the bill. ODH must review and update the model protocol not less than once every two years for consistency with standard clinical practices.

Board of health protocol

The bill authorizes a board of health of a city or general health district or authority having the duties of a board of health to establish, through a physician serving as the board's health commissioner or medical director, a protocol under which one or more pharmacists and any of the pharmacy interns supervised by the pharmacist or pharmacists may dispense naloxone without a prescription. The protocol must not be less stringent than the model protocol developed by ODH.¹⁰

A board of health that establishes its own protocol must provide ODH with a copy. The board must review and update its protocol not less than once every two years for consistency with both standard clinical practices and the ODH model protocol.

Rulemaking

The bill authorizes the State Board of Pharmacy to adopt rules as it considers necessary to implement the bill. These rules must be adopted in accordance with the Administrative Procedure Act (Chapter 119. of the Revised Code).¹¹

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) An authorized individual;
- (3) A pharmacist or pharmacy intern;

¹⁰ R.C. 3707.56.

¹¹ R.C. 4729.44.



(4) A board of health.¹²

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.¹³

Naloxone administration

Current law authorizes a licensed health professional to personally furnish or prescribe naloxone to a person in a position to assist an individual at risk of an opioid overdose. This authorization applies only to naloxone that can be administered intranasally or through an autoinjector. Under the bill, the licensed health professional may furnish or prescribe any form of naloxone.¹⁴

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.¹⁵

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.¹⁶

¹² R.C. 4729.44 and 4731.941.

¹³ R.C. 2925.61.

¹⁴ R.C. 4723.488, 4730.431, and 4731.94.

¹⁵ R.C. 4723.488, 4730.341, and 4731.94.

¹⁶ R.C. 4729.51.



HISTORY

ACTION

DATE

Introduced	01-28-15
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Passed House (98–0)	03-04-15

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