



Ohio Legislative Service Commission

Bill Analysis

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H.B. 4

131st General Assembly
(As Introduced)

Reps. Sprague, Rezabek

BILL SUMMARY

- Allows a physician to authorize an individual 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 physician's protocol.
- Requires that a physician's naloxone protocol be in writing and include certain information.
- Grants a physician acting in good faith who authorizes an individual to furnish naloxone and an authorized individual acting in good faith immunity from civil and criminal liability or professional discipline for the actions or omissions of the person to whom the drug is furnished.
- 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 the naloxone in accordance with the bill.

CONTENT AND OPERATION

Naloxone

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

Current law regarding naloxone

Current law 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 Licensed health professionals and others who act in good faith in accordance with this law are immune from criminal liability.⁴ Licensed health professionals acting in good faith are also immune from civil liability and professional discipline for 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 the authority to personally furnish or dispense naloxone to individuals who are not authorized to prescribe drugs. Authorization may be granted under the bill to individuals authorized by a physician to personally furnish naloxone and to pharmacists and pharmacy interns dispensing naloxone in accordance with a physician's protocol.⁶ This authority to furnish or dispense applies only to naloxone that

¹ U.S. Food and Drug Administration, *Role of Naloxone in Opioid Overdose Fatality Prevention* (last visited February 6, 2015), available at <<http://www.fda.gov/downloads/Drugs/NewsEvents/UCM318909.pdf>>.

² United Nations Office on Drugs and Crime and World Health Organization, *Opioid overdose: preventing and reducing opioid overdose mortality* (last visited February 6, 2015), available at <http://www.who.int/substance_abuse/publications/opioid_overdose.pdf?ua=1>.

³ R.C. 4723.488 and 4730.431 (not in the bill) and R.C. 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 and 4731.941.



can be administered intranasally or through an autoinjector (similar to an EpiPen®) in a manufactured dosage form.

Individual authorized by a physician

The bill permits a physician who establishes a protocol that meets the bill's requirements to authorize another individual 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 medical services either immediately before or immediately 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 constitute pharmacy or the unauthorized practice of pharmacy.⁷

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 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 medical services either immediately before or immediately 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.

⁷ R.C. 4729.29.

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 authorized individuals or dispensed by pharmacists specified by the physician and pharmacy interns under the supervision of the 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

Immunity

Under the bill, a physician who in good faith authorizes another individual to personally furnish naloxone in accordance with the physician's protocol or an

⁸ R.C. 4729.44 and 4731.941.

authorized individual who furnishes naloxone in good faith is not liable for or subject to any of the following for any action or omission of the person to whom the naloxone is furnished:

- (1) Damages in any civil action;
- (2) Prosecution in any criminal proceeding;
- (3) Professional disciplinary action.⁹

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.¹⁰

The bill does not grant a pharmacist or pharmacy intern who dispenses naloxone in accordance with a physician's protocol or a physician who establishes a protocol for pharmacists or pharmacy interns immunity from civil or criminal liability or professional discipline for an action or omission of the person to whom the drug is dispensed.

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

HISTORY

ACTION	DATE
Introduced	01-28-15

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⁹ R.C. 4731.941.

¹⁰ R.C. 2925.61.

¹¹ R.C. 4729.44.

