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Bill Analysis

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Primary Sponsors: Sens. Manning and S. Huffman

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SUMMARY

- Generally expands existing naloxone access authority, including by authorizing access for all persons and government entities to purchase, possess, distribute, dispense, personally furnish, sell, or otherwise obtain or provide naloxone and any instrument or device to administer it.
- Consolidates, but largely maintains, other more specific naloxone provisions in current law, including those related to maintaining naloxone supplies, the authority of various health care providers, and immunities from liability.
- Adds that physician assistants and advanced practice registered nurses may authorize a pharmacist or pharmacy intern to dispense naloxone without a prescription pursuant to a protocol.
- Expressly authorizes an individual, when not otherwise authorized to administer drugs under Ohio law, to administer naloxone if the individual is in a position to assist another who is apparently experiencing an opioid-related overdose.
- Authorizes the use of fentanyl test strips and other narcotic testing products and equipment, and provides immunity from criminal prosecution and civil damages associated with that use.

DETAILED ANALYSIS

Naloxone access

Naloxone is federally approved medication that can rapidly reverse opioid overdose. It is generally considered to be safe for laypersons to administer in emergency situations.¹ Since

¹ National Institutes of Health, National Institute on Drug Abuse, [Naloxone DrugFacts](#).

2014, Ohio has enacted numerous laws designed to increase access to naloxone, and those laws are located throughout the Revised Code as they relate to law enforcement and criminal immunities (Chapter 2925), boards of health (Chapter 3707), and various licensed health care professionals (Chapters 4723 (advanced practice registered nurses), 4729 (pharmacists and pharmacy interns), 4730 (physician assistants), and 4731 (physicians)). As discussed below, the bill expands naloxone access, and also consolidates much of the existing law by moving it to Ohio's Pure Food and Drug Law (Chapter 3715).²

General access

While the bill largely maintains several of Ohio's more specific naloxone access laws (discussed in greater detail below), it expands access by establishing a more general, broadly applicable access. Specifically, the bill authorizes persons and government entities to purchase, possess, distribute, dispense, personally furnish, sell, or otherwise obtain or provide naloxone and any instrument or device to administer it, if the following conditions are met:³

1. The naloxone is in its original manufacturer's packaging;
2. Its packaging contains the manufacturer's instructions for use;
3. It is stored in accordance with the manufacturer's or distributor's instructions.

The bill's expanded access provisions do not affect other existing authority to issue a prescription for, or personally furnish a supply of, naloxone.⁴

Emergency naloxone supplies and automated distribution

In addition to the general access provision, the bill authorizes persons and government entities to obtain and maintain a supply of naloxone for use in emergency situations and for distribution through an automated mechanism.⁵ This is similar to, although arguably more expansive than, current law, which authorizes (1) terminal distributors of dangerous drugs to acquire and maintain a supply of naloxone for use in emergency situations and for distribution through an automated mechanism⁶ and (2) service entities – public and private entities that provide services to or interact with individuals who there is reason to believe may be at risk of overdosing on opioids, such as churches, schools, libraries, health departments, courts, prisons,

² R.C. 3715.50 through 3715.505; R.C. 2925.61, 3707.56 through 3707.562, 4723.484 through 4723.486, 4729.514, 4729.515, 4730.434 through 4730.436, and 4731.94 through 4731.943, all repealed; conforming changes in R.C. 149.43, 4729.01, 4729.16, 4729.28, 4729.29, 4729.51, 4729.541, and 4729.60; R.C. 4765.44 renumbered to R.C. 3715.505.

³ R.C. 3715.50(A).

⁴ R.C. 3715.50(D)(1).

⁵ R.C. 3715.50(B).

⁶ R.C. 4729.515, repealed.

and homeless shelters – to procure and maintain a supply of naloxone to use in emergency situations and for personally furnishing under a protocol (discussed below).⁷

Similar to existing law for supplies maintained by terminal distributors, a person or government entity that maintains a supply of naloxone for use in emergencies as authorized by the bill must:⁸

- Provide to individuals who access the naloxone instructions on emergency administration, including an instruction to summon emergency services as necessary;
- Establish a process to replace accessed naloxone within a reasonable time period;
- Store the naloxone in accordance with manufacturer or distributor instructions.

Similar to existing rules for automated distribution by terminal distributors,⁹ a person or government entity that maintains a supply of naloxone for automated distribution under the bill must:¹⁰

- Ensure that the mechanism is securely fastened to a permanent structure or is of a size and weight to reasonably prevent it from being removed from its intended location;
- Provide to individuals who access the naloxone emergency administration instructions, including an instruction to summon emergency services as necessary;
- Develop a process for monitoring and replenishing the supply;
- Store the naloxone in accordance with the manufacturer or distributor instructions.

Exemption from licensure as a terminal distributor

Related to the general access provision, the bill exempts all persons and government entities that possess naloxone, including those that use automated mechanisms, from the requirement to be licensed as a terminal distributor of dangerous drugs. The bill also expressly exempts health care practitioners from the licensure requirement in order to maintain naloxone for use in personally furnishing supplies of the drug. Under current law, licensure exemptions apply only to law enforcement agencies and its officers and to service entities that maintain naloxone.¹¹

Immunity

The bill provides various immunities related to the general access and supply authorizations discussed above. The immunities are similar to those in existing law. Specifically,

⁷ R.C. 4729.514, repealed.

⁸ R.C. 3715.50(B)(1).

⁹ Ohio Administrative Code 4729:5-3-19.

¹⁰ R.C. 3715.50(B)(2).

¹¹ R.C. 4729.541(A)(11) and (12).

a person or government entity that exercises the authority granted by the bill is not subject to administrative action or criminal prosecution, and is not liable for civil damages arising from exercising that authority.¹² Additionally, after naloxone has been dispensed or personally furnished, the person or government entity is not liable for damages in a civil action, criminal prosecution, or professional disciplinary action.¹³

The bill does not eliminate, limit, or reduce any other immunity or defense that a person or government entity may have under existing law governing the general immunity of public officers and employees,¹⁴ political subdivision tort liability,¹⁵ emergency medical personnel immunity,¹⁶ or any other provision of Ohio law or common law of Ohio.¹⁷

Issuing prescriptions and personally furnishing supplies

The bill generally maintains current law that authorizes physicians, physician assistants, and advanced practice registered nurses to issue prescriptions for naloxone and personally furnish supplies of naloxone without having examined the individual to whom it may be administered.¹⁸ Similar to current law, the practitioner must provide to the individual receiving the prescription or supply instructions regarding the emergency administration, including a specific instruction to summon emergency services as necessary.

The bill specifies that if a prescription for naloxone does not include the name of the individual to whom the drug may be administered, a pharmacist or pharmacy intern may dispense the naloxone to the individual who received the prescription.¹⁹

The bill provides immunity from civil damages, criminal prosecution, and professional disciplinary action for practitioners who prescribe, personally furnish, or dispense in accordance with the authority described above.²⁰

¹² R.C. 3715.50(C)(1); see also R.C. 2925.61, repealed.

¹³ R.C. 3715.50(C)(2).

¹⁴ R.C. 9.86, not in the bill.

¹⁵ R.C. Chapter 2744, not in the bill.

¹⁶ R.C. 4765.49, not in the bill.

¹⁷ R.C. 3715.50(D)(2).

¹⁸ R.C. 3715.501(B)(1); see also R.C. 4723.484, 4730.434, and 4731.94, all repealed.

¹⁹ R.C. 3715.501(B)(2). Current law instead specifies that 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 is a “prescription” under Ohio law (R.C. 4729.01(H)(2), eliminated by the bill).

²⁰ R.C. 3715.501(C).

Protocols for pharmacist dispensing of naloxone

The bill modifies existing law related to who may authorize a pharmacist or pharmacy intern to dispense naloxone without a prescription pursuant to a protocol. Under current law, physicians and boards of health may authorize dispensing pursuant to a protocol. The bill eliminates the authority for boards of health to authorize dispensing pursuant to a protocol,²¹ but expands the authority to physician assistants and advanced practice registered nurses (in addition to physicians, whose current authority is maintained).²² The bill otherwise maintains current law regarding the details of a pharmacist and pharmacy intern dispensing pursuant to a protocol, such as who naloxone may be dispensed to, emergency instructions, and immunity provisions.

Protocols for others to personally furnish naloxone

In addition to the above protocol authority, the bill continues to authorize physicians, physician assistants, and advanced practice registered nurses to establish protocols authorizing any individual to personally furnish a supply of naloxone to another individual pursuant to a protocol. The person furnishing the naloxone need not examine the individual to whom the naloxone may be administered.²³

A protocol established must include all of the following:²⁴

1. Any limitations concerning individuals to whom naloxone may be personally furnished;
2. The dosage that may be furnished, and any variation in the dosage based on circumstances specified in the protocol;
3. Any labeling, storage, recordkeeping, and administrative requirements;
4. Training requirements for individuals to dispense or furnish naloxone;
5. Any instructions or training that the authorized person must provide to the individual who is provided naloxone.

The bill eliminates existing requirements that the protocol include a description of the clinical pharmacology of naloxone and precautions and contraindications concerning furnishing naloxone.²⁵

²¹ R.C. 3707.56, repealed; R.C. 3715.502 (renumbered from R.C. 4729.44). There is likely no practical effect to eliminating board of health authority given the broad authority in R.C. 3715.50, and because physicians, including presumably a physician serving as a board's health commissioner or medical director, will continue to be able to authorize dispensing without a prescription pursuant to a protocol.

²² R.C. 3715.502(B); see R.C. 4731.942, repealed.

²³ R.C. 3715.503(B).

²⁴ R.C. 3715.503(C).

²⁵ R.C. 4723.485(C)(1) and (2), 4730.435(C)(1) and (2), and 4731.941(C)(1) and (2), all repealed.

The bill maintains the immunity in current law from civil damages, criminal prosecution, and professional disciplinary action for physicians, physician assistants, and advanced practice registered nurses who in good faith authorize personally furnishing naloxone in accordance with a protocol, and for individuals who personally furnish in good faith.²⁶

Administering naloxone

The bill expressly authorizes an individual, when not otherwise authorized by the Revised Code to administer drugs, to administer naloxone if the individual is in a position to assist another who is apparently experiencing an opioid-related overdose.²⁷ While current law does not contain such a generally applicable express authorization, it does provide immunity to such individuals and others who administer naloxone in good faith.²⁸ The bill generally maintains similar immunity, providing that an individual who administers naloxone is not liable for damages in a civil action, or subject to administrative action or criminal prosecution, so long as the individual, acting in good faith, (1) obtains the naloxone in a manner authorized by the bill, (2) administers it to an individual who is apparently experiencing an opioid-related overdose, and (3) attempts to summon emergency services as soon as practicable, unless emergency services have already been summoned or are present.²⁹

It appears the bill's express authorization to administer naloxone encompasses a more specific authorization from current law that is eliminated by the bill, which permits certain prescribers to authorize, through a protocol, individuals associated with services entities (described above) to administer naloxone to individuals who are apparently experiencing opioid-related overdoses.³⁰

Fentanyl test strips and other narcotic testing products

The bill provides that, notwithstanding existing criminal law that prohibits the use and possession of drug paraphernalia,³¹ a person is authorized to provide, administer, or use narcotic testing products and equipment, including fentanyl test strips, to determine whether toxic or hazardous substances are present. A person who, in good faith, provides, administers, or uses those testing products or equipment as authorized by the bill is immune from criminal

²⁶ R.C. 3715.305(D).

²⁷ R.C. 3715.504(A).

²⁸ R.C. 2925.61, repealed.

²⁹ R.C. 3715.504(B).

³⁰ R.C. 4723.486, 4730.436, and 4731.943, all repealed. The bill also eliminates board of health authority related to protocols to personally furnish supplies, and related to service entities. R.C. 3707.561 and 3707.562, repealed.

³¹ R.C. 2925.14, not in the bill.

prosecution and is not liable for civil damages associated with providing, administering, or using narcotic testing products and equipment.³²

HISTORY

Action	Date
Introduced	02-15-22

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³² R.C. 2925.142.