# Ohio Legislative Service Commission

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## Sub. S.B. 319

131st General Assembly
(As Passed by the Senate)

**Sens.** Eklund, Manning, Beagle, Tavares, Brown, Coley, Faber, Jones, Obhof, Skindell, Thomas, Uecker, Williams

## BILL SUMMARY

### PHARMACY AND DRUG LAWS

### Pharmacy technician registration

- Establishes a system of registration through the State Board of Pharmacy for registered pharmacy technicians, certified pharmacy technicians, and pharmacy technician trainees that replaces existing law governing employment as a pharmacy technician.

- Specifies requirements for registration, including age, education and experience, character, criminal records check, and certification requirements.

- Specifies certain activities, excluding any that require the exercise of professional judgment, that a pharmacy technician or trainee may, under the direct supervision of a pharmacist, engage in at a location licensed as a terminal distributor of dangerous drugs.

- Specifies conduct for which the Board may impose disciplinary sanctions on a pharmacy technician or trainee.

- Requires the Board to suspend the registration of a pharmacy technician or trainee who is or becomes addicted to controlled substances.

### Pharmacist and pharmacy intern discipline

- Authorizes the Board to restrict a pharmacist or pharmacy intern's license or reprimand the license holder.

- Makes changes to the conduct for which the Board can impose sanctions, including specifying additional actions that constitute unprofessional conduct in the practice of pharmacy.

## Selling, purchasing, distributing, delivering, or possessing dangerous drugs

- Makes changes to provisions regarding the occasional sale of drugs at wholesale.

- Prohibits the unauthorized distribution of dangerous drugs at retail, which is in addition to the existing prohibition on the unauthorized retail sale and possession of dangerous drugs for sale at retail.

- Provides that a registered wholesale distributor of dangerous drugs is exempt only from the prohibition on possession of dangerous drugs, and is not exempt from the prohibition on selling, or possessing for sale, dangerous drugs at retail.

- Specifies that business entities whose members are authorized to provide the professional services being offered by the entity are exempt from the prohibition on possession of dangerous drugs.

- Requires prescribers and certain business entities through which prescribers provide professional services to be licensed as terminal distributors of dangerous drugs to possess, have custody or control of, or distribute schedule I, II, III, IV, or V controlled substances.

- Establishes a reduced fee of $60 for certain business entities and other persons required by the bill to obtain licenses as terminal distributors of dangerous drugs.

- Reorganizes, with certain modifications, other laws governing the authority to sell, purchase, distribute, deliver, or possess dangerous drugs.

## Board powers, duties, and procedures

- Authorizes the Board to maintain its books and records in electronic format.

- Authorizes the Board to adopt rules requiring a licensee or registrant to report to the Board a violation of state or federal law, including any rule adopted under the authority of the Pharmacy Law.

- Requires pharmacy interns, pharmacy technicians, pharmacy technician trainees, terminal distributors of dangerous drugs, and wholesale distributors of dangerous drugs to cooperate with federal, state, and local government investigations and to divulge all relevant information when requested by a government agency.

- Authorizes the Board to designate certain attorneys as hearing examiners to conduct any administrative hearing the Board is empowered to hold or undertake.

### Disciplinary action – controlled substances and dangerous drugs

- Expands the circumstances under which a licensing board may suspend a license, certificate, or evidence of registration without a hearing for actions related to controlled substances and extends this authority to actions related to other dangerous drugs.

## NALOXONE

### Access and administration

- Permits naloxone to be available for administration at locations that serve individuals who may be at risk of experiencing an opioid-related overdose.

- Permits a board of health to authorize one or more individuals to personally furnish a supply of naloxone to certain individuals.

- Modifies a board of health's authority to authorize a pharmacist or pharmacy intern to dispense naloxone without a prescription.

- Specifies that peace officers are entitled to qualified immunity for any act or omission associated with procuring, maintaining, accessing, or using naloxone.

### Project DAWN grants

- Authorizes county health departments to use grant funding to provide naloxone through a Project DAWN program within the county if the funds currently available for naloxone grants are not being used by local law enforcement, emergency personnel, and first responders.

## OPIOID ANALGESICS

### Outpatient prescriptions limited

- Limits the authority of a pharmacist, pharmacy intern, or terminal distributor of dangerous drugs to dispense or sell an opioid analgesic pursuant to an outpatient prescription.

- Specifies that not more than a 90-day supply may be dispensed or sold and that a prescription cannot be filled if more than 14 days have elapsed since it was issued or, if the prescription specifies the earliest date on which it may be filled, 14 days since that date.

## OFFICE-BASED OPIOID TREATMENT

### Licensure as terminal distributors

- Requires the State Board of Pharmacy to regulate facilities, clinics, or other locations at which office-based opioid treatment is provided to more than 30 patients, or that meet criteria specified in Board rules, through a licensing process that is similar to the Board's licensure of pain management clinics.

- Provides for such facilities, clinics, or other locations to be licensed as category III terminal distributors of dangerous drugs with an office-based opioid treatment classification.

- Authorizes the imposition of sanctions against a person who fails to obtain the required licensure or fails to comply with the bill's requirements for office-based opioid treatment.

## METHADONE TREATMENT FACILITIES

### Licensing requirements

- Eliminates existing provisions that require an applicant for a license to maintain a methadone treatment facility to (1) be operated by a nonprofit or government entity and (2) have been a fully certified services provider for at least two years immediately preceding the application date.

- Requires the Department of Mental Health and Addiction Services (ODMHAS) to adopt rules specifying any additional licensing requirements.

- Requires ODMHAS to conduct an analysis of unmet needs for methadone treatment in Ohio and the impact of the changes to the licensing requirements on the overall treatment capacity in Ohio.

## DRUG COURT PROGRAMS

### Medication-assisted treatment

- Authorizes a community addiction services provider to provide access to time-limited recovery supports as part of providing medication-assisted treatment services for certain addicted offenders.

- Specifies that recovery support is a form of assistance intended to help initiate and sustain recovery from alcoholism, drug addiction, or mental illness, but it does not include treatment or prevention services.

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# CONTENT AND OPERATION

## PHARMACY AND DRUG LAWS

### Pharmacy technician registration

The bill establishes a system of registration for two kinds of pharmacy technicians (registered pharmacy technicians and certified pharmacy technicians) and pharmacy technician trainees. Under current law, pharmacy technicians are not licensed or registered. Instead, persons who meet certain age, education, examination, and criminal background check requirements are designated as "qualified pharmacy technicians." Current law prohibits anyone who is not a pharmacist, pharmacy intern, or qualified pharmacy technician from engaging in certain activities that constitute part of the practice of pharmacy. Pharmacists, as well as pharmacy owners and managers,

cannot allow this prohibition to be violated by any person they employ or otherwise control.[1]

The bill repeals those provisions and instead creates a registration requirement for pharmacy technicians and trainees. The registration process is to be administered by the State Board of Pharmacy.

## Registration of registered and certified pharmacy technicians

### Registered pharmacy technicians – eligibility

The bill requires an applicant for registration as a registered pharmacy technician to meet all of the following conditions:

(1) Be at least 18 years old;

(2) Possess a high school diploma or certificate of high school equivalence (often referred to as a general equivalence diploma or GED), or have been employed continuously since before April 8, 2009, as a pharmacy technician without a high school diploma or GED;

(3) Be of good moral character, as defined in rules adopted by the Board;

(4) Comply with certain criminal records check requirements in existing law or, if the applicant meets the requirements to be a qualified pharmacy technician under existing law and had a criminal records check conducted within 24 months of the application date, authorize release of those results;

(5) Obtain from a pharmacy's responsible person an attestation that the applicant has successfully completed education and training that meets the requirements established by the Board in rules the bill requires the Board to adopt, except that for two years after the bill takes effect, an applicant who meets the requirements in existing law to be a qualified pharmacy technician may submit an attestation from a pharmacy's responsible person that the applicant has completed a pharmacy training and education program that is appropriate for a qualified pharmacy technician under current rules (including instruction in packaging and labeling drugs; pharmacy terminology; basic drug information; basic calculations; quality control procedures; non-sterile drug compounding; and state and federal statutes, rules, and regulations).[2]

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[1] R.C. 4729.90, 4729.901, 4729.92, and 4729.921; R.C. 4729.42, repealed.

[2] R.C. 4729.90, 4776.02, and 4776.04; R.C. 4729.42, repealed.

Under the bill, "responsible person" has the same meaning as in rules adopted by the Board.[3]

Under current law repealed by the bill, a qualified pharmacy technician must meet the same age and education (or experience if employed continuously since before April 8, 2009, without a high school diploma or GED) requirements as a registered pharmacy technician under the bill. Under current law, qualified pharmacy technician applicants also must comply with requesting and reporting requirements of criminal records check provisions that are applicable to applicants for an initial or restored license from a licensing agency and pass a competency examination approved by the Board.

**Certified pharmacy technicians – eligibility**

The bill requires an applicant for registration as a certified pharmacy technician to comply with the same age, moral character, and criminal records check requirements as an applicant for registration as a registered pharmacy technician. The applicant must also meet all of the following:

(1) Possess a high school diploma or GED;

(2) Obtain from a pharmacy's responsible person an attestation that the applicant has successfully completed education and training that meets the requirements established by the Board in rules the bill requires the Board to adopt, except that for two years after the bill takes effect, an applicant who meets the requirements in existing law to be a qualified pharmacy technician may submit an attestation from a pharmacy's responsible person that the applicant has completed a pharmacy training and education program that is appropriate under current rules (described above) plus instruction on sterile drug compounding and on preparing and mixing intravenous drugs that are to be injected into a human being;

(3) Have a current pharmacy technician certification from an organization that has been recognized by the Board.[4]

**Application process**

The bill requires an applicant for registration as a pharmacy technician to file an application with the Board in the form and manner prescribed by the Board in rules the

[3] R.C. 4729.90(A).

[4] R.C. 4729.90; R.C. 4729.42, repealed.

bill requires the Board to adopt. The application must be accompanied by a nonrefundable $55 application fee.

If the Board is satisfied that the applicant meets the requirements discussed above and any additional requirements the Board establishes, and if the Board determines that the results of the criminal records check do not make the applicant ineligible, the Board is required to register the applicant as a registered pharmacy technician or certified pharmacy technician, as applicable. A pharmacist or pharmacy intern whose license has been denied, revoked, suspended, or otherwise restricted by the Board cannot be registered as a pharmacy technician under the bill.

Registration is valid for a period specified by the Board in rules the bill requires the Board to adopt, but the period cannot exceed 24 months unless the Board extends the period in the rules to adjust license renewal schedules.[5]

**Registration renewal**

A registered pharmacy technician or certified pharmacy technician who wishes to renew must file an application for registration renewal in the form and manner prescribed by the Board in rules the bill requires the Board to adopt. Registration must be renewed in accordance with the Board's rules and standard renewal procedures established under existing law. The renewal fee is $25 per year.

A registered pharmacy technician or certified pharmacy technician who fails to renew registration in accordance with the bill's requirements is prohibited from engaging in authorized activities, which are discussed below.

If a registration not renewed by the date specified in the rules has not lapsed for more than 90 days, it may be reinstated if the applicant submits a renewal application, the renewal fee, and a late fee of $50. Registration that has lapsed for more than 90 days cannot be renewed, but the registration holder may reapply for registration.[6]

**Authorized activities**

The bill provides that registered pharmacy technicians and certified pharmacy technicians may, under the direct supervision of a pharmacist, engage in certain activities at a location licensed as a terminal distributor of dangerous drugs to the extent that the activities do not require the exercise of professional judgment. Terminal

[5] R.C. 4729.901.

[6] R.C. 4729.902.

distributors of dangerous drugs are entities, such as pharmacies, that sell prescription drugs at retail.

For registered pharmacy technicians, the activities authorized by the bill are:

(1) Accepting new prescription orders from a prescriber or a prescriber's agent;

(2) Entering information into and retrieving information from a database or patient profile;

(3) Preparing and affixing labels;

(4) Stocking dangerous drugs and retrieving those drugs from inventory;

(5) Counting and pouring dangerous drugs into containers;

(6) Placing dangerous drugs into patient storage containers;

(7) Non-sterile drug compounding as authorized in rules the Board is required to adopt under the bill;

(8) Other activities specified by the Board in rules to be adopted under the bill.[7]

Certified pharmacy technicians are authorized to conduct all of the activities a registered pharmacy technician is authorized to conduct plus the following:

(1) Accepting or requesting refill authorizations for dangerous drugs that are not controlled substances from a prescriber or the prescriber's agent, so long as there is no change from the original prescription;

(2) Sterile drug compounding as authorized in rules the Board is required to adopt under the bill;

(3) Other activities specified by the Board in rules to be adopted under the bill.[8]

## Pharmacy technician trainee registration

### Eligibility

The bill requires an applicant for registration as a pharmacy technician trainee to comply with the same age, high school diploma (or GED or continuous employment

[7] R.C. 4729.91(A).

[8] R.C. 4729.91(B).

since before April 8, 2009), and moral character requirements as an applicant for registration as a registered pharmacy technician, as discussed above. The applicant must be enrolled in or plan to enroll in education and training that will allow the applicant to meet the requirements established by the Board in rules to be adopted under the bill. The applicant also must comply with criminal records check requirements in existing law.[9]

#### Application process

A pharmacy technician trainee applicant is required by the bill to file an application with the Board in the form and manner prescribed by the Board in rules required to be adopted under the bill. The application must include a nonrefundable $25 application fee.

The Board is required to register the applicant as a pharmacy technician trainee if it is satisfied that the applicant meets the requirements described above plus any additional requirements established by the Board and determines that the results of the criminal records check do not make the applicant ineligible. A pharmacist or pharmacy intern whose license has been denied, revoked, suspended, or otherwise restricted by the Board cannot be registered as a pharmacy technician trainee.

Registration is valid for one year from the date of registration and is not renewable. However, an individual may reapply if the individual's previous registration has lapsed for more than five years or with Board approval.[10]

#### Authorized activities

A pharmacy technician trainee may, under the direct supervision of a pharmacist, engage in the same activities as a registered pharmacy technician, as described above.[11]

### Sanctions for registered pharmacy technicians and trainees

The bill specifies that the Board, after notice and a hearing in accordance with the Administrative Procedure Act (R.C. Chapter 119.), may impose certain sanctions if a registered pharmacy technician, certified pharmacy technician, or pharmacy technician trainee is found to:

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[9] R.C. 4729.92.

[10] R.C. 4729.921.

[11] R.C. 4729.93.

(1) Have been convicted of a felony, or a crime of moral turpitude, as defined under existing law;

(2) Have engaged in dishonesty or unprofessional conduct, as prescribed in rules the Board is required to adopt under the bill;

(3) Be addicted to or abusing alcohol or drugs, or impaired physically or mentally to such a degree as to render the individual unable to perform the individual's duties;

(4) Have violated, conspired to violate, attempted to violate, or aided and abetted the violation of any provisions of the Pharmacy Law, Drug Offenses Law, Controlled Substances Law, certain provisions of the Pure Food and Drug Law, or any rules adopted by the Board under any of those laws;

(5) Have committed fraud, misrepresentation, or deception in applying for or securing a registration issued by the Board;

(6) Have failed to comply with an order of the Board or a settlement agreement;

(7) Have engaged in any other conduct for which the Board may impose discipline as set forth in rules that the Board is required to adopt under the bill.

The sanctions the Board may impose are:

(1) Revoking, suspending, restricting, limiting, or refusing to grant or renew a registration;

(2) Reprimanding or placing the registration holder on probation;

(3) Imposing a fine or forfeiture not to exceed in severity any fine designated under existing law for a similar offense, or if existing law does not have a penalty, a fine or forfeiture not to exceed $500. [12]

The bill states that if the Administrative Procedure Act requires the Board to give notice of an opportunity for a hearing and an applicant or registrant does not make a timely request for a hearing in accordance with the Act, the Board is not required to hold a hearing, but may adopt a final order that contains the Board's findings. In the final order, the Board may impose any of the sanctions listed above.[13]

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[12] R.C. 4729.96(A).

[13] R.C. 4729.96(D).

The bill provides that an individual authorized to practice as a pharmacy technician trainee, registered pharmacy technician, or certified pharmacy technician accepts the privilege of practicing in this state subject to supervision by the Board. The act of filing an application for or holding registration constitutes consent to submitting to a mental or physical examination when ordered by the Board in writing, as well as a waiver of all objections to the admissibility of testimony or examination reports that constitute privileged communications.

The bill authorizes the Board to require a pharmacy technician or trainee to submit to a physical or mental examination, or both, if the Board has reasonable cause to believe that the individual is physically or mentally impaired. The bill specifies that the expense of the examination is the responsibility of the individual to be examined.

If the individual fails to submit to the ordered examination, absent circumstances beyond the individual's control, the allegations will be deemed admitted and a suspension order must be entered without taking testimony or presenting evidence. Any subsequent administrative hearing concerning the failure to submit to an examination is limited to consideration of whether the failure was beyond the individual's control.

If, based on the results of an ordered examination, the Board determines that the individual's ability to practice is impaired, the Board is required to suspend the individual's registration or deny the individual's application. The Board must require submission to a physical or mental examination and treatment as a condition of initial, continued, reinstated, or renewed registration to practice.

An order of suspension issued by the Board cannot be suspended by a court while an administrative appeal is pending.[14]

Regarding the sealing of records, the bill provides that, notwithstanding existing law that specifies that if records pertaining to a criminal case are sealed the proceedings are deemed not to have occurred, sealing the following records on which the Board has based an action for sanctions does not have an effect on the Board's action or any sanction imposed: records of any conviction, guilty plea, judicial finding of guilt resulting from a plea of no contest, or a judicial finding of eligibility for a pretrial diversion program or intervention in lieu of conviction. The bill provides that the Board is not required to seal, destroy, redact, or otherwise modify its records to reflect the court's sealing of conviction records.[15]

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[14] R.C. 4729.96(C).

[15] R.C. 4729.96(E).

### Criminal acts

The bill prohibits a registered pharmacy technician, certified pharmacy technician, or pharmacy technician trainee from knowingly engaging in any of the following:

(1) Dishonesty or unprofessional conduct, as prescribed in rules the Board is required to adopt under the bill;

(2) Violation, or conspiracy, attempting, or aiding in the violation of, any provisions of the Pharmacy Law, Drug Offenses Law, Controlled Substances Law, certain provisions of the Pure Food and Drug Law, or any rules adopted by the Board under any of those laws;

(3) Fraud, misrepresentation, or deception in applying for or securing a registration issued by the Board;

(4) Any other conduct for which the Board may impose discipline as set forth in rules that the Board is required to adopt under the bill.

Under the bill, a violation of the prohibition described above is a minor misdemeanor, unless a different penalty is specified in the Revised Code.[16]

### License suspension for controlled substance addiction or other harm

The bill adds persons who are registered pharmacy technicians, certified pharmacy technicians, or pharmacy technician trainees to the licensed health professionals whose license, certificate, or registration must be suspended by the board that issued it if the person is or becomes addicted to the use of controlled substances. The State Board of Pharmacy may suspend a technician or trainee's registration under that provision by telephone conference call. Under existing law maintained by the bill, the suspension lasts until the person offers satisfactory proof that the person is no longer addicted to the use of controlled substances.[17]

Current law also provides that if the issuing board determines that there is clear and convincing evidence that the continuation of a person's professional practice or method of prescribing or personally furnishing controlled substances presents a danger of immediate and serious harm to others, the board may suspend the person's license, certificate, or registration without a hearing. The bill provides that such a summary suspension is also authorized when dangerous drugs are involved, as well as if the

[16] R.C. 4729.96(F) and 4729.99.

[17] R.C. 3719.121(A) and 4729.96(B).

person's administration or dispensing of controlled substances or other dangerous drugs presents the danger of immediate or serious harm.

### Prohibitions and penalties

The bill prohibits a person who is not a pharmacist, pharmacy intern, registered pharmacy technician, certified pharmacy technician, or pharmacy technician trainee from knowingly engaging in any of the activities that a registered pharmacy technician or certified pharmacy technician is authorized to engage in at a location licensed as a terminal distributor of dangerous drugs, or while performing the function of a terminal distributor. However, the bill provides that it does not prevent a licensed health professional from engaging in activities that are authorized as part of the health professional's practice. A person who violates this prohibition is guilty of unauthorized pharmacy-related drug conduct, which is a second degree misdemeanor unless the offender previously has been convicted of or pleaded guilty to a violation of that prohibition or the prohibitions discussed below.[18]

Current law contains a similar prohibition and penalty for pharmacists, pharmacy interns, and qualified pharmacy technicians, except that it only prohibits engaging in the compounding of any drug, packaging or labeling any drug, and preparing or mixing any intravenous drug to be injected.

The bill, similar to current law, also prohibits (1) a pharmacist from knowingly allowing any person employed by or otherwise under the control of the pharmacist to violate the prohibition described above, and (2) a terminal distributor of dangerous drugs from knowingly allowing any person employed by or otherwise under the control of the person who owns, manages, or conducts the terminal distributor to violate the prohibition described above. As under current law, a person who violates this prohibition is guilty of permitting unauthorized pharmacy-related drug conduct, which is a second degree misdemeanor unless the person is a repeat offender.

The bill does not maintain current law that prohibits a qualified pharmacy technician from modifying or altering, or allowing another to modify or alter any item, record, or information contained in a criminal records check report or to submit or use it for any purpose or in any manner that would constitute the crime of falsification under existing law. Under current law, an individual who violates the provision being eliminated by the bill is guilty of the crime of falsification and forever disqualified from performing services as a qualified pharmacy technician, health care professional, or health care worker. However, as discussed above, the bill does permit the Board to

[18] R.C. 3719.21, 4729.95 and 4729.99; R.C. 4729.42, repealed.

discipline for committing fraud, misrepresentation, or deception in applying for or securing a registration issued by the Board.

### Rules on registration of pharmacy technicians and trainees

In addition to the rules described above concerning forms, education and training requirements, additional authorized activities, compounding requirements, and conduct for which a technician may be disciplined, the bill requires the Board to adopt rules specifying continuing education requirements. The Board may also adopt other rules that it considers appropriate to implement the provisions regarding registered pharmacy technicians, certified pharmacy technicians, and pharmacy technician trainees.[19]

### Other eliminated provisions regarding qualified pharmacy technicians

In requiring registration for pharmacy technicians and trainees, in addition to the changes discussed above, the bill eliminates a provision stating that examination materials submitted to the Board by a person that develops or administers a pharmacy technician examination are not public records under Ohio's Public Records Law. It also eliminates several "grandfathering" provisions that apply to qualified pharmacy technicians employed as pharmacy technicians after April 8, 2009.[20]

## Disciplinary actions and penalties for pharmacists and pharmacy interns

### Restrictions and reprimands

The bill makes several changes to existing provisions authorizing the State Board of Pharmacy to impose sanctions on pharmacists and pharmacy interns.[21] Under current law, the Board may revoke, suspend, limit, place on probation, or refuse to grant or renew an identification card. Alternatively, the Board may impose a fine or forfeiture not to exceed in severity any fine designated for a similar offense, or in the case of a violation that does not bear a penalty, a fine or forfeiture of not more than $500. The bill adds that the Board also may restrict a license and reprimand a license holder.

### Grounds for discipline

The bill also makes several changes concerning the conduct for which a licensee may be disciplined.[22] Under current law, one reason a sanction may be imposed is if the

[19] R.C. 4729.94.

[20] R.C. 4729.42, repealed.

[21] R.C. 4729.16.

[22] R.C. 4729.16.

Board finds a pharmacist or pharmacy intern guilty of a felony or gross immorality. The bill instead permits a sanction to be imposed if the Board finds that the individual has been convicted of a felony or a crime of moral turpitude, as defined under existing law. Additionally, the bill authorizes the Board to impose sanctions if a pharmacist or pharmacy intern has done either of the following:

(1) Failed to comply with an order of the Board or a settlement agreement;

(2) Engaged in any other conduct for which the Board may impose discipline as set forth in rules the Board may adopt under the bill.

Another circumstance in which the Board may impose sanctions under current law is if the person has engaged in unprofessional conduct in the practice of pharmacy. Current law defines the unprofessional practice of pharmacy and the bill adds that it also includes the following:

(1) Failing to conform to prevailing standards of care of similar pharmacists or pharmacy interns under the same or similar circumstances, whether or not actual injury to the patient is established;

(2) Engaging in any other conduct that the Board specifies as unprofessional conduct in the practice of pharmacy in rules that the bill authorizes the Board to adopt.

### Board-ordered physical or mental examinations

Current law authorizes the Board to require a pharmacist or pharmacy intern to submit to a physical or mental examination, or both, if the Board has reasonable cause to believe that the individual is physically or mentally impaired, based on an adjudication under the Administrative Procedure Act (R.C. Chapter 119.). The bill removes the requirement that the Board's belief be based on an administrative adjudication.

Instead, the bill provides that an individual authorized to practice as a pharmacist or pharmacy intern accepts the privilege of practicing in Ohio subject to supervision of the Board. By filing an application or holding a license to practice as a pharmacist or pharmacy intern, an individual gives consent to submit to a physical or mental examination when ordered to do so by the Board in writing. The individual also waives all objections to the admissibility of testimony or examination reports that constitute privileged communications.

The bill adds that if the individual fails to submit to the ordered examination, absent circumstances beyond the individual's control, the allegations will be deemed admitted and a suspension order must be entered without taking testimony or

presenting evidence. Any subsequent administrative hearing concerning failure to submit to an examination is limited to consideration of whether the failure was beyond the individual's control.

If the Board determines, based on the results of an ordered physical or mental examination, that the individual's ability to practice is impaired, the Board is required to suspend the individual's license or deny the individual's application. The Board must require submission to a physical or mental examination and treatment as a condition of an initial, continued, reinstated, or renewed license to practice. The bill specifies that the expense of the examination is the responsibility of the individual to be examined.

An order of suspension issued under the bill's provisions cannot be suspended by a court while an administrative appeal is pending.[23]

### Timely requests for hearings

The bill adds a provision regarding hearings conducted by the Board. It provides that if the Administrative Procedure Act requires the Board to give notice of an opportunity for a hearing and an applicant or licensee does not make a timely request for a hearing in accordance with the Act, the Board is not required to hold a hearing, but may adopt a final order that contains the Board's findings. In the final order, the Board may impose any of the sanctions listed above.[24]

### Sealing of records

Regarding the sealing of records, the bill provides that, notwithstanding existing law that specifies that if records pertaining to a criminal case are sealed the proceedings are deemed not to have occurred, the sealing of the following records on which the Board has based an action for sanctions does not have an effect on the Board's action or any sanction imposed: records of any conviction, guilty plea, judicial finding of guilt resulting from a plea of no contest, or a judicial finding of eligibility for a pretrial diversion program or intervention in lieu of conviction. The bill provides that the Board is not required to seal, destroy, redact, or otherwise modify its records to reflect the court's sealing of conviction records.[25]

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[23] R.C. 4729.16(E) and 4729.18.

[24] R.C. 4729.16(F).

[25] R.C. 4729.16(G).

### Criminal penalties

The bill clarifies the conduct for which the Board may impose a criminal penalty. Under current law, engaging in any conduct for which the Board may impose sanctions constitutes a minor misdemeanor. Instead, the bill specifies that a criminal penalty can be imposed when a person knowingly engages in any of the following sanctionable conduct:

(1) Dishonesty or unprofessional conduct in the practice of pharmacy;

(2) Having violated, conspired to violate, attempted to violate, or aided and abetted the violation of any provisions of the Pharmacy Law, Drug Offenses Law, Controlled Substances Law, certain provisions of the Pure Food and Drug Law, or any rules adopted by the Board under any of those laws;

(3) Permitting someone other than a pharmacist or pharmacy intern to engage in the practice of pharmacy;

(4) Knowingly lending the pharmacist or pharmacy intern's name to an illegal practitioner of pharmacy, or having a professional connection with an illegal practitioner;

(5) Dividing or agreeing to divide remuneration made in the practice of pharmacy with another individual;

(6) Violating the terms of a pharmacist consult agreement;

(7) Committing fraud, misrepresentation, or deception in applying for or securing a license or identification card issued under the Pharmacy Law, the Pure Food and Drug Law, or the Controlled Substances Law;

(8) Engaging in any other conduct for which the Board may impose discipline as set forth in rules adopted by the Board.

The criminal penalty remains a minor misdemeanor under the bill, unless a different penalty is specified in the Revised Code.[26]

## Selling, purchasing, distributing, or delivering dangerous drugs

The bill makes both substantive and organizational changes to existing law that governs selling, purchasing, distributing, and delivering dangerous drugs, including

[26] R.C. 4729.16(A) and (H) and 4729.99.

changes to which persons are exempt from licensure as a terminal distributor of dangerous drugs.

### Who may make wholesale sales of dangerous drugs

As under current law, the bill generally prohibits any person other than a registered wholesale distributor of dangerous drugs from possessing for sale, selling, distributing, or delivering, at wholesale, dangerous drugs. Current law provides for several exceptions to that prohibition, and the bill makes both substantive and organizational changes to those exceptions. The bill provides the following exceptions:

(1) A licensed terminal distributor of dangerous drugs that is a pharmacy may make occasional sales of dangerous drugs at wholesale (instead of current law which provides that a pharmacist who is a licensed terminal distributor, or employed by a licensed terminal distributor, may make occasional sales of dangerous drugs at wholesale);

(2) A licensed terminal distributor of dangerous drugs having more than one licensed location may transfer or deliver dangerous drugs from one licensed location to another licensed location owned by that terminal distributor if the license issued for each location is in effect at the time of the transfer or delivery (instead of current law which refers to a licensed terminal distributor having more than one "establishment or place" instead of "licensed location");

(3) A licensed terminal distributor of dangerous drugs that is not a pharmacy may make occasional sales of naloxone at wholesale (instead of current law which specifies that a board of health or health department may make occasional sales of naloxone at wholesale to state or local law enforcement).[27]

The bill moves one other exception in current law to a new section of the Revised Code. Regarding donation of inhalers and epinephrine autoinjectors, the bill continues to permit a manufacturer of dangerous drugs to donate inhalers and epinephrine autoinjectors to boards of education, community schools, STEM schools, college-preparatory boarding schools, and chartered or nonchartered nonpublic schools.[28]

### Who a wholesale distributor may sell dangerous drugs to

The bill continues to prohibit a registered wholesale distributor of dangerous drugs from possessing for sale, or selling, at wholesale, dangerous drugs, and adds that

[27] R.C. 4729.51(A).

[28] R.C. 4729.513.

the distributor also may not distribute dangerous drugs, except to specified persons. Current law lists 16 persons to whom a wholesale distributor may sell dangerous drugs. Instead, the bill classifies many of those persons as persons exempt from licensure as a terminal distributor of dangerous drugs. Accordingly, the specified persons to whom a wholesale distributor may sell dangerous drugs to under the bill are the following:

(1) A licensed terminal distributor of dangerous drugs, subject to existing limitations based on the category of the terminal distributor's license;

(2) Any person exempt from licensure as a terminal distributor of dangerous drugs as described in the bill, subject to limitations for prescribers employed by a pain management clinic or an office-based opioid treatment facility (described below);

(3) A registered wholesale distributor of dangerous drugs;

(4) Terminal or wholesale distributors of dangerous drugs that are located in another state, not engaged in the sale of dangerous drugs within Ohio, and actively licensed to engage in the sale of dangerous drugs by the state in which the distributor conducts business.

The bill does not maintain provisions designating the following persons as persons to whom a wholesale distributor may sell dangerous drugs:

(1) A licensed optometrist who holds a topical ocular pharmaceutical agents certificate;

(2) A manufacturer of dangerous drugs;

(3) Carriers or warehouses for the purpose of carriage or storage.[29]

**Limitation on a wholesaler selling dangerous drugs to certain prescribers**

Similar to current law, the bill continues to prohibit a registered wholesale distributor of dangerous drugs from possessing for sale, selling, or distributing, at wholesale, dangerous drugs to a prescriber who is employed by a pain management clinic that is not licensed as a terminal distributor of dangerous drugs with a pain management clinic classification issued under existing law. However, the bill removes a provision of current law that prohibits selling to certain business entities that are or operate a pain management clinic without a license as a terminal distributor with a pain management clinic classification.

[29] R.C. 4729.51(B) and 4729.541 (primary) and 2947.231.

The bill also prohibits selling dangerous drugs at wholesale to a prescriber who is employed by an office-based opioid treatment facility pursuant to the bill's provisions requiring licensure of those facilities (described below).

#### Limitation on a wholesaler selling dangerous drugs to a terminal distributor

The bill maintains provisions in current law that restrict the category of dangerous drugs a wholesaler may sell at wholesale to a licensed terminal distributor of dangerous drugs. The bill also applies that restriction to the distribution of such drugs by a registered wholesale distributor to a licensed terminal distributor.[30]

### Prohibition on the retail sale and possession of dangerous drugs

Subject to numerous exceptions, current law maintained by the bill prohibits the following:

(1) Selling dangerous drugs at retail;

(2) Possessing dangerous drugs for sale at retail;

(3) Possessing dangerous drugs.

The bill clarifies that the unauthorized distributing of dangerous drugs at retail is also prohibited.[31]

#### Exemptions to all three prohibitions

The following persons and entities currently exempt from the prohibitions listed above are maintained by the bill:

(1) A licensed terminal distributor of dangerous drugs;

(2) A person who possesses, or possesses for sale or sells, at retail, a dangerous drug in accordance with the Controlled Substances Law, Pharmacy Law, and laws governing the following licensed health professionals: dentists, nurses, optometrists, pharmacists, physician assistants, physicians, and veterinarians;

(3) An individual who holds a current license, certificate, or registration issued under Title XLVII of the Revised Code and has been certified to conduct diabetes education by a national certifying body if diabetes education is within the individual's scope of practice;

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[30] R.C. 4729.51(D).

[31] R.C. 4729.51(E) (primary) and 2929.14.

(4) An individual who holds a valid certificate issued by a nationally recognized S.C.U.B.A. diving certifying organization with respect to medical oxygen that will be used for the purpose of emergency care or treatment at the scene of a diving emergency.

Additionally, the bill adds that the following are exempt from all three prohibitions:

(1) A business entity that under Ohio law is a corporation, limited liability company, or professional association if the entity has a sole shareholder who is a prescriber and is authorized to provide the professional services being offered by the entity;

(2) A business entity that under Ohio law is a corporation, limited liability company, partnership or limited liability partnership, or professional association if, to be a shareholder, member, or partner, an individual is required to be licensed, certified, or otherwise legally authorized under Ohio law governing occupations and professions to perform the professional service provided by the entity and each such individual is a prescriber;

(3) A facility that is owned and operated by the United States Departments of Defense or Veterans Affairs.[32]

**Exemptions to the prohibition on possession only**

Under current law, a registered wholesale distributor of dangerous drugs is exempt from all three prohibitions listed above. Under the bill, a wholesaler is exempt only from the prohibition on possession of dangerous drugs. Similar to current law, the following remain exempt from the prohibition on possession of dangerous drugs:

(1) Schools and camps possessing epinephrine autoinjectors and inhalers in accordance with existing law;

(2) With respect to naloxone that may be possessed under existing law, a law enforcement agency and its peace officers (under current law, a law enforcement agency or the agency's peace officers are exempt from the prohibition on possessing drugs if the agency or officers possess naloxone for administration to individuals who are apparently experiencing opioid-related overdoses).

[32] R.C. 4729.51(E)(2)(a).

The bill also adds to the list of persons exempted from the prohibition on possession a service entity that may possess naloxone under the bill.[33]

### Purchase of dangerous drugs

Current law prohibits a licensed terminal distributor of dangerous drugs from purchasing dangerous drugs from any person other than a registered wholesale distributor of dangerous drugs, subject to numerous exceptions. The bill maintains this and adds that persons exempt from licensure under the bill's reorganized provisions[34] (see "**Exemption from licensure as a terminal distributor of dangerous drugs**," below) are also subject to that prohibition.[35]

#### Exception for occasional purchases

Regarding exceptions to that prohibition, current law provides that a licensed terminal distributor may make occasional purchases of dangerous drugs from a pharmacist who is a licensed terminal distributor or is employed by a licensed terminal distributor. Instead, the bill provides that a licensed terminal distributor or person exempt from licensure under the bill's reorganized provisions may make occasional purchases of dangerous drugs in accordance with the following:

(1) The person is making an occasional purchase of dangerous drugs from a pharmacy that is making an occasional sale of dangerous drugs at wholesale;

(2) The person is making an occasional purchase of naloxone from a terminal distributor of dangerous drugs that is not a pharmacy and that is making an occasional sale of naloxone at wholesale.[36]

#### Exception for more than one establishment or place of business

Current law provides that a licensed terminal distributor having more than one establishment or place of business may transfer or receive dangerous drugs from one licensed establishment or place of business to another. The bill generally maintains this but instead refers to a licensed terminal distributor having more than one licensed location, instead of establishment or place of business. This reflects terminology changes elsewhere in the bill. The bill also refers to delivering dangerous drugs from

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[33] R.C. 4729.51(E)(2)(b).

[34] See R.C. 4729.541.

[35] R.C. 4729.51

[36] R.C. 4729.51(F)(1).

one licensed location to another, instead of receiving dangerous drugs between locations.[37]

### Distribution of epinephrine autoinjectors and inhalers in schools

Regarding the existing authorization for schools to deliver epinephrine autoinjectors and inhalers, the bill instead provides that the schools may distribute the autoinjectors and inhalers in accordance with provisions in existing law.[38]

## Exemption from licensure as a terminal distributor of dangerous drugs

Subject to several exceptions, current law provides that certain business entities whose members are authorized to provide the professional services being offered by the entity may possess, have custody or control of, and distribute drugs in Category I, II, and III without holding a terminal distributor of dangerous drugs license. Instead, the bill provides that the following are exempt from licensure as a terminal distributor of dangerous drugs:

(1) A licensed health professional authorized to prescribe drugs;

(2) A business entity that is a corporation, limited liability company, or professional association formed under Ohio law if the entity has a sole shareholder who is a prescriber and is authorized to provide the professional services being offered by the entity (current law authorizes such an entity to possess, control, or distribute category I, II, or III drugs without holding a terminal distributor license);

(3) A business entity that is a corporation, limited liability company, partnership, limited liability partnership, or professional association formed under Ohio law, if, to be a shareholder, member, or partner, an individual is required to be licensed, certified, or otherwise legally authorized under Title XLVII of the Revised Code to perform the professional service provided by the entity and each such individual is a prescriber (current law authorizes such an entity to possess, control, or distribute category I, II, or III drugs without holding a terminal distributor license);

(4) An individual who holds a current license, certificate, or registration issued under Title XLVII of the Revised Code and has been certified to conduct diabetes education by a national certifying body, but only with respect to insulin that will be used for the purpose of diabetes education and only if diabetes education is within the

[37] R.C. 4729.51(F)(2).

[38] R.C. 4729.51(I).

individual's scope of practice under statutes and rules regulating the individual's profession;

(5) An individual who holds a valid certificate issued by a nationally recognized S.C.U.B.A. diving certifying organization approved by the State Board of Pharmacy, but only with respect to medical oxygen that will be used for the purpose of emergency care or treatment at the scene of a diving emergency;

(6) With respect to epinephrine autoinjectors that may be possessed under existing law, any of the following: the board of education of a city, local, exempted village, or joint vocational school district; a chartered or nonchartered nonpublic school; a community school; a STEM school; a college-preparatory boarding school; a residential camp; a child day camp; or a child day camp operated by any county, township, municipal corporation, township park district, park district, or joint recreation district;

(7) With respect to inhalers that may be possessed under existing law, any of the following: the board of education of a city, local, exempted village, or joint vocational school district; a chartered or nonchartered nonpublic school; a community school; a STEM school; a college-preparatory boarding school; a residential camp; a child day camp; or a child day camp operated by any county, township, municipal corporation, township park district, park district; or joint recreation district;

(8) With respect to naloxone that may be possessed under current law,[39] a law enforcement agency and its peace officers;

(9) With respect to naloxone that may be possessed under the bill, a service entity;

(10) A facility that is owned and operated by the United States Department of Defense, United States Department of Veterans Affairs, or any other federal agency.[40]

### Exceptions to the exemption from licensure

#### Pain management clinics and office-based opioid treatment providers

The bill requires persons otherwise exempt from licensure as a terminal distributor of dangerous drugs under the bill to obtain such a license if the person is a pain management clinic or operates a pain management clinic. This is similar to current law that requires a business entity that is or is operating a pain management clinic to

[39] See R.C. 2925.61.

[40] R.C. 4729.541(A) (primary) and 4729.68.

hold a license as a terminal distributor of dangerous drugs with a pain management clinic classification. The bill maintains this requirement and applies it to all persons otherwise exempt from licensure as a terminal distributor under the bill's provisions. Therefore, any pain management clinic or person operating a pain management clinic must be licensed as a terminal distributor of dangerous drugs with a pain management clinic classification.

Similar to pain management clinics, the bill adds that the exemption from licensure does not apply to persons operating a facility, clinic, or other location described in the office-based opioid treatment provisions of the bill if those provisions require the person to hold a category III terminal distributor of dangerous drugs license with an office-based opioid treatment classification.[41]

**Prescribers and their professional business entities**

The bill also contains an exception to the exemption from licensure when certain drugs are involved. It requires licensed health professionals authorized to prescribe drugs and certain business entities held by those professionals to hold a license as a terminal distributor of dangerous drugs to possess, have custody or control of, or distribute both compounded drugs and schedule I, II, III, IV, or V controlled substances.

Under current law, a business entity owned by a health professional to provide professional services is exempt from the requirement to be licensed as a terminal distributor of dangerous drugs, except that such an entity is required to be licensed to possess, have custody or control of, and distribute dangerous drugs that are compounded or used for the purpose of compounding. The bill maintains this exception and applies it to all persons exempted from licensure under the bill.

The bill also limits current law's exemption from licensure for those business entities by providing that the exemption does not apply in the case of possession, custody or control of, or distribution of a schedule I, II, III, IV, or V controlled substance. Because many of the exemptions relate to drugs that are not controlled substances (such as insulin, medical oxygen, epinephrine, medication in inhalers, and naloxone), the primary effect of the bill's provision is to require prescribers and the business entities that they provide professional services through to be licensed as terminal distributors of dangerous drugs to possess, have custody or control of, or distribute controlled substances.

The bill's exception regarding controlled substances replaces an exemption in current law specifically for possession, custody or control of, or distribution of

[41] R.C. 4729.541(B) and (C).

controlled substances containing buprenorphine used to treat drug dependence or addiction.[42]

### Terminal distributor fees

The fee for a terminal distributor license ranges from $45 to $150 depending on which drugs the license holder is authorized to possess. Under the bill, the fee is $60 for a person who would otherwise be exempt from licensure but must obtain a license because the person possesses, has custody or control of, or distributes compounded drugs or controlled substances under the exception described above. The bill maintains a reduced fee in current law for business entities organized for the purpose of practicing veterinary medicine. The fee for such entities is $40.[43]

### Conditions a wholesale distributor must meet before selling dangerous drugs

Under current law, before a registered wholesale distributor of dangerous drugs may sell dangerous drugs at wholesale to any person, the wholesale distributor generally must obtain from the purchaser a certificate indicating that the purchaser is a licensed terminal distributor of dangerous drugs. Current law exempts from that requirement most persons to whom a wholesaler is authorized to sell to under current law, except for individuals holding valid S.C.U.B.A. diving certifications and business entities whose members are authorized to provide the professional services being offered by the entity. The bill expands the exemption to include those previously unexempted individuals and entities by providing that a wholesale distributor does not have to obtain the certificate from any person exempted from licensure as a terminal distributor of dangerous drugs under the bill's reorganized provisions.[44]

## Board powers, duties, and procedures

The bill makes several additional changes to the laws administered by the State Board of Pharmacy.

### Books and registers

The bill authorizes the books and registers of the Board to be in electronic format, and also makes changes related to the bill's provisions for registering pharmacy technicians and trainees. Current law requires the Board to keep a record of its proceedings and a record of all identification cards and licenses granted to pharmacists

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[42] R.C. 4729.541(D).

[43] R.C. 4729.54(G).

[44] R.C. 4729.60 and 4729.541(A).

and pharmacy interns, as well as each renewal, suspension, or revocation. The bill specifies that the Board must keep the same records for registrations as it is required to keep for identification cards and licenses.

The bill adds a provision that an official statement from the Board that it appears from the Board's records that a person has been subjected to disciplinary action is prima-facie evidence of the record of the Board in any court or before an officer of the state. Current law contains the same provision with regard to an official statement of the Board concerning whether an identification card or license has been issued, revoked or suspended. The bill applies those provisions to registrations as well.[45]

### Duty to report violations to the Board

The bill authorizes the Board to adopt rules requiring a licensee or registrant to report to the Board violation of state or federal law, including any rule adopted under the authority of the Pharmacy Law. In the absence of fraud or bad faith, a person who makes such a report or testifies in an adjudication will not be liable to any person for damages in a civil action as a result of the report or testimony.[46]

### Cooperation with investigations

Current law requires pharmacists to cooperate with federal, state, and local government investigations and to divulge all relevant information when requested by a government agency. The bill applies this requirement to pharmacy interns, pharmacy technician trainees, registered pharmacy technicians, certified pharmacy technicians, licensed terminal distributors of dangerous drugs, and registered wholesale distributors of dangerous drugs.[47]

### Selecting generically equivalent drugs

The bill adds a provision specifically prohibiting a pharmacist from knowingly failing to comply with provisions in current law that impose (1) conditions on a pharmacist's substitution of a generically equivalent drug when filling a prescription for a drug prescribed by its brand name, and (2) labeling requirements for dispensed drugs. As under current law, violation of those provisions is a minor misdemeanor.[48]

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[45] R.C. 4729.06.

[46] R.C. 4729.10.

[47] R.C. 4729.19.

[48] R.C. 4729.38 and 4729.99.

### Hearing examiners

The bill permits the Board to designate one or more attorneys who have been admitted to the practice of law, and who are classified as either administrative law attorney examiners or as administrative law attorney examiner administrators under the State Job Classification Plan adopted under existing law, as hearing examiners, subject to the Administrative Procedure Act. Or, under an exception in the bill, the Board may enter into a personal service contract with an attorney admitted to the practice of law in Ohio to serve as a hearing examiner.[49]

Hearing examiners are permitted to conduct any hearing the Board is empowered to hold or undertake pursuant to the Administrative Procedure Act. Hearing examiners must hear and consider the evidence introduced by the parties and issue in writing proposed findings of fact and conclusions of law to the Board for its consideration within 30 days after the hearing.

The bill requires that the Board be given copies of the transcript of the hearing record and all exhibits and documents presented by the parties at the hearing. The Board is required to render a decision and take action within 90 days following the receipt of the hearing examiner's proposed findings of fact and conclusions of law.

The bill requires the final decision of the Board in any hearing to be in writing and contain findings of fact and conclusions of law. Copies of the decision must be delivered to the parties personally or by certified mail. The decision is final on delivery or mailing, but it may be appealed as provided by the Administrative Procedure Act.

## Disciplinary action regarding controlled substances and dangerous drugs

The bill expands the circumstances under which a board that licenses professionals may suspend a license, certificate, or evidence of registration without a hearing for actions related to drugs. Under current law, if a licensing board determines there is clear and convincing evidence that continuation of a professional's practice or method of prescribing or personally furnishing controlled substances presents a danger of immediate and serious harm to others, the agency may suspend the license, certificate, or registration without a hearing. The bill permits a board to also take this action based on the professional's method of administering or dispensing controlled substances. This makes the provision applicable to professionals such as nurses who administer controlled substances and pharmacists who dispense them. The bill further permits a licensing board to take action based on the method of prescribing,

[49] R.C. 4729.40.

administering, dispensing, or personally furnishing dangerous drugs that are not controlled substances.[50]

Under continuing law, a dangerous drug is essentially any drug that can legally be dispensed only on a prescription. A controlled substance is a dangerous drug that is subject to additional restrictions because of its potential for abuse. Controlled substances include such drugs as narcotics, depressants, and stimulants.

## NALOXONE

### Service entities

#### Procuring naloxone

The bill permits entities, referred to as "service entities," that serve individuals who may be at risk of experiencing an opioid-related overdose to procure naloxone for use in emergency situations.[51] It defines "service entity" as a public or private entity that provides services to individuals who there is reason to believe may be at risk of experiencing an opioid-related overdose. The bill includes the following as service entities: a college or university, school, local health department, community addiction services provider, court, probation department, halfway house, prison, jail, community residential center, homeless shelter, or similar entity.[52]

With respect to naloxone, the bill exempts service entities from licensure as terminal distributors of dangerous drugs.[53] This exemption permits a service entity to purchase and possess naloxone without obtaining a license from the State Board of Pharmacy.[54]

#### Authority to administer naloxone

The bill permits a service entity employee, volunteer, or contractor who is authorized to do so by a physician or board of health to administer naloxone to an individual who is apparently experiencing an opioid-related overdose. To be eligible to authorize naloxone administration, a physician or board of health must establish a written protocol for administering naloxone. In the case of a board of health, the

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[50] R.C. 3719.121(B).

[51] R.C. 4729.514(B).

[52] R.C. 4729.514(A).

[53] R.C. 4729.541(A).

[54] R.C. 4729.51.

protocol must be established through a physician acting as the board's health commissioner or medical director. The protocol must include the following:[55]

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

(2) Precautions and contraindications concerning the administration of naloxone;

(3) Any limitations concerning the individuals to whom naloxone may be administered;

(4) The naloxone dosage that may be administered 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 can be authorized to administer naloxone.

An authorized service entity employee, volunteer, or contractor must obtain the naloxone from the service entity, comply with the protocol, and summon emergency services as soon as practicable.[56] An employee, volunteer, or contractor, acting in good faith, who administers naloxone in accordance with the bill to an individual who is apparently experiencing an opioid-related overdose is immune from criminal prosecution for unauthorized practice of medicine or violation of Ohio drug laws.[57] This criminal immunity does not apply to peace officers or emergency medical technicians; however, current law provides similar immunity for a peace officer who obtains naloxone from the officer's law enforcement agency and administers it to an individual who is apparently experiencing an opioid-related overdose. The bill removes the condition that the naloxone be obtained from the officer's law enforcement agency.[58]

### Qualified immunity

The bill provides qualified immunity for acts related to procuring and administering naloxone by service entities and service entity employees, volunteers, and contractors.

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[55] R.C. 3707.59(D) and 4731.943(D).

[56] R.C. 3707.59(C) and 4731.943(C).

[57] R.C. 2925.61(C).

[58] R.C. 2925.61(D) and (E).

Under the bill, a board of health is immune from liability for damages in any civil action for an act or omission of a service entity employee, volunteer, or contractor who the board, in good faith, authorizes to administer naloxone. A physician, including a physician serving as a board's health commissioner or medical director, is immune from liability and is not subject to damages in any civil action, prosecution in any criminal proceeding, or professional disciplinary action for an act or omission of a service entity employee, volunteer, or contractor who the physician in good faith authorizes to administer naloxone.[59]

The bill provides further that a service entity or service entity employee, volunteer, or contractor is not liable for damages in any civil action or subject to prosecution in any criminal proceeding or professional disciplinary action for any act or omission associated with procuring, maintaining, accessing, or using naloxone under the bill, unless the act or omission constitutes willful or wanton misconduct. The bill provides that this immunity does not eliminate, limit, or reduce any other immunity or defense to which a service entity or employee, volunteer, or contractor may be entitled under the Revised Code or Ohio's common law.[60] Common law is the law developed over time by custom and court decisions.

## Boards of health

### Personally furnishing naloxone by individuals

The bill permits a board of health that 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:[61]

(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 board's protocol and must instruct the individual to whom the naloxone is furnished to summon emergency services as soon as practicable.[62]

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[59] R.C. 3707.59(E) and 4731.943(E).

[60] R.C. 3707.59(E), 4729.514(C), 4731.943(E).

[61] R.C. 3707.58(B).

[62] R.C. 3707.58(C).

A board of health's protocol authorizing personally furnishing naloxone must be established through a physician serving as the board's health commissioner or medical director, be in writing and include the following:[63]

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

(2) Precautions and contraindications concerning the furnishing of naloxone;

(3) Any limitations the board 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 can be authorized to furnish naloxone;

(7) Any instructions or training that the authorized individual must provide to an individual to whom naloxone is furnished.

The bill provides that a board of health is not liable for damages in any civil action for an act or omission of an individual to whom naloxone is personally furnished, if the board in good faith authorized the individual to personally furnish the naloxone. A physician serving as a board's health commission or medical director who on good faith authorizes an individual to personally furnish naloxone under the bill is not liable for damages in any civil action or subject to prosecution in any criminal proceeding or professional disciplinary action for an act or omission of an individual to whom the naloxone is personally furnished.

An individual authorized under the bill to personally furnish naloxone who does so in good faith is not liable for damages in any civil action or subject to prosecution in any criminal proceeding or professional disciplinary action for any act or omission of the individual to whom the naloxone is furnished.[64]

### Dispensing naloxone by pharmacists and pharmacy interns

Current law permits a board of health to authorize a pharmacist or pharmacy intern to dispense naloxone without a prescription pursuant to a protocol established

[63] R.C. 3707.58(D).

[64] R.C. 3707.58(E).

by the State Board of Pharmacy. Under this law, a board of health may extend this authority only to pharmacists and pharmacy interns who work in the board's jurisdiction. Under the bill, a board of health may extend the authority to any pharmacist or pharmacy intern who practices pharmacy in a county that includes all or part of the health district represented by the board.[65] In Ohio, each city constitutes a city health district and the townships and villages in each county are combined as a general health district, so health district boundaries differ from those of counties.[66]

## Immunity for peace officers

Under current law, a peace officer is immune from administrative action and criminal prosecution for administering naloxone to an individual who is apparently experiencing an opioid-related overdose if the peace officer is employed by a law enforcement agency and obtains naloxone from that law enforcement agency. The bill removes the conditions that a peace officer must be employed by a law enforcement agency and have obtained the naloxone from that agency to be eligible for the immunity.[67]

Under continuing law, peace officers are generally immune from liability in a civil action for damage or injury caused in the performance of the officer's duties, unless the officer acted with malicious purpose, in bad faith, or in a wanton or reckless manner.[68] The bill expressly states that peace officers are entitled to this immunity for any act or omission associated with procuring, maintaining, accessing, or using naloxone.[69]

## Grants for Project DAWN

Current law appropriates up to $500,000 in each fiscal year for use by county health departments in enhancing access to naloxone across Ohio through a grant program to local law enforcement, emergency personnel, and first responders. The bill provides that if these entities are not making use of the naloxone grant, the county

[65] R.C. 3707.56.

[66] R.C. 3709.01, not in the bill.

[67] R.C. 2925.61(E).

[68] R.C. 9.86, not in the bill, and 2744.03, not in the bill.

[69] R.C. 2925.61(F).

health department is permitted to use grant funding to provide naloxone through a Project DAWN (Deaths Avoided with Naloxone) program within the county.[70]

According to the Ohio Department of Health, a Project DAWN program is a community-based overdose education and naloxone distribution program. Participants receive training on (1) recognizing the signs and symptoms of overdose, (2) distinguishing between different types of overdose, (3) performing rescue breathing, (4) calling emergency medical services, and (5) administering intranasal naloxone.[71]

## OPIOID ANALGESICS

### Limits on dispensing or selling opioid analgesics

#### 90-day supply

The bill limits the authority of a pharmacist, pharmacy intern, or terminal distributor of dangerous drugs to dispense or sell an opioid analgesic pursuant to a prescription for a drug to be used on an outpatient basis. It prohibits dispensing or selling more than a 90-day supply of the drug, as determined according to the prescription's instructions for use of the drug, regardless of whether the prescription was issued for a greater amount.

The bill permits the State Board of Pharmacy to adopt rules establishing additional limitations on the authority of a pharmacist, pharmacy intern, or terminal distributor of dangerous drugs to dispense or sell an opioid analgesic. The rules must be adopted in accordance with Chapter 119. of the Revised Code.[72]

#### 14-day prescription deadline

The bill also prohibits dispensing or selling an opioid analgesic pursuant to a prescription if the prescription indicates the earliest date on which the prescription may be filled and more than 14 days have elapsed since that date. For prescriptions that do not indicate such a date, the bill prohibits dispensing or selling an opioid analgesic pursuant to the prescription if more than 14 days have elapsed since it was issued.[73]

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[70] Sections 3 and 4, amending Section 331.120 of H.B. 64 of the 131st General Assembly, the main operating budget act for fiscal years 2016 and 2017.

[71] Ohio Department of Health, *Project DAWN*, available at <http://www.healthy.ohio.gov/vipp/drug/ProjectDAWN.aspx/>.

[72] R.C. 4729.45.

[73] R.C. 4729.45(B).

### Out-of-state delivery

The bill specifies that these prohibitions do not apply when the pharmacist, pharmacy intern, or terminal distributor dispenses or sells an opioid analgesic that is to be delivered outside of the state by mail, parcel post, or common carrier to a patient who resides outside of the state.[74]

### Limitations established in rules

The bill permits a state board that licenses prescribers to adopt rules limiting the amount of an opioid analgesic that may be prescribed by a prescriber licensed by the board pursuant to a single prescription. The rules must be adopted in accordance with Chapter 119. of the Revised Code.[75] The prescribers referred to are physicians, dentists, and veterinarians and certain optometrists, physician assistants, and advanced practice registered nurses.

### Definition

Under current law, "opioid analgesic" is defined as a controlled substance that has analgesic pharmacologic activity at the opioid receptors of the central nervous system. It includes such drugs as buprenorphine, codeine, fentanyl, hydrocodone, methadone, morphine sulfate, and oxycodone.[76]

## OFFICE-BASED OPIOID TREATMENT

## Licensing

The bill prohibits a person from knowingly operating a facility, clinic, or other location where a prescriber provides office-based opioid treatment to more than 30 patients, or that meets any other identifying criteria in rules the State Board of Pharmacy must adopt under the bill, without holding a category III terminal distributor of dangerous drugs license with an office-based opioid treatment classification.[77] Under current law, a category III license authorizes the holder to possess, have custody or control of, or distribute any controlled substance. The license fee is $150.[78]

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[74] R.C. 4729.45(C).

[75] R.C. 3719.062.

[76] R.C. 3719.01, not in the bill.

[77] R.C. 4729.553.

[78] R.C. 4729.54.

A prescriber who provides the office-based opioid treatment described by the bill must apply for licensure in the same way as other terminal distributors and meet the requirements that apply to terminal distributors, as well as meet the bill's additional requirements for such prescribers. The licensing process established by the bill is similar to the licensing process for pain management clinics under existing law.[79]

"Office-based opioid treatment" is defined by the bill as the treatment of opioid dependence or addiction using a controlled substance.

### Exemptions

Under the bill, the following are excluded from its office-based opioid treatment licensing requirements: (1) hospitals, (2) facilities for the treatment of opioid dependence or addiction that are operated by a hospital, (3) physician practices owned or controlled, in whole or in part, by a hospital or an entity that owns or controls, in whole or in part, one or more hospitals, (4) facilities that only conduct clinical research and use controlled substances in studies approved by a hospital-based institutional review board or an institutional review board that is accredited by the Association for the Accreditation of Human Research Protections Programs, Inc., (5) facilities that hold a category III terminal distributor of dangerous drugs license for the purpose of treating drug dependence or addiction as part of an opioid treatment program and are already subject to certification by the U.S. Substance and Mental Health Services Administration (SAMHSA), or (6) programs or facilities that are licensed or certified by the Ohio Department of Mental Health and Addiction Services.

## Office operation

In addition to meeting the requirements for licensure as a terminal distributor, an applicant for licensure as a terminal distributor with an office-based opioid treatment classification must submit evidence satisfactory to the Board that the applicant's office-based opioid treatment will be operated in accordance with the bill's requirements. Under those requirements, the license holder must do all of the following:

(1) Be in control of a facility that is owned and operated solely by one or more physicians authorized by the State Medical Board to practice medicine or osteopathic medicine;

(2) Comply with requirements for conducting office-based opioid treatment that are established by the Medical Board under existing law;

[79] R.C. 4729.552, not in the bill.

(3) Require any person with ownership of the facility to submit to a criminal records check and send the result directly to the Pharmacy Board for review;

(4) Require all employees of the facility to submit to a criminal records check and ensure that no person is employed who has previously been convicted of or pleaded guilty to any federal felony theft or drug offense or a felony theft or drug offense in Ohio or another state;

(5) Maintain a list of each person with ownership of the facility and notify the Pharmacy Board of any changes.

The bill prohibits a person from knowingly failing to remain in compliance with these requirements.[80]

### Criminal records check

To obtain a criminal records check, a person must submit a request to Ohio's Bureau of Criminal Identification and Investigation (BCII). The request must be accompanied by the appropriate form, a set of fingerprint impressions, and the fee established by BCII. The person must also request that BCII obtain from the Federal Bureau of Investigation (FBI) any information it has on the person. The results of the criminal records check must be sent directly to the Pharmacy Board for review. Information provided by BCII or the FBI is to be made available only to the person who requested the records check and the employer or potential employer specified in the request.[81]

## License issuance

If the Pharmacy Board determines that an applicant meets the requirements to provide office-based opioid treatment, the Board must issue the category III terminal distributor license with the office-based opioid treatment classification to the applicant. If the applicant does not meet the requirements, the Board is prohibited from issuing the license.[82]

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[80] R.C. 4729.553(C) to (E).

[81] R.C. 4729.071(B), 4776.02(A) and (B)(2), and 4776.04(B).

[82] R.C. 4729.553(C) and 4729.55.

## Sanctions for illegal or improper operation

### Pharmacy Board sanctions

The bill authorizes the Pharmacy Board to impose a fine of not more than $5,000 on a person that fails to comply with the requirements for operation of a facility subject to licensure as a terminal distributor with an office-based opioid treatment classification. A separate fine may be imposed for each day of violation. The sanction must be imposed in accordance with the Administrative Procedure Act (R.C. Chapter 119.), which requires the Board to give the terminal distributor notice and an opportunity for a hearing.

In addition, the bill authorizes the Pharmacy Board to suspend, without a prior hearing, the license of a terminal distributor with an office-based opioid treatment classification if the Board determines by clear and convincing evidence that there is danger of immediate and serious harm to others. If the license holder is a physician, the Board must consult with the secretary of the Medical Board or, if the secretary is unavailable, another physician member of the Board before suspending the license.[83]

### Medical Board sanctions

Current law authorizes the Medical Board, by an affirmative vote of not fewer than six members, to take disciplinary action against a physician for any of a number of reasons specified in statute. The Board may limit, revoke, or suspend a physician's certificate to practice, refuse to register a physician, refuse to reinstate a physician's certificate, or reprimand or place a physician on probation. Generally, the Board must impose disciplinary action in accordance with the Administrative Procedure Act. If the Board determines by clear and convincing evidence, however, that a violation of the law governing physicians has occurred and the physician's continued practice presents a danger of immediate and serious harm to the public, the Board may suspend the physician's license without a prior hearing.

The bill authorizes the Medical Board to take professional disciplinary action against a physician who does either of the following:

--Practices at a facility, clinic, or other location that is subject to licensure as a terminal distributor of dangerous drugs with an office-based opioid treatment classification unless the person operating that place has obtained and maintains the license with the classification;

[83] R.C. 4729.553(F) and 4729.571.

--Owns a facility, clinic, or other location that is subject to licensure as a distributor of dangerous drugs with an office-based opioid treatment classification unless that place is licensed with the classification.[84]

### Criminal sanctions

The bill provides that failure to comply with the office-based opioid treatment requirements is a felony of the fifth degree. If the offender has previously been convicted of or pleaded guilty to the same offense or a violation of pharmacy or drug laws, the offense is a felony of the fourth degree. Failure to obtain the required license carries the same criminal penalties.[85]

## Rules

The bill requires the Pharmacy Board to adopt rules as it considers necessary to implement and administer the provisions regarding licensure of terminal distributors of dangerous drugs with an office-based opioid treatment classification. The rules must be adopted in accordance with the Administrative Procedure Act.[86]

## Background – federal law

Federal law generally prohibits a physician from providing opioids to treat addiction unless the opioids are administered as part of a narcotic treatment program (NTP) that has been approved by the U.S. Drug Enforcement Administration (DEA) and SAMHSA.[87] The federal Drug Addiction Treatment Act of 2000 (DATA 2000)[88] waives the NTP requirements for physicians who dispense or prescribe opioids listed in schedules III, IV, or V that have been approved by the U.S. Food and Drug Administration (FDA) for opioid addiction treatment. To qualify for a waiver, a physician must first notify the U.S. Secretary for Health and Human Services (HHS) in writing of the physician's intent to prescribe opioids for opioid addiction and certify that the physician meets the federally mandated qualifications for state licensure, certification, and training or experience in the area of addiction treatment.[89] A physician

[84] R.C. 4731.22(B)(49) and (50).

[85] R.C. 4729.99(E).

[86] R.C. 4729.553(G).

[87] 21 United States Code (U.S.C.) 823(g)(1); 21 Code of Federal Regulations (C.F.R.) 1306.07(a).

[88] Title XXXV, Section 3502 of the federal Children's Health Act, Pub. L. 106-310, 21 U.S.C. Sec. 823(g)(2).

[89] 21 C.F.R. 1301.28.

must obtain both HHS and DEA approval before prescribing opioids under the DATA 2000 waiver.

Federal law currently limits the number of patients to whom a physician may prescribe opioids to treat opioid addiction. For the first year after qualifying for the waiver, that number is 30; thereafter, a physician may request to increase the number to 100. Currently, the only controlled substances listed in schedules III, IV, or V that have been approved by the FDA to treat opioid addiction are certain buprenorphine products, including Suboxone.[90] With the goal of expanding access to medication-assisted treatment, HHS recently finalized a rule that would permit qualified physicians to prescribe buprenorphine to as many as 275 patients.[91] There are two ways physicians can become eligible to increase their patient limit to 275: (1) by having additional credentialing in addiction medicine or addiction psychiatry from a specialty medical board or professional society, or (2) by working in a qualified practice setting. Additionally, during emergency situations, other physicians who are approved to treat up to 100 patients are eligible to raise their patient limit up to 275 to ensure continuity of care for patients.

## METHADONE TREATMENT FACILITIES

### License requirements

Effective 180 days after its effective date, the bill eliminates two of the existing requirements an applicant for licensure to maintain a methadone treatment facility must meet to receive the license from the Department of Mental Health and Addiction Services (ODMHAS). The requirements eliminated relate to the provider and are as follows:

(1) The provider is operated by a private, nonprofit organization or by a government entity;

(2) The provider has been fully certified as a community addiction services provider for at least two years immediately preceding the application.[92]

The bill provides instead that an applicant must meet any additional requirements established by ODMHAS in rules.

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[90] National Association of Boards of Pharmacy, *HHS Proposes Increasing Buprenorphine Patient Limit for Medication-Assisted Treatment*, available at <https://www.nabp.net/news/hhs-proposes-increasing-buprenorphine-patient-limit-for-medication-assisted-treatment>.

[91] 81 Fed. Reg. 44711.

[92] R.C. 5119.391(C)(1) and (2).

The bill requires ODMHAS, not later than 180 days after the bill's effective date, to adopt rules that revise the requirements governing licensure of methadone treatment providers. The rules must include the following requirements for licensure:

(1) Being in good standing with the Medicaid program, Medicare program, and the United States Drug Enforcement Administration;

(2) Being in good standing in any other jurisdiction in which the community addiction services provider provides services that are comparable to the methadone treatment services authorized by Ohio law;

(3) The ability to meet treatment standards established by certain federal regulations (42 Code of Federal Regulations 8.12) and accepted standards of medical care for opioid treatment services established by the American Society of Addiction Medicine.

The bill also requires, not later than two years after the bill's effective date, ODMHAS to conduct an analysis of unmet needs for methadone treatment in Ohio and the impact of the elimination of the licensure requirements discussed above on the overall treatment capacity in Ohio. ODMHAS is required to complete a report of its findings within 180 days after beginning the analysis. It must publish the report on its website.[93]

## DRUG COURT PROGRAMS

### Medication-assisted treatment and recovery supports

Under a current program conducted by ODMHAS and certain courts with certification from the Ohio Supreme Court as a specialized docket program for drugs, medication-assisted treatment for addiction is made available to certain offenders in the criminal justice system. The treatment must be provided by an ODMHAS-certified community addiction services provider. The provider must comply with specified requirements.

The bill permits a participating community addiction services provider to provide access to time-limited recovery supports. For purposes of this provision, the bill specifies that recovery support is a form of assistance intended to help an individual with addiction or mental health needs, or a member of the family of such an individual, to initiate and sustain the individual's recovery from alcoholism, drug addiction, or

[93] Section 5.

mental illness. It specifies that a recovery support does not include an addiction or mental health treatment or prevention service.[94]

## HISTORY

| ACTION | DATE |
|---|---|
| Introduced | 04-25-16 |
| Reported, S. Health & Human Services | 05-25-16 |
| Passed Senate (33-0) | 05-25-16 |

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[94] Sections 3 and 4, amending Section 331.90 of H.B. 64 of the 131st General Assembly.