

AN ACT

To amend sections 3728.03, 4729.16, 4729.23, 4729.28, 4729.41, 4729.43, 4729.45, 4729.553, 4729.99, and 4731.96 and to enact sections 3707.60, 4729.382, 4729.47, and 4731.961 of the Revised Code to establish provisions to be known as the "Epinephrine Accessibility Act" and to make other changes to the laws governing the State Board of Pharmacy.

Be it enacted by the General Assembly of the State of Ohio:

SECTION 1. That sections 3728.03, 4729.16, 4729.23, 4729.28, 4729.41, 4729.43, 4729.45, 4729.553, 4729.99, and 4731.96 be amended and sections 3707.60, 4729.382, 4729.47, and 4731.961 of the Revised Code be enacted to read as follows:

Sec. 3707.60. (A) As used in this section, "board of health" means a board of health of a city or general health district or the authority having the duties of a board of health under section 3709.05 of the Revised Code.

(B) A board of health that has, through a physician serving as the board's health commissioner or medical director, established a protocol that meets the requirements specified by the state board of pharmacy in rules adopted under section 4729.47 of the Revised Code may authorize pharmacists and pharmacy interns practicing pharmacy in a county that includes all or part of the health district represented by the board to use the protocol for the purpose of dispensing epinephrine under section 4729.47 of the Revised Code.

Sec. 3728.03. (A) A qualified entity may acquire and maintain a supply of epinephrine autoinjectors that, in accordance with section 4723.483, 4730.433, or 4731.96 of the Revised Code, pursuant to either of the following:

(1) The autoinjectors are personally furnished by a prescriber, or obtained pursuant to a prescription issued by a prescriber, in accordance with section 4723.483, 4730.433, or 4731.96 of the Revised Code.

(2) The autoinjectors are dispensed by a pharmacist or pharmacy intern in accordance with a protocol as authorized under section 4729.47 of the Revised Code.

(B) Epinephrine autoinjectors acquired pursuant to this section shall be stored in a location readily accessible in an emergency and maintained in accordance with the manufacturer's instructions and any additional requirements that may be established by the department of health under section 3728.11 of the Revised Code.

(C) A qualified entity that acquires epinephrine autoinjectors pursuant to this section shall designate one or more individuals who are employees or agents of the entity and have successfully completed anaphylaxis training in accordance with section 3728.04 of the Revised Code to be responsible for oversight of the epinephrine autoinjectors, including storage, maintenance, and

control. The qualified entity may authorize those individuals and other individuals who have successfully completed the anaphylaxis training to administer epinephrine.

Sec. 4729.16. (A)(1) The state board of pharmacy, after notice and hearing in accordance with Chapter 119. of the Revised Code, may impose any one or more of the following sanctions on a pharmacist or pharmacy intern if the board finds the individual engaged in any of the conduct set forth in division (A)(2) of this section:

(a) Revoke, suspend, restrict, limit, or refuse to grant or renew a license;

(b) Reprimand or place the license holder on probation;

(c) Impose a monetary penalty or forfeiture not to exceed in severity any fine designated under the Revised Code for a similar offense, or in the case of a violation of a section of the Revised Code that does not bear a penalty, a monetary penalty or forfeiture of not more than five hundred dollars.

(2) The board may impose the sanctions listed in division (A)(1) of this section if the board finds a pharmacist or pharmacy intern:

(a) Has been convicted of a felony, or a crime of moral turpitude, as defined in section 4776.10 of the Revised Code;

(b) Engaged in dishonesty or unprofessional conduct in the practice of pharmacy;

(c) Is addicted to or abusing alcohol or drugs or is impaired physically or mentally to such a degree as to render the pharmacist or pharmacy intern unfit to practice pharmacy;

(d) Has been convicted of a misdemeanor related to, or committed in, the practice of pharmacy;

(e) Violated, conspired to violate, attempted to violate, or aided and abetted the violation of any of the provisions of this chapter, sections 3715.52 to 3715.72 of the Revised Code, Chapter 2925. or 3719. of the Revised Code, or any rule adopted by the board under those provisions;

(f) Permitted someone other than a pharmacist or pharmacy intern to practice pharmacy;

(g) Knowingly lent the pharmacist's or pharmacy intern's name to an illegal practitioner of pharmacy or had a professional connection with an illegal practitioner of pharmacy;

(h) Divided or agreed to divide remuneration made in the practice of pharmacy with any other individual, including, but not limited to, any licensed health professional authorized to prescribe drugs or any owner, manager, or employee of a health care facility, residential care facility, or nursing home;

(i) Violated the terms of a consult agreement entered into pursuant to section 4729.39 of the Revised Code;

(j) Committed fraud, misrepresentation, or deception in applying for or securing a license issued by the board under this chapter or under Chapter 3715. or 3719. of the Revised Code;

(k) Failed to comply with an order of the board or a settlement agreement;

(l) Engaged in any other conduct for which the board may impose discipline as set forth in rules adopted under section 4729.26 of the Revised Code.

(B) Any individual whose license is revoked, suspended, or refused, shall return the license to the offices of the state board of pharmacy within ten days after receipt of notice of such action.

(C) As used in this section:

"Unprofessional conduct in the practice of pharmacy" includes any of the following:

(1) Advertising or displaying signs that promote dangerous drugs to the public in a manner that is false or misleading;

(2) Except as provided in section 4729.281 ~~or~~ 4729.44, or 4729.47 of the Revised Code, the dispensing or sale of any drug for which a prescription is required, without having received a prescription for the drug;

(3) Knowingly dispensing medication pursuant to false or forged prescriptions;

(4) Knowingly failing to maintain complete and accurate records of all dangerous drugs received or dispensed in compliance with federal laws and regulations and state laws and rules;

(5) Obtaining any remuneration by fraud, misrepresentation, or deception;

(6) 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 a patient is established;

(7) Engaging in any other conduct that the board specifies as unprofessional conduct in the practice of pharmacy in rules adopted under section 4729.26 of the Revised Code.

(D) The board may suspend a license under division (B) of section 3719.121 of the Revised Code by utilizing a telephone conference call to review the allegations and take a vote.

(E) For purposes of this division, an individual authorized to practice as a pharmacist or pharmacy intern accepts the privilege of practicing in this state subject to supervision by the board. By filing an application for or holding a license to practice as a pharmacist or pharmacy intern, an individual gives consent to submit to a mental or physical examination when ordered to do so by the board in writing and waives all objections to the admissibility of testimony or examination reports that constitute privileged communications.

If the board has reasonable cause to believe that an individual who is a pharmacist or pharmacy intern is physically or mentally impaired, the board may require the individual to submit to a physical or mental examination, or both. The expense of the examination is the responsibility of the individual required to be examined.

Failure of an individual who is a pharmacist or pharmacy intern to submit to a physical or mental examination ordered by the board, unless the failure is due to circumstances beyond the individual's control, constitutes an admission of the allegations and a suspension order shall be entered without the taking of testimony or presentation of evidence. Any subsequent adjudication hearing under Chapter 119. of the Revised Code concerning 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 examination ordered under this division, the board determines that the individual's ability to practice is impaired, the board shall suspend the individual's license or deny the individual's application and shall require the individual, as a condition for an initial, continued, reinstated, or renewed license to practice, to submit to a physical or mental examination and treatment.

An order of suspension issued under this division shall not be subject to suspension by a court during pendency of any appeal filed under section 119.12 of the Revised Code.

(F) If the board is required under Chapter 119. of the Revised Code to give notice of an opportunity for a hearing and the applicant or licensee does not make a timely request for a hearing in accordance with section 119.07 of the Revised Code, 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 in division (A) of this section.

(G) Notwithstanding the provision of division (C)(2) of section 2953.32 of the Revised Code specifying that if records pertaining to a criminal case are sealed under that section the proceedings in the case must be deemed not to have occurred, sealing of the following records on which the board has based an action under this section shall have no effect on the board's action or any sanction imposed by the board under this section: 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 board shall not be required to seal, destroy, redact, or otherwise modify its records to reflect the court's sealing of conviction records.

(H) No pharmacist or pharmacy intern shall knowingly engage in any conduct described in divisions (A)(2)(b) or (A)(2)(e) to (l) of this section.

Sec. 4729.23. (A) Except as provided in division (B) of this section, information received by the state board of pharmacy pursuant to an investigation is confidential, is not a public record, and is not subject to discovery in any civil action. ~~Any record that identifies a patient, confidential informant, or individual who files a complaint with the board or may reasonably lead to the identification of the patient, informant, or complainant is not a public record for purposes of section 149.43 of the Revised Code and is not subject to inspection or copying under section 1347.08 of the Revised Code.~~

(B) The board shall conduct all investigations or inspections and proceedings in a manner that protects the confidentiality of patients, confidential informants, and individuals who file complaints with the board. The board shall not make public the names or any other identifying information of patients, confidential informants, or complainants unless proper consent is given or, in the case of a patient, a waiver of the patient privilege exists under division (B) of section 2317.02 of the Revised Code. The consent or waiver is not required if the board possesses reliable and substantial evidence that no bona fide physician-patient relationship exists.

On request, the board may share any information it receives pursuant to an investigation or inspection, including patient records and patient record information, with law enforcement agencies, other licensing boards, and other state or federal governmental agencies that are prosecuting, adjudicating, or investigating alleged violations of statutes or administrative rules. An agency or board that receives the information shall comply with the same requirements regarding confidentiality as those with which the state board of pharmacy must comply, notwithstanding any conflicting provision of the Revised Code or agency procedure that applies when the agency is dealing with other information in its possession.

Any information the board receives from a state or federal agency is subject to the same confidentiality requirements as the agency from which it was received and shall not be released by the board without prior authorization from that agency.

The board may, for good cause shown, disclose or authorize disclosure of information gathered pursuant to an investigation.

(C) Any board activity that involves continued monitoring of an individual for treatment or recovery purposes as part of or following any disciplinary action taken under ~~section 4729.16, 4729.56, or 4729.57 of the Revised Code~~ this chapter shall be conducted in a manner that maintains

an individual's confidentiality with respect to the individual's treatment or recovery program. Information received or maintained by the board with respect to the board's monitoring activities is not subject to discovery in any civil action, is not a public record, and is confidential, except that the board may disclose information to law enforcement officers and government entities for purposes of an investigation of a license or certificate holder.

Sec. 4729.28. No (A) As used in this section, "dispense" has the meaning specified by the state board of pharmacy in rules adopted under section 4729.26 of the Revised Code.

(B)(1) Except as provided in division (B)(2) of this section, no person who is not a pharmacist or a pharmacy intern under the personal supervision of a pharmacist shall compound, dispense, or sell dangerous drugs or otherwise engage in the practice of pharmacy.

(2) Except as provided in sections 3701.048, 4729.44, and 4729.47 of the Revised Code or rules adopted by the board under section 4729.26 of the Revised Code, no person who is not a pharmacist shall dispense dangerous drugs.

Sec. 4729.382. (A) As used in this section, "epinephrine autoinjector" means a device used to administer epinephrine only in a manufactured dosage form.

(B) Subject to division (C) of this section, a pharmacist dispensing an epinephrine autoinjector pursuant to a prescription that identifies a specific type of epinephrine autoinjector may substitute the prescribed autoinjector with another epinephrine autoinjector, but only if the form of epinephrine contained in the autoinjector to be dispensed by substitution meets either of the following conditions:

(1) It is identical to the form of epinephrine in the type of autoinjector that was prescribed.

(2) It is a pharmaceutical equivalent of the form of epinephrine in the type of autoinjector that was prescribed in that it contains identical amounts of the identical active ingredients, but not necessarily the same inactive ingredients; it has been approved by the United States food and drug administration; and it has not been excluded from recognition as a pharmaceutical equivalent form of epinephrine by rules adopted under division (H) of this section.

(C) All of the following conditions apply with respect to a pharmacist's authority to dispense an epinephrine autoinjector by substitution:

(1) The pharmacist shall not make the substitution if the person receiving the autoinjector pursuant to the prescription instructs otherwise.

(2) The pharmacist shall not make the substitution if either of the following applies to the prescription:

(a) In the case of a written or electronic prescription, including a computer-generated prescription, the prescriber handwrites or actively causes to display on the prescription "dispense as written," "D.A.W.," "do not substitute," "medically necessary as prescribed," or any other statement or numerical code that indicates the prescriber's intent to prevent substitution. Such a designation shall not be preprinted or stamped on the prescription, but a reminder to the prescriber of the designation procedure may be preprinted or displayed on the prescription form or electronic system the prescriber uses to issue the prescription.

(b) In the case of an oral prescription, the prescriber specifies that the epinephrine autoinjector as prescribed is medically necessary or otherwise indicates the prescriber's intent to prevent substitution.

(3) The pharmacist shall not make the substitution unless its price to the patient is less than or equal to the price of the prescribed epinephrine autoinjector, except that a pharmacist may substitute an epinephrine autoinjector with a price to the patient that is greater than the prescribed autoinjector if the patient specifically requests the more expensive autoinjector.

(4) The pharmacist, or a pharmacy intern or agent of the pharmacist, shall make a reasonable attempt to inform the patient or the patient's representative if a type of epinephrine autoinjector is available at a lower or equal cost.

(5) The pharmacist, or a pharmacy intern or agent of the pharmacist, shall inform the patient or the patient's representative of the person's right to refuse substitution of the prescribed epinephrine autoinjector.

(D)(1) Unless the prescriber instructs otherwise, the label for every epinephrine autoinjector dispensed shall include the epinephrine autoinjector's name, if any, and the distributor of the autoinjector. Abbreviations may be used as necessary.

(2) When dispensing at retail an epinephrine autoinjector by substitution, the pharmacist shall indicate on the autoinjector's label or container that a substitution was made.

(3) The labeling requirements established by divisions (D)(1) and (2) of this section are in addition to all other labeling requirements as required in rules adopted by the state board of pharmacy.

(E) When a pharmacist dispenses an epinephrine autoinjector by substitution, the pharmacist or a pharmacy intern shall provide to the person receiving the device instruction on the proper method of administering epinephrine with the device, except that the instruction does not have to be provided if the person is receiving the same device that was dispensed when the person last received the device by having a prescription filled or refilled.

(F) A pharmacist who dispenses an epinephrine autoinjector pursuant to this section assumes no greater liability for dispensing the autoinjector by substitution than would be incurred for dispensing the autoinjector identified on the prescription.

(G) The failure of a prescriber to restrict a prescription by indicating an intent to prevent substitution pursuant to this section shall not constitute evidence of the prescriber's negligence unless the prescriber had reasonable cause to believe that the health condition of the patient for whom the epinephrine autoinjector was intended warranted the prescription of a specific type of epinephrine autoinjector and no other. No prescriber shall be liable for civil damages or in any criminal prosecution arising from a pharmacist dispensing an epinephrine autoinjector by substitution, unless the type of autoinjector prescribed would have reasonably caused the same loss, damage, injury, or death.

(H) The state board of pharmacy may adopt rules in accordance with Chapter 119. of the Revised Code to implement this section. The rules may specify forms of epinephrine that are not to be recognized as pharmaceutical equivalents of other forms of epinephrine for purposes of this section.

(I) No pharmacist shall knowingly engage in conduct that is prohibited by division (C) or (D) of this section.

Sec. 4729.41. (A)(1) A pharmacist licensed under this chapter who meets the requirements of division (B) of this section, and a pharmacy intern licensed under this chapter who meets the

requirements of division (B) of this section and is working under the direct supervision of a pharmacist who meets the requirements of that division, may do any of the following:

(a) Administer immunizations for influenza to individuals who are seven years of age or older;

(b) Only pursuant to a prescription, administer to individuals who are seven years of age or older but not more than thirteen years of age any of the immunizations included in division (A)(2) of this section;

(c) Administer to individuals who are thirteen years of age or older any of the immunizations included in division (A)(2) of this section.

(2) A pharmacist or pharmacy intern may administer in accordance with divisions (A)(1)(b) and (c) of this section either of the following:

(a) Any immunization that on ~~the effective date of this amendment~~ March 19, 2015, is included in either of the following immunization schedules recommended by the advisory committee on immunization practices of the centers for disease control and prevention in the United States department of health and human services:

(i) The recommended immunization schedule for persons aged zero through eighteen years;

(ii) The recommended adult immunization schedule.

(b) Any other immunization specified in rules adopted under division (E)(1)(d) of this section.

(3) As part of engaging in the administration of immunizations or supervising a pharmacy intern's administration of immunizations, a pharmacist may administer epinephrine or diphenhydramine, or both, to individuals in emergency situations resulting from adverse reactions to the immunizations administered by the pharmacist or pharmacy intern.

(B) For a pharmacist or pharmacy intern to be authorized to engage in the administration of immunizations pursuant to division (A) of this section, the pharmacist or pharmacy intern shall do all of the following:

(1) Successfully complete a course in the administration of immunizations that has been approved by the state board of pharmacy as meeting the standards established for such courses by the centers for disease control and prevention;

(2) Receive and maintain certification to perform basic life-support procedures by successfully completing a basic life-support training course that is certified by the American red cross or American heart association or approved by the state board of pharmacy;

(3) Practice in accordance with a definitive set of treatment guidelines specified in a protocol established by a physician and approved by the state board of pharmacy.

(C) The protocol required by division (B)(3) of this section shall include provisions for implementation of the following requirements:

(1) The pharmacist or pharmacy intern who administers an immunization shall observe the individual who receives the immunization to determine whether the individual has an adverse reaction to the immunization. The length of time and location of the observation shall comply with the standards specified in rules adopted by the state board of pharmacy under division (E) of this section for the approval of protocols. The protocol shall specify procedures to be followed by a pharmacist when administering epinephrine, diphenhydramine, or both, to an individual who has an

adverse reaction to an immunization administered by the pharmacist or a pharmacy intern.

(2) For each immunization administered to an individual by a pharmacist or pharmacy intern, other than an immunization for influenza administered to an individual eighteen years of age or older, the pharmacist or pharmacy intern shall notify the individual's family physician or, if the individual has no family physician, the board of health of the health district in which the individual resides or the authority having the duties of a board of health for that district under section 3709.05 of the Revised Code. The notice shall be given not later than thirty days after the immunization is administered.

(3) For each immunization administered by a pharmacist or pharmacy intern to an individual younger than eighteen years of age pursuant to division (A)(1) of this section, the pharmacist or a pharmacy intern shall obtain permission from the individual's parent or legal guardian in accordance with the procedures specified in rules adopted under division (E) of this section.

(D)(1) No pharmacist shall do either of the following:

(a) Engage in the administration of immunizations unless the requirements of division (B) of this section have been met;

(b) Delegate to any person the pharmacist's authority to engage in or supervise the administration of immunizations.

(2) No pharmacy intern shall engage in the administration of immunizations unless the requirements of division (B) of this section have been met.

(E)(1) The state board of pharmacy shall adopt rules to implement this section. The rules shall be adopted in accordance with Chapter 119. of the Revised Code and shall include the following:

(a) Provisions for approval of courses in administration of immunizations;

(b) Provisions for approval of protocols to be followed by pharmacists and pharmacy interns in engaging in the administration of immunizations, including protocols that contain provisions specifying the locations at which a pharmacist or pharmacy intern may engage in the administration of immunizations;

(c) Procedures to be followed by pharmacists and pharmacy interns in obtaining from the individual's parent or legal guardian permission to administer immunizations to an individual younger than eighteen years of age pursuant to division (A)(1) of this section;

(d) Provisions specifying any immunizations that may be administered under division (A)(2)(b) of this section.

(2) Prior to adopting rules regarding approval of protocols to be followed by pharmacists and pharmacy interns in engaging in the administration of immunizations, the state board of pharmacy shall consult with the state medical board and the board of nursing.

(3) Prior to adopting rules specifying any immunizations that may be administered under division (A)(2)(b) of this section, the state board of pharmacy shall consult with the state medical board.

(F) In addition to the rules it adopts under division (E) of this section, the board may adopt rules that change the immunizations authorized by division (A)(2)(a) of this section to reflect changes in the recommendations of the advisory committee on immunization practices. The rules shall be adopted in accordance with Chapter 119, of the Revised Code.

Sec. 4729.43. (A) As used in this section:

(1) "Home health agency" has the same meaning as in section 3701.881 of the Revised Code.

(2) "Hospice care program" and "hospice patient" have the same meanings as in section 3712.01 of the Revised Code.

(B) With regard to a dangerous drug that is indicated for the treatment of cancer or a cancer-related illness, must be administered intravenously or by subcutaneous injection, and cannot reasonably be self-administered by the patient to whom the drug is prescribed or by an individual assisting the patient with the self-administration, a pharmacist ~~or pharmacy intern~~ shall not dispense the drug by delivering the drug directly to any of the following or causing the drug to be delivered directly to any of the following:

(1) The patient;

(2) The patient's representative, which may include the patient's guardian or a family member or friend of the patient;

(3) The patient's private residence unless any of the following is the case:

(a) The patient's private residence is a nursing home, residential care facility, rehabilitation facility, or similar institutional facility or health care facility.

(b) If the patient is an adult and a hospice patient or client of a home health agency, the patient, the licensed health professional authorized to prescribe drugs who prescribed the drug to the patient, or an employee or agent of the prescriber has notified the pharmacist ~~or pharmacy intern~~ that the patient is a hospice patient or client of a home health agency and an employee or agent of the hospice care program or home health agency will be administering the drug to the patient.

(c) If the patient is a minor and a hospice patient or client of a home health agency, either of the following has notified the pharmacist ~~or pharmacy intern~~ that the patient is a client of a home health agency and an employee or agent of the hospice care program or home health agency will be administering the drug to the patient:

(i) The licensed health professional authorized to prescribe drugs who prescribed the drug to the patient or an employee or agent of the prescriber;

(ii) The parent, guardian, or other person who has care or charge of the patient and is authorized to consent to medical treatment on behalf of the patient.

Sec. 4729.45. (A) As used in this section, "physician" means an individual authorized under Chapter 4731. of the Revised Code to practice medicine and surgery or osteopathic medicine and surgery.

(B)(1) Subject to division (C) of this section, a pharmacist licensed under this chapter may administer by injection any of the following drugs as long as the drug that is to be administered has been prescribed by a physician and the individual to whom the drug was prescribed has an ongoing physician-patient relationship with the physician:

(a) An opioid antagonist used for treatment of drug addiction and administered in a long-acting or extended-release form;

(b) An antipsychotic drug administered in a long-acting or extended-release form;

(c) Hydroxyprogesterone caproate;

(d) Medroxyprogesterone acetate;

(e) Cobalamin.

(2) As part of engaging in the administration of drugs by injection pursuant to this section, a pharmacist may administer epinephrine or diphenhydramine, or both, to an individual in an emergency situation resulting from an adverse reaction to a drug administered by the pharmacist.

(C) To be authorized to administer drugs pursuant to this section, a pharmacist must do all of the following:

(1) Successfully complete a course in the administration of drugs that satisfies the requirements established by the state board of pharmacy in rules adopted under division (H)(1)(a) of this section;

(2) Receive and maintain certification to perform basic life-support procedures by successfully completing a basic life-support training course that is certified by the American red cross or American heart association or approved by the state board of pharmacy;

(3) Practice in accordance with a protocol that meets the requirements of division (F) of this section.

(D) Each time a pharmacist administers a drug pursuant to this section, the pharmacist shall do all of the following:

(1) Obtain permission in accordance with the procedures specified in rules adopted under division (H) of this section and comply with the following requirements:

(a) Except as provided in division (D)(1)(c) of this section, for each drug administered by a pharmacist to an individual who is eighteen years of age or older, the pharmacist shall obtain permission from the individual.

(b) For each drug administered by a pharmacist to an individual who is under eighteen years of age, the pharmacist shall obtain permission from the individual's parent or other person having care or charge of the individual.

(c) For each drug administered by a pharmacist to an individual who lacks the capacity to make informed health care decisions, the pharmacist shall obtain permission from the person authorized to make such decisions on the individual's behalf.

(2) In the case of an opioid antagonist described in division (B) of this section, obtain in accordance with division (E) of this section test results indicating that it is appropriate to administer the drug to the individual if either of the following is to be administered:

(a) The initial dose of the drug;

(b) Any subsequent dose, if the administration occurs more than thirty days after the previous dose of the drug was administered.

(3) Observe the individual to whom the drug is administered to determine whether the individual has an adverse reaction to the drug;

(4) Notify the physician who prescribed the drug that the drug has been administered to the individual.

(E) A pharmacist may obtain the test results described in division (D)(2) of this section in either of the following ways:

(1) From the physician;

(2) By ordering blood and urine tests for the individual to whom the opioid antagonist is to be administered.

If a pharmacist orders blood and urine tests, the pharmacist shall evaluate the results of the

tests to determine whether they indicate that it is appropriate to administer the opioid antagonist. A pharmacist's authority to evaluate test results under this division does not authorize the pharmacist to make a diagnosis.

(F) All of the following apply with respect to the protocol required by division (C)(3) of this section:

(1) The protocol must be established by a physician who has a scope of practice that includes treatment of the condition for which the individual has been prescribed the drug to be administered.

(2) The protocol must satisfy the requirements established in rules adopted under division (H)(1)(b) of this section.

(3) The protocol must do all of the following:

(a) Specify a definitive set of treatment guidelines;

(b) Specify the locations at which a pharmacist may engage in the administration of drugs pursuant to this section;

(c) Include provisions for implementing the requirements of division (D) of this section, including for purposes of division (D)(3) of this section provisions specifying the length of time and location at which a pharmacist must observe an individual who receives a drug to determine whether the individual has an adverse reaction to the drug;

(d) Specify procedures to be followed by a pharmacist when administering epinephrine, diphenhydramine, or both, to an individual who has an adverse reaction to a drug administered by the pharmacist.

(G) A pharmacist shall not do either of the following:

(1) Engage in the administration of drugs pursuant to this section unless the requirements of division (C) of this section have been met;

(2) Delegate to any person the pharmacist's authority to engage in the administration of drugs pursuant to this section.

(H)(1) The state board of pharmacy shall adopt rules to implement this section. The rules shall be adopted in accordance with Chapter 119. of the Revised Code and include all of the following:

(a) Requirements for courses in administration of drugs;

(b) Requirements for protocols to be followed by pharmacists in administering drugs pursuant to this section;

(c) Procedures to be followed by a pharmacist in obtaining permission to administer a drug to an individual.

(2) The board shall consult with the state medical board before adopting rules regarding requirements for protocols under this section.

Sec. 4729.47. (A) As used in this section:

(1) "Board of health" means a board of health of a city or general health district or an authority having the duties of a board of health under section 3709.05 of the Revised Code.

(2) "Physician" means an individual authorized under Chapter 4731. of the Revised Code to practice medicine and surgery, osteopathic medicine and surgery, or podiatric medicine and surgery.

(B) If use of a protocol that has been developed pursuant to rules adopted under division (G) of this section has been authorized under section 3707.60 or 4731.961 of the Revised Code, a

pharmacist or pharmacy intern may dispense epinephrine without a prescription in accordance with that protocol to either of the following individuals so long as the individual is at least eighteen years of age:

(1) An individual who there is reason to believe is experiencing or at risk of experiencing anaphylaxis if the pharmacy affiliated with the pharmacist or intern has a record of previously dispensing epinephrine to the individual in accordance with a prescription issued by a licensed health professional authorized to prescribe drugs;

(2) An individual acting on behalf of a qualified entity, as defined in section 3728.01 of the Revised Code.

(C)(1) A pharmacist or pharmacy intern who dispenses epinephrine under this section shall instruct the individual to whom epinephrine is dispensed to summon emergency services as soon as practicable either before or after administering epinephrine.

(2) A pharmacist or pharmacy intern who dispenses epinephrine to an individual identified in division (B)(1)(a) of this section shall provide notice of the dispensing to the individual's primary care provider, if known, or to the prescriber who issued the individual the initial prescription for epinephrine.

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

(E) This section does not affect the authority of a pharmacist or pharmacy intern to fill or refill a prescription for epinephrine.

(F) A board of health that in good faith authorizes a pharmacist or pharmacy intern to dispense epinephrine without a prescription in accordance with a protocol developed pursuant to rules adopted under division (G) of this section is not liable for or subject to any of the following for any action or omission of the individual to whom the epinephrine is dispensed: damages in any civil action, prosecution in any criminal proceeding, or professional disciplinary action.

A physician who in good faith authorizes a pharmacist or pharmacy intern to dispense epinephrine without a prescription in accordance with a protocol developed pursuant to rules adopted under division (G) of this section is not liable for or subject to any of the following for any action or omission of the individual to whom the epinephrine is dispensed: damages in any civil action, prosecution in any criminal proceeding, or professional disciplinary action.

A pharmacist or pharmacy intern authorized under this section to dispense epinephrine without a prescription who does so in good faith is not liable for or subject to any of the following for any action or omission of the individual to whom the epinephrine is dispensed: damages in any civil action, prosecution in any criminal proceeding, or professional disciplinary action.

(G) Not later than ninety days after the effective date of this section, the state board of pharmacy shall, after consulting with the state medical board, adopt rules to implement this section. The rules shall specify minimum requirements for protocols established by physicians under which pharmacists or pharmacy interns may dispense epinephrine without a prescription.

All rules adopted under this section shall be adopted in accordance with Chapter 119. of the Revised Code.

Sec. 4729.553. (A) As used in this section:

(1) "Controlled substance" has the same meaning as in section 3719.01 of the Revised Code.

(2) "Hospital" means a hospital registered with the department of health under section 3701.07 of the Revised Code.

(3) "Office-based opioid treatment" means the treatment of opioid dependence or addiction using a controlled substance.

(B)(1) Except as provided in division (B)(2) of this section, no person shall knowingly operate a facility, clinic, or other location where a prescriber provides office-based opioid treatment to more than thirty patients or that meets any other identifying criteria established in rules adopted under ~~division (G)~~ of this section without holding a category III terminal distributor of dangerous drugs license with an office-based opioid treatment classification.

(2) Division (B)(1) of this section does not apply to any of the following:

(a) A hospital;

(b) A facility for the treatment of opioid dependence or addiction that is operated by a hospital;

(c) A physician practice owned or controlled, in whole or in part, by a hospital or by an entity that owns or controls, in whole or in part, one or more hospitals;

(d) A facility that conducts only clinical research and uses 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 protection programs, inc.;

(e) A facility that holds a category III terminal distributor of dangerous drugs license in accordance with section 4729.54 of the Revised Code for the purpose of treating drug dependence or addiction as part of an opioid treatment program and is the subject of a current, valid certification from the substance abuse and mental health services administration of the United States department of health and human services pursuant to 42 C.F.R. 8.11;

(f) A program or facility that ~~is licensed or certified~~ holds a license or certification issued by the department of mental health and addiction services under Chapter 5119. of the Revised Code if the license or certification is approved by the state board of pharmacy;

(g) A federally qualified health center or federally qualified health center look-alike, as defined in section 3701.047 of the Revised Code;

(h) A state or local correctional facility, as defined in section 5163.45 of the Revised Code;

(i) Any other facility specified in rules adopted under this section.

(C) To be eligible to receive a license as a category III terminal distributor of dangerous drugs with an office-based opioid treatment classification, an applicant shall submit evidence satisfactory to the ~~state board of pharmacy~~ that the applicant's office-based opioid treatment will be operated in accordance with the requirements specified in division (D) of this section and that the applicant meets any other applicable requirements of this chapter.

If the board determines that an applicant meets all of the requirements, the board shall issue to the applicant a license as a category III terminal distributor of dangerous drugs with an office-based opioid treatment classification.

(D) The holder of a category III terminal distributor license with an office-based opioid treatment classification shall do all of the following:

(1) Be in control of a facility that is owned and operated solely by one or more physicians

authorized under Chapter 4731. of the Revised Code to practice medicine and surgery or osteopathic medicine and surgery, unless the state board of pharmacy ~~has exempted the holder from~~ waives this requirement for the holder;

(2) Comply with the requirements for conducting office-based opioid treatment, as established by the state medical board in rules adopted under section 4731.056 of the Revised Code;

(3) Require any person with ownership of the facility to submit to a criminal records check in accordance with section 4776.02 of the Revised Code and send the results of the criminal records check directly to the state board of pharmacy for review and decision under section 4729.071 of the Revised Code;

(4) ~~Require all employees of each person employed by or seeking employment with the facility to submit to a criminal records check in accordance with section 4776.02 of the Revised Code and ensure;~~

(5) Ensure that no a person is not employed who has previously been by the facility if the person, within the ten years immediately preceding the date the person applied for employment, was convicted of; or pleaded guilty to; either of the following, unless the state board of pharmacy permits the person to be employed by waiving this requirement for the facility:

(a) A theft offense, described in division (K)(3) of section 2913.01 of the Revised Code, that would constitute a felony under the laws of this state, any other state, or the United States;

(b) A felony drug offense, as defined in section 2925.01 of the Revised Code.

~~(5)(6)~~ Maintain a list of each person with ownership of the facility and notify the state board of pharmacy of any change to that list.

(E) No person subject to licensure as a category III terminal distributor of dangerous drugs with an office-based opioid treatment classification shall knowingly fail to remain in compliance with the requirements of division (D) of this section and any other applicable requirements of this chapter.

(F) The state board of pharmacy may impose a fine of not more than five thousand dollars on a person who violates division (B) or (E) of this section. A separate fine may be imposed for each day the violation continues. In imposing the fine, the board's actions shall be taken in accordance with Chapter 119. of the Revised Code.

(G) The state board of pharmacy shall adopt rules as it considers necessary to implement and administer this section. The rules shall be adopted in accordance with Chapter 119. of the Revised Code.

Sec. 4729.99. (A) Whoever violates division (H) of section 4729.16, division (G) of section 4729.38, division (I) of section 4729.382, section 4729.57, or division (F) of section 4729.96 of the Revised Code is guilty of a minor misdemeanor, unless a different penalty is otherwise specified in the Revised Code. Each day's violation constitutes a separate offense.

(B) Whoever violates section 4729.27, 4729.28, or 4729.36 of the Revised Code is guilty of a misdemeanor of the third degree. Each day's violation constitutes a separate offense. If the offender previously has been convicted of or pleaded guilty to a violation of this chapter, that person is guilty of a misdemeanor of the second degree.

(C) Whoever violates section 4729.32, 4729.33, or 4729.34 of the Revised Code is guilty of a misdemeanor.

(D) Whoever violates division (A), (B), (C), (D), (F), or (G) of section 4729.51 of the Revised Code is guilty of a misdemeanor of the first degree.

(E)(1) Whoever violates section 4729.37, division (E)(1)(b) of section 4729.51, division (J) of section 4729.54, division (B) or (D) of section 4729.553, or section 4729.61 of the Revised Code is guilty of a felony of the fifth degree. If the offender previously has been convicted of or pleaded guilty to a violation of this chapter or a violation of Chapter 2925. or 3719. of the Revised Code, that person is guilty of a felony of the fourth degree.

(2) If an offender is convicted of or pleads guilty to a violation of section 4729.37, division (E) of section 4729.51, division (J) of section 4729.54, or section 4729.61 of the Revised Code, if the violation involves the sale, offer to sell, or possession of a schedule I or II controlled substance, with the exception of marihuana, and if the court imposing sentence upon the offender finds that the offender as a result of the violation is a major drug offender, as defined in section 2929.01 of the Revised Code, and is guilty of a specification of the type described in division (A) of section 2941.1410 of the Revised Code, the court, in lieu of the prison term authorized or required by division (E)(1) of this section and sections 2929.13 and 2929.14 of the Revised Code and in addition to any other sanction imposed for the offense under sections 2929.11 to 2929.18 of the Revised Code, shall impose upon the offender, in accordance with division (B)(3) of section 2929.14 of the Revised Code, the mandatory prison term specified in that division.

(3) Notwithstanding any contrary provision of section 3719.21 of the Revised Code, the clerk of court shall pay any fine imposed for a violation of section 4729.37, division (E) of section 4729.51, division (J) of section 4729.54, or section 4729.61 of the Revised Code pursuant to division (A) of section 2929.18 of the Revised Code in accordance with and subject to the requirements of division (F) of section 2925.03 of the Revised Code. The agency that receives the fine shall use the fine as specified in division (F) of section 2925.03 of the Revised Code.

(F) Whoever violates section 4729.531 of the Revised Code or any rule adopted thereunder or section 4729.532 of the Revised Code is guilty of a misdemeanor of the first degree.

(G) Whoever violates division (E)(1)(a) of section 4729.51 of the Revised Code is guilty of a felony of the fourth degree. If the offender has previously been convicted of or pleaded guilty to a violation of this chapter, or of a violation of Chapter 2925. or 3719. of the Revised Code, that person is guilty of a felony of the third degree.

(H) Whoever violates division (E)(1)(c) of section 4729.51 of the Revised Code is guilty of a misdemeanor of the first degree. If the offender has previously been convicted of or pleaded guilty to a violation of this chapter, or of a violation of Chapter 2925. or 3719. of the Revised Code, that person is guilty of a felony of the fifth degree.

(I)(1) Whoever violates division (A) of section 4729.95 of the Revised Code is guilty of unauthorized pharmacy-related drug conduct. Except as otherwise provided in this section, unauthorized pharmacy-related drug conduct is a misdemeanor of the second degree. If the offender previously has been convicted of or pleaded guilty to a violation of division (A), (B), or (C) of that section, unauthorized pharmacy-related drug conduct is a misdemeanor of the first degree on a second offense and a felony of the fifth degree on a third or subsequent offense.

(2) Whoever violates division (B) or (C) of section 4729.95 of the Revised Code is guilty of permitting unauthorized pharmacy-related drug conduct. Except as otherwise provided in this

section, permitting unauthorized pharmacy-related drug conduct is a misdemeanor of the second degree. If the offender previously has been convicted of or pleaded guilty to a violation of division (A), (B), or (C) of that section, permitting unauthorized pharmacy-related drug conduct is a misdemeanor of the first degree on a second offense and a felony of the fifth degree on a third or subsequent offense.

(3) Notwithstanding any contrary provision of section 3719.21 of the Revised Code or any other provision of law that governs the distribution of fines, the clerk of the court shall pay any fine imposed pursuant to division (I)(1) or (2) of this section to the state board of pharmacy if the board has adopted a written internal control policy under division (F)(2) of section 2925.03 of the Revised Code that addresses fine moneys that it receives under Chapter 2925. of the Revised Code and if the policy also addresses fine moneys paid under this division. The state board of pharmacy shall use the fines so paid in accordance with the written internal control policy to subsidize the board's law enforcement efforts that pertain to drug offenses.

(J)(1) Whoever violates division (A)(1) of section 4729.86 of the Revised Code is guilty of a misdemeanor of the third degree. If the offender has previously been convicted of or pleaded guilty to a violation of division (A)(1), (2), or (3) of section 4729.86 of the Revised Code, that person is guilty of a misdemeanor of the first degree.

(2) Whoever violates division (A)(2) of section 4729.86 of the Revised Code is guilty of a misdemeanor of the first degree. If the offender has previously been convicted of or pleaded guilty to a violation of division (A)(1), (2), or (3) of section 4729.86 of the Revised Code, that person is guilty of a felony of the fifth degree.

(3) Whoever violates division (A)(3) of section 4729.86 of the Revised Code is guilty of a felony of the fifth degree. If the offender has previously been convicted of or pleaded guilty to a violation of division (A)(1), (2), or (3) of section 4729.86 of the Revised Code, that person is guilty of a felony of the fourth degree.

(K) A person who violates division (C) of section 4729.552 of the Revised Code is guilty of a misdemeanor of the first degree. If the person previously has been convicted of or pleaded guilty to a violation of division (C) of section 4729.552 of the Revised Code, that person is guilty of a felony of the fifth degree.

Sec. 4731.96. (A) As used in this section and section 4731.961 of the Revised Code, "physician" means an individual authorized under this chapter to practice medicine and surgery, osteopathic medicine and surgery, or podiatric medicine and surgery.

(B)(1) Subject to division (B)(2) of this section, and notwithstanding any provision of this chapter or rule adopted by the state medical board, a physician may do either of the following without having examined an individual to whom epinephrine may be administered:

(a) Personally furnish a supply of epinephrine autoinjectors for use in accordance with sections 3313.7110, 3313.7111, 3314.143, 3326.28, 3328.29, 3728.03 to 3728.05, and 5101.76 of the Revised Code;

(b) Issue a prescription for epinephrine autoinjectors for use in accordance with sections 3313.7110, 3313.7111, 3314.143, 3326.28, 3328.29, 3728.03 to 3728.05, and 5101.76 of the Revised Code.

(2) An epinephrine autoinjector personally furnished or prescribed under division (B)(1) of

this section must be furnished or prescribed in such a manner that it may be administered only in a manufactured dosage form.

(C) A physician who acts in good faith in accordance with this section is not liable for or subject to any of the following for any action or omission of an entity to which an epinephrine autoinjector is furnished or a prescription is issued: damages in any civil action, prosecution in any criminal proceeding, or professional disciplinary action.

Sec. 4731.961. A physician who has established a protocol that meets the requirements specified by the state board of pharmacy in rules adopted under section 4729.47 of the Revised Code may authorize one or more pharmacists and any of the pharmacy interns supervised by the pharmacist or pharmacists to use the protocol for the purpose of dispensing epinephrine under section 4729.47 of the Revised Code.

SECTION 2. That existing sections 3728.03, 4729.16, 4729.23, 4729.28, 4729.41, 4729.43, 4729.45, 4729.553, 4729.99, and 4731.96 of the Revised Code are hereby repealed.

SECTION 3. The provisions of this act that amend and enact sections 3707.60, 3728.03, 4729.16, 4729.382, 4729.47, 4729.99, 4731.96, and 4731.961 of the Revised Code shall be known as the "Epinephrine Accessibility Act."

Speaker _____ *of the House of Representatives.*

President _____ *of the Senate.*

Passed _____, 20____

Approved _____, 20____

Governor.

The section numbering of law of a general and permanent nature is complete and in conformity with the Revised Code.

Director, Legislative Service Commission.

Filed in the office of the Secretary of State at Columbus, Ohio, on the ____ day of _____, A. D. 20 ____.

Secretary of State.

File No. _____ Effective Date _____