(131st General Assembly)
(Amended Substitute House Bill Number 4)

AN ACT

To amend sections 2925.61, 3719.13, 3719.27, 4723.488, 4729.01, 4729.16, 4729.29, 4729.291, 4729.51, 4729.60, 4730.431, 4731.94, and 5119.371 and to enact sections 3707.56, 4729.292, 4729.44, 4731.941, 4731.942, and 5119.372 of the Revised Code to modify the laws governing the authority to dispense or furnish naloxone for opioid overdoses, to establish standards for certain opioid treatment programs, and to declare an emergency.

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

SECTION 1. That sections 2925.61, 3719.13, 3719.27, 4723.488, 4729.01, 4729.16, 4729.29, 4729.291, 4729.51, 4729.60,

4730.431, 4731.94, and 5119.371 be amended and sections 3707.56, 4729.292, 4729.44, 4731.941, 4731.942, and 5119.372 of the Revised Code be enacted to read as follows:

Sec. 2925.61. (A) As used in this section:

(1) ~~"Administer naloxone" means to give naloxone to a person by either of the following routes:~~

~~(a) Using a device manufactured for the intranasal administration of liquid drugs;~~

~~(b) Using an autoinjector in a manufactured dosage form.~~

~~(2)~~ "Law enforcement agency" means a government entity that employs peace officers to perform law enforcement duties.

~~(3)~~ (2) "Licensed health professional" means all of the following:

(a) A physician ~~who is authorized under Chapter 4731. of the Revised Code to practice medicine and surgery, osteopathic medicine and surgery, or podiatric medicine and surgery~~;

(b) A physician assistant who holds a certificate to prescribe issued under Chapter 4730. of the Revised Code;

(c) A clinical nurse specialist, certified nurse-midwife, or certified nurse practitioner who holds a certificate to prescribe issued under section 4723.48 of the Revised Code.

~~(4)~~ (3) "Peace officer" has the same meaning as in section 2921.51 of the Revised Code.

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

(B) A family member, friend, or other individual who is in a position to assist an individual who is apparently experiencing or at risk of experiencing an opioid-related overdose, is not subject to criminal prosecution for a violation of section 4731.41 of the Revised Code or criminal prosecution under this chapter if the individual, acting in good faith, does all of the following:

(1) Obtains naloxone ~~from a licensed health professional or~~ pursuant to a prescription ~~for naloxone from~~ issued by a licensed health professional or obtains naloxone from one of the following: a licensed health professional, an individual who is authorized by a physician under

section 4731.941 of the Revised Code to personally furnish naloxone, or a pharmacist or pharmacy intern who is authorized by a physician or board of health under section 4729.44 of the Revised Code to dispense naloxone without a prescription;

(2) Administers ~~that~~ the naloxone obtained as described in division (B)(1) of this section to an individual who is apparently experiencing an opioid-related overdose;

(3) Attempts to summon emergency services as soon as practicable either ~~immediately~~ before or ~~immediately~~ after administering the naloxone.

(C) Division (B) of this section does not apply to a peace officer or to an emergency medical technician-basic, emergency medical technician-intermediate, or emergency medical technician-paramedic, as defined in section 4765.01 of the Revised Code.

(D) A peace officer employed by a law enforcement agency is not subject to administrative action, criminal prosecution for a violation of section 4731.41 of the Revised Code, or criminal prosecution under this chapter if the peace officer, acting in good faith, obtains naloxone from the peace officer's law enforcement agency and administers the naloxone to an individual who is apparently experiencing an opioid-related overdose.

Sec. 3707.56. (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, through a physician serving as the board's health commissioner or medical director, may authorize pharmacists and pharmacy interns working in the board's jurisdiction to use the protocol developed pursuant to rules adopted under section 4729.44 of the Revised Code for the purpose of dispensing naloxone under section 4729.44 of the Revised Code.

Sec. 3719.13. Prescriptions, orders, and records, required by Chapter 3719. of the Revised Code, and stocks of dangerous drugs and controlled substances, shall be open for inspection only to federal, state, county, and municipal officers, and employees of the state board of pharmacy whose duty it is to enforce the laws of this state or of the United States relating to controlled substances. Such prescriptions, orders, records, and stocks shall be open for inspection by employees of the state medical board for purposes of enforcing Chapters 4730. and 4731. of the Revised Code ~~and~~ , employees of the board of nursing for purposes of enforcing Chapter 4723. of the Revised Code, and employees of the department of mental health and addiction services for purposes of section 5119.372 of the Revised Code. No person having knowledge of any such prescription, order, or record shall divulge such knowledge, except in connection with a prosecution or proceeding in court or before a licensing or registration board or officer, to which prosecution or proceeding the person to whom such prescriptions, orders, or records relate is a party.

Sec. 3719.27. (A) Persons required~~,~~ by Chapter 3719. of the Revised Code~~,~~ to keep files or records shall, upon the written request of an officer or employee designated by the state board of pharmacy, make such files or records available to such officer or employee, at all reasonable hours, for inspection and copying, and accord to such officer or employee full opportunity to check the correctness of such files or records, including opportunity to make inventory of all stocks of controlled substances on hand. No person shall fail to make such files or records available or to accord such opportunity to check their correctness.

(B) Persons required by Chapter 3719. of the Revised Code to keep files or records shall, upon the written request of an employee designated by the director of mental health and addiction services, make such files or records available to the employee for the purpose of section 5119.372 of the Revised Code, at all reasonable hours, for inspection and copying, and accord to such employee full opportunity to check the correctness of such files or records. No person shall fail to make such files or records available or to accord such opportunity to check their correctness.

Sec. 4723.488. (A) Notwithstanding any provision of this chapter or rule adopted by the board of nursing, a clinical nurse specialist, certified nurse-midwife, or certified nurse practitioner who holds a certificate to prescribe issued under section 4723.48 of the Revised Code may personally furnish a supply of naloxone, or issue a prescription for naloxone, without having examined the individual to whom it may be administered if ~~all~~ both of the following conditions are met:

(1) The naloxone supply is furnished to, or the prescription is issued to and in the name of, a family member, friend, or other individual in a position to assist an individual who there is reason to believe is at risk of experiencing an opioid-related overdose.

(2) The nurse instructs the individual receiving the naloxone supply or prescription to summon emergency services as soon as practicable either ~~immediately~~ before or ~~immediately~~ after administering naloxone to an individual apparently experiencing an opioid-related overdose.

~~(3) The naloxone is personally furnished or prescribed in such a manner that it may be administered by only either of the following routes:~~

~~(a) Using a device manufactured for the intranasal administration of liquid drugs;~~

~~(b) Using an autoinjector in a manufactured dosage form.~~

(B) A nurse who under division (A) of this section in good faith furnishes a supply of naloxone or issues a prescription for naloxone is not liable for or subject to any of the following for any action or omission of the individual to whom the naloxone is furnished or the prescription is issued: damages in any civil action, prosecution in any criminal proceeding, or professional disciplinary action.

Sec. 4729.01. As used in this chapter:

(A) "Pharmacy," except when used in a context that refers to the practice of pharmacy, means any area, room, rooms, place of business, department, or portion of any of the foregoing where the practice of pharmacy is conducted.

(B) "Practice of pharmacy" means providing pharmacist care requiring specialized knowledge, judgment, and skill derived from the principles of biological, chemical, behavioral, social, pharmaceutical, and clinical sciences. As used in this division, "pharmacist care" includes the following:

(1) Interpreting prescriptions;

(2) Dispensing drugs and drug therapy related devices;

(3) Compounding drugs;

(4) Counseling individuals with regard to their drug therapy, recommending drug therapy related devices, and assisting in the selection of drugs and appliances for treatment of common diseases and injuries and providing instruction in the proper use of the drugs and appliances;

(5) Performing drug regimen reviews with individuals by discussing all of the drugs that the individual is taking and explaining the interactions of the drugs;

(6) Performing drug utilization reviews with licensed health professionals authorized to prescribe drugs when the pharmacist determines that an individual with a prescription has a drug regimen that warrants additional discussion with the prescriber;

(7) Advising an individual and the health care professionals treating an individual with regard to the individual's drug therapy;

(8) Acting pursuant to a consult agreement with a physician authorized under Chapter 4731. of the Revised Code to practice medicine and surgery or osteopathic medicine and surgery, if an agreement has been established with the physician;

(9) Engaging in the administration of immunizations to the extent authorized by section 4729.41 of the Revised Code.

(C) "Compounding" means the preparation, mixing, assembling, packaging, and labeling of one or more drugs in any of the following circumstances:

(1) Pursuant to a prescription issued by a licensed health professional authorized to prescribe

drugs;

(2) Pursuant to the modification of a prescription made in accordance with a consult agreement;

(3) As an incident to research, teaching activities, or chemical analysis;

(4) In anticipation of orders for drugs pursuant to prescriptions, based on routine, regularly observed dispensing patterns;

(5) Pursuant to a request made by a licensed health professional authorized to prescribe drugs for a drug that is to be used by the professional for the purpose of direct administration to patients in the course of the professional's practice, if all of the following apply:

(a) At the time the request is made, the drug is not commercially available regardless of the reason that the drug is not available, including the absence of a manufacturer for the drug or the lack of a readily available supply of the drug from a manufacturer.

(b) A limited quantity of the drug is compounded and provided to the professional.

(c) The drug is compounded and provided to the professional as an occasional exception to the normal practice of dispensing drugs pursuant to patient-specific prescriptions.

(D) "Consult agreement" means an agreement to manage an individual's drug therapy that has been entered into by a pharmacist and a physician authorized under Chapter 4731. of the Revised Code to practice medicine and surgery or osteopathic medicine and surgery.

(E) "Drug" means:

(1) Any article recognized in the United States pharmacopoeia and national formulary, or any supplement to them, intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in humans or animals;

(2) Any other article intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in humans or animals;

(3) Any article, other than food, intended to affect the structure or any function of the body of humans or animals;

(4) Any article intended for use as a component of any article specified in division (E)(1), (2), or (3) of this section; but does not include devices or their components, parts, or accessories.

(F) "Dangerous drug" means any of the following:

(1) Any drug to which either of the following applies:

(a) Under the "Federal Food, Drug, and Cosmetic Act," 52 Stat. 1040 (1938), 21 U.S.C.A. 301, as amended, the drug is required to bear a label containing the legend "Caution: Federal law prohibits dispensing without prescription" or "Caution: Federal law restricts this drug to use by or on the order of a licensed veterinarian" or any similar restrictive statement, or the drug may be dispensed only upon a prescription;

(b) Under Chapter 3715. or 3719. of the Revised Code, the drug may be dispensed only upon a prescription.

(2) Any drug that contains a schedule V controlled substance and that is exempt from Chapter 3719. of the Revised Code or to which that chapter does not apply;

(3) Any drug intended for administration by injection into the human body other than through a natural orifice of the human body.

(G) "Federal drug abuse control laws" has the same meaning as in section 3719.01 of the Revised Code.

(H) "Prescription" means ~~a~~ both of the following:

(1) A written, electronic, or oral order for drugs or combinations or mixtures of drugs to be used by a particular individual or for treating a particular animal, issued by a licensed health professional authorized to prescribe drugs;

(2) For purposes of section 2925.61, 4723.488, 4729.44, 4730.431, and 4731.94 of the Revised Code, a written, electronic, or oral order for naloxone issued to and in the name of a family member, friend, or other individual in a position to assist an individual who there is

reason to believe is at risk of experiencing an opioid-related overdose.

(I) "Licensed health professional authorized to prescribe drugs" or "prescriber" means an individual who is authorized by law to prescribe drugs or dangerous drugs or drug therapy related devices in the course of the individual's professional practice, including only the following:

(1) A dentist licensed under Chapter 4715. of the Revised Code;

(2) A clinical nurse specialist, certified nurse-midwife, or certified nurse practitioner who holds a certificate to prescribe issued under section 4723.48 of the Revised Code;

(3) An optometrist licensed under Chapter 4725. of the Revised Code to practice optometry under a therapeutic pharmaceutical agents certificate;

(4) A physician authorized under Chapter 4731. of the Revised Code to practice medicine and surgery, osteopathic medicine and surgery, or podiatric medicine and surgery;

(5) A physician assistant who holds a certificate to prescribe issued under Chapter 4730. of the Revised Code;

(6) A veterinarian licensed under Chapter 4741. of the Revised Code.

(J) "Sale" and "sell" include delivery, transfer, barter, exchange, or gift, or offer therefor, and each such transaction made by any person, whether as principal proprietor, agent, or employee.

(K) "Wholesale sale" and "sale at wholesale" mean any sale in which the purpose of the purchaser is to resell the article purchased or received by the purchaser.

(L) "Retail sale" and "sale at retail" mean any sale other than a wholesale sale or sale at wholesale.

(M) "Retail seller" means any person that sells any dangerous drug to consumers without assuming control over and responsibility for its administration. Mere advice or instructions regarding administration do not constitute control or establish responsibility.

(N) "Price information" means the price charged for a prescription for a particular drug product and, in an easily understandable manner, all of the following:

(1) The proprietary name of the drug product;

(2) The established (generic) name of the drug product;

(3) The strength of the drug product if the product contains a single active ingredient or if the drug product contains more than one active ingredient and a relevant strength can be associated with the product without indicating each active ingredient. The established name and quantity of each active ingredient are required if such a relevant strength cannot be so associated with a drug product containing more than one ingredient.

(4) The dosage form;

(5) The price charged for a specific quantity of the drug product. The stated price shall include all charges to the consumer, including, but not limited to, the cost of the drug product, professional fees, handling fees, if any, and a statement identifying professional services routinely furnished by the pharmacy. Any mailing fees and delivery fees may be stated separately without repetition. The information shall not be false or misleading.

(O) "Wholesale distributor of dangerous drugs" means a person engaged in the sale of dangerous drugs at wholesale and includes any agent or employee of such a person authorized by the person to engage in the sale of dangerous drugs at wholesale.

(P) "Manufacturer of dangerous drugs" means a person, other than a pharmacist, who manufactures dangerous drugs and who is engaged in the sale of those dangerous drugs within this state.

(Q) "Terminal distributor of dangerous drugs" means a person who is engaged in the sale of dangerous drugs at retail, or any person, other than a wholesale distributor or a pharmacist, who has possession, custody, or control of dangerous drugs for any purpose other than for that person's own use and consumption, and includes pharmacies, hospitals, nursing homes, and laboratories and all other persons who procure dangerous drugs for sale or other distribution by

or under the supervision of a pharmacist or licensed health professional authorized to prescribe drugs.

(R) "Promote to the public" means disseminating a representation to the public in any manner or by any means, other than by labeling, for the purpose of inducing, or that is likely to induce, directly or indirectly, the purchase of a dangerous drug at retail.

(S) "Person" includes any individual, partnership, association, limited liability company, or corporation, the state, any political subdivision of the state, and any district, department, or agency of the state or its political subdivisions.

(T) "Finished dosage form" has the same meaning as in section 3715.01 of the Revised Code.

(U) "Generically equivalent drug" has the same meaning as in section 3715.01 of the Revised Code.

(V) "Animal shelter" means a facility operated by a humane society or any society organized under Chapter 1717. of the Revised Code or a dog pound operated pursuant to Chapter 955. of the Revised Code.

(W) "Food" has the same meaning as in section 3715.01 of the Revised Code.

(X) "Pain management clinic" has the same meaning as in section 4731.054 of the Revised Code.

Sec. 4729.16. (A) The state board of pharmacy, after notice and hearing in accordance with Chapter 119. of the Revised Code, may revoke, suspend, limit, place on probation, or refuse to grant or renew an identification card, or may 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, if the board finds a pharmacist or pharmacy intern:

(1) Guilty of a felony or gross immorality;

(2) Guilty of dishonesty or unprofessional conduct in the practice of pharmacy;

(3) Addicted to or abusing liquor or drugs or impaired physically or mentally to such a degree as to render the pharmacist or pharmacy intern unfit to practice pharmacy;

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

(5) Guilty of willfully violating, conspiring to violate, attempting to violate, or aiding and abetting 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;

(6) Guilty of permitting anyone other than a pharmacist or pharmacy intern to practice pharmacy;

(7) Guilty of knowingly lending the pharmacist's or pharmacy intern's name to an illegal practitioner of pharmacy or having professional connection with an illegal practitioner of pharmacy;

(8) Guilty of dividing or agreeing 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;

(9) Has violated the terms of a consult agreement entered into pursuant to section 4729.39 of the Revised Code;

(10) Has committed fraud, misrepresentation, or deception in applying for or securing a license or identification card issued by the board under this chapter or under Chapter 3715. or 3719. of the Revised Code.

(B) Any individual whose identification card is revoked, suspended, or refused, shall return the identification card and 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 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.

(D) The board may suspend a license or identification card 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) If, pursuant to an adjudication under Chapter 119. of the Revised Code, the board has reasonable cause to believe that a pharmacist or pharmacy intern is physically or mentally impaired, the board may require the pharmacist or pharmacy intern to submit to a physical or mental examination, or both.

Sec. 4729.29. Divisions (A) and (B) of section 4729.01 and section 4729.28 of the Revised Code do not do any of the following:

(A) Apply to a licensed health professional authorized to prescribe drugs who is acting within the prescriber's scope of professional practice;

(B) Prevent a prescriber from personally furnishing the prescriber's patients with drugs, within the prescriber's scope of professional practice, that seem proper to the prescriber, as long as the drugs are furnished in accordance with section 4729.291 of the Revised Code;

(C) Apply to an individual who personally furnishes a supply of naloxone under authority conferred by a physician under section 4731.941 of the Revised Code or prevent that individual from personally furnishing the supply of naloxone in accordance with a protocol established by the physician under section 4731.941 of the Revised Code;

(D) Apply to the sale of oxygen, the sale of peritoneal dialysis solutions, or the sale of drugs that are not dangerous drugs by a retail dealer, in original packages when labeled as required by the "Federal Food, Drug, and Cosmetic Act," 52 Stat. 1040 (1938), 21 U.S.C.A. 301, as amended.

Sec. 4729.291. (A) When a licensed health professional authorized to prescribe drugs personally furnishes drugs to a patient pursuant to division (B) of section 4729.29 of the Revised Code, the prescriber shall ensure that the drugs are labeled and packaged in accordance with state and federal drug laws and any rules and regulations adopted pursuant to those laws. Records of purchase and disposition of all drugs personally furnished to patients shall be maintained by the prescriber in accordance with state and federal drug statutes and any rules adopted pursuant to those statutes.

(B) When personally furnishing to a patient RU-486 (mifepristone), a prescriber is subject to section 2919.123 of the Revised Code. A prescription for RU-486 (mifepristone) shall be in writing and in accordance with section 2919.123 of the Revised Code.

(C)(1) Except as provided in ~~division~~ divisions (D) and (E) of this section, no prescriber shall do either of the following:

(a) In any thirty-day period, personally furnish to or for patients, taken as a whole, controlled substances in an amount that exceeds a total of two thousand five hundred dosage units;

(b) In any seventy-two-hour period, personally furnish to or for a patient an amount of a controlled substance that exceeds the amount necessary for the patient's use in a seventy-two-

hour period.

(2) The state board of pharmacy may impose a fine of not more than five thousand dollars on a prescriber who fails to comply with the limits established under division (C)(1) of this section. A separate fine may be imposed for each instance of failing to comply with the limits. In imposing the fine, the board's actions shall be taken in accordance with Chapter 119. of the Revised Code.

(D)~~(1)~~ None of the following shall be counted in determining whether the amounts specified in division (C)(1) of this section have been exceeded:

~~(a)~~ (1) Methadone ~~provided~~ personally furnished to patients for the purpose of treating drug dependence or addiction, if the prescriber meets the conditions specified in 21 C.F.R. 1306.07;

~~(b)~~ (2) Buprenorphine ~~provided~~ personally furnished to patients for the purpose of treating drug dependence or addiction as part of an opioid treatment program that possesses a terminal distributor of dangerous drugs license issued under section 4729.54 of the Revised Code, 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, and ~~distributes both buprenorphine~~ meets either of the following criteria:

(a) Buprenorphine and methadone~~;~~ are personally furnished by physicians treating patients participating in the program.

(b) Buprenorphine, but not methadone, is personally furnished by physicians treating patients participating in the program, the program is accredited by a national accrediting organization approved by the substance abuse and mental health services administration, the service of personally furnishing buprenorphine has, notwithstanding section 5119.371 of the Revised Code, been certified by the department of mental health and addiction services under section 5119.36 of the Revised Code, and the program maintains in the record of a patient to whom buprenorphine has been administered or personally furnished a copy of the physician's signed and dated written order for that act.

(c) Controlled substances ~~provided~~ personally furnished to research subjects by a facility conducting clinical research in studies approved by a hospital-based institutional review board or an institutional review board accredited by the association for the accreditation of human research protection programs.

~~(2)~~ (E) Division (C)(1) of this section does not apply to a prescriber who is a veterinarian.

Sec. 4729.292. The state board of pharmacy shall annually conduct an on-site inspection of a community mental health services provider or community addiction services provider that is an opioid treatment program described in division (D)(2)(b) of section 4729.291 of the Revised Code.

Sec. 4729.44. (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 the protocol developed pursuant to rules adopted under division (G) of this section has been authorized under section 3707.56 or 4731.942 of the Revised Code, a pharmacist or pharmacy intern may dispense naloxone without a prescription to either of the following in accordance with that protocol:

(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 an individual who there is reason to believe is at risk of experiencing an opioid-related overdose.

(C) A pharmacist or pharmacy intern who dispenses naloxone under this section shall instruct

the individual to whom naloxone is dispensed to summon emergency services as soon as practicable either before or after administering naloxone.

(D) A pharmacist may document the dispensing of naloxone 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 naloxone.

(F) A board of health that in good faith authorizes a pharmacist or pharmacy intern to dispense naloxone 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 naloxone 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 naloxone 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 naloxone 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 naloxone 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 naloxone is dispensed: damages in any civil action, prosecution in any criminal proceeding, or professional disciplinary action.

(G) The state board of pharmacy shall, after consulting with the department of health and state medical board, adopt rules to implement this section. The rules shall specify a protocol under which pharmacists or pharmacy interns may dispense naloxone without a prescription.

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

Sec. 4729.51. (A)(1) Except as provided in division (A)(2) of this section, no person other than a registered wholesale distributor of dangerous drugs shall possess for sale, sell, distribute, or deliver, at wholesale, dangerous drugs, except as follows:

(a) A pharmacist who is a licensed terminal distributor of dangerous drugs or who is employed by a licensed terminal distributor of dangerous drugs may make occasional sales of dangerous drugs at wholesale~~;~~.

(b) A licensed terminal distributor of dangerous drugs having more than one establishment or place may transfer or deliver dangerous drugs from one establishment or place for which a license has been issued to the terminal distributor to another establishment or place for which a license has been issued to the terminal distributor if the license issued for each establishment or place is in effect at the time of the transfer or delivery.

(c) A licensed terminal distributor of dangerous drugs may make occasional sales of naloxone at wholesale to a state or local law enforcement agency if the terminal distributor is any of the following:

(i) A board of health of a city or general health district;

(ii) An authority having the duties of a board of health under section 3709.05 of the Revised Code;

(iii) A health department operated by such a board or authority.

(2) A manufacturer of dangerous drugs may donate epinephrine autoinjectors to any of the following:

(a) The board of education of a city, local, exempted village, or joint vocational school district;

(b) A community school established under Chapter 3314. of the Revised Code;

(c) A STEM school established under Chapter 3326. of the Revised Code;

(d) A college-preparatory boarding school established under Chapter 3328. of the Revised Code;

(e) A chartered or nonchartered nonpublic school.

(B)(1) No registered wholesale distributor of dangerous drugs shall possess for sale, or sell, at wholesale, dangerous drugs to any person other than the following:

(a) Except as provided in division (B)(2)(a) of this section, a licensed health professional authorized to prescribe drugs;

(b) An optometrist licensed under Chapter 4725. of the Revised Code who holds a topical ocular pharmaceutical agents certificate;

(c) A registered wholesale distributor of dangerous drugs;

(d) A manufacturer of dangerous drugs;

(e) Subject to division (B)(3) of this section, a licensed terminal distributor of dangerous drugs;

(f) Carriers or warehouses for the purpose of carriage or storage;

(g) Terminal or wholesale distributors of dangerous drugs who are not engaged in the sale of dangerous drugs within this state;

(h) 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 specified in rules adopted by the state board of pharmacy under section 4729.68 of the Revised Code, but only with respect to insulin that will be used for the purpose of diabetes education and only if diabetes education is within the individual's scope of practice under statutes and rules regulating the individual's profession;

(i) 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 in rule, 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;

(j) Except as provided in division (B)(2)(b) of this section, a business entity that is a corporation formed under division (B) of section 1701.03 of the Revised Code, a limited liability company formed under Chapter 1705. of the Revised Code, or a professional association formed under Chapter 1785. of the Revised Code if the entity has a sole shareholder who is a licensed health professional authorized to prescribe drugs and is authorized to provide the professional services being offered by the entity;

(k) Except as provided in division (B)(2)(c) of this section, a business entity that is a corporation formed under division (B) of section 1701.03 of the Revised Code, a limited liability company formed under Chapter 1705. of the Revised Code, a partnership or a limited liability partnership formed under Chapter 1775. of the Revised Code, or a professional association formed under Chapter 1785. of the Revised Code, 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 licensed health professional authorized to prescribe drugs;

(l) With respect to epinephrine autoinjectors that may be possessed under section 3313.7110, 3313.7111, 3314.143, 3326.28, or 3328.29 of the Revised Code, 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 established under Chapter 3314. of the Revised Code; a STEM school established under Chapter 3326. of the Revised Code; or a college-preparatory boarding school established under Chapter 3328. of the Revised Code;

(m) With respect to epinephrine autoinjectors that may be possessed under section 5101.76 of the Revised Code, any of the following: a residential camp, as defined in section 2151.011 of the Revised Code; a child day camp, as defined in section 5104.01 of the Revised Code; or a child day camp operated by any county, township, municipal corporation, township park district

created under section 511.18 of the Revised Code, park district created under section 1545.04 of the Revised Code, or joint recreation district established under section 755.14 of the Revised Code;

(n) With respect to naloxone that may be possessed under section 2925.61 of the Revised Code, a law enforcement agency and its peace officers.

(2) No registered wholesale distributor of dangerous drugs shall possess for sale, or sell, at wholesale, dangerous drugs to any of the following:

(a) 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 section 4729.552 of the Revised Code;

(b) A business entity described in division (B)(1)(j) of this section that is, or is operating, a pain management clinic without a license as a terminal distributor of dangerous drugs with a pain management clinic classification issued under section 4729.552 of the Revised Code;

(c) A business entity described in division (B)(1)(k) of this section that is, or is operating, a pain management clinic without a license as a terminal distributor of dangerous drugs with a pain management clinic classification issued under section 4729.552 of the Revised Code.

(3) No registered wholesale distributor of dangerous drugs shall possess dangerous drugs for sale at wholesale, or sell such drugs at wholesale, to a licensed terminal distributor of dangerous drugs, except as follows:

(a) In the case of a terminal distributor with a category I license, only dangerous drugs described in category I, as defined in division (A)(1) of section 4729.54 of the Revised Code;

(b) In the case of a terminal distributor with a category II license, only dangerous drugs described in category I and category II, as defined in divisions (A)(1) and (2) of section 4729.54 of the Revised Code;

(c) In the case of a terminal distributor with a category III license, dangerous drugs described in category I, category II, and category III, as defined in divisions (A)(1), (2), and (3) of section 4729.54 of the Revised Code;

(d) In the case of a terminal distributor with a limited category I, II, or III license, only the dangerous drugs specified in the certificate furnished by the terminal distributor in accordance with section 4729.60 of the Revised Code.

(C)(1) Except as provided in division (C)(4) of this section, no person shall sell, at retail, dangerous drugs.

(2) Except as provided in division (C)(4) of this section, no person shall possess for sale, at retail, dangerous drugs.

(3) Except as provided in division (C)(4) of this section, no person shall possess dangerous drugs.

(4) Divisions (C)(1), (2), and (3) of this section do not apply to a registered wholesale distributor of dangerous drugs, a licensed terminal distributor of dangerous drugs, or a person who possesses, or possesses for sale or sells, at retail, a dangerous drug in accordance with Chapters 3719., 4715., 4723., 4725., 4729., 4730., 4731., and 4741. of the Revised Code.

Divisions (C)(1), (2), and (3) of this section do not apply to 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 specified in rules adopted by the state board of pharmacy under section 4729.68 of the Revised Code, but only to the extent that the individual possesses insulin or personally supplies insulin solely for the purpose of diabetes education and only if diabetes education is within the individual's scope of practice under statutes and rules regulating the individual's profession.

Divisions (C)(1), (2), and (3) of this section do not apply to 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 in rule, but only to the extent that the individual possesses

medical oxygen or personally supplies medical oxygen for the purpose of emergency care or treatment at the scene of a diving emergency.

Division (C)(3) of this section does not apply to the board of education of a city, local, exempted village, or joint vocational school district, a school building operated by a school district board of education, a chartered or nonchartered nonpublic school, a community school, a STEM school, or a college-preparatory boarding school for the purpose of possessing epinephrine autoinjectors under section 3313.7110, 3313.7111, 3314.143, 3326.28, or 3328.29 of the Revised Code.

Division (C)(3) of this section does not apply to a residential camp, as defined in section 2151.011 of the Revised Code, a child day camp, as defined in section 5104.01 of the Revised Code, or a child day camp operated by any county, township, municipal corporation, township park district created under section 511.18 of the Revised Code, park district created under section 1545.04 of the Revised Code, or joint recreation district established under section 755.14 of the Revised Code for the purpose of possessing epinephrine autoinjectors under section 5101.76 of the Revised Code.

Division (C)(3) of this section does not apply to a law enforcement agency or the agency's peace officers if the agency or officers possess naloxone for administration to individuals who are apparently experiencing opioid-related overdoses.

(D) No licensed terminal distributor of dangerous drugs shall purchase for the purpose of resale dangerous drugs from any person other than a registered wholesale distributor of dangerous drugs, except as follows:

(1) A licensed terminal distributor of dangerous drugs may make occasional purchases of dangerous drugs for resale from a pharmacist who is a licensed terminal distributor of dangerous drugs or who is employed by a licensed terminal distributor of dangerous drugs;

(2) A licensed terminal distributor of dangerous drugs having more than one establishment or place may transfer or receive dangerous drugs from one establishment or place for which a license has been issued to the terminal distributor to another establishment or place for which a license has been issued to the terminal distributor if the license issued for each establishment or place is in effect at the time of the transfer or receipt.

(E) No licensed terminal distributor of dangerous drugs shall engage in the sale or other distribution of dangerous drugs at retail or maintain possession, custody, or control of dangerous drugs for any purpose other than the distributor's personal use or consumption, at any establishment or place other than that or those described in the license issued by the state board of pharmacy to such terminal distributor.

(F) Nothing in this section shall be construed to interfere with the performance of official duties by any law enforcement official authorized by municipal, county, state, or federal law to collect samples of any drug, regardless of its nature or in whose possession it may be.

(G) Notwithstanding anything to the contrary in this section, the board of education of a city, local, exempted village, or joint vocational school district may deliver epinephrine autoinjectors to a school under its control for the purpose of possessing epinephrine autoinjectors under section 3313.7110 of the Revised Code.

Sec. 4729.60. (A) Before a registered wholesale distributor of dangerous drugs may sell dangerous drugs at wholesale to any person, other than the persons specified in divisions (B)(1)(a) to (d), (f) to (h), and (l)~~, and (m)~~ to (n) of section 4729.51 of the Revised Code, such wholesale distributor shall obtain from the purchaser and the purchaser shall furnish to the wholesale distributor a certificate indicating that the purchaser is a licensed terminal distributor of dangerous drugs. The certificate shall be in the form that the state board of pharmacy shall prescribe, and shall set forth the name of the licensee, the number of the license, a description of the place or establishment or each place or establishment for which the license was issued, the category of licensure, and, if the license is a limited category I, II, or III license, the dangerous

drugs that the licensee is authorized to possess, have custody or control of, and distribute.

If no certificate is obtained or furnished before a sale is made, it shall be presumed that the sale of dangerous drugs by the wholesale distributor is in violation of division (B) of section 4729.51 of the Revised Code and the purchase of dangerous drugs by the purchaser is in violation of division (C) of section 4729.51 of the Revised Code. If a registered wholesale distributor of dangerous drugs obtains or is furnished a certificate from a terminal distributor of dangerous drugs and relies on the certificate in selling dangerous drugs at wholesale to the terminal distributor of dangerous drugs, the wholesale distributor of dangerous drugs shall be deemed not to have violated division (B) of section 4729.51 of the Revised Code in making the sale.

(B) Before a licensed terminal distributor of dangerous drugs may purchase dangerous drugs at wholesale, the terminal distributor shall obtain from the seller and the seller shall furnish to the terminal distributor the number of the seller's registration certificate to engage in the sale of dangerous drugs at wholesale.

If no registration number is obtained or furnished before a purchase is made, it shall be presumed that the purchase of dangerous drugs by the terminal distributor is in violation of division (D) of section 4729.51 of the Revised Code and the sale of dangerous drugs by the seller is in violation of division (A) of section 4729.51 of the Revised Code. If a licensed terminal distributor of dangerous drugs obtains or is furnished a registration number from a wholesale distributor of dangerous drugs and relies on the registration number in purchasing dangerous drugs at wholesale from the wholesale distributor of dangerous drugs, the terminal distributor shall be deemed not to have violated division (D) of section 4729.51 of the Revised Code in making the purchase.

Sec. 4730.431. (A) Notwithstanding any provision of this chapter or rule adopted by the state medical board, a physician assistant who holds a certificate to prescribe issued under this chapter may personally furnish a supply of naloxone, or issue a prescription for naloxone, without having examined the individual to whom it may be administered if ~~all~~ both of the following conditions are met:

(1) The naloxone supply is furnished to, or the prescription is issued to and in the name of, a family member, friend, or other individual in a position to assist an individual who there is reason to believe is at risk of experiencing an opioid-related overdose.

(2) The physician assistant instructs the individual receiving the naloxone supply or prescription to summon emergency services as soon as practicable either ~~immediately~~ before or ~~immediately~~ after administering naloxone to an individual apparently experiencing an opioid-related overdose.

~~(3) The naloxone is personally furnished or prescribed in such a manner that it may be administered by only either of the following routes:~~

~~(a) Using a device manufactured for the intranasal administration of liquid drugs;~~

~~(b) Using an autoinjector in a manufactured dosage form.~~

(B) A physician assistant who under division (A) of this section in good faith furnishes a supply of naloxone or issues a prescription for naloxone is not liable for or subject to any of the following for any action or omission of the individual to whom the naloxone is furnished or the prescription is issued: damages in any civil action, prosecution in any criminal proceeding, or professional disciplinary action.

Sec. 4731.94. (A) As used in this section and sections 4731.941 and 4731.942 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) Notwithstanding any provision of this chapter or rule adopted by the state medical board, a physician may personally furnish a supply of naloxone, or issue a prescription for naloxone, without having examined the individual to whom it may be administered if ~~all~~ both of the

following conditions are met:

(1) The naloxone supply is furnished to, or the prescription is issued to and in the name of, a family member, friend, or other individual in a position to assist an individual who there is reason to believe is at risk of experiencing an opioid-related overdose.

(2) The physician instructs the individual receiving the naloxone supply or prescription to summon emergency services as soon as practicable either ~~immediately~~ before or ~~immediately~~ after administering the naloxone to an individual apparently experiencing an opioid-related overdose.

~~(3) The naloxone is personally furnished or prescribed in such a manner that it may be administered by only either of the following routes:~~

~~(a) Using a device manufactured for the intranasal administration of liquid drugs;~~

~~(b) Using an autoinjector in a manufactured dosage form.~~

(C) A physician who under division (B) of this section in good faith furnishes a supply of naloxone or issues a prescription for naloxone is not liable for or subject to any of the following for any action or omission of the individual to whom the naloxone is furnished or the prescription is issued: damages in any civil action, prosecution in any criminal proceeding, or professional disciplinary action.

Sec. 4731.941. (A)(1) A physician who has established a protocol that meets the requirements of division (C) of this section may authorize one or more other individuals to personally furnish a supply of naloxone pursuant to the protocol to either of the following:

(a) An individual who there is reason to believe is experiencing or at risk of experiencing an opioid-related overdose;

(b) A family member, friend, or other person in a position to assist an individual who there is reason to believe is at risk of experiencing an opioid-related overdose.

(2) An individual authorized under this section to personally furnish naloxone may do so without having examined the individual to whom it may be administered.

(B) An individual authorized by a physician under this section may personally furnish naloxone to an individual described in division (A)(1)(a) or (b) of this section if both of the following conditions are met:

(1) The authorized individual complies with the protocol established by the authorizing physician, including having completed the training required by the protocol.

(2) The authorized individual instructs the individual to whom naloxone is furnished to summon emergency services as soon as practicable either before or after administering naloxone.

(C) A protocol established by a physician for purposes of this section shall be established in writing and include all of the following:

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

(2) Precautions and contraindications concerning furnishing naloxone;

(3) Any limitations the physician 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 will be authorized to furnish naloxone;

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

(D) A physician who in good faith authorizes another individual to personally furnish naloxone in accordance with a protocol established by the physician under this section is not liable for or subject to any of the following for any action or omission of the individual to whom the naloxone is furnished: damages in any civil action, prosecution in any criminal proceeding,

or professional disciplinary action.

An individual authorized under this section to personally furnish naloxone 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 naloxone is furnished: damages in any civil action, prosecution in any criminal proceeding, or professional disciplinary action.

Sec. 4731.942. A physician may authorize one or more pharmacists and any of the pharmacy interns supervised by the pharmacist or pharmacists to use the protocol developed pursuant to rules adopted under section 4729.44 of the Revised Code for the purpose of dispensing naloxone under section 4729.44 of the Revised Code.

Sec. 5119.371. (A) In lieu of a determination by the director of mental health and addiction services of whether the services of a community mental health services provider or a community addiction services provider satisfy the standards for certification under section 5119.36 of the Revised Code, the director shall accept appropriate accreditation of an applicant's mental health services, alcohol and drug addiction services, integrated mental health and alcohol and other drug addiction services, integrated mental health and physical health services, or integrated alcohol and other drug addiction and physical health services being provided in this state from any of the following national accrediting organizations as evidence that the applicant satisfies the standards for certification:

(1) The joint commission;

(2) The commission on accreditation of rehabilitation facilities;

(3) The council on accreditation;

(4) Other behavioral health accreditation as determined by the director.

(B) If the director determines that an applicant's accreditation is current, is appropriate for the services for which the applicant is seeking certification, and the applicant meets any other requirements established under this section or in rules adopted under this section, the director shall certify the applicant's services that are accredited. Except as provided in division (C)(2) of this section, the director shall issue the certification without further evaluation of the services.

(C) For purposes of this section, all of the following apply:

(1) The director may review the accrediting organizations listed in division (A) of this section to evaluate whether the accreditation standards and processes used by the organizations are consistent with service delivery models the director considers appropriate for mental health services, alcohol or other drug addiction services, physical health services, or both. The director may communicate to an accrediting organization any identified concerns, trends, needs, and recommendations.

(2) The director may conduct an on-site review or otherwise evaluate a community mental health services provider or a community addiction services provider at any time based on cause, including complaints made by or on behalf of persons receiving services and confirmed or alleged deficiencies brought to the attention of the director. This authority does not affect the director's duty to conduct the annual inspections required by section 5119.372 of the Revised Code.

(3) The director shall require a community mental health services provider and a community addiction services provider to notify the director not later than ten days after any change in the provider's accreditation status. The provider may notify the director by providing a copy of the relevant document the provider received from the accrediting organization.

(4) The director shall require a community mental health services provider and a community addiction services provider to submit to the director reports of major unusual incidents.

(5) The director may require a community mental health services provider or a community addiction services provider to submit to the director cost reports pertaining to the provider.

(D) The director shall adopt rules in accordance with Chapter 119. of the Revised Code to implement this section. In adopting the rules, the director shall do all of the following:

(1) Specify the documentation that must be submitted as evidence of holding appropriate accreditation;

(2) Establish a process by which the director may review the accreditation standards and processes used by the national accrediting organizations listed in division (A) of this section;

(3) Specify the circumstances under which reports of major unusual incidents and provider cost reports must be submitted to the director;

(4) Specify the circumstances under which the director may conduct an on-site review or otherwise evaluate a community mental health services provider and a community addiction services provider for cause;

(5) Establish a process by which the director, based on deficiencies identified as a result of conducting an on-site review or evaluating a community mental health services provider or a community addiction services provider under division (C)(2) of this section, may take any of a range of corrective actions, with the most stringent being revocation of the certification of the provider's services.

Sec. 5119.372. The director of mental health and addiction services shall annually conduct an on-site review of each community mental health services provider and community addiction services provider that is an opioid treatment program described in division (D)(2)(b) of section 4729.291 of the Revised Code. The review may include an inspection of pharmacy records as described in section 3719.13 of the Revised Code and an inspection of patient treatment records. If the director has reason to believe that a violation of local, state, or federal drug law, including any provision of Chapter 2925., 3715., 3719., or 4729. of the Revised Code, has occurred, the director shall report that information to the state board of pharmacy.

The director may adopt rules in accordance with Chapter 119. of the Revised Code to implement this section.

SECTION 2. That existing sections 2925.61, 3719.13, 3719.27, 4723.488, 4729.01, 4729.16, 4729.29, 4729.291, 4729.51, 4729.60, 4730.431, 4731.94, and 5119.371 of the Revised Code are hereby repealed.

Section 3. This act is hereby declared to be an emergency measure necessary for the immediate preservation of the public peace, health, and safety. The reason for such necessity is that abuse of buprenorphine is a growing concern in this state and immediate action is necessary to protect patients being treated with buprenorphine in opioid treatment programs. Therefore, this action shall go into immediate effect.

_____

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 _____