As Reported by the House Natural Resources Committee

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Senator Brenner

Cosponsors: Senators Lang, Cirino, DeMora, Hicks-Hudson, Liston, Patton, Reineke, Roegner

Representative Mathews, T.

To amend sections 4729.01, 4729.36, 4729.531, 4729.532, 4729.54, and 4729.55 of the Revised Code to allow wild animal rehabilitation facilities to receive a limited license to administer euthanasia drugs and to modify the law regarding the use of terms that are limited to pharmacies and pharmacists.

BE IT ENACTED BY THE GENERAL ASSEMBLY OF THE STATE OF OHIO:

Section 1. That sections 4729.01, 4729.36, 4729.531, 4729.532, 4729.54, and 4729.55 of the Revised Code be amended to read as follows:

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, if an agreement has been established;

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

(10) Engaging in the administration of drugs to the extent

authorized by section 4729.45 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 that has been entered into under section 4729.39 of the Revised Code.

(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.

"Drug" does not include "hemp" or a "hemp product" as those terms are defined in section 928.01 of the Revised Code.

(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;

(4) Any drug that is a biological product, as defined in section 3715.01 of the Revised Code.

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

(H) "Prescription" means all 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 sections 4723.4810, 4729.282, 4730.432, and 4731.93 of the Revised Code, a written, electronic, or oral order for a drug to treat chlamydia, gonorrhea, or trichomoniasis issued to and in the name of a patient who is not the intended user of the drug but is the sexual partner of the intended user;

(3) For purposes of sections 3313.7110, 3313.7111, 3314.143, 3326.28, 3328.29, 4723.483, 4729.88, 4730.433, 4731.96, and 5101.76 of the Revised Code, a written, electronic, or oral order for an epinephrine autoinjector issued to and in the name of a school, school district, or camp;

(4) For purposes of Chapter 3728. and sections 4723.483, 4729.88, 4730.433, and 4731.96 of the Revised Code, a written, electronic, or oral order for an epinephrine autoinjector issued to and in the name of a qualified entity, as defined in section 3728.01 of the Revised Code;

(5) For purposes of sections 3313.7115, 3313.7116, 3314.147, 3326.60, 3328.38, 4723.4811, 4730.437, 4731.92, and 5101.78 of the Revised Code, a written, electronic, or oral order for injectable or nasally administered glucagon in the name of a school, school district, or camp.

(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 current, valid license issued under Chapter 4723. of the Revised Code to practice nursing as an advanced practice registered nurse;

(3) A certified registered nurse anesthetist who holds a current, valid license issued under Chapter 4723. of the Revised Code to practice nursing as an advanced practice registered nurse, but only to the extent of the nurse's authority under sections 4723.43 and 4723.434 of the Revised Code;

(4) An optometrist licensed under Chapter 4725. of the Revised Code to practice optometry;

(5) A physician authorized under Chapter 4731. of the

Revised Code to practice medicine and surgery, osteopathic medicine and surgery, or podiatric medicine and surgery;

(6) A physician assistant who holds a license to practice as a physician assistant issued under Chapter 4730. of the Revised Code, holds a valid prescriber number issued by the state medical board, and has been granted physician-delegated prescriptive authority;

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

(8) A certified mental health assistant licensed under Chapter 4772. of the Revised Code who has been granted physician-delegated prescriptive authority by the physician supervising the certified mental health assistant.

(J) "Sale" or "sell" includes any transaction made by any person, whether as principal proprietor, agent, or employee, to do or offer to do any of the following: deliver, distribute, broker, exchange, gift or otherwise give away, or transfer, whether the transfer is by passage of title, physical movement, or both.

(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" or "wholesale distributor" 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" or "manufacturer" means a person, other than a pharmacist or prescriber, who

manufactures dangerous drugs and who is engaged in the sale of those dangerous drugs.

(Q) "Terminal distributor of dangerous drugs" or "terminal distributor" means a person who is engaged in the sale of dangerous drugs at retail, or any person, other than a manufacturer, repackager, outsourcing facility, third-party logistics provider, wholesale distributor, or pharmacist, who has possession, custody, or control of dangerous drugs for any purpose other than for that person's own use and consumption. "Terminal distributor" 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, licensed health professional authorized to prescribe drugs, or other person authorized by the state board of pharmacy.

(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)(1) "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.

(2) "County dog warden" means a dog warden or deputy dog warden appointed or employed under section 955.12 of the Revised Code.

(3) "Wild animal rehabilitation facility" means a facility that holds a permit issued by the chief of the division of wildlife for rehabilitation purposes in accordance with section 1533.08 of the Revised Code or rules adopted by the chief.

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

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

(W) "Investigational drug or product" means a drug or product that has successfully completed phase one of the United States food and drug administration clinical trials and remains under clinical trial, but has not been approved for general use by the United States food and drug administration. "Investigational drug or product" does not include controlled substances in schedule I, as defined in section 3719.01 of the Revised Code.

(X) "Product," when used in reference to an investigational drug or product, means a biological product, other than a drug, that is made from a natural human, animal, or microorganism source and is intended to treat a disease or medical condition.

(Y) "Third-party logistics provider" means a person that provides or coordinates warehousing or other logistics services pertaining to dangerous drugs including distribution, on behalf of a manufacturer, wholesale distributor, or terminal distributor of dangerous drugs, but does not take ownership of

the drugs or have responsibility to direct the sale or disposition of the drugs.

(Z) "Repackager of dangerous drugs" or "repackager" means a person that repacks and relabels dangerous drugs for sale or distribution.

(AA) "Outsourcing facility" means a facility that is engaged in the compounding and sale of sterile drugs and is registered as an outsourcing facility with the United States food and drug administration.

(BB) "Laboratory" means a laboratory licensed under this chapter as a terminal distributor of dangerous drugs and entrusted to have custody of any of the following drugs and to use the drugs for scientific and clinical purposes and for purposes of instruction: dangerous drugs that are not controlled substances, as defined in section 3719.01 of the Revised Code; dangerous drugs that are controlled substances, as defined in that section; and controlled substances in schedule I, as defined in that section.

(CC) "Overdose reversal drug" means both of the following:

(1) Naloxone;

(2) Any other drug that the state board of pharmacy, through rules adopted in accordance with Chapter 119. of the Revised Code, designates as a drug that is approved by the federal food and drug administration for the reversal of a known or suspected opioid-related overdose.

Sec. 4729.36. (A) No place except a pharmacy licensed as a terminal distributor of dangerous drugs and no person except a licensed pharmacist shall knowingly display any sign or advertise in any fashion~~,~~ using the words "pharmacy," "drugs,"

"drug store," "drug store supplies," "pharmacist," "druggist," "pharmaceutical chemist," ~~"apothecary,"~~ "drug sundries," or "medicine~~,~~" or knowingly use any ~~of these words or their~~ equivalent~~,~~ of those words in any manner that would lead or tend to lead the public to believe that the place is a pharmacy or the person is a pharmacist.

(B) A pharmacy making retail sales may advertise by name or therapeutic class the availability for sale or dispensing of any dangerous drug provided that the advertising includes the price information specified in the definition of that term in section 4729.01 of the Revised Code.

Sec. 4729.531. (A) The state board of pharmacy may issue a limited license to an animal shelter, a wild animal rehabilitation facility, or county dog warden solely for the purpose of purchasing, possessing, and administering drugs that are distributed in a manufactured dosage form as described in section 4729.532 of the Revised Code. Unless otherwise approved by the board, no such license shall authorize or permit the distribution of these drugs to any person other than the originating wholesale distributor of the drugs. An application for licensure shall include the information the board requires by rule under this section. If the application meets the requirements of the rules adopted under this section, the board shall issue the license.

(B) The board, in accordance with Chapter 119. of the Revised Code, shall adopt any rules necessary to administer and enforce this section. The rules shall do all of the following:

(1) Require as a condition of licensure that an agent or employee of an animal shelter or wild animal rehabilitation facility or an agent or employee of a county dog warden, other

than a registered veterinary technician as defined in section 4741.01 of the Revised Code, has successfully completed a euthanasia technician certification course described in section 4729.532 of the Revised Code;

(2) Specify the information the animal shelter, wild animal rehabilitation facility, or county dog warden must provide the board for issuance or renewal of a license;

(3) Address any other matters the board considers necessary or appropriate for the administration and enforcement of this section.

Sec. 4729.532. (A) No agent or employee of an animal shelter, no agent or employee of a wild animal rehabilitation facility, and no county dog warden or agent or employee of a county dog warden shall perform euthanasia by means of lethal injection on an animal by use of any substance other than a substance in a manufactured dosage form that the state veterinary medical licensing board, in consultation with the state board of pharmacy, approves by rule adopted in accordance with Chapter 119. of the Revised Code.

The agent or employee of an animal shelter or wild animal rehabilitation facility, county dog warden, or agent or employee of a county dog warden when using a lethal solution to perform euthanasia on an animal shall use the solution in accordance with the following methods:

(1) Intravenous injection by hypodermic needle;

(2) Intraperitoneal injection by hypodermic needle;

(3) Intracardial injection by hypodermic needle, but only on an animal verified to be unconscious;

(4) Oral administration of solution or powder.

(B) Before euthanasia, a euthanasia technician may administer a solution of one or more drugs exclusively for the purpose of inducing anesthesia, sedation, or unconsciousness prior to euthanasia. Only those drugs that have been approved by rule adopted in accordance with Chapter 119. of the Revised Code by the state board of pharmacy, in consultation with the state veterinary medical licensing board, may be used.

(C) No agent or employee of an animal shelter or wild animal rehabilitation facility and no county dog warden or agent or employee of a county dog warden, other than a registered veterinary technician as defined in section 4741.01 of the Revised Code, shall perform euthanasia by means of lethal injection on an animal or administer pre-euthanasia drugs that induce anesthesia, sedation, or unconsciousness unless the agent or employee or county dog warden has received certification after successfully completing a euthanasia technician certification course as described in this division.

The curriculum for a euthanasia technician certification course shall be one that has been approved by the state veterinary medical licensing board, shall be at least sixteen hours in length, and shall include information in at least all of the following areas:

(1) The pharmacology, proper administration, and storage of euthanasia, sedation, and anesthesia solutions;

(2) Federal and state laws regulating the storage and accountability of euthanasia, sedation, and anesthesia solutions;

(3) Euthanasia technician stress management;

(4) Proper disposal of euthanized animals.

(D)(1) No agent or employee of an animal shelter or wild animal rehabilitation facility shall perform euthanasia by means of lethal injection on animals or administer pre-euthanasia drugs that induce anesthesia, sedation, or unconsciousness under this section unless the facility in which the agent or employee works or is employed is licensed with the state board of pharmacy under section 4729.531 of the Revised Code. No agent or employee of a county dog warden shall perform euthanasia by means of lethal injection on animals or administer pre-euthanasia drugs that induce anesthesia, sedation, or unconsciousness under this section unless the county dog warden is licensed under section 4729.531 of the Revised Code.

(2) Any agent or employee of an animal shelter or wild animal rehabilitation —facility or county dog warden performing euthanasia by means of lethal injection or administering pre-euthanasia drugs that induce anesthesia, sedation, or unconsciousness shall do so only in a humane and proficient manner that is in conformity with the methods described in divisions (A) and (B) of this section and not in violation of Chapter 959. of the Revised Code.

(E) Nothing in this section precludes a licensed veterinarian or registered veterinary technician as defined in section 4741.01 of the Revised Code from engaging in the practice of veterinary medicine as authorized in Chapter 4741. of the Revised Code.

Sec. 4729.54. (A) As used in this section:

(1) "Category II" means any dangerous drug that is not included in category III.

(2) "Category III" means any controlled substance that is contained in schedule I, II, III, IV, or V.

(3) "Emergency medical service organization" has the same meaning as in section 4765.01 of the Revised Code.

(4) "Emergency medical service organization satellite" means a location where dangerous drugs are stored that is separate from, but associated with, the headquarters of an emergency medical service organization. "Emergency medical service organization satellite" does not include the units under the control of the emergency medical service organization.

(5) "Person" includes an emergency medical service organization or an emergency medical service organization satellite.

(6) "Schedule I," "schedule II," "schedule III," "schedule IV," and "schedule V" have the same meanings as in section 3719.01 of the Revised Code.

(B)(1) A person seeking to be licensed as a terminal distributor of dangerous drugs shall file with the executive director of the state board of pharmacy a verified application. After it is filed, the application may not be withdrawn without approval of the board.

(2) An application shall contain all the following that apply in the applicant's case:

(a) Information that the board requires relative to the qualifications of a terminal distributor of dangerous drugs set forth in section 4729.55 of the Revised Code;

(b) A statement as to whether the person is seeking to be licensed as a category II, category III, limited category II, or

limited category III terminal distributor of dangerous drugs;

(c) If the person is seeking to be licensed as a limited category II or limited category III terminal distributor of dangerous drugs, a list of the dangerous drugs that the person is seeking to possess, have custody or control of, and distribute, which list shall also specify the purpose for which those drugs will be used and their source;

(d) If the person is an emergency medical service organization, the information that is specified in divisions (C)(1) and (2) of this section, and if the person is an emergency medical service organization satellite, the information required under division (D) of this section;

(e) Except with respect to the units under the control of an emergency medical service organization, the identity of the one establishment or place at which the person intends to engage in the sale or other distribution of dangerous drugs at retail, and maintain possession, custody, or control of dangerous drugs for purposes other than the person's own use or consumption;

(f) If the application pertains to a pain management clinic, information that demonstrates, to the satisfaction of the board, compliance with division (A) of section 4729.552 of the Revised Code.

(C)(1) Each emergency medical service organization that applies for a terminal distributor of dangerous drugs license shall submit with its application all of the following:

(a) A copy of its standing orders or protocol, which orders or protocol shall be signed by a physician;

(b) A list of the dangerous drugs that the units under its control may carry, expressed in standard dose units, which shall

be signed by a physician;

(c) A list of the personnel employed or used by the organization to provide emergency medical services in accordance with Chapter 4765. of the Revised Code.

In accordance with Chapter 119. of the Revised Code, the board shall adopt rules specifying when an emergency medical service organization that is licensed as a terminal distributor must notify the board of any changes in its documentation submitted pursuant to division (C)(1) of this section.

(2) An emergency medical service organization seeking to be licensed as a terminal distributor of dangerous drugs shall list in its application for licensure the following additional information:

(a) The units under its control that the organization determines will possess dangerous drugs for the purpose of administering emergency medical services in accordance with Chapter 4765. of the Revised Code;

(b) With respect to each such unit, whether the dangerous drugs that the organization determines the unit will possess are in category II or III.

(3) An emergency medical service organization that is licensed as a terminal distributor of dangerous drugs shall file a new application for such licensure if there is any change in the number or location of any of its units or if there is any change in the category of the dangerous drugs that any unit will possess.

(4) A unit listed in an application for licensure pursuant to division (C)(2) of this section may obtain the dangerous drugs it is authorized to possess from its emergency medical

service organization or, on a replacement basis, from a hospital pharmacy. If units will obtain dangerous drugs from a hospital pharmacy, the organization shall file, and maintain in current form, the following items with the pharmacist who is responsible for the hospital's terminal distributor of dangerous drugs license:

(a) A copy of its standing orders or protocol;

(b) A list of the personnel employed or used by the organization to provide emergency medical services in accordance with Chapter 4765. of the Revised Code, who are authorized to possess the drugs, which list also shall indicate the personnel who are authorized to administer the drugs.

(D) Each emergency medical service organization satellite that applies for a terminal distributor of dangerous drugs license shall submit with its application all of the information that the board requires to be submitted with the application, as specified in rules the board shall adopt in accordance with Chapter 119. of the Revised Code.

(E) There shall be four categories of terminal distributor of dangerous drugs licenses. The categories are as follows:

(1) Category II license. A person who obtains this license may possess, have custody or control of, and distribute only the dangerous drugs described in category II.

(2) Limited category II license. A person who obtains this license may possess, have custody or control of, and distribute only the dangerous drugs described in category II that were listed in the application for licensure.

(3) Category III license, which may include a pain management clinic classification issued under section 4729.552

of the Revised Code. A person who obtains this license may possess, have custody or control of, and distribute the dangerous drugs described in category II and category III. If the license includes a pain management clinic classification, the person may operate a pain management clinic.

(4) Limited category III license. A person who obtains this license may possess, have custody or control of, and distribute only the dangerous drugs described in category II or category III that were listed in the application for licensure.

(F) Except for an application made by a county dog warden or on behalf of an animal shelter or wild animal rehabilitation facility, if an applicant for a limited category II license or limited category III license intends to administer dangerous drugs to a person or animal, the applicant shall submit, with the application, a copy of its protocol or standing orders. The protocol or orders shall be signed by a licensed health professional authorized to prescribe drugs, specify the dangerous drugs to be administered, and list personnel who are authorized to administer the dangerous drugs in accordance with federal law or the law of this state.

An application made by a county dog warden or on behalf of an animal shelter or wild animal rehabilitation facility shall include a list of the dangerous drugs to be administered to animals and the personnel who are authorized to administer the drugs to animals in accordance with section 4729.532 of the Revised Code.

In accordance with Chapter 119. of the Revised Code, the board shall adopt rules specifying when a licensee must notify the board of any changes in its documentation submitted pursuant to this division.

(G)(1) Except as provided in division (G)(3) of this section, each applicant for licensure as a terminal distributor of dangerous drugs shall submit, with the application, a license fee. The amount assessed shall not be returned to the applicant if the applicant fails to qualify for the license.

(2) The following fees apply under division (G)(1) of this section:

(a) Except as provided in division (G)(2)(b) of this section:

(i) Three hundred twenty dollars for a category II or limited category II license;

(ii) Four hundred forty dollars for a category III license, including a license with a pain management clinic classification issued under section 4729.552 of the Revised Code, or a limited category III license.

(b) One hundred twenty dollars for all of the following:

(i) A person who is required to hold a license as a terminal distributor of dangerous drugs pursuant to division (C) of section 4729.541 of the Revised Code;

(ii) A professional association, corporation, partnership, or limited liability company organized for the purpose of practicing veterinary medicine that is not included in division (G)(2)(b)(i) of this section;

(iii) An emergency medical service organization satellite.

(3) No fee applies for a license issued to a charitable pharmacy, as defined in section 3719.811 of the Revised Code, if the charitable pharmacy is participating in the drug repository program established under section 3715.87 of the Revised Code.

(H)(1) The board shall issue a terminal distributor of dangerous drugs license to each person who submits an application for such licensure in accordance with this section, pays the required license fee, is determined by the board to meet the requirements set forth in section 4729.55 of the Revised Code, and satisfies any other applicable requirements of this section.

(2) Except for the license of a county dog warden, the license shall describe the one establishment or place at which the licensee may engage in the sale or other distribution of dangerous drugs at retail and maintain possession, custody, or control of dangerous drugs for purposes other than the licensee's own use or consumption. The one establishment or place shall be that which is identified in the application for licensure.

No such license shall authorize or permit the terminal distributor of dangerous drugs named in it to engage in the sale or other distribution of dangerous drugs at retail or to maintain possession, custody, or control of dangerous drugs for any purpose other than the distributor's own use or consumption, at any establishment or place other than that described in the license, except that an agent or employee of an animal shelter or wild animal rehabilitation facility or county dog warden may possess and use dangerous drugs in the course of business as provided in section 4729.532 of the Revised Code.

(3) The license of an emergency medical service organization shall cover the organization's headquarters and, in addition, shall cover and describe all the units of the organization listed in its application for licensure.

(I)(1) All licenses issued or renewed pursuant to this

section shall be effective for a period specified by the board in rules adopted under section 4729.26 of the Revised Code. The effective period for an initial or renewed license shall not exceed twenty-four months unless the board extends the period in rules to adjust license renewal schedules. A license shall be renewed by the board according to the provisions of this section, the standard renewal procedure of Chapter 4745. of the Revised Code, and rules adopted by the board under section 4729.26 of the Revised Code. A person seeking to renew a license shall submit an application for renewal and pay the required fee on or before the date specified in the rules adopted by the board. The fee required for the renewal of a license shall be the same as the license fee that applies under division (G)(2) of this section.

(2)(a) Subject to division (I)(2)(b) of this section, a license that has not been renewed by the date specified in rules adopted by the board may be reinstated only upon payment of the required renewal fee and a penalty fee of one hundred ten dollars.

(b) If an application for renewal has not been submitted by the sixty-first day after the renewal date specified in rules adopted by the board, the license is considered void and cannot be renewed, but the license holder may reapply for licensure.

(3) A terminal distributor of dangerous drugs that fails to renew licensure in accordance with this section and rules adopted by the board is prohibited from engaging in the retail sale, possession, or distribution of dangerous drugs until a valid license is issued by the board.

(J)(1) No emergency medical service organization that is licensed as a terminal distributor of dangerous drugs shall fail

to comply with division (C)(1), (3), or (4) of this section.

(2) No licensed terminal distributor of dangerous drugs shall possess, have custody or control of, or distribute dangerous drugs that the terminal distributor is not entitled to possess, have custody or control of, or distribute by virtue of its category of licensure.

(3) No licensee that is required by division (F) of this section to notify the board of changes in its protocol or standing orders, or in personnel, shall fail to comply with that division.

(K) The board may enter into agreements with other states, federal agencies, and other entities to exchange information concerning licensing and inspection of terminal distributors of dangerous drugs located within or outside this state and to investigate alleged violations of the laws and rules governing distribution of drugs by terminal distributors. Any information received pursuant to such an agreement is subject to the same confidentiality requirements applicable to the agency or entity from which it was received and shall not be released without prior authorization from that agency or entity.

Sec. 4729.55. No license shall be issued to an applicant for licensure as a terminal distributor of dangerous drugs unless the applicant has furnished satisfactory proof to the state board of pharmacy that:

(A) The applicant is equipped as to land, buildings, and equipment to properly carry on the business of a terminal distributor of dangerous drugs within the category of licensure approved by the board.

(B) <u>One of the following will maintain supervision and</u>

control over the possession and custody of dangerous drugs and controlled substances that may be acquired by or on behalf of the applicant:

(1) A pharmacist, licensed health professional authorized to prescribe drugs, or other person authorized by the board~~,~~;

(2) An animal shelter, wild animal rehabilitation facility, or county dog warden licensed under section 4729.531 of the Revised Code~~, or~~ ;

(3) A laboratory ~~will maintain supervision and control over the possession and custody of dangerous drugs and controlled substances that may be acquired by or on behalf of the applicant~~.

(C) Adequate safeguards are assured to prevent the sale or other distribution of dangerous drugs by any person other than a pharmacist or licensed health professional authorized to prescribe drugs.

(D) Adequate safeguards are assured that the applicant will carry on the business of a terminal distributor of dangerous drugs in a manner that allows pharmacists and pharmacy interns employed by the terminal distributor to practice pharmacy in a safe and effective manner.

(E) If the applicant, or any agent or employee of the applicant, has been found guilty of violating section 4729.51 of the Revised Code, the "Federal Food, Drug, and Cosmetic Act," 52 Stat. 1040 (1938), 21 U.S.C.A. 301, the federal drug abuse control laws, Chapter 2925., 3715., 3719., or 4729. of the Revised Code, or any rule of the board, adequate safeguards are assured to prevent the recurrence of the violation.

(F) If the application is made on behalf of an animal

shelter, wild animal rehabilitation facility, or county dog warden, at least one of the agents or employees of the animal shelter or county dog warden is certified in compliance with section 4729.532 of the Revised Code.

(G) In the case of an applicant who is a retail seller of peritoneal dialysis solutions in original packages labeled as required by the "Federal Food, Drug, and Cosmetic Act," 52 Stat. 1040 (1938), 21 U.S.C.A. 301, the applicant will maintain supervision and control over the possession, custody, and retail sale of the peritoneal dialysis solutions.

(H) In the case of an applicant who is a pain management clinic, the applicant meets the requirements to receive a license with a pain management clinic classification issued under section 4729.552 of the Revised Code.

Section 2. That existing sections 4729.01, 4729.36, 4729.531, 4729.532, 4729.54, and 4729.55 of the Revised Code are hereby repealed.