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Representative Webster

Cosponsors: Representatives Setzer, Stebelton, Wagner, Williams, S., Schindel, McGregor, J., Fessler, Evans, Seitz, Latta, Yuko, Koziura, Coley, Combs, Collier, Fende, Peterson, Heard, Ujvagi, Hughes, Reinhard, Letson, Otterman, Williams, B., Uecker, Aslanides, Bacon, Batchelder, Brown, Budish, Chandler, Daniels, DeBose, Dodd, Domenick, Dyer, Flowers, Gibbs, Goodwin, Hagan, J., Huffman, Luckie, Patton, Schlichter, Schneider, Wachtmann, Wagoner, Yates, Zehringer
Senators Schuring, Seitz, Wagoner, Miller, D., Morano

A B I L L

To amend sections 2947.23, 3715.521, 3715.55, 3715.63, 4729.41, 4729.51, and 4729.54 and to enact sections 2947.231, 3715.88, 3715.89, 3715.90, 3715.91, 3715.92, and 4729.541 of the Revised Code to permit pharmacy schools to accept for instructional purposes donations of certain dangerous drugs, including expired drugs, to eliminate the requirement that certain professional business entities be licensed as a terminal distributor of dangerous drugs, and to permit the Board of Pharmacy to recover investigation costs in certain cases.

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

Section 1. That sections 2947.23, 3715.521, 3715.55, 3715.63, 4729.41, 4729.51, and 4729.54 be amended and sections 2947.231, 3715.88, 3715.89, 3715.90, 3715.91, 3715.92, and 4729.541 of the Revised Code be enacted to read as follows:

Sec. 2947.23. (A)(1) In all criminal cases, including violations of ordinances, the judge or magistrate shall include in the sentence the costs of prosecution, including any costs under section 2947.231 of the Revised Code, and render a judgment against the defendant for such costs. At the time the judge or magistrate imposes sentence, the judge or magistrate shall notify the defendant of both of the following:

(a) If the defendant fails to pay that judgment or fails to timely make payments towards that judgment under a payment schedule approved by the court, the court may order the defendant to perform community service in an amount of not more than forty hours per month until the judgment is paid or until the court is satisfied that the defendant is in compliance with the approved payment schedule.

(b) If the court orders the defendant to perform the community service, the defendant will receive credit upon the judgment at the specified hourly credit rate per hour of community service performed, and each hour of community service performed will reduce the judgment by that amount.

(2) The following shall apply in all criminal cases:

(a) If a jury has been sworn at the trial of a case, the fees of the jurors shall be included in the costs, which shall be paid to the public treasury from which the jurors were paid.

(b) If a jury has not been sworn at the trial of a case because of a defendant's failure to appear without good cause, the costs incurred in summoning jurors for that particular trial may be included in the costs of prosecution. If the costs incurred in summoning jurors are assessed against the defendant, those costs shall be paid to the public treasury from which the jurors were paid.

(B) If a judge or magistrate has reason to believe that a defendant has failed to pay the judgment described in division (A) of this section or has failed to timely make payments towards that judgment under a payment schedule approved by the judge or magistrate, the judge or magistrate shall hold a hearing to determine whether to order the offender to perform community service for that failure. The judge or magistrate shall notify both the defendant and the prosecuting attorney of the place, time, and date of the hearing and shall give each an opportunity to present evidence. If, after the hearing, the judge or magistrate determines that the defendant has failed to pay the judgment or to timely make payments under the payment schedule and that imposition of community service for the failure is appropriate, the judge or magistrate may order the offender to perform community service in an amount of not more than forty hours per month until the judgment is paid or until the judge or magistrate is satisfied that the offender is in compliance with the approved payment schedule. If the judge or magistrate orders the defendant to perform community service under this division, the defendant shall receive credit upon the judgment at the specified hourly credit rate per hour of community service performed, and each hour of community service performed shall reduce the judgment by that amount. Except for the credit and reduction provided in this division, ordering an offender to perform community service under this division does not lessen the amount of the judgment and does not preclude the state from taking

any other action to execute the judgment.

(C) As used in this section, "specified hourly credit rate" means the wage rate that is specified in 26 U.S.C.A. 206(a)(1) under the federal Fair Labor Standards Act of 1938, that then is in effect, and that an employer subject to that provision must pay per hour to each of the employer's employees who is subject to that provision.

Sec. 2947.231. If a business entity described in division (B)(1)(j) or (k) of section 4729.51 of the Revised Code pleads guilty or no contest to or is found guilty of any criminal offense, the judge or magistrate shall include in the sentence any costs incurred by the state board of pharmacy in an investigation leading to the plea or conviction. Investigative costs include staff salaries, administrative costs, travel expenses, attorney's fees, and any other reasonable expense incurred by the board. The board shall set forth the costs the entity is required to pay in an itemized statement provided to the judge or magistrate.

Sec. 3715.521. No person shall sell, offer for sale, or deliver at retail or to the consumer, any of the following:

(A) Any drug after the expiration date required by 21 C.F.R. 211.137 except pursuant to sections 3715.88 to 3715.92 of the Revised Code;

(B) Any infant formula after the "use by" date required by 21 C.F.R. 107.20;

(C) Any baby food after any expiration date, "use by" date, or sale date required by state or federal law or marked on the container by the manufacturer, processor, or packager.

Sec. 3715.55. (A) As used in this section, "expired" means:

(1) In the case of a drug, that the expiration date required

by 21 C.F.R. 211.137 has passed;

(2) In the case of infant formula, the "use by" date required by 21 C.F.R. 107.20 has passed;

(3) In the case of baby food, that any expiration date, "use by" date, or sale date established by state or federal law or marked on the container by the manufacturer, processor, or packager has passed.

(B) ~~Whenever~~ Except as otherwise provided in this division, whenever the director of agriculture or the state board of pharmacy finds or has cause to believe, that any food, drug, device, or cosmetic is adulterated, or so misbranded as to be dangerous or fraudulent, within the meaning of sections 3715.01 and 3715.52 to 3715.72 of the Revised Code, or that a drug, infant formula, or baby food is expired, the director or board shall affix to the article a tag or other appropriate marking, giving notice that the article is, or is suspected of being, adulterated, misbranded, or expired and has been detained or embargoed, and warning all persons not to remove or dispose of the article by sale or otherwise until permission for removal or disposal is given by the director or the board or the court. No person may remove or dispose of a detained or embargoed article by sale or otherwise without such permission. This division does not apply to expired drugs donated pursuant to sections 3715.88 to 3715.92 of the Revised Code.

(C) When an article detained or embargoed has been found by the director or board to be adulterated, misbranded, or expired, the director or board shall petition the municipal or county court in whose jurisdiction the article is detained or embargoed for an order for condemnation of the article. When the director or the board has not found within ten days that an article so detained or embargoed is adulterated, misbranded, or expired, the director or board shall remove the tag or other marking.

(D) If the court finds that a detained or embargoed article is adulterated, misbranded, or expired, the article shall, after entry of the decree, be destroyed at the expense of the claimant thereof, under the supervision of the director or the board, and all court costs, fees, storage, and other proper expenses shall be taxed against the claimant of the article or the claimant's agent; provided, that when the adulteration or misbranding can be corrected by proper labeling or processing of the article, the court, after entry of the decree and after such costs, fees, and expenses have been paid and a good and sufficient bond, conditioned that the article shall be so labeled or processed, has been executed, may by order direct that the article be delivered to the claimant thereof for labeling or processing under the supervision of the director or the board. The expense of supervision shall be paid by the claimant. The bond shall be returned to the claimant of the article on representation to the court by the director or the board that the article is no longer in violation of sections 3715.01 and 3715.52 to 3715.72 of the Revised Code, and that the expenses of supervision have been paid.

(E) Whenever the director finds in any room, building, vehicle of transportation, or other structure, any meat, ~~sea food~~ seafood, poultry, vegetable, fruit, or other perishable articles that are unsound, or contain any filthy, decomposed, or putrid substance, or that may be poisonous or deleterious to health or otherwise unsafe, the articles are declared to be a nuisance, and the director shall forthwith condemn or destroy the articles, or in any other manner render the articles unsalable as human food.

Sec. 3715.63. (A) A drug or device is adulterated within the meaning of sections 3715.01 and 3715.52 to 3715.72 of the Revised Code, if any of the following apply:

~~(A)~~(1) It consists, in whole or in part, of any filthy,

putrid, or decomposed substance.

~~(B)~~(2) It has been produced, processed, prepared, packed, or held under unsanitary conditions whereby it may have been contaminated with filth, or whereby it may have been rendered injurious to health.

~~(C)~~(3) It is a drug and its container is composed, in whole or in part, of any poisonous or deleterious substance that may render the contents injurious to health.

~~(D)~~(4) It is a drug and it bears or contains, for purposes of coloring only, a coal-tar color other than one from a batch certified under authority of the "Federal Food, Drug, and Cosmetic Act," 52 Stat. 1040 (1938), 21 U.S.C.A. 301, as amended.

~~(E)~~(5) It purports to be or is represented as a drug the name of which is recognized in the United States pharmacopoeia and national formulary, or any supplement to them, and its strength differs from or its quality or purity falls below the standard set forth in those compendiums. A determination as to strength, quality, or purity shall be made in accordance with the tests or methods of assay set forth in the compendiums, or in the absence or inadequacy of such tests or methods of assay, those prescribed under the authority of the "Federal Food, Drug, and Cosmetic Act." A drug recognized in the compendiums is not adulterated under this division because it differs from the standard of strength, quality, or purity set forth for that drug in the compendiums, if the difference in strength, quality, or purity is plainly stated on its label. Whenever a drug is recognized in both the homoeopathic pharmacopoeia of the United States and in the United States pharmacopoeia and national formulary, including their supplements, it shall be subject to the requirements of the United States pharmacopoeia and national formulary unless it is labeled and offered for sale as a homoeopathic drug, in which case it shall be subject to the provisions of the homoeopathic

pharmacopoeia of the United States and not to those of the United States pharmacopoeia and national formulary.

~~(F)~~(6) It is not subject to the provisions of division ~~(E)~~(A)(5) of this section, and its strength differs from or its purity or quality falls below that which it purports or is represented to possess.

~~(G)~~(7) It is a drug and any substance has been:

~~(1)~~(a) Mixed or packed with the drug so as to reduce the drug's quality or strength;

~~(2)~~(b) Substituted wholly or in part for the drug.

(B) An expired drug is not adulterated within the meaning of sections 3715.01 and 3715.52 to 3715.72 of the Revised Code if the drug is donated pursuant to sections 3715.88 to 3715.92 of the Revised Code.

Sec. 3715.88. As used in this section and in sections 3715.89 to 3715.92 of the Revised Code:

(A) "Expired" has the same meaning as in section 3715.55 of the Revised Code.

(B) "National drug code number" means the number registered for a drug pursuant to the listing system established by the United States food and drug administration under the "Drug Listing Act of 1972," 86 Stat. 559, 21 U.S.C. 360, as amended.

(C) "Pharmacy school" means a school, college, university, or other educational institution that operates a pharmacy program recognized and approved by the state board of pharmacy.

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

(E) "Manufacturer of dangerous drugs," "terminal distributor of dangerous drugs," and "wholesale distributor of dangerous

drugs" have the same meanings as in section 4729.01 of the Revised Code.

Sec. 3715.89. (A) Subject to divisions (B) and (C) of this section, any manufacturer of dangerous drugs, terminal distributor of dangerous drugs, or wholesale distributor of dangerous drugs may donate a dangerous drug, including a dangerous drug that has expired, to a pharmacy school.

(B) A dangerous drug donation to a pharmacy school shall meet all of the following requirements:

(1) The dangerous drug is not a controlled substance.

(2) Each container in which a dangerous drug is donated contains a single national drug code number of that drug and no other drugs.

(3) If the dangerous drug is of a type that deteriorates with time, the container in which the drug is contained is plainly marked with the drug's expiration date.

(C) A dangerous drug donation to a pharmacy school shall be accompanied by a form signed by a representative of the manufacturer, terminal distributor, or wholesale distributor donating the drug. On delivery, a representative of the pharmacy school accepting the drug donation shall also sign the form. The form shall do both of the following:

(1) Confirm the acceptance of the dangerous drug donation by the pharmacy school;

(2) Confirm that both the manufacturer, terminal distributor, or wholesale distributor donating the dangerous drug and the pharmacy school accepting the donation understand the immunity provisions of section 3719.92 of the Revised Code.

Sec. 3715.90. (A) A pharmacy school may accept a donation of

a dangerous drug if the donation is made in accordance with section 3715.89 of the Revised Code.

(B) All of the following apply to a dangerous drug donated to a pharmacy school:

(1) The dangerous drug shall be used solely for instructional purposes.

(2) The dangerous drug shall not be sold or transferred for consideration of any kind.

(3) In accordance with 21 C.F.R. 201.125, the dangerous drug shall not be used for a clinical use. "Clinical use" includes the drug being furnished to a human or animal with the intent or understanding that the human or animal will ingest or otherwise absorb the drug into the human's or animal's body.

Sec. 3715.91. The state board of pharmacy shall, in accordance with Chapter 119. of the Revised Code, adopt rules as necessary to give effect to sections 3715.89 and 3715.90 of the Revised Code.

Sec. 3715.92. The state board of pharmacy, any manufacturer of dangerous drugs, terminal distributor of dangerous drugs, or wholesale distributor of dangerous drugs that in good faith donates a dangerous drug under section 3715.89 of the Revised Code, and any pharmacy school that accepts a dangerous drug donation under section 3715.90 of the Revised Code, shall not, in the absence of bad faith, be subject to any of the following for matters related to the donation or acceptance of the drug: criminal prosecution; liability in tort or other civil action for injury, death, or loss to person or property; or professional liability.

Sec. 4729.41. (A)(1) A pharmacist licensed under this chapter

who meets the requirements of division (B) of this section may do ~~either or both~~ any of the following:

(a) Administer immunizations for influenza to individuals fourteen years of age or older;

(b) Administer immunizations to individuals eighteen years of age or older for any of the following:

(i) Pneumonia;

(ii) Tetanus;

(iii) Hepatitis A;

(iv) Hepatitis B;

(v) Meningitis;

(vi) Diphtheria;

(vii) Pertussis.

(c) Administer to individuals eighteen years of age or older any other immunization listed in the rule adopted under division (E)(1)(d) of this section.

(2) A pharmacy intern licensed under this chapter who meets the requirements of division (B) of this section and is working under the direct supervision of a pharmacist who meets the requirements of that division may administer immunizations for influenza to individuals eighteen years of age or older.

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

(B) For a pharmacist or pharmacy intern to be authorized to engage in the administration of immunizations as specified in

division (A) of this section, the pharmacist or pharmacy intern shall do all of the following:

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

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

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

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

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

(2) For each immunization administered to an individual by a pharmacist, other than an immunization for influenza administered

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

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

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

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

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

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

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

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

(b) ~~Approval~~ Provisions for approval of protocols to be followed by pharmacists and pharmacy interns in engaging in the administration of immunizations, including protocols that contain

provisions specifying the locations at which a pharmacist or pharmacy intern may engage in the administration of immunizations;

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

(d) A list of immunizations that may be administered under division (A)(1)(c) of this section.

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

(3) Prior to adopting a rule listing immunizations that may be administered under division (A)(1)(c) of this section, the state board of pharmacy shall consult with the state medical board.

Sec. 4729.51. (A) 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:

(1) 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;

(2) 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.

(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) 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) A licensed terminal distributor of dangerous drugs, subject to division (B)(2) of this section;

(f) Carriers or warehousers 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 47 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 pharmacy board 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) 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) 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.

(2) 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 to:

(a) A terminal distributor who has 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) A terminal distributor who has 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) A terminal distributor who has 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) A terminal distributor who has 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 pharmacy board 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.

(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 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.

Sec. 4729.54. (A) As used in this section and section 4729.541 of the Revised Code:

(1) "Category I" means single-dose injections of intravenous fluids, including saline, Ringer's lactate, five per cent dextrose and distilled water, and other intravenous fluids or parenteral solutions included in this category by rule of the board of pharmacy, that have a volume of one hundred milliliters or more and that contain no added substances, or single-dose injections of epinephrine to be administered pursuant to sections 4765.38 and 4765.39 of the Revised Code.

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

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

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

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

(6) "Schedule I, schedule II, schedule III, schedule IV, and schedule V" mean controlled substance schedules I, II, III, IV, and V, respectively, as established pursuant to section 3719.41 of the Revised Code and as amended.

(B) A person who desires to be licensed as a terminal distributor of dangerous drugs shall file with the executive

director of the board of pharmacy a verified application that contains the following:

(1) 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;

(2) A statement that the person wishes to be licensed as a category I, category II, category III, limited category I, limited category II, or limited category III terminal distributor of dangerous drugs;

(3) If the person wishes to be licensed as a limited category I, limited category II, or limited category III terminal distributor of dangerous drugs, a notarized list of the dangerous drugs that the person wishes 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;

(4) If the person is an emergency medical service organization, the information that is specified in division (C)(1) of this section;

(5) Except for 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.

(C)(1) An emergency medical service organization that wishes 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 I, II, or III.

(2) 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 any change in the category of the dangerous drugs that any unit will possess.

(3) A unit listed in an application for licensure pursuant to division (C)(1) 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 that applies for a terminal distributor of dangerous drugs license shall submit with its application the following:

(1) A notarized copy of its standing orders or protocol, which orders or protocol shall be signed by a physician and specify the dangerous drugs that its units may carry, expressed in standard dose units;

(2) 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.

An emergency medical service organization that is licensed as a terminal distributor shall notify the board immediately of any changes in its standing orders or protocol.

(E) There shall be six categories of terminal distributor of dangerous drugs licenses, which categories shall be as follows:

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

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

(3) 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 I and category II.

(4) 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 I or category II that were listed in the application for licensure.

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

(6) 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 I, category II, or category III that were listed in the application for licensure.

(F) Except for an application made on behalf of an animal shelter, if an applicant for licensure as a limited category I, II, or III terminal distributor of dangerous drugs intends to administer dangerous drugs to a person or animal, the applicant shall submit, with the application, a notarized copy of its protocol or standing orders, which 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 on behalf of an animal shelter shall include a notarized 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. After obtaining a terminal distributor license, a licensee shall notify the board immediately of any changes in its protocol or standing orders, or in such personnel.

(G)(1) Except as provided in division (G)(2) of this section, each applicant for licensure as a terminal distributor of dangerous drugs shall submit, with the application, a license fee determined as follows:

(a) For a category I or limited category I license, forty-five dollars;

(b) For a category II or limited category II license, one hundred twelve dollars and fifty cents;

(c) For a category III or limited category III license, one hundred fifty dollars.

(2) For a professional association, corporation, partnership, or limited liability company organized for the purpose of practicing veterinary medicine, the fee shall be forty dollars.

Fees assessed under divisions (G)(1) and (2) of this section

shall not be returned if the applicant fails to qualify for registration.

(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) The license of a person other than an emergency medical service organization 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 described 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 may possess and use dangerous drugs in the course of business as provided in division (D) of section 4729.532 of the Revised Code.

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

(4) The license of every terminal distributor of dangerous drugs shall indicate, on its face, the category of licensure. If the license is a limited category I, II, or III license, it shall specify, and shall authorize the licensee to possess, have custody

or control of, and distribute only, the dangerous drugs that were listed in the application for licensure.

(I) All licenses issued pursuant to this section shall be effective for a period of twelve months from the first day of January of each year. A license shall be renewed by the board for a like period, annually, according to the provisions of this section, and the standard renewal procedure of Chapter 4745. of the Revised Code. A person who desires to renew a license shall submit an application for renewal and pay the required fee on or before the thirty-first day of December each year. The fee required for the renewal of a license shall be the same as the fee paid for the license being renewed, and shall accompany the application for renewal.

A license that has not been renewed during December in any year and by the first day of February of the following year may be reinstated only upon payment of the required renewal fee and a penalty fee of fifty-five dollars.

(J)(1) No emergency medical service organization that is licensed as a terminal distributor of dangerous drugs shall fail to comply with division (C)(2) or (3) of this section.

(2) No emergency medical service organization that is licensed as a terminal distributor of dangerous drugs shall fail to comply with division (D) of this section.

(3) 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.

(4) 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.

Sec. 4729.541. A person described in division (B)(1)(j) or (k) of section 4729.51 of the Revised Code may possess, have custody or control of, and distribute the dangerous drugs in category I, category II, and category III of section 4729.54 of the Revised Code without holding a terminal distributor of dangerous drugs license issued under that section.

Section 2. That existing sections 2947.23, 3715.521, 3715.55, 3715.63, 4729.41, 4729.51, and 4729.54 of the Revised Code are hereby repealed.