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Representatives Huffman, Pelanda

Cosponsors: Representatives Becker, Johnson, T., Sprague, Ginter, Barnes, Brown, Butler, Schuring, Amstutz, Anielski, Antonio, Baker, Burkley, Dovilla, Gonzales, Green, Grossman, McClain, O'Brien, S., Rogers, Sears, Smith, R., Sweeney

A BILL

To amend sections 3715.01, 3715.64, 4729.01, 4729.38, and 4729.99 and to enact section 3715.011 of the Revised Code regarding the regulation of biological products and the substitution of interchangeable biological products when dispensed by pharmacists.

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

Section 1. That sections 3715.01, 3715.64, 4729.01, 4729.38, and 4729.99 of the Revised Code be amended and section 3715.011 of the Revised Code be enacted to read as follows:

Sec. 3715.01. (A) As used in this chapter:

(1) "Person" means an individual, partnership, corporation, or association.

(2) "Food" means:

(a) Articles used for food or drink for humans or animals;

(b) Chewing gum;

(c) Articles used for components of any such articles.

(3) "Drug" means:

(a) Articles recognized in the United States pharmacopoeia and national formulary, or any supplement to them;

(b) Articles intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in humans or animals;

(c) Articles, other than food, intended to affect the structure or any function of the body of humans or other animals;

(d) Articles intended for use as a component of any of the foregoing articles, other than devices or their components, parts, or accessories.

(4) "Device," except when used in division (B)(1) of this section and in division (A)(10) of section 3715.52, division (F) of section 3715.60, division (A)(5) of section 3715.64, and division (C) of section 3715.67 of the Revised Code, means any instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar or related article, including any component, part, or accessory, that is any of the following:

(a) Recognized in the United States pharmacopoeia and national formulary, or any supplement to them;

(b) Intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease in humans or animals;

(c) Intended to affect the structure or any function of

the body of humans or animals, and that does not achieve any of its principal intended purposes through chemical action within or on the body of humans or animals and is not dependent upon being metabolized for the achievement of any of its principal intended purposes.

(5) "Cosmetic" means:

(a) Articles intended to be rubbed, poured, sprinkled, or sprayed on, introduced into, or otherwise applied to the human body or any part thereof for cleansing, beautifying, promoting attractiveness, or altering the appearance;

(b) Articles intended for use as a component of any such article, except that "cosmetic" does not include soap.

(6) "Label" means a display of written, printed, or graphic matter upon the immediate container, exclusive of package liners, of any article.

Any word, statement, or other information required by this chapter to appear on the label must appear on the outside container or wrapper, if any, of the retail package of the article, or the label must be easily legible through the outside container or wrapper.

(7) "Labeling" means all labels and other written, printed, or graphic matter:

(a) Upon an article or any of its containers or wrappers;

(b) Accompanying such article.

(8) "Advertisement" means all representations disseminated in any manner or by any means, other than by labeling, for the purpose of inducing, or that are likely to induce, directly or indirectly, the purchase of food, drugs, devices, or cosmetics.

(9) "New drug" means:

(a) Any drug the composition of which is such that the drug is not generally recognized among experts qualified by scientific training and experience to evaluate the safety of drugs, as safe for use under the conditions prescribed, recommended, or suggested in the labeling thereof;

(b) Any drug the composition of which is such that the drug, as a result of investigation to determine its safety for use under such conditions, has become so recognized, but that has not, other than in an investigation, been used to a material extent or for a material time under such conditions.

(10) "Contaminated with filth" applies to any food, drug, device, or cosmetic that has not been protected as far as may be necessary by all reasonable means from dust, dirt, and all foreign or injurious substances.

(11) "Honey" means the nectar and saccharine exudation of plants that has been gathered, modified, and stored in a honeycomb by honeybees.

(12) "Finished dosage form" means the form of a drug that is, or is intended to be, dispensed or administered to humans or animals and requires no further manufacturing or processing other than packaging, reconstituting, or labeling.

(13)(a) "Manufacture" means the planting, cultivating, harvesting, processing, making, preparing, or otherwise engaging in any part of the production of a drug by propagating, compounding, converting, or processing, either directly or indirectly by extracting from substances of natural origin, or independently by means of chemical synthesis, or by a combination of extraction and chemical synthesis, and includes

the following:

(i) Any packaging or repackaging of the drug or labeling or relabeling of its container, the promotion and marketing of the drug, and other activities incident to production;

(ii) The preparation and promotion of commercially available products from bulk compounds for resale by pharmacies, licensed health professionals authorized to prescribe drugs, or other persons.

(b) "Manufacture" does not include the preparation, compounding, packaging, or labeling of a drug by a pharmacist as an incident to either of the following:

(i) Dispensing a drug in the usual course of professional practice;

(ii) Providing a licensed health professional authorized to prescribe drugs with a drug for the purpose of administering to patients or for using the drug in treating patients in the professional's office.

(14) "Dangerous drug" has the same meaning as in section 4729.01 of the Revised Code.

(15) "Generically equivalent drug" means a drug that contains identical amounts of the identical active ingredients, but not necessarily containing the same inactive ingredients, that meets the identical compendial or other applicable standard of identity, strength, quality, and purity, including potency, and where applicable, content uniformity, disintegration times, or dissolution rates, as the prescribed brand name drug and the manufacturer or distributor holds, if applicable, either an approved new drug application or an approved abbreviated new drug application unless other approval by law or from the

federal food and drug administration is required.

No drug shall be considered a generically equivalent drug for the purposes of this chapter if it has been listed by the federal food and drug administration as having proven bioequivalence problems.

(16) "Licensed health professional authorized to prescribe drugs" and "prescriber" have the same meanings as in section 4729.01 of the Revised Code.

(17) "Home" means the primary residence occupied by the residence's owner, on the condition that the residence contains only one stove or oven used for cooking, which may be a double oven, designed for common residence usage and not for commercial usage, and that the stove or oven be operated in an ordinary kitchen within the residence.

(18) "Potentially hazardous food" means a food that is natural or synthetic, to which any of the following apply:

(a) It has a pH level greater than 4.6 when measured at seventy-five degrees fahrenheit or twenty-four degrees celsius.

(b) It has a water activity value greater than 0.85.

(c) It requires temperature control because it is in a form capable of supporting the rapid and progressive growth of infectious or toxigenic microorganisms, the growth and toxin production of clostridium botulinium, or in the case of raw shell eggs, the growth of salmonella enteritidis.

(19) "Cottage food production operation" means a person who, in the person's home, produces food items that are not potentially hazardous foods, including bakery products, jams, jellies, candy, fruit butter, and similar products specified in

rules adopted pursuant to section 3715.025 of the Revised Code.

(20) "Biological product" means, except as provided in section 3715.011 of the Revised Code, a drug that is a biological product, as defined on the effective date of this amendment in subsection (i) of section 351 of the "Public Health Service Act," 42 U.S.C. 262(i).

(21) "Interchangeable biological product" means, except as provided in section 3715.011 of the Revised Code, both of the following:

(a) A biological product that, on the effective date of this amendment, has been determined by the United States food and drug administration to meet the standards for interchangeability set forth in subsection (k) of section 351 of the "Public Health Service Act," 42 U.S.C. 262(k), as amended, and has been licensed under that subsection;

(b) A biological product that, prior to the effective date of this amendment, was determined by the United States food and drug administration to be therapeutically equivalent as set forth in its publication titled "Approved Drug Products with Therapeutic Equivalence Evaluations."

(B) For the purposes of sections 3715.52 to 3715.72 of the Revised Code:

(1) If an article is alleged to be misbranded because the labeling is misleading, or if an advertisement is alleged to be false because it is misleading, then in determining whether the labeling or advertisement is misleading, there shall be taken into account, among other things, not only representations made or suggested by statement, word, design, device, sound, or in any combination thereof, but also the extent to which the

labeling or advertisement fails to reveal facts material in the light of such representations or material with respect to consequence which may result from the use of the article to which the labeling or advertisement relates under the conditions of use prescribed in the labeling or advertisement thereof or under such conditions of use as are customary or usual.

(2) The provisions regarding the selling of food, drugs, devices, or cosmetics include the manufacture, production, processing, packing, exposure, offer, possession, and holding of any such article for sale; and the sale, dispensing, and giving of any such article, and the supplying or applying of any such articles in the conduct of any food, drug, or cosmetic establishment. The provisions do not prohibit a licensed health professional authorized to prescribe drugs from administering or personally furnishing a drug or device to a patient.

(3) The representation of a drug, in its labeling or advertisement, as an antiseptic is a representation that it is a germicide, except in the case of a drug purporting to be, or represented as, an antiseptic for inhibitory use as a wet dressing, ointment, dusting powder, or other use that involves prolonged contact with the body.

(4) Whenever jurisdiction is vested in the director of agriculture or the state board of pharmacy, the jurisdiction of the board shall be limited to the sale, offering for sale, giving away, delivery, or dispensing in any manner of drugs at the wholesale and retail levels or to the consumer and shall be exclusive in the case of such sale, offering for sale, giving away, delivery, or dispensing in any manner of drugs at the wholesale and retail levels or to the consumer in any place where prescriptions are dispensed or compounded.

(5) To assist in effectuating the provisions of those sections, the director of agriculture or state board of pharmacy may request assistance or data from any government or private agency or individual.

Sec. 3715.011. (A) When one of the following changes occurs under federal law with respect to a biological product or interchangeable biological product, the change is automatically effected under this chapter and Chapter 4729. of the Revised Code, subject to any rule adopted under division (B) of this section to the contrary:

(1) An article is added to or removed from the definition of biological product in subsection (i) of section 351 of the "Public Health Service Act," 42 U.S.C. 262(i).

(2) The United States food and drug administration determines that a biological product meets the standards for interchangeability set forth in section 351 of the "Public Health Service Act," 42 U.S.C. 262(k), and the product is licensed under that subsection.

(3) The United States food and drug administration determines that a biological product no longer meets the standards for interchangeability set forth in section 351 of the "Public Health Service Act," 42 U.S.C. 262(k), and the product's license under that subsection is suspended or revoked.

(B) The state board of pharmacy may adopt rules that exclude a biological product or interchangeable biological product that, pursuant to division (A) of this section, would otherwise be included under this chapter and Chapter 4729. of the Revised Code. The board's rules shall establish criteria to be used in determining whether a product is to be excluded.

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

Sec. 3715.64. (A) A drug or device is misbranded within the meaning of sections 3715.01 and 3715.52 to 3715.72 of the Revised Code, if:

(1) Its labeling is false or misleading in any particular.

(2) It is in package form and does not bear a label containing both of the following:

(a) In clearly legible form, the name and place of business of the manufacturer, packer, or distributor;

(b) An accurate statement of the quantity of the contents in terms of weight, measure, or numerical count; but reasonable variations shall be permitted, and exemptions as to small packages shall apply as established by rules adopted by the director of agriculture or state board of pharmacy.

(3) It is a dangerous drug and does not bear a label containing in clearly legible form the name and place of business of the manufacturer of the finished dosage form and, if different, the packer or distributor.

(4) It is a dangerous drug in finished solid oral dosage form and it does not have clearly and prominently marked or imprinted on it an individual symbol, company name, national drug code number or other number, words, letters, or any combination thereof, identifying the drug and its manufacturer or distributor. This requirement does not apply to drugs that are compounded by a licensed pharmacist. The manufacturer or distributor of each such drug shall make available to the state board of pharmacy descriptive material identifying the mark or imprint used by the manufacturer or distributor. The board shall

provide this information to all poison control centers in this state. Upon application by a manufacturer or distributor, the board may exempt a drug from the requirements of this division on the grounds that marking or imprinting the drug is not feasible because of its size, texture, or other unique characteristic.

(5) Any word, statement, or other information that is required by or under authority of sections 3715.01 and 3715.52 to 3715.72 of the Revised Code to appear on the label or labeling is not prominently placed on the label or labeling in a conspicuous manner, as compared with other words, statements, designs, or devices on the label or labeling, and in terms that render it likely to be read and understood by the ordinary individual under customary conditions of purchase and use.

(6) It is a drug and it is not designated solely by a name recognized in the United States pharmacopoeia and national formulary, or any supplement to them, unless its label bears:

(a) The common or usual name of the drug, if any;

(b) In case it is fabricated from two or more ingredients, the common or usual name of each active ingredient the drug contains, including the kind and quantity or proportion of any alcohol, and also including whether active or not, the name and quantity or proportion of any bromides, ether, chloroform, acetanalid, acetophenetidin, aminopyrine, atropine, hyoscine, hyoscyamine, arsenic, digitalis, digitalis glycosides, mercury, ouabain, strophanthin, strychnine, thyroid, or any derivative or preparation of any such substances; but to the extent that compliance with these requirements is impracticable, exemptions shall apply as established by rules adopted by the director of agriculture or state board of pharmacy.

(7) Its labeling does not bear the following:

(a) Adequate directions for use of the drug or device, except that when compliance with this requirement is not necessary for a particular drug or device to protect the public health, the director shall adopt rules exempting the drug or device from the requirement;

(b) Adequate warnings against use in those pathological conditions or by children when its use may be dangerous to health, or against unsafe dosage or methods or duration of administration or application, presented in a manner and form as necessary for the protection of users.

(8) It purports to be a drug the name of which is recognized in the United States pharmacopoeia and national formulary, or any supplement to them, and it is not packaged and labeled as prescribed in those compendiums, except that the method of packing may be modified with the consent of the director of agriculture. 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 with respect to packaging and labeling 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.

(9) It has been found by the director of agriculture to be a drug liable to deterioration, unless it is packaged in the form and manner, and its label bears a statement of precautions, as required by rules adopted by the director as necessary for

the protection of public health. No rule shall be established for any drug recognized in the United States pharmacopoeia and national formulary, or any supplements to them, until the director has informed the appropriate bodies charged with the revision of those compendiums of the need for packaging or labeling requirements and those bodies have failed within a reasonable time to prescribe such requirements.

(10)(a) It is a drug and its container is so made, formed, or filled as to be misleading.

(b) It is an imitation of another drug.

(c) It is offered for sale under the name of another drug.

(d) The drug sold or dispensed is not the brand or drug specifically prescribed or ordered or, when dispensed by a pharmacist upon prescription, the drug is neither the brand or drug prescribed nor a generically equivalent drug or, in the case of a drug that is a biological product, is neither the brand or biological product prescribed nor an interchangeable biological product.

(11) It is dangerous to health when used in the dosage, or with the frequency or duration prescribed, recommended, or suggested in its labeling.

(12) It is a drug intended for human use to which the following apply:

(a) Because of its toxicity or other potentiality for harmful effect, the method of its use, or the collateral measures necessary to its use, the drug is not safe for use except under the supervision of a licensed health professional authorized to prescribe drugs;

(b) The drug is limited by an effective application under section 505 of the "Federal Food, Drug, and Cosmetic Act," 52 Stat. 1040 (1938), 21 U.S.C.A. 301, as amended, to use under professional supervision by a licensed health professional authorized to prescribe drugs, unless it is dispensed only:

(i) Upon a written or electronic prescription;

(ii) Upon an oral prescription, which is reduced promptly to writing by the pharmacist;

(iii) By refilling a prescription if refilling is authorized by the prescriber either in the original prescription or by oral order, which is promptly reduced to writing by the pharmacist.

(B)(1) Any drug dispensed pursuant to a written, electronic, or oral prescription of a licensed health professional authorized to prescribe drugs shall be exempt from the requirements of division (A) of this section, except divisions (A)(1) and (10) of this section, if the drug bears a label containing the name and address of the dispenser, the serial number and the date the prescription is dispensed, the name of the prescriber, the name of the patient, and, if stated in the prescription, the directions for use and cautionary statements. ~~Unless~~

(2) Unless the ~~prescription directions prohibit labeling~~prescriber instructs otherwise, the label for the dispensed drug shall include information that meets the following requirements, using abbreviations as necessary:

(a) Except as provided in divisions (B)(2)(b) and (c) of this section, the label shall include the dispensed drug's brand name~~ of the drug dispensed~~. ~~If~~

(b) If the drug dispensed has no brand name and is a generically equivalent drug, the label shall include the generic name of the drug and the distributor of the finished dosage form ~~shall be included~~.

(c) If the drug dispensed has no brand name and is an interchangeable biological product, the label shall include the name of the interchangeable biological product, the manufacturer, and if the distributor is not the same as the manufacturer, the distributor of the finished dosage form.

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 one or more physicians authorized under Chapter 4731. of the Revised Code to practice medicine and surgery or osteopathic medicine and surgery, 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.

(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.

(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 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 sections 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.

(3) 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.

(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 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;

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

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

Sec. 4729.38. (A) As used in this section, "biological product," "finished dosage form," "generically equivalent drug," and "interchangeable biological product" have the same meanings as in section 3715.01 of the Revised Code.

(B) Unless instructed otherwise by the person receiving the drug pursuant to the prescription, a pharmacist filling a prescription for a drug prescribed by its brand name may, subject to the following conditions, select a generically equivalent drug, ~~as defined in section 3715.01 of the Revised Code, subject to the following conditions~~ or, in the case of a drug that is a biological product, select an interchangeable biological product:

(1) The pharmacist shall not select a generically equivalent drug or interchangeable biological product if ~~the prescriber~~ either of the following applies:

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

(b) In the case of an oral prescription, the prescriber specifies that the ~~prescribed~~ drug as prescribed is medically necessary or otherwise indicates the prescriber's intent to

prevent substitution. ~~These designations shall not be preprinted or stamped on the prescription. Division (A)(1) of this section does not preclude a reminder of the procedure required to prohibit the selection of a generically equivalent drug from being preprinted on the prescription.~~

(2) The pharmacist shall not select a generically equivalent drug or interchangeable biological product unless its price to the patient is less than or equal to the price of the ~~prescribed~~ drug as prescribed.

(3) The pharmacist~~,~~ or the pharmacist's agent, assistant, or employee shall inform the patient or the patient's agent if a generically equivalent drug or interchangeable biological product is available at a lower or equal cost~~,~~ and of the person's right to refuse the drug selected. Division ~~(A)~~ (B)(3) of this section does not apply to any:

(a) Prescription that is billed to any agency, division, or department of this state which will reimburse the pharmacy;

(b) Prescriptions for patients of a hospital, nursing home, or similar patient care facility.

~~(B)~~ (C)(1) Unless the prescriber instructs otherwise, the label for every drug dispensed shall include information that meets the following requirements, using abbreviations as necessary:

(a) Except as provided in divisions (C)(1)(b) and (c) of this section, the label shall include the dispensed drug's brand name~~, if any, or its generic name and the name of the~~ .

(b) If the drug dispensed has no brand name and is a generically equivalent drug, the label shall include the generic name of the drug and the distributor~~, using abbreviations if~~

~~necessary~~ of the finished dosage form.

(c) If the drug dispensed has no brand name and is an interchangeable biological product, the label shall include the name of the interchangeable biological product, the manufacturer, and if the distributor is not the same as the manufacturer, the distributor of the finished dosage form.

(2) When dispensing at retail a drug that is a generically equivalent drug or interchangeable biological product for ~~the brand name~~ a drug prescribed by its brand name, the pharmacist shall indicate on the drug's label or container that a ~~generic~~ substitution was made. ~~The~~

(3) The labeling requirements established by ~~this division~~ divisions (C)(1) and (2) of this section are in addition to all other labeling requirements of Chapter 3715. of the Revised Code.

~~(C)~~ (D) A pharmacist who selects a drug that is a generically equivalent drug or interchangeable biological product pursuant to this section assumes no greater liability for selecting the dispensed drug than would be incurred in filling a prescription for a drug prescribed by its brand name.

~~(D)~~ (E) The failure of a prescriber to restrict a prescription by ~~specifying "dispense as written," or "D.A.W.,"~~ indicating an intent to prevent substitution pursuant to division ~~(A)~~(B)(1) of this section shall not constitute evidence of the prescriber's negligence unless the prescriber had reasonable cause to believe that the health condition of the patient for whom the drug was intended warranted the prescription of a specific brand name drug and no other. No prescriber shall be liable for civil damages or in any criminal

prosecution arising from the ~~interchange~~ substitution of a generically equivalent drug or interchangeable biological product for a prescribed brand name drug by a pharmacist, unless the prescribed brand name drug would have reasonably caused the same loss, damage, injury, or death.

(F)(1)(a) Except as provided in division (F)(1)(b) of this section, not later than five business days after a pharmacist dispenses a drug for which an interchangeable biological product is available, regardless of whether a substitution is made, the pharmacist or an individual designated by the pharmacist shall communicate to the prescriber information identifying the specific biological product that was dispensed, including the name of the biological product and its manufacturer.

(b) Communication of the information is not required when a biological product is dispensed by refilling a prescription and the product that is dispensed is the same product that was dispensed when the same prescription was last filled or refilled.

(2) When possible, communication of the information shall be conveyed by entering the information into a recordkeeping system that can reasonably be presumed to be electronically accessible to the prescriber. Such a system may include any of the following:

(a) An interoperable electronic medical records system;

(b) An electronic prescribing system;

(c) An electronic pharmacy benefit management system;

(d) An electronic pharmacy record system.

(3) Entering the complete information into one of the

recordkeeping systems listed in division (F)(2) of this section is presumed to provide notice to the prescriber.

(4) When it is not possible to communicate the information by using one of the recordkeeping systems listed in division (F)(2) of this section, communication of the information shall be conveyed by telephone, facsimile, another form of electronic communication, or any other prevailing means of communication.

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

Sec. 4729.99. (A) Whoever violates section 4729.16, division ~~(A) or (B)~~ (G) of section 4729.38, or section 4729.57 of the Revised Code is guilty of a minor misdemeanor. Each day's violation constitutes a separate offense.

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

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

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

(E)(1) Whoever violates section 4729.37, division (C)(2) of section 4729.51, division (J) of section 4729.54, or section 4729.61 of the Revised Code is guilty of a felony of the fifth degree. If the offender previously has been convicted of or pleaded guilty to a violation of this chapter or a violation of

Chapter 2925. or 3719. of the Revised Code, that person is guilty of a felony of the fourth degree.

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

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

(F) Whoever violates section 4729.531 of the Revised Code

or any rule adopted thereunder or section 4729.532 of the Revised Code is guilty of a misdemeanor of the first degree.

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

(H) Whoever violates division (C)(3) of section 4729.51 of the Revised Code is guilty of a misdemeanor of the first degree. If the offender has previously been convicted of or pleaded guilty to a violation of this chapter, or of a violation of Chapter 2925. or 3719. of the Revised Code, that person is guilty of a felony of the fifth degree.

(I)(1) Whoever violates division (B) of section 4729.42 of the Revised Code is guilty of unauthorized pharmacy-related drug conduct. Except as otherwise provided in this section, unauthorized pharmacy-related drug conduct is a misdemeanor of the second degree. If the offender previously has been convicted of or pleaded guilty to a violation of division (B), (C), (D), or (E) of that section, unauthorized pharmacy-related drug conduct is a misdemeanor of the first degree on a second offense and a felony of the fifth degree on a third or subsequent offense.

(2) Whoever violates division (C) or (D) of section 4729.42 of the Revised Code is guilty of permitting unauthorized pharmacy-related drug conduct. Except as otherwise provided in this section, permitting unauthorized pharmacy-related drug conduct is a misdemeanor of the second degree. If the offender previously has been convicted of or pleaded guilty to a

violation of division (B), (C), (D), or (E) of that section, permitting unauthorized pharmacy-related drug conduct is a misdemeanor of the first degree on a second offense and a felony of the fifth degree on a third or subsequent offense.

(3) Whoever violates division (E) of section 4729.42 of the Revised Code is guilty of the offense of falsification under section 2921.13 of the Revised Code. In addition to any other sanction imposed for the violation, the offender is forever disqualified from engaging in any activity specified in division (B)(1), (2), or (3) of section 4729.42 of the Revised Code and from performing any function as a health care professional or health care worker. As used in this division, "health care professional" and "health care worker" have the same meanings as in section 2305.234 of the Revised Code.

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

(J)(1) Whoever violates division (A)(1) of section 4729.86 of the Revised Code is guilty of a misdemeanor of the third degree. If the offender has previously been convicted of or

pleaded guilty to a violation of division (A)(1), (2), or (3) of section 4729.86 of the Revised Code, that person is guilty of a misdemeanor of the first degree.

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

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

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

Section 2. That existing sections 3715.01, 3715.64, 4729.01, 4729.38, and 4729.99 of the Revised Code are hereby repealed.

Section 3. Section 4729.01 of the Revised Code is presented in this act as a composite of the section as amended by both Sub. H.B. 124 and Am. Sub. H.B. 188 of the 131st General Assembly. The General Assembly, applying the principle stated in division (B) of section 1.52 of the Revised Code that amendments

are to be harmonized if reasonably capable of simultaneous operation, finds that the composite is the resulting version of the section in effect prior to the effective date of the section as presented in this act.