As Introduced

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H. B. No. 421

Representative LaTourette

Cosponsors: Representatives Sprague, Koehler, Hambley, Sheehy

A BILL

To amend section 4729.01 and to enact sections 4729.45, 4730.412, and 4731.057 of the Revised Code to authorize a pharmacist to administer by injection certain prescribed drugs.

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

Section 1. That section 4729.01 be amended and sections 4729.45, 4730.412, and 4731.057 of the Revised Code be enacted 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 with a physician authorized under Chapter 4731. of the Revised Code to practice medicine and surgery or osteopathic medicine and surgery, if an agreement has been established with the physician;

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

(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 to manage an

individual's drug therapy that has been entered into by a pharmacist and a physician authorized under Chapter 4731. of the Revised Code to practice medicine and surgery or osteopathic medicine and surgery.

(E) "Drug" means:

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

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

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

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

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

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

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

(b) Under Chapter 3715. or 3719. of the Revised Code, the

drug may be dispensed only upon a prescription.

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

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

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

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

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

(2) For purposes of ~~section~~ 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.

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

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

Sec. 4729.45. (A)(1) A pharmacist licensed under this chapter who meets the requirements of division (B) of this section may administer by injection any of the following drugs as long as the drug that is to be administered has been prescribed by a health professional with authority to prescribe the drug:

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

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

(c) Hydroxyprogesterone caproate;

(d) Medroxyprogesterone acetate.

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

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

(1) Successfully complete a course in the administration of drugs that has been approved by the state board of pharmacy;

(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 protocol that meets the requirements of division (D) of this section.

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

(1) Observe the individual who receives the drug to determine whether the individual has an adverse reaction to the drug;

(2) Notify the health professional who prescribed the drug;

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

(a) Except as provided in division (C)(3)(c) of this section, for each drug administered by a pharmacist to an individual who is eighteen years of age or older, the pharmacist shall obtain permission from the individual.

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

(c) For each drug administered by a pharmacist to an individual who lacks the capacity to make informed health care

decisions, the pharmacist shall obtain permission from the person authorized to make such decisions on the individual's behalf.

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

(1) The protocol must be established by a physician authorized under Chapter 4731. of the Revised Code to practice medicine and surgery or osteopathic medicine and surgery and must be approved by the state board of pharmacy before it is implemented.

(2) The board shall review each protocol it receives from an individual seeking approval of the protocol. If the board determines that the protocol meets the requirements of division (D)(3) of this section and all other requirements for approval established in rules adopted under this section, the board shall approve the protocol.

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

(a) Specify a definitive set of treatment guidelines;

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

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

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

the pharmacist.

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

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

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

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

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

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

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

(2) The provisions for approval of protocols shall establish standards regarding the length of time and location at which a pharmacist must observe an individual to whom a drug is administered to determine whether the individual has an adverse reaction.

(3) The board shall consult with the state medical board and the board of nursing before adopting rules regarding approval of protocols under this section.

Sec. 4730.412. The state medical board, in consultation with the state board of pharmacy, shall adopt rules in

accordance with Chapter 119. of the Revised Code that establish standards and procedures to be followed by a physician assistant when prescribing a drug that may be administered by a pharmacist pursuant to section 4729.45 of the Revised Code. The state medical board may determine whether the rules apply in situations in which the physician assistant reasonably believes that the drug will be administered by an individual other than a pharmacist.

Sec. 4731.057. As used in this section, "physician" means an individual authorized under this chapter to practice medicine and surgery or osteopathic medicine and surgery.

The state medical board, in consultation with the state board of pharmacy, shall adopt rules in accordance with Chapter 119. of the Revised Code that establish standards and procedures to be followed by physicians when prescribing a drug that may be administered by a pharmacist pursuant to section 4729.45 of the Revised Code. The state medical board may determine whether the rules apply in situations in which the physician reasonably believes that the drug will be administered by an individual other than a pharmacist.

Section 2. That existing section 4729.01 of the Revised Code is 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 Am. Sub. H.B. 4 and Sub. S.B. 110 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.