As Reported by the Senate Health, Human Services and Aging Committee

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Am. S. B. No. 58

Senator Coughlin

Cosponsors: Senators Mumper, Gardner, Miller, D., Clancy

A B I L L

To amend sections 4729.01, 4729.17, and 4729.41 of the Revised Code to modify the authority of pharmacists to administer immunizations and to make changes in certain voting procedures of the State Board of Pharmacy.

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

Section 1. That sections 4729.01, 4729.17, and 4729.41 of the Revised Code be amended to read as follows:

Sec. 4729.01. As used in this chapter:

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

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

(1) Interpreting prescriptions;

(2) Dispensing drugs and drug therapy related devices;

(3) Compounding drugs;

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

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

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

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

(8) Acting pursuant to a consult agreement 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) ~~Administering the adult~~ Engaging in the administration of immunizations ~~specified in~~ to the extent authorized by section 4729.41 of the Revised Code~~, if the pharmacist has met the requirements of that section~~.

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

(1) Pursuant to a prescription issued by a licensed health

professional authorized to prescribe drugs;

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

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

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

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

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

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

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

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

(E) "Drug" means:

(1) Any article recognized in the United States pharmacopoeia

and national formulary, or any supplement to them, intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in humans or animals;

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

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

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

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

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

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

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

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

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

(G) "Federal drug abuse control laws" has the same meaning as

in section 3719.01 of the Revised Code.

(H) "Prescription" means a 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.

(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 podiatry;

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

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

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

(K) "Wholesale sale" and "sale at wholesale" mean any sale in

which the purpose of the purchaser is to resell the article purchased or received by the purchaser.

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

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

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

(1) The proprietary name of the drug product;

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

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

(4) The dosage form;

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

or misleading.

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

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

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

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

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

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

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

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

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

Sec. 4729.17. Any investigation, inquiry, or hearing, which the state board of pharmacy is empowered to hold or undertake may be held or undertaken by or before any member or members of the board and the finding or order of such member or members shall be deemed to be the order of said board when approved and confirmed by a majority of the board members present and voting at a meeting of the board at which there is a quorum.

Sec. 4729.41. (A)(1) A pharmacist licensed under this chapter who meets the requirements of division (B) of this section may ~~administer adult~~ do either or both 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:

~~(1) Influenza;~~

~~(2)~~(i) Pneumonia;

~~(3)~~(ii) Tetanus;

~~(4)~~(iii) Hepatitis A;

~~(5)~~(iv) Hepatitis B;

(v) Meningitis;

(vi) Diphtheria;

(vii) Pertussis.

(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) ~~To~~ For a pharmacist or pharmacy intern to be authorized to ~~administer~~ engage in the ~~adult~~ administration of immunizations as specified in division (A) of this section, ~~a~~ the pharmacist or pharmacy intern shall do all of the following:

(1) Successfully complete a course in the administration of ~~adult~~ 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. ~~The~~

(C) The protocol required by division (B)(3) of this section shall include provisions ~~requiring that the pharmacist do both~~ for implementation of the following requirements:

~~(a) Observe an individual who has been immunized by the~~ (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 ~~be~~ comply with the standards specified in rules adopted by the state board of pharmacy under division ~~(D)~~ (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.

~~(b) Not later than thirty days after administering an adult immunization to an individual,~~ (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.

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

~~(1)~~(a) Engage in the administration of ~~adult~~ immunizations ~~by injection~~ unless the requirements of division (B) of this section

have been met;

~~(2)~~(b) Delegate to any person the pharmacist's authority to ~~administer adult~~ 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.

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

(a) Approval of courses in administration of ~~adult~~ immunizations ~~and approval~~;

(b) Approval of protocols to be followed by pharmacists and pharmacy interns in ~~administering adult~~ 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. ~~Prior~~

(2) Prior to adopting ~~the~~ 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. ~~The rules shall be adopted in accordance with Chapter 119. of the Revised Code.~~

Section 2. That existing sections 4729.01, 4729.17, and

4729.41 of the Revised Code are hereby repealed.