As Introduced

135th General Assembly
Regular Session
2023-2024

H. B. No. 80

Representative Lipps

A BILL

To amend sections 4729.01 and 4729.45 and to enact section 4729.21 of the Revised Code regarding pharmacist care.

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

Section 1. That sections 4729.01 and 4729.45 be amended and section 4729.21 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, if an agreement has been established;

(9) To the extent authorized by section 4729.21 of the Revised Code, and in accordance with a statewide written protocol, conducting screenings and ordering laboratory and diagnostic tests, evaluating the results of such screenings and tests, and treating health conditions;

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

~~(10)~~ (11) Engaging in the administration of drugs to the extent authorized by section 4729.45 of the Revised Code.

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

(1) Pursuant to a prescription issued by a licensed health professional authorized to prescribe drugs;

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

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

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

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

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

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

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

(D) "Consult agreement" means an agreement that has been

entered into under section 4729.39 of the Revised Code.

(E) "Drug" means:

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

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

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

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

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

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

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

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

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

drug may be dispensed only upon a prescription.

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

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

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

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

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

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

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

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

(4) For purposes of Chapter 3728. and sections 4723.483,

4729.88, 4730.433, and 4731.96 of the Revised Code, a written, electronic, or oral order for an epinephrine autoinjector issued to and in the name of a qualified entity, as defined in section 3728.01 of the Revised Code;

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

(I) "Licensed health professional authorized to prescribe drugs" or "prescriber" means an individual who is authorized by law to prescribe drugs or dangerous drugs or drug therapy related devices in the course of the individual's professional practice, including only the following:

(1) A dentist licensed under Chapter 4715. of the Revised Code;

(2) A clinical nurse specialist, certified nurse-midwife, or certified nurse practitioner who holds a current, valid license issued under Chapter 4723. of the Revised Code to practice nursing as an advanced practice registered nurse;

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

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

(5) A physician authorized under Chapter 4731. of the Revised Code to practice medicine and surgery, osteopathic

medicine and surgery, or podiatric medicine and surgery;

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

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

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

(K) "Wholesale sale" and "sale at wholesale" mean any sale in which the purpose of the purchaser is to resell the article purchased or received by the purchaser.

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

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

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

(1) The proprietary name of the drug product;

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

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

(4) The dosage form;

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

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

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

(Q) "Terminal distributor of dangerous drugs" or "terminal distributor" means a person who is engaged in the sale of

dangerous drugs at retail, or any person, other than a manufacturer, repackager, outsourcing facility, third-party logistics provider, wholesale distributor, or pharmacist, who has possession, custody, or control of dangerous drugs for any purpose other than for that person's own use and consumption. "Terminal distributor" includes pharmacies, hospitals, nursing homes, and laboratories and all other persons who procure dangerous drugs for sale or other distribution by or under the supervision of a pharmacist, licensed health professional authorized to prescribe drugs, or other person authorized by the state board of pharmacy.

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

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

(T)(1) "Animal shelter" means a facility operated by a humane society or any society organized under Chapter 1717. of the Revised Code or a dog pound operated pursuant to Chapter 955. of the Revised Code.

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

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

the Revised Code.

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

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

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

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

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

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

food and drug administration.

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

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

(1) Naloxone;

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

Sec. 4729.21. (A) Pursuant to a statewide written protocol established by the state board of pharmacy in rules adopted under this section, a pharmacist may conduct screenings and order laboratory and diagnostic tests and evaluate the results of the screenings conducted and tests that are ordered, in order to treat the following health conditions:

(1) Influenza;

(2) COVID-19;

(3) Pharyngitis caused by the bacteria known as group A streptococcus.

(B) For purposes of the screening and testing authorized

by this section:

(1) A pharmacist may use any established screening procedures that can safely be performed by a pharmacist.

(2) A pharmacist may use any tests to guide diagnosis or clinical decision-making that qualify for a waiver under the "Clinical Laboratory Improvement Amendments of 1988," 42 U.S.C. 263a, or the federal regulations adopted thereunder, as determined by the United States centers for medicare and medicaid services.

(3) Notwithstanding any provision of the Revised Code to the contrary, a pharmacist may delegate technical and administrative tasks associated with screening and testing to any of the following who is working under the direct supervision of the pharmacist: a pharmacy intern, registered pharmacy technician, or certified pharmacy technician.

(C) As part of treating a health condition under this section, a pharmacist may initiate drug therapy, notwithstanding the definition of "licensed health professional authorized to prescribe drugs" in section 4729.01 of the Revised Code.

(D) The board shall adopt rules as necessary to implement this section, including rules establishing the statewide written protocol described in division (A) of this section. The rules shall be adopted in accordance with Chapter 119. of the Revised Code.

(E) This section is an alternative to the authority granted by sections 4729.39 and 4729.42 of the Revised Code.

Sec. 4729.45. (A) As used in this section, "physician" means an individual authorized under Chapter 4731. of the Revised Code to practice medicine and surgery or osteopathic

medicine and surgery.

(B)(1) Subject to division (C) of this section, a pharmacist licensed under this chapter may administer by injection any of the following drugs as long as the drug that is to be administered has been prescribed by a physician and the individual to whom the drug was prescribed has an ongoing physician-patient relationship with the physician:

(a) An addiction treatment drug administered in a long-acting or extended-release form;

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

(c) A human immunodeficiency virus treatment drug administered in a long-acting or extended-release form;

(d) Hydroxyprogesterone caproate;

~~(d)~~ (e) Medroxyprogesterone acetate;

~~(e)~~ (f) Cobalamin;

(g) Any other drug that is specified in rules adopted under division (H)(2) of this section.

(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.

(C) 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 satisfies the requirements established ~~by the~~

~~state board of pharmacy~~ in rules adopted under division (H)(1)(a) of this section;

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

(3) Practice in accordance with a protocol that meets the requirements of division (F) of this section.

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

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

(a) Except as provided in division (D)(1)(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.

(2) In the case of an addiction treatment drug described

in division (B)(1)(a) of this section, obtain in accordance with division (E) of this section test results indicating that it is appropriate to administer the drug to the individual if either of the following is to be administered:

(a) The initial dose of the drug;

(b) Any subsequent dose, if the administration occurs more than thirty days after the previous dose of the drug was administered.

(3) Observe the individual to whom the drug is administered to determine whether the individual has an adverse reaction to the drug;

(4) Notify the physician who prescribed the drug that the drug has been administered to the individual.

(E) A pharmacist may obtain the test results described in division (D)(2) of this section in either of the following ways:

(1) From the physician;

(2) By ordering blood and urine tests for the individual to whom the drug is to be administered.

If a pharmacist orders blood and urine tests, the pharmacist shall evaluate the results of the tests to determine whether they indicate that it is appropriate to administer the drug. A pharmacist's authority to evaluate test results under this division does not authorize the pharmacist to make a diagnosis.

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

(1) The protocol must be established by a physician who

has a scope of practice that includes treatment of the condition for which the individual has been prescribed the drug to be administered.

(2) The protocol must satisfy the requirements established in rules adopted under division (H)(1)(b) of this section.

(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 (D) of this section, including for purposes of division (D)(3) of this section 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.

(G) 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 (C) 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.

(H)(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) Requirements for courses in administration of drugs;

(b) Requirements for 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 board may adopt rules in accordance with Chapter 119. of the Revised Code to specify other drugs that a pharmacist may administer by injection in accordance with this section.

(3) The board shall consult with the state medical board before adopting rules ~~regarding requirements for protocols~~ under divisions (H)(1)(b) and (2) of this section.

Section 2. That existing sections 4729.01 and 4729.45 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 H.B. 509 and H.B. 558 of the 134th 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.