As Passed by the Senate

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Senators Burke, Manning
Cosponsors: Senators Brown, Seitz, Beagle, Hite, Gardner, Tavares, Balderson, Coley, Eklund, Hughes, Jones, Sawyer, Thomas, Uecker, Yuko

A BILL

To amend sections 4729.01, 4729.281, and 4729.39 of the Revised Code to revise the laws governing pharmacist consult agreements and the laws governing the circumstances under which a pharmacist may dispense or sell a drug without a prescription.

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

Section 1. That sections 4729.01, 4729.281, and 4729.39 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~~ 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 ~~with the physician~~;

(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 ~~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~~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.

(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 podiatric medicine and surgery;

(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.

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

Sec. 4729.281. (A) A pharmacist may dispense or sell a

dangerous drug, other than a schedule II controlled substance as defined in section 3719.01 of the Revised Code, without a written or oral prescription from a licensed health professional authorized to prescribe drugs if all of the following conditions are met:

(1) The pharmacy at which the pharmacist works has a record of a prescription for the drug in the name of the patient who is requesting it, but the prescription does not provide for a refill or the time permitted by rules adopted by the state board of pharmacy for providing refills has elapsed.

(2) The pharmacist is unable to obtain authorization to refill the prescription from the health care professional who issued the prescription or another health professional responsible for the patient's care.

(3) In the exercise of the pharmacist's professional judgment:

(a) The drug is essential to sustain the life of the patient or continue therapy for a chronic condition of the patient.

(b) Failure to dispense or sell the drug to the patient could result in harm to the health of the patient.

(4) ~~The~~ (a) Except as provided in division (A)(4)(b) of this section, the amount of the drug that is dispensed or sold under this section does not exceed a seventy-two~~-~~hour supply as provided in the prescription.

(b)(i) Subject to division (A)(4)(b)(ii) of this section, if the drug dispensed or sold under this section is not a controlled substance and the patient has been on a consistent drug therapy as demonstrated by records maintained by a

pharmacy, the amount of the drug dispensed or sold does not exceed a thirty-day supply as provided in the prescription or, if the standard unit of dispensing for the drug exceeds a thirty-day supply, the amount of the drug dispensed or sold does not exceed the standard unit of dispensing.

(ii) A pharmacist shall not dispense or sell a particular drug to the same patient in an amount described in division (A)(4)(b)(i) of this section more than once in any twelve-month period.

(B) A pharmacist who dispenses or sells a drug under this section shall do all of the following:

(1) For one year after the date of dispensing or sale, maintain a record in accordance with this chapter of the drug dispensed or sold, including the name and address of the patient and the individual receiving the drug, if the individual receiving the drug is not the patient, the amount dispensed or sold, and the original prescription number;

(2) Notify the health professional who issued the prescription described in division (A)(1) of this section or another health professional responsible for the patient's care not later than seventy-two hours after the drug is sold or dispensed;

(3) If applicable, obtain authorization for additional dispensing from one of the health professionals described in division (B)(2) of this section.

(C) A pharmacist who dispenses or sells a drug under this section may do so once for each prescription described in division (A)(1) of this section.

Sec. 4729.39. (A) ~~A pharmacist~~ One or more pharmacists may

enter into a consult agreement with ~~a physician~~ one or more physicians authorized under Chapter 4731. of the Revised Code to practice medicine and surgery or osteopathic medicine and surgery if all of the following conditions are met:

(1) Each physician has an ongoing physician-patient relationship with each patient whose drug therapy is being managed.

(2) The diagnosis for which each patient has been prescribed drug therapy is within the scope of each physician's practice.

(3) Each pharmacist has training and experience related to the particular diagnosis for which drug therapy is prescribed.

~~Under~~ (B) With respect to consult agreements, all of the following apply:

(1) Under a consult agreement, a pharmacist is authorized to ~~manage an individual's drug therapy~~do both of the following, but only to the extent specified in the agreement, this section, and the rules adopted under this section:

(a) Manage drug therapy for treatment of specified diagnoses or diseases for each patient who is subject to the agreement, including all of the following:

(i) Changing the duration of treatment for the current drug therapy;

(ii) Adjusting a drug's strength, dose, dosage form, frequency of administration, or route of administration;

(iii) Discontinuing the use of a drug;

(iv) Administering a drug;

(v) Notwithstanding the definition of "licensed health professional authorized to prescribe drugs" in section 4729.01 of the Revised Code, adding a drug to the patient's drug therapy.

(b)(i) Order blood and urine tests and evaluate results related to the drug therapy being managed.

(ii) A pharmacist's authority to evaluate blood and urine tests under division (B)(1)(b)(i) of this section does not authorize the pharmacist to make a diagnosis.

~~(B) All of the following apply to a consult agreement that authorizes a pharmacist to manage the drug therapy of an individual who is not a patient of a hospital, as defined in section 3727.01 of the Revised Code, or a resident in a long-term care facility, as defined in section 3729.01 of the Revised Code:~~

~~(1) A separate consult agreement must be entered into for each individual whose drug therapy is to be managed by a pharmacist. A consult agreement applies only to the particular diagnosis for which a physician prescribed an individual's drug therapy. If a different diagnosis is made for the individual, the pharmacist and physician must enter into a new or additional consult agreement.~~

~~(2) Management of an individual's drug therapy by a pharmacist under a consult agreement may include monitoring and modifying a prescription that has been issued for the individual. Except as provided in section 4729.38 of the Revised Code for the selection of generically equivalent drugs, management of an individual's drug therapy by a pharmacist under a consult agreement shall not include dispensing a drug that has~~

~~not been prescribed by the physician.~~

~~(3) Each consult agreement shall be in writing, except that a consult agreement may be entered into verbally if it is immediately reduced to writing.~~

~~(4) A physician entering into a consult agreement shall specify in the agreement the extent to which the pharmacist is authorized to manage the drug therapy of the individual specified in the agreement.~~

~~(5) A physician entering into a consult agreement may specify one other physician who has agreed to serve as an alternate physician in the event that the primary physician is unavailable to consult directly with the pharmacist. The pharmacist may specify one other pharmacist who has agreed to serve as an alternate pharmacist in the event that the primary pharmacist is unavailable to consult directly with the physician.~~

~~(6) A consult agreement may not be implemented until it has been signed by the primary pharmacist, the primary physician, and the individual whose drug therapy will be managed or another person who has the authority to provide consent to treatment on behalf of the individual. Once the agreement is signed by all required parties, the physician shall include in the individual's medical record the fact that a consult agreement has been entered into with a pharmacist.~~

~~(7) Prior to commencing any action to manage an individual's drug therapy under a consult agreement, the pharmacist shall make reasonable attempts to contact and confer with the physician who entered into the consult agreement with the pharmacist. A pharmacist may commence an action to manage an~~

~~individual's drug therapy prior to conferring with the physician or the physician's alternate, but shall immediately cease the action that was commenced if the pharmacist has not conferred with either physician within forty-eight hours.~~

~~A pharmacist acting under a consult agreement shall maintain a record of each action taken to manage an individual's drug therapy. The pharmacist shall send to the individual's physician a written report of all actions taken to manage the individual's drug therapy at intervals the physician shall specify when entering into the agreement. The physician shall include the pharmacist's report in the medical records the physician maintains for the individual.~~

~~(8)~~ (2)(a) A consult agreement, or the portion of the agreement that applies to a particular patient, may be terminated by ~~either the~~ any of the following:

(i) A pharmacist ~~or~~ who entered into the agreement;

(ii) A physician who entered into the agreement~~. By withdrawing consent, the individual~~ ;

(iii) A patient whose drug therapy is being managed~~ or the~~;

(iv) An individual who consented to the treatment on behalf of ~~the individual may terminate a consult agreement~~a patient or an individual authorized to act on behalf of a patient.

~~The~~ (b) The pharmacist or physician who receives the ~~individual's withdrawal of consent~~ notice of a patient's termination of the agreement shall provide written notice to ~~the opposite party~~every other pharmacist or physician who is a party to the agreement. A pharmacist or physician who terminates a

consult agreement with regard to one or more patients shall provide written notice to ~~the opposite party~~ all other pharmacists and physicians who entered into the agreement and to ~~the~~ each individual who consented to treatment under the agreement. The termination of a consult agreement with regard to one or more patients shall be recorded by the pharmacist and physician in the medical records ~~they maintain on the individual being treated~~of each patient to whom the termination applies.

~~(9) Except as described in division (B)(5) of this section, the authority of a pharmacist to manage an individual's drug therapy under a consult agreement does not permit the pharmacist to manage drug therapy prescribed by any other physician.~~

~~(C) All of the following apply to a consult agreement that authorizes a pharmacist to manage the drug therapy of an individual who is a patient of a hospital, as defined in section 3727.01 of the Revised Code, or a resident in a long-term care facility, as defined in section 3729.01 of the Revised Code:~~

~~(1) Before a consult agreement may be entered into and implemented, a hospital or long-term care facility shall adopt a policy for consult agreements. For any period of time during which a pharmacist or physician acting under a consult agreement is not physically present and available at the hospital or facility, the policy shall require that another pharmacist and physician be available at the hospital or facility.~~

~~(2) The~~ (3) A consult agreement shall be made in writing and shall ~~comply with the hospital's or facility's policy on consult agreements~~include all of the following:

(a) The diagnoses and diseases being managed under the

agreement, including whether each disease is primary or comorbid;

(b) A description of the drugs or drug categories the agreement involves;

(c) A description of the procedures, decision criteria, and plan the pharmacist is to follow in acting under a consult agreement;

(d) A description of how the pharmacist is to comply with division (B)(5) and (6) of this section.

~~(3)~~ (4) The content of ~~the~~ a consult agreement shall be communicated to ~~the individual~~ each patient whose drug therapy ~~will be~~ is managed ~~in a manner consistent with the hospital's or facility's policy on consult agreements~~under the agreement.

~~(4)~~ (5) A pharmacist acting under a consult agreement shall maintain ~~in the individual's medical record~~ a record of each action taken for each patient whose drug therapy is managed under the agreement.

~~(5)~~ (6) Communication between a pharmacist and physician acting under ~~the~~ a consult agreement shall take place at regular intervals specified by the primary physician acting under the agreement. The agreement may include a requirement that a pharmacist send a consult report to each consulting physician.

~~(6) A consult agreement may be terminated by the individual, a person authorized to act on behalf of the individual, the primary physician acting under the agreement, or the primary pharmacist acting under the agreement. When a consult agreement is terminated, all parties to the agreement shall be notified and the termination shall be recorded in the individual's medical record.~~

(7) ~~The authority of a pharmacist acting under a~~ A consult agreement is effective for two years and may be renewed if the conditions specified in division (A) of this section are met.

(8) A consult agreement does not permit ~~the~~ a pharmacist to ~~act under the agreement in a hospital long-term care facility at which the pharmacist is not authorized to practice~~manage drug therapy prescribed by a physician who has not entered into the agreement.

~~(D)~~ (C) The state board of pharmacy, in consultation with the state medical board, shall adopt rules to be followed by pharmacists, and the state medical board, in consultation with the state board of pharmacy, shall adopt rules to be followed by physicians, that establish standards and procedures for entering into a consult agreement and managing ~~an individual's~~ a patient's drug therapy under a consult agreement. The boards shall specify in the rules any categories of drugs or types of diseases for which a consult agreement may not be established. Either board may adopt any other rules it considers necessary for the implementation and administration of this section. All rules adopted under this division shall be adopted in accordance with Chapter 119. of the Revised Code.

(D)(1) Subject to division (D)(2) of this section, both of the following apply:

(a) A pharmacist is not liable in damages in a tort or other civil action for injury or loss to person or property allegedly arising from a physician's change in a drug for a patient whose drug therapy the pharmacist is managing under a consult agreement, but only if the pharmacist acted in accordance with the consult agreement as it relates to the physician's change in the drug.

(b) A physician is not liable in damages in a tort or other civil action for injury or loss to person or property allegedly arising from a pharmacist's change in a drug for a patient whose drug therapy the pharmacist is managing under a consult agreement, but only if either of the following is the case:

(i) The physician acted in accordance with the consult agreement as it relates to the pharmacist's change in the drug;

(ii) The physician did not authorize the pharmacist to make the specific change in the drug.

(2) Division (D)(1) of this section does not limit a physician's or pharmacist's liability in damages in a tort or other civil action for injury or loss to person or property allegedly arising from actions that are not related to the physician's or pharmacist's change in a drug for a patient whose drug therapy is being managed under a consult agreement.

Section 2. That existing sections 4729.01, 4729.281, and 4729.39 of the Revised Code are hereby repealed.