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Legislative Service Commission

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136th General Assembly
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To enact section 3792.08 of the Revised Code regarding prescribing, dispensing, and administering drugs and to name this act the Jeff, Dave, and Angie Patient Right to Try Act.

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

Section 1. That section 3792.08 of the Revised Code be enacted to read as follows:

Sec. 3792.08. (A) As used in this section:

(1) "Health-related licensing board" has the same meaning as in section 3719.062 of the Revised Code.

(2) "Hospital" has the same meaning as in section 3722.01 of the Revised Code and includes a hospital owned or operated by the United States department of veterans affairs.

(3) "In-house physician" means a physician who:

(a) Is part of the team involved in the care of a hospital or inpatient facility patient; and

(b) Is employed or contracted by the hospital or inpatient facility where the patient is being treated, or who has hospital

privileges at the hospital where the patient is being treated.

(4) "Inpatient facility" means either or both of the following:

(a) A skilled nursing facility as defined in section 5165.01 of the Revised Code;

(b) A freestanding inpatient rehabilitation facility licensed under section 3702.30 of the Revised Code.

(5) "Off-label use" means the use of a drug that meets both of the following:

(a) The drug is approved by the United States food and drug administration to treat or prevent a disease, illness, or infection, but prescribed for or used by a patient to treat or prevent another disease, illness, or infection.

(b) The drug is legal for use in this state.

(6) "Patient's personal representative" has the same meaning as in section 3701.74 of the Revised Code.

(7) "Pharmacist" means an individual who holds a license issued under section 4729.08 of the Revised Code authorizing the individual to practice pharmacy.

(8) "Physician" means an individual licensed under Chapter 4731. of the Revised Code to practice medicine and surgery, osteopathic medicine and surgery, or podiatric medicine and surgery.

(9) "State agency" means any organized agency, board, body, commission, department, institution, office, or other entity established by the laws of the state for the exercise of any function of state government. "State agency" does not

include a court.

(B)(1) A pharmacist shall dispense, and a hospital, inpatient facility, outpatient health care facility, or pharmacy shall allow the dispensing of a drug, including for off-label use, prescribed by a physician, to a patient except in either of the following circumstances:

(a) As provided in section 4743.10 of the Revised Code, the pharmacist, hospital, inpatient facility, outpatient health care facility, or pharmacy has a moral, ethical, or religious belief or conviction that conflicts with the drug's dispensing.

(b) The pharmacist has documented that the patient has a history of a life-threatening allergic reaction to the prescribed drug, there is a life-threatening contraindication or life-threatening drug interaction for that patient, or the drug has a high probability of causing serious disability or serious injury to that patient.

(2) When neither exception in division (B)(1)(a) or (b) of this section applies and a pharmacist must dispense, or a hospital, inpatient facility, outpatient health care facility, or pharmacy must allow the dispensing of, a drug, including for off-label use, for a patient pursuant to this section, but the pharmacist, hospital, inpatient facility, outpatient health care facility, or pharmacy has an objective, good faith, and scientific objection to the administration or dosage of the drug for that patient or that patient's condition, then after informing the physician of the objection, if it is still the clinical judgment of the physician to dispense the drug, the pharmacist, hospital, inpatient facility, outpatient health care facility, or pharmacy shall dispense the drug and shall be immune from criminal liability, civil liability and damages,

professional discipline, and sanctions or fines imposed by any licensing authority or other regulatory authority for any harm that may arise from the dispensing or administration of the drug starting from the date of dispensing if the pharmacist, hospital, inpatient facility, outpatient health care facility, or pharmacy meets the following minimum requirements:

(a) Documents in the patient's medical record that the objective, good faith, and scientific objection to the named drug was discussed with the physician and notes the date of the discussion. The objection is not required to be described in detail.

(b) Documents the objective, good faith, and scientific objection within twenty-four hours of dispensing the drug.

(3) Nothing in this section is intended to prevent compliance with federal laws or laws of this state governing the practice of pharmacy and the dispensing or administration of drugs, but it establishes that the final decision on whether a prescribed drug is dispensed pursuant to division (B)(1) of this section shall be made by the physician.

(4) In the case of a pharmacist who practices within a hospital's or inpatient facility's pharmacy and where an in-house physician issues a prescription for a drug, including for off-label use, that is neither in stock nor listed on the hospital's or facility's formulary, and the patient can obtain the drug at an outpatient pharmacy, then the hospital or inpatient facility must permit the drug to be brought into the hospital or inpatient facility to be identified for the patient's use. To be identified for the patient's use, the hospital or inpatient facility must determine that the drug was prescribed for the patient, is in the original manufacturer's

packaging or is labeled from an outpatient retail pharmacy for the patient, has been approved by the physician for the patient's use, and is not outside of its beyond-use or expiration date. If the drug is able to be identified according to the hospital or inpatient facility's drug identification procedure, then the drug shall be administered to the patient in the hospital or inpatient facility.

(5) When a hospital or inpatient facility patient or a patient's personal representative wishes to try a drug to treat a patient's condition, but there is no in-house physician willing to prescribe the drug, the hospital or inpatient facility shall not obstruct or intentionally delay the transfer of that patient to another hospital, inpatient facility, or hospice that is willing to accept and treat the patient, nor shall the hospital or inpatient facility prevent the patient's discharge if that is the wish of the patient or the patient's personal representative.

(6) When there is a safety concern regarding a prescription for a drug, including a drug for off-label use, a pharmacist should discuss any prescription dosage recommendations or other clinical concerns with the physician, the patient, or the patient's personal representative. There should be risk-benefit discussions between the physician, the patient or the patient's personal representative, and other inpatient and outpatient medical staff directly involved in the patient's care. Outside of emergency situations, the ultimate decision to take a drug, including a drug for off-label use, prescribed by the physician should be made by the consenting patient or the patient's personal representative.

(C) In an outpatient pharmacy setting, if a drug is not

covered by a patient's health benefit plan or the patient does not want to wait for prior authorization, the physician or pharmacist shall notify the patient of the option to pay for the drug out of pocket. The physician or pharmacist must notify the patient of the estimated out-of-pocket costs for the drug, and the pharmacist must offer the drug at an upfront, out-of-pocket cost to the patient.

(D) Except as provided in division (F) of this section, a health-related licensing board, the department of health, or another state agency responsible for the licensure or regulation of health care professionals or health care facilities shall not consider the action of prescribing, dispensing, or administering a drug for off-label use to a consenting patient or with the consent of the patient's personal representative by a physician, pharmacist, hospital, inpatient facility, outpatient health care facility, or pharmacy under this section to be unlawful, unethical, unauthorized, or unprofessional conduct and shall not pursue professional discipline or fines or other regulatory sanctions against the physician, pharmacist, hospital, facility, or pharmacy except in cases where the prescribing, dispensing, or administering of the drug to that patient was not done in accordance with the minimal standard of care. The state medical board shall not determine that the prescribing, dispensing, or administering of a drug for off-label use is considered below the minimal standard of care because it is being used to treat a particular condition that is not commonly treated with that drug. This section does not provide a physician immunity from civil liability. Except as provided in division (B)(2) of this section, this section does not provide a pharmacist, hospital, inpatient facility, outpatient health care facility, or pharmacy immunity from civil liability.

(E) A health care professional should be free to engage in scientific debate. A health-related licensing board, the department of health, or other state agency responsible for the licensure or regulation of health care professionals shall not pursue or threaten to pursue professional discipline or fines or other regulatory sanctions against a physician, pharmacist, or other licensed health care professional for doing either of the following:

(1) Publicly expressing an opinion regarding the safety, risks, benefits, or efficacy of a drug approved or authorized by the United States food and drug administration, including a drug prescribed for off-label use, or other medical intervention because that opinion does not align with the opinions of the board, department, other state agency, a board of health of a city or general health district, or other health authority.

(2) Informing a patient or a patient's personal representative of safety concerns or risks that may be associated with a drug, including a drug prescribed for off-label use, or other medical intervention.

This division does not provide a health care professional immunity from civil liability to a patient under the health care professional's care in a private care setting.

(F) Except for division (E) of this section, no portion of this section applies to, repeals, or supersedes existing law regarding prescribing, dispensing, or administering any of the following:

(1) Controlled substances, including opioids;

(2) Drugs subject to a United States food and drug administration risk evaluation and mitigation strategy;

(3) Cross-sex hormones or puberty-blocking drugs, as defined in section 3129.01 of the Revised Code, to be used in violation of section 3129.02 of the Revised Code;

(4) Abortifacients when prescribed, dispensed, or administered to patients who are believed to be pregnant;

(5) Drugs that are known to be used for the intent or purpose of euthanasia.

Section 2. This act shall be known as the Jeff, Dave, and Angie Patient Right to Try Act.