As Pending in the Senate Health Committee

135th General Assembly

Regular Session **Sub. H. B. No. 73**

2023-2024

Representatives Gross, Loychik

Cosponsors: Representatives Jordan, Dean, Swearingen, Edwards, Klopfenstein, Williams, Barhorst, Wiggam, Creech, Claggett, Miller, M., Miller, K., Hall, Fowler Arthur, Abrams, Carruthers, Click, Cutrona, Dobos, Galonski, Jones, Lear, Lorenz, Mathews, McClain, Miller, A., Richardson, Schmidt, Stein, Willis, Young, T.

A BILL

To enact section 3792.06 of the Revised Code to authorize the prescribing of off-label medications and if prescribed, to generally require their dispensing and to name this act the Dave and Angie Patient and Health Provider Protection Act.

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

Section 1. That section 3792.06 of the Revised Code be enacted to read as follows:

Sec. 3792.06. (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) "Identified" means that a hospital or inpatient

facility pharmacist has determined that the drug in question is the drug prescribed by the patient's prescriber and that the patient's prescribed drug is in the original manufacturer's packaging or is labeled from an outpatient retail pharmacy, has been approved by the prescriber for use, and is not outside of its beyond use date.

(4) "Informed consent" means the communication between a patient, patient's parent/guardian, or person holding a health care power of attorney and a physician that results in the patient, patient's parent/guardian, or person holding a health care power of attorney authorizing, or agreeing to accept, a specific drug, treatment, or intervention. The physician, as part of such communication, shall provide all of the following information: the patient's diagnosis, if known; the nature and purpose of the recommended drug, treatment, or intervention; the burdens, risks, and expected benefits of all drug, treatment, or intervention options, including the option of forgoing treatment; and any conflicts of interest the physician may have regarding the recommended drug, treatment, or intervention.

(5) "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.

(6) "Off-label drug" means a drug that meets all 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.

(c) The drug is not a controlled substance as defined in section 3719.01 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) "Political subdivision" means a county, township, municipal corporation, school district, or other body corporate and politic responsible for governmental activities in a geographic area smaller than that of the state. "Political subdivision" also includes a board of health of a city or general health district.

(9) "Prescriber" has the same meaning as in section 4729.01 of the Revised Code.

(10) "Public official" means any officer, employee, or duly authorized agent or representative of a state agency or political subdivision.

(11) "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) A prescriber may issue for a patient a prescription for any drug, including an off-label drug, if the prescriber has obtained the informed consent of any of the following: the patient, patient's parent/guardian, or person holding the

patient's health care power of attorney. All of the following apply to the prescribing of an off-label drug under this division:

(1) The prescriber is not required to obtain or show a test result for a particular disease, illness, or infection before issuing the prescription for the patient's use of the drug at home or for outpatient treatment or in a hospital or inpatient facility.

(2) The patient is not required to have had a positive screen or test result for a particular disease, illness, or infection before the prescriber issues the prescription.

(3) The patient is not required to have been exposed to a disease, illness, or infection before the prescriber issues the prescription for the patient's prophylactic use of the drug.

(4) In the case of a drug subject to a United States food and drug administration risk evaluation and mitigation strategy, the usage of the drug for an off-label purpose must be consistent with any requirements or recommendations the strategy establishes.

(C)(1) A pharmacist shall dispense, and a hospital or inpatient facility shall allow the dispensing of, an off-label drug to a patient if a prescriber has issued for the patient a prescription for the drug as described in division (B) of this section, except if either of the following is the case:

(a) As provided in section 4743.10 of the Revised Code, the pharmacist, hospital, or inpatient facility 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 off-label drug or there is a life-threatening contraindication.

(2) When a pharmacist must dispense, or a hospital or inpatient facility must allow the dispensing of, an off-label drug for a patient pursuant to this section, but the pharmacist, hospital, or inpatient facility has an objective, good faith, and scientific objection to the administration or dosage of the drug for that patient, the pharmacist, hospital, or inpatient facility shall be immune from administrative or civil liability for any harm that may arise from the dispensing or use of the off-label drug starting from the date of dispensing, so long as, at the time of dispensing, the pharmacist, hospital, or inpatient facility documents in the patient's medical record the objective, good faith, and scientific objection, by stating with particularity the basis of that objection, which must be based on an individualized assessment of the patient and the off-label drug.

(3)(a) In the case of a pharmacist who practices within a hospital's or inpatient facility's pharmacy and where an in-house treating prescriber issues for a hospital or facility patient a prescription for an off-label drug that is neither in stock nor listed on the hospital's or facility's formulary, the pharmacist must document in the patient's medical record that a good faith effort was made to find out if the drug is available from another hospital or inpatient facility or another United States distributor. If available, the drug must be offered to the patient at an upfront out-of-pocket cost to the patient. The hospital or inpatient facility may require payment prior to ordering the drug.

(b) If the hospital or inpatient facility pharmacist is unable to obtain the off-label drug from another hospital, inpatient facility, or distributor or if the hospital, hospital pharmacist, inpatient facility, or pharmacist declines to fill the prescription for the reasons provided in section 4743.10 of the Revised Code, and the patient has access to the drug through a pharmacy outside the hospital or inpatient facility or has the drug available at home, then both of the following apply:

(i) The hospital or inpatient facility must permit that drug to be brought into the hospital or inpatient facility to be identified for the patient's use. If identified, the drug will be administered to the patient within the hospital or inpatient facility.

(ii) When the hospital or inpatient facility or the patient's in-house treating prescriber or other in-house treating clinician is unwilling to administer the identified drug to the patient for reasons provided in section 4743.10 of the Revised Code, then another prescriber or prescriber's delegate may administer the drug.

(4) When a patient's condition is so serious that the patient cannot be safely transported out of a hospital or inpatient facility and the patient, patient's parent/guardian, or person holding the patient's health care power of attorney wishes to try an off-label drug to treat the patient's condition, but there is no in-house prescriber willing to prescribe the drug, then the patient's outpatient physician prescriber, after a prompt consultation with the patient's hospital or inpatient facility care team and a review of all of the patient's drugs, shall be allowed to immediately begin applying for temporary privileges with oversight, based on

criteria within the hospital or inpatient facility medical staff bylaws used to determine the issuance of temporary privileges. The temporary privileges approval process is not to exceed five days.

If the outpatient physician prescriber does not meet the hospital's or facility's medical staff bylaw requirements and the outpatient physician prescriber feels that temporary privileges were wrongfully denied to the physician, then the physician may file a complaint with the department of health. The complaint shall include the name of the hospital or facility, the hospital's or facility's stated reason for the denial, and the name of the drug that the outpatient physician prescriber was seeking temporary privileges in order to prescribe. The department shall keep a record of the complaint, including the aforementioned information. The complaint's information shall be kept on file with the department for seven years and shall be made available to any citizen of this state within ten days of the citizen's written request.

If the outpatient physician prescriber meets the hospital's or facility's medical staff bylaw requirements for temporary privileges, then he/she shall immediately be allowed to participate in the patient's care in the narrowed scope of practice regarding the administering and monitoring of the prescribed off-label drug within the hospital or inpatient facility until the patient is in a condition where the patient can be safely transported to a hospital or inpatient facility where the outpatient physician prescriber has privileges. In such a case, all of the following apply:

(a) The patient may be required to pay out-of-pocket for the prescribed off-label drug before it is ordered.

(b) If the hospital or inpatient facility cannot obtain the off-label drug being prescribed by the outpatient physician prescriber, then the requirements of divisions (C)(3)(b)(i) and (ii) apply.

(c) The in-house pharmacist, hospital, or inpatient facility and the in-house physician responsible for the patient's care shall be immune from administrative and civil liability for any harm that may arise from the patient's use of the off-label drug prescribed by the outpatient physician prescriber starting from the date of dispensing.

(5) All of the following apply to the dispensing of an off-label drug under division (C)(1) or (2) of this section:

(a) The pharmacist is not required to obtain or show a test result before dispensing the drug for the patient's use at home or for other outpatient treatment.

(b) The patient is not required to have had a positive screen or test result for a particular disease, illness, or infection before the pharmacist dispenses the drug.

(c) The patient is not required to have been exposed to a disease, illness, or infection before the pharmacist dispenses the drug for prophylactic use.

(6) Nothing in this section prevents a pharmacist from discussing a prescription with the prescriber who issued the prescription. The ultimate decision to accept a drug prescribed by the prescriber shall be made by one of the following who has given informed consent: the patient, patient's parent/guardian, or person holding the patient's health care power of attorney.

(D) A health-related licensing board, department of health, state board of pharmacy, or other state board or agency

responsible for the licensure or regulation of health care professionals shall not consider any action taken by a prescriber or pharmacist or hospital or inpatient facility under this section to be unlawful, unethical, unauthorized, or unprofessional conduct and shall not pursue an administrative or disciplinary action against the prescriber, pharmacist, hospital, or facility, except in cases of recklessness or gross negligence.

A health-related licensing board, department of health, state board of pharmacy, or other state board or agency responsible for the licensure or regulation of health care professionals shall not pursue an administrative or disciplinary action against a prescriber, pharmacist, or other licensed health care professional or hospital or inpatient facility for publicly or privately expressing a medical opinion that does not align with the opinions of the board or agency, a board of health of a city or general health district, or the department of health.

(E) The world health organization shall have no jurisdiction in this state. Therefore, no political subdivision, public official, or state agency shall enforce or use any state funding to implement any guideline, mandate, recommendation, or rule issued by the world health organization that prohibits issuing a prescription for or dispensing an off-label drug.

(F) At no time shall a patient in a hospital or inpatient facility be denied sufficient means of fluids or nutrition, unless that wish is clearly stated in the patient's end of life health directive, as that directive is defined by the patient, patient's parent/guardian, or person holding the patient's health care power of attorney, or the denial is necessary for a

medical procedure, including a diagnostic or surgical procedure, and then only for the shortest amount of time medically possible and with the informed consent of the patient or person holding the patient's health care power of attorney.

Section 2. This act shall be known as the Dave and Angie Patient and Health Provider Protection Act.