As Passed by the Senate

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.

Senators Huffman, S., Cirino, Romanchuk

A BILL

To enact section 3792.06 of the Revised Code regarding the prescribing and dispensing of off-label drugs 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" for this section means the communication between a patient, minor patient's parent/guardian, or person holding a health care power of attorney and a physician that results in the patient, minor 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; informed consent consistent with current law and practices for on-label usage and any other available information related to the risks and benefits of the drug, treatment, or intervention options pertaining to its off-label uses, including the option of forgoing treatment; and any financial 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 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.

(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.

(12) "Gross negligence" means intentional failure to perform an apparent duty in reckless disregard of the consequences concerning the life or property of another.

(B) Except as provided in division (G) of this section, a

prescriber may issue for a human patient a prescription for an off-label drug that is approved for human use if the prescriber has obtained the informed consent of any of the following: the patient, minor patient's parent/guardian, or person holding the patient's health care power of attorney.

(C)(1) Except as provided in division (G) of this section, during a public health emergency or period in which an order or rule issued under division (C) of section 3701.13 of the Revised Code or section 3701.14, 3709.20, or 3709.21 of the Revised Code remains in effect, a pharmacist practicing in a hospital or inpatient facility shall dispense, and the 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 off-label drug as described in division (B) of this section, except if any 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 off-label 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 or life-threatening drug interaction.

(c) The pharmacist, hospital, or inpatient facility has an objective, good faith, and scientific objection to the administration or dosage of the off-label drug for that patient or that patient's condition.

(2)(a) When an in-house treating prescriber issues for the 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 off-label drug is available from another hospital or inpatient facility or another United States distributor. If the off-label drug is available, but the off-label drug is not authorized under insurance, or the patient does not want to wait for authorization, then the patient must be notified of estimated out-of-pocket costs and the off-label drug shall 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 off-label 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 off-label drug through a pharmacy outside the hospital or inpatient facility or has the off-label drug available at home, then both of the following apply:

(i) The hospital or inpatient facility must permit that off-label drug to be brought into the hospital or inpatient facility to be identified for the patient's use. If it is able to be identified according to the hospital or inpatient facility drug identification procedure, the off-label 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 off-label 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 off-label drug.

(3) When the patient's condition is so serious that the patient cannot be safely transported out of the hospital and the patient, minor 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 off-label drug, then the patient's outpatient Ohio-licensed physician prescriber, after a prompt consultation with the patient's hospital care team and a review of all of the patient's drugs, shall be allowed to immediately begin applying for temporary privileges, based on criteria within the hospital medical staff bylaws used to determine the issuance of temporary privileges to treat that patient only. Hospital bylaws for outpatient physicians seeking temporary privileges under this section shall not be more restrictive than those for other physicians seeking temporary privileges.

Nothing in this section prevents the physician applicant from withdrawing the physician's application during the application process. Nothing in this section prevents the hospital from revoking the outpatient physician's temporary privileges if at any point the physician's license is found not to be in good standing.

If the outpatient physician prescriber meets the hospital'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 until the patient is in a condition where the patient can be safely transported to a hospital or inpatient facility that is willing to provide that off-label drug, or discharge home, or within the maximum number of days temporary privileges are allowed within the hospital's bylaws, whichever comes first. In such a case, all of the following apply:

(a) If the off-label drug is not covered by insurance, or the patient does not want to wait for authorization, then the patient shall be offered the option to pay out-of-pocket, upfront for the prescribed off-label drug before it is ordered. The patient must be notified of estimated out-of-pocket costs prior to ordering.

(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)(2)(b)(i) and (ii) of this section apply.

(c) The in-house pharmacist, hospital, or inpatient facility and the in-house physicians or other licensed health care professionals 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.

(d) The outpatient physician with temporary privileges shall make a good faith effort to maintain ongoing consultation with the patient's care team during the duration that the privileges are in effect.

(e) In a case where there is a disagreement between the care team and the outpatient physician on the continued use of the off-label drug, then the decision to continue the use of the off-label drug prescribed by the outpatient physician shall be made by the patient, minor patient's parent/guardian, or person holding the patient's health care power of attorney after having a discussion with the outpatient physician and the hospital care team on the risks and benefits of continuing the off-label drug and giving informed consent.

(4) Nothing in this section prevents the pharmacist from discussing a prescription or expressing any dosage recommendations or other concerns with the prescriber who issued the prescription. The ultimate decision to accept an off-label drug prescribed by the prescriber shall be made by one of the following who has given informed consent: the patient, minor 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 the action of prescribing or dispensing an off-label drug, other than one described in division (G) of this section, by a prescriber, pharmacist, or other licensed health care professional 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, professional, hospital, or facility, except in cases where the prescribing or dispensing of the off-label drug was done with 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 neither infringe on medical free speech nor threaten to pursue, or 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 an opinion about off-label prescribing that does not align with the opinions of the board or agency, a board of health of a city or general health district, the department of health, or other health authority.

(E) The world health organization has no jurisdiction in this state. Therefore, no political subdivision, public official, or state agency shall enforce or use any state funding to implement or incentivize any health policy guideline, mandate, recommendation, or rule issued by the world health organization, including the prohibition of issuing a prescription for or dispensing of 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, minor 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.

(G) No person shall prescribe, dispense, or administer an off-label drug if the person knows, or has reasonable cause to

know, that the off-label drug is any of the following:

(1) A controlled substance that is not intended for a medical purpose;

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

(3) A cross-sex hormone or puberty-blocking drug, as defined in section 3129.01 of the Revised Code, to be used in violation of section 3129.02 of the Revised Code;

(4) A drug to be used for euthanasia.

(H) If any portion of this section is determined by a court to be illegal or unconstitutional, the section's remaining portions shall remain in effect.

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