

I\_135\_3007-1

135th General Assembly  
Regular Session  
2023-2024

Sub. H. B. No. 73

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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.

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**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:

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**Sec. 3792.06. (A) As used in this section:**

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

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(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.

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(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

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patient's prescribed drug is in the original manufacturer's 17  
packaging or is labeled from an outpatient retail pharmacy, has 18  
been approved by the prescriber for use, and is not outside of 19  
its beyond use date. 20

(4) "Informed consent" for this section means the 21  
communication between a patient, minor patient's 22  
parent/guardian, or person holding a health care power of 23  
attorney and a physician that results in the patient, minor 24  
patient's parent/guardian, or person holding a health care power 25  
of attorney authorizing, or agreeing to accept, a specific drug, 26  
treatment, or intervention. The physician, as part of such 27  
communication, shall provide all of the following information: 28  
the patient's diagnosis, if known; informed consent consistent 29  
with current law and practices for on-label usage and any other 30  
available information related to the risks and benefits of the 31  
drug, treatment, or intervention options pertaining to its off- 32  
label uses, including the option of forgoing treatment; and any 33  
financial conflicts of interest the physician may have regarding 34  
the recommended drug, treatment, or intervention. 35

(5) "Inpatient facility" means either or both of the 36  
following: 37

(a) A skilled nursing facility as defined in section 38  
5165.01 of the Revised Code; 39

(b) A freestanding inpatient rehabilitation facility 40  
licensed under section 3702.30 of the Revised Code. 41

(6) "Off-label drug" means a drug that meets both of the 42  
following: 43

(a) The drug is approved by the United States food and 44  
drug administration to treat or prevent a disease, illness, or 45

<u>infection, but prescribed for or used by a patient to treat or prevent another disease, illness, or infection.</u>	46
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(b) <u>The drug is legal for use in this state.</u>	48
(7) <u>"Pharmacist" means an individual who holds a license issued under section 4729.08 of the Revised Code authorizing the individual to practice pharmacy.</u>	49
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(8) <u>"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.</u>	52
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(9) <u>"Prescriber" has the same meaning as in section 4729.01 of the Revised Code.</u>	58
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(10) <u>"Public official" means any officer, employee, or duly authorized agent or representative of a state agency or political subdivision.</u>	60
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(11) <u>"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.</u>	63
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(12) <u>"Gross negligence" means intentional failure to perform an apparent duty in reckless disregard of the consequences concerning the life or property of another.</u>	68
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(B) <u>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</u>	71
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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

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patient's medical record that a good faith effort was made to 103  
find out if the off-label drug is available from another 104  
hospital or inpatient facility or another United States 105  
distributor. If the off-label drug is available, but the off- 106  
label drug is not authorized under insurance, or the patient 107  
does not want to wait for authorization, then the patient must 108  
be notified of estimated out-of-pocket costs and the off-label 109  
drug shall be offered to the patient at an upfront, out-of- 110  
pocket cost to the patient. The hospital or inpatient facility 111  
may require payment prior to ordering the off-label drug. 112

(b) If the hospital or inpatient facility pharmacist is 113  
unable to obtain the off-label drug from another hospital, 114  
inpatient facility, or distributor or if the hospital, hospital 115  
pharmacist, inpatient facility, or pharmacist declines to fill 116  
the prescription for the reasons provided in section 4743.10 of 117  
the Revised Code, and the patient has access to the off-label 118  
drug through a pharmacy outside the hospital or inpatient 119  
facility or has the off-label drug available at home, then both 120  
of the following apply: 121

(i) The hospital or inpatient facility must permit that 122  
off-label drug to be brought into the hospital or inpatient 123  
facility to be identified for the patient's use. If it is able 124  
to be identified according to the hospital or inpatient facility 125  
drug identification procedure, the off-label drug will be 126  
administered to the patient within the hospital or inpatient 127  
facility. 128

(ii) When the hospital or inpatient facility or the 129  
patient's in-house treating prescriber or other in-house 130  
treating clinician is unwilling to administer the identified 131  
off-label drug to the patient for reasons provided in section 132

4743.10 of the Revised Code, then another prescriber or prescriber's delegate may administer the off-label drug. 133  
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(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. 135  
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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. 151  
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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 157  
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is in a condition where the patient can be safely transported to 163  
a hospital or inpatient facility that is willing to provide that 164  
off-label drug, or discharge home, or within the maximum number 165  
of days temporary privileges are allowed within the hospital's 166  
bylaws, whichever comes first. In such a case, all of the 167  
following apply: 168

(a) If the off-label drug is not covered by insurance, or 169  
the patient does not want to wait for authorization, then the 170  
patient shall be offered the option to pay out-of-pocket, 171  
upfront for the prescribed off-label drug before it is ordered. 172  
The patient must be notified of estimated out-of-pocket costs 173  
prior to ordering. 174

(b) If the hospital or inpatient facility cannot obtain 175  
the off-label drug being prescribed by the outpatient physician 176  
prescriber, then the requirements of divisions (C) (2) (b) (i) and 177  
(ii) of this section apply. 178

(c) The in-house pharmacist, hospital, or inpatient 179  
facility and the in-house physicians or other licensed health 180  
care professionals responsible for the patient's care shall be 181  
immune from administrative and civil liability for any harm that 182  
may arise from the patient's use of the off-label drug 183  
prescribed by the outpatient physician prescriber starting from 184  
the date of dispensing. 185

(d) The outpatient physician with temporary privileges 186  
shall make a good faith effort to maintain ongoing consultation 187  
with the patient's care team during the duration that the 188  
privileges are in effect. 189

(e) In a case where there is a disagreement between the 190  
care team and the outpatient physician on the continued use of 191

the off-label drug, then the decision to continue the use of the 192  
off-label drug prescribed by the outpatient physician shall be 193  
made by the patient, minor patient's parent/guardian, or person 194  
holding the patient's health care power of attorney after having 195  
a discussion with the outpatient physician and the hospital care 196  
team on the risks and benefits of continuing the off-label drug 197  
and giving informed consent. 198

(4) Nothing in this section prevents the pharmacist from 199  
discussing a prescription or expressing any dosage 200  
recommendations or other concerns with the prescriber who issued 201  
the prescription. The ultimate decision to accept an off-label 202  
drug prescribed by the prescriber shall be made by one of the 203  
following who has given informed consent: the patient, minor 204  
patient's parent/guardian, or person holding the patient's 205  
health care power of attorney. 206

(D) A health-related licensing board, department of 207  
health, state board of pharmacy, or other state board or agency 208  
responsible for the licensure or regulation of health care 209  
professionals shall not consider the action of prescribing or 210  
dispensing an off-label drug, other than one described in 211  
division (G) of this section, by a prescriber, pharmacist, or 212  
other licensed health care professional or hospital or inpatient 213  
facility under this section to be unlawful, unethical, 214  
unauthorized, or unprofessional conduct and shall not pursue an 215  
administrative or disciplinary action against the prescriber, 216  
pharmacist, professional, hospital, or facility, except in cases 217  
where the prescribing or dispensing of the off-label drug was 218  
done with recklessness or gross negligence. 219

A health-related licensing board, department of health, 220  
state board of pharmacy, or other state board or agency 221

responsible for the licensure or regulation of health care 222  
professionals shall neither infringe on medical free speech nor 223  
threaten to pursue, or pursue, an administrative or disciplinary 224  
action against a prescriber, pharmacist, or other licensed 225  
health care professional or hospital or inpatient facility for 226  
publicly or privately expressing an opinion about off-label 227  
prescribing that does not align with the opinions of the board 228  
or agency, a board of health of a city or general health 229  
district, the department of health, or other health authority. 230

(E) The world health organization has no jurisdiction in 231  
this state. Therefore, no political subdivision, public 232  
official, or state agency shall enforce or use any state funding 233  
to implement or incentivize any health policy guideline, 234  
mandate, recommendation, or rule issued by the world health 235  
organization, including the prohibition of issuing a 236  
prescription for or dispensing of an off-label drug. 237

(F) At no time shall a patient in a hospital or inpatient 238  
facility be denied sufficient means of fluids or nutrition, 239  
unless that wish is clearly stated in the patient's end of life 240  
health directive, as that directive is defined by the patient, 241  
minor patient's parent/guardian, or person holding the patient's 242  
health care power of attorney, or the denial is necessary for a 243  
medical procedure, including a diagnostic or surgical procedure, 244  
and then only for the shortest amount of time medically possible 245  
and with the informed consent of the patient or person holding 246  
the patient's health care power of attorney. 247

(G) No person shall prescribe, dispense, or administer an 248  
off-label drug if the person knows, or has reasonable cause to 249  
know, that the off-label drug is any of the following: 250

(1) A controlled substance that is not intended for a 251

<u>medical purpose;</u>	252
(2) <u>A drug subject to a United States food and drug administration risk evaluation and mitigation strategy;</u>	253
(3) <u>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;</u>	255
(4) <u>A drug to be used for euthanasia.</u>	258
(H) <u>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.</u>	259
<b>Section 2.</b> This act shall be known as the Dave and Angie Patient and Health Provider Protection Act.	262
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