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135th General Assembly
Regular Session
2023-2024

Sub. H. B. No. 73

A BILL

To enact section 3792.06 of the Revised Code 1
regarding the prescribing and dispensing of off- 2
label drugs and to name this act the Dave and 3
Angie Patient and Health Provider Protection 4
Act. 5

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

Section 1. That section 3792.06 of the Revised Code be 6
enacted to read as follows: 7

Sec. 3792.06. (A) As used in this section: 8

(1) "Health-related licensing board" has the same meaning 9
as in section 3719.062 of the Revised Code. 10

(2) "Hospital" has the same meaning as in section 3722.01 11
of the Revised Code and includes a hospital owned or operated by 12
the United States department of veterans affairs. 13

(3) "Identified" means that a hospital or inpatient 14
facility pharmacist has determined that the drug in question is 15
the drug prescribed by the patient's prescriber and that the 16



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

infection, but prescribed for or used by a patient to treat or 46
prevent another disease, illness, or infection. 47

(b) The drug is legal for use in this state. 48

(7) "Pharmacist" means an individual who holds a license 49
issued under section 4729.08 of the Revised Code authorizing the 50
individual to practice pharmacy. 51

(8) "Political subdivision" means a county, township, 52
municipal corporation, school district, or other body corporate 53
and politic responsible for governmental activities in a 54
geographic area smaller than that of the state. "Political 55
subdivision" also includes a board of health of a city or 56
general health district. 57

(9) "Prescriber" has the same meaning as in section 58
4729.01 of the Revised Code. 59

(10) "Public official" means any officer, employee, or 60
duly authorized agent or representative of a state agency or 61
political subdivision. 62

(11) "State agency" means any organized agency, board, 63
body, commission, department, institution, office, or other 64
entity established by the laws of the state for the exercise of 65
any function of state government. "State agency" does not 66
include a court. 67

(12) "Gross negligence" means intentional failure to 68
perform an apparent duty in reckless disregard of the 69
consequences concerning the life or property of another. 70

(B) Except as provided in division (G) of this section, a 71
prescriber may issue for a human patient a prescription for an 72
off-label drug that is approved for human use if the prescriber 73

has obtained the informed consent of any of the following: the 74
patient, minor patient's parent/guardian, or person holding the 75
patient's health care power of attorney. 76

(C) (1) Except as provided in division (G) of this section, 77
during a public health emergency or period in which an order or 78
rule issued under division (C) of section 3701.13 of the Revised 79
Code or section 3701.14, 3709.20, or 3709.21 of the Revised Code 80
remains in effect, a pharmacist practicing in a hospital or 81
inpatient facility shall dispense, and the hospital or inpatient 82
facility shall allow the dispensing of, an off-label drug to a 83
patient if a prescriber has issued for the patient a 84
prescription for the off-label drug as described in division (B) 85
of this section, except if any of the following is the case: 86

(a) As provided in section 4743.10 of the Revised Code, 87
the pharmacist, hospital, or inpatient facility has a moral, 88
ethical, or religious belief or conviction that conflicts with 89
the off-label drug's dispensing. 90

(b) The pharmacist has documented that the patient has a 91
history of a life-threatening allergic reaction to the 92
prescribed off-label drug or there is a life-threatening 93
contraindication or life-threatening drug interaction. 94

(c) The pharmacist, hospital, or inpatient facility has an 95
objective, good faith, and scientific objection to the 96
administration or dosage of the off-label drug for that patient 97
or that patient's condition. 98

(2) (a) When an in-house treating prescriber issues for the 99
hospital or facility patient a prescription for an off-label 100
drug that is neither in stock nor listed on the hospital's or 101
facility's formulary, the pharmacist must document in the 102

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 133
prescriber's delegate may administer the off-label drug. 134

(3) When the patient's condition is so serious that the 135
patient cannot be safely transported out of the hospital and the 136
patient, minor patient's parent/guardian, or person holding the 137
patient's health care power of attorney wishes to try an off- 138
label drug to treat the patient's condition, but there is no in- 139
house prescriber willing to prescribe the off-label drug, then 140
the patient's outpatient Ohio-licensed physician prescriber, 141
after a prompt consultation with the patient's hospital care 142
team and a review of all of the patient's drugs, shall be 143
allowed to immediately begin applying for temporary privileges, 144
based on criteria within the hospital medical staff bylaws used 145
to determine the issuance of temporary privileges to treat that 146
patient only. Hospital bylaws for outpatient physicians seeking 147
temporary privileges under this section shall not be more 148
restrictive than those for other physicians seeking temporary 149
privileges. 150

Nothing in this section prevents the physician applicant 151
from withdrawing the physician's application during the 152
application process. Nothing in this section prevents the 153
hospital from revoking the outpatient physician's temporary 154
privileges if at any point the physician's license is found not 155
to be in good standing. 156

If the outpatient physician prescriber meets the 157
hospital's medical staff bylaw requirements for temporary 158
privileges, then he/she shall immediately be allowed to 159
participate in the patient's care in the narrowed scope of 160
practice regarding the administering and monitoring of the 161
prescribed off-label drug within the hospital until the patient 162

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
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.

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(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.

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(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.

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

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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

medical purpose; 252

(2) A drug subject to a United States food and drug 253
administration risk evaluation and mitigation strategy; 254

(3) A cross-sex hormone or puberty-blocking drug, as 255
defined in section 3129.01 of the Revised Code, to be used in 256
violation of section 3129.02 of the Revised Code; 257

(4) A drug to be used for euthanasia. 258

(H) If any portion of this section is determined by a 259
court to be illegal or unconstitutional, the section's remaining 260
portions shall remain in effect. 261

Section 2. This act shall be known as the Dave and Angie 262
Patient and Health Provider Protection Act. 263