I_135_0502-5

135th General Assembly Regular Session 2023-2024

Sub. H. B. No. 73

A BILL

То	enact section 3792.06 of the Revised Code to	1
	authorize the prescribing of off-label	2
	medications and if prescribed, to generally	3
	require their dispensing and to name this act	4
	the Dave and Angie Patient and Health Provider	5
	Protection Act.	6

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

Section 1. That section 3792.06 of the Revised Code be	7
enacted to read as follows:	8
Sec. 3792.06. (A) As used in this section:	9
(1) "Health-related licensing board" has the same meaning	10
as in section 3719.062 of the Revised Code.	11
(2) "Hospital" has the same meaning as in section 3722.01	12
of the Revised Code and includes a hospital owned or operated by	13
the United States department of veterans affairs.	14
(3) "Identified" means that a hospital or inpatient	15
facility pharmacist has determined that a patient's off-label	16



drug is in the original manufacturer's packaging or is labeled	17
from an outpatient retail pharmacy, has been approved by the	18
prescriber for use, and is not outside of its beyond use date.	19
(4) "Inpatient facility" means either or both of the	20
<pre>following:</pre>	21
(a) A skilled nursing facility as defined in section	22
5165.01 of the Revised Code;	23
(b) A freestanding inpatient rehabilitation facility	24
licensed under section 3702.30 of the Revised Code.	25
(5) "Off-label drug" means a drug that is both of the	26
<pre>following:</pre>	27
(a) Approved by the United States food and drug	28
administration to treat or prevent a disease, illness, or	29
infection, but prescribed for or used by a patient to treat or	30
prevent another disease, illness, or infection;	31
(b) Legal for use in this state.	32
(6) "Pharmacist" means an individual who holds a license	33
issued under section 4729.08 of the Revised Code authorizing the	34
individual to practice pharmacy.	35
(7) "Political subdivision" means a county, township,	36
municipal corporation, school district, or other body corporate	37
and politic responsible for governmental activities in a	38
geographic area smaller than that of the state. "Political	39
subdivision" also includes a board of health of a city or	4 C
general health district.	41
(8) "Prescriber" has the same meaning as in section	42
4729.01 of the Revised Code.	43

(9) "Public official" means any officer, employee, or duly	44
authorized agent or representative of a state agency or	45
political subdivision.	46
(10) "State agency" means any organized agency, board,	47
body, commission, department, institution, office, or other	48
entity established by the laws of the state for the exercise of	49
any function of state government. "State agency" does not	50
include a court.	51
(B) A prescriber may issue for a patient a prescription	52
for any drug, including an off-label drug, if the prescriber has	53
obtained the patient's informed consent or the consent of the	54
person holding the patient's health care power of attorney. All	55
of the following apply to the prescribing of an off-label drug	56
under this division:	57
(1) The prescriber is not required to obtain a test result	58
before issuing the prescription for the patient's use of the	59
drug at home or for other outpatient treatment.	60
(2) The patient is not required to have had a positive	61
screen for a particular disease, illness, or infection before	62
the prescriber issues the prescription.	63
(3) The patient is not required to have been exposed to a	64
disease, illness, or infection before the prescriber issues the	65
prescription for the patient's prophylactic use of the drug.	66
(C)(1) A pharmacist shall dispense, and a hospital or	67
inpatient facility shall allow the dispensing of, an off-label	68
drug to a patient if a prescriber has issued for the patient a	69
prescription for the drug as described in division (B) of this	70
section, except if either of the following is the case:	71
(a) As provided in section 4743.10 of the Revised Code,	72

the pharmacist, hospital, or inpatient facility has a moral,	73
ethical, or religious belief or conviction that conflicts with	74
the drug's dispensing.	75
(b) The pharmacist has documented that the patient has a	76
history of a life-threatening allergic reaction to the	77
prescribed off-label drug or there is a life-threatening	78
<pre>contraindication.</pre>	79
(2) When a pharmacist must dispense, or a hospital or	80
inpatient facility must allow the dispensing of, an off-label	81
drug for a patient pursuant to this section, but the pharmacist,	82
hospital, or inpatient facility has an objective, good faith,	83
and scientific objection to the administration or dosage of the	84
drug for that patient, the pharmacist, hospital, or inpatient	85
facility shall be immune from administrative or civil liability	86
for any harm that may arise from the dispensing or use of the	87
off-label drug starting from the date of dispensing, so long as	88
both of the following are done:	89
(a) At the time of dispensing, the pharmacist, hospital,	90
or inpatient facility documents in the patient's medical record	91
the objective, good faith, and scientific objection, by stating	92
with particularity the basis of that objection, which must be	93
based on an individualized assessment of the patient and the	94
off-label drug.	95
(b) The pharmacist submits to the board of pharmacy or the	96
hospital or inpatient facility submits to the department of	97
health the objective, good faith, and scientific objection by	98
stating with particularity the basis of that objection, which	99
must be based on an individualized assessment of the patient and	100
the off-label drug.	101

(3) (a) In the case of a pharmacist who practices within a	102
hospital's or inpatient facility's pharmacy and where an in-	103
house treating prescriber issues for a hospital or facility	104
patient a prescription for an off-label drug that is neither in	105
stock nor listed on the hospital's or facility's formulary, the	106
pharmacist must document in the patient's medical record that a	107
good faith effort was made to find out if the drug is available	108
from another hospital or inpatient facility or another	109
distributor. If available, the drug must be offered to the	110
patient at an upfront out-of-pocket cost to the patient. The	111
hospital or inpatient facility may require payment prior to	112
ordering the drug.	113
(b) If the hospital or inpatient facility pharmacist is	114
unable to obtain the off-label drug from another hospital,	115
inpatient facility, or distributor or if the hospital, hospital	116
pharmacist, inpatient facility, or pharmacist declines to fill	117
the prescription for the reasons provided in section 4743.10 of	118
the Revised Code, and the patient has access to the drug through	119
a pharmacy outside the hospital or inpatient facility or has the	120
drug available at home, then both of the following apply:	121
(i) The hospital or inpatient facility must permit that	122
drug to be brought into the hospital or inpatient facility to be	123
identified for the patient's use and administration within the	124
hospital or inpatient facility.	125
(ii) When the hospital or inpatient facility or the	126
patient's in-house treating prescriber or other in-house	127
treating clinician is unwilling to administer the drug to the	128
patient for reasons provided in section 4743.10 of the Revised	129
Code, then another prescriber or prescriber's delegate may	130
administer the drug.	131

(4) When a patient cannot be safely transported out of a	132
hospital or inpatient facility and the patient or person holding	133
the patient's health care power of attorney wishes to try an	134
off-label drug to treat the patient's condition, but there is no	135
in-house prescriber willing to prescribe the drug, then the	136
patient's outpatient physician prescriber, after a prompt	137
consultation with the patient's hospital or inpatient facility	138
care team and a review of all of the patient's drugs, shall be	139
allowed to immediately begin applying for temporary privileges	140
with oversight, based on criteria within the hospital or	141
inpatient facility medical staff bylaws. The temporary	142
privileges approval process is not to exceed five days. If the	143
outpatient physician prescriber does not meet the facility's	144
medical staff bylaw requirements, then the denial shall be	145
reported to the Ohio department of health. If the outpatient	146
physician prescriber meets the facility's medical staff bylaw	147
requirements, then he/she shall immediately be allowed to	148
participate in the patient's care in the narrowed scope of	149
practice regarding the administering and monitoring of the	150
prescribed off-label drug within the hospital or inpatient	151
facility until the patient is in a condition where the patient	152
can be safely transported to a hospital or inpatient facility	153
where the outpatient physician prescriber is credentialed. In	154
such a case, all of the following apply:	155
(a) The patient may be required to pay out-of-pocket for	156
the prescribed off-label drug before it is ordered.	157
(b) If the hospital or inpatient facility cannot obtain	158
the off-label drug being prescribed by the outpatient physician	159
prescriber, then the requirements of divisions (C)(3)(b)(i) and	160
(ii) apply.	161

(c) The in-house pharmacist, hospital, or inpatient	162
facility and the in-house physician responsible for the	163
patient's care shall be immune from administrative and civil	164
liability for any harm that may arise from the patient's use of	165
the off-label drug prescribed by the outpatient physician	166
prescriber starting from the date of dispensing.	167
(5) All of the following apply to the dispensing of an	168
off-label drug under division (C)(1) or (2) of this section:	169
(a) The pharmacist is not required to obtain a test result	170
before dispensing the drug for the patient's use at home or for	171
<pre>other outpatient treatment.</pre>	172
(b) The patient is not required to have had a positive	173
screen for a particular disease, illness, or infection before	174
the pharmacist dispenses the drug.	175
(c) The patient is not required to have been exposed to a	176
disease, illness, or infection before the pharmacist dispenses	177
the drug for prophylactic use.	178
(6) Nothing in this section prevents a pharmacist from	179
discussing a prescription with the prescriber who issued the	180
prescription.	181
(D) A health-related licensing board, department of	182
health, state board of pharmacy, or other state board or agency	183
responsible for the licensure or regulation of health care	184
professionals shall not consider any action taken by a	185
prescriber or pharmacist or hospital or inpatient facility under	186
this section to be unlawful, unethical, unauthorized, or	187
unprofessional conduct and shall not pursue an administrative or	188
disciplinary action against the prescriber, pharmacist,	189
hospital, or facility, except in cases of recklessness or gross	190

negligence.	191
A health-related licensing board, department of health,	192
state board of pharmacy, or other state board or agency	193
responsible for the licensure or regulation of health care	194
professionals shall not pursue an administrative or disciplinary	195
action against a prescriber, pharmacist, or other licensed	196
health care professional or hospital or inpatient facility for	197
publicly or privately expressing a medical opinion that does not	198
align with the opinions of the board or agency, a board of	199
health of a city or general health district, or the department	200
of health.	201
(E) A political subdivision, public official, or state	202
agency shall not enforce any rule or order issued by a federal	203
agency that prohibits issuing a prescription for or dispensing	204
an off-label drug.	205
(F) At no time shall a patient in a hospital or inpatient	206
facility be denied sufficient means of fluids or nutrition,	207
unless that wish is clearly stated in the patient's end of life	208
health directive, as that directive is defined by the patient or	209
patient's health care power of attorney, or the denial is	210
necessary for a medical procedure, including a diagnostic or	211
surgical procedure, and then only for the shortest amount of	212
time medically possible and with the informed consent of the	213
patient or person holding the patient's health care power of	214
attorney.	215
Section 2. This act shall be known as the Dave and Angie	216
Patient and Health Provider Protection Act.	217