

As Introduced

136th General Assembly

Regular Session

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S. B. No. 209

Senators Cutrona, Reynolds

Cosponsors: Senators Lang, Brenner, Roegner

To enact section 3792.08 of the Revised Code 1
regarding prescribing, dispensing, and 2
administering drugs and to name this act the 3
Jeff, Dave, and Angie Patient Right to Try Act. 4

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

Section 1. That section 3792.08 of the Revised Code be 5
enacted to read as follows: 6

Sec. 3792.08. (A) As used in this section: 7

(1) "Health-related licensing board" has the same meaning 8
as in section 3719.062 of the Revised Code. 9

(2) "Hospital" has the same meaning as in section 3722.01 10
of the Revised Code and includes a hospital owned or operated by 11
the United States department of veterans affairs. 12

(3) "In-house physician" means a physician who is employed 13
or contracted by the hospital or inpatient facility where a 14
patient is being treated, or who has hospital privileges at the 15
hospital where a patient is being treated. 16

(4) "Inpatient facility" means either or both of the 17
following: 18

<u>(a) A skilled nursing facility as defined in section</u>	19
<u>5165.01 of the Revised Code;</u>	20
<u>(b) A freestanding inpatient rehabilitation facility</u>	21
<u>licensed under section 3702.30 of the Revised Code.</u>	22
<u>(5) "Off-label use" means the use of a drug that meets</u>	23
<u>both of the following:</u>	24
<u>(a) The drug is approved by the United States food and</u>	25
<u>drug administration to treat or prevent a disease, illness, or</u>	26
<u>infection, but prescribed for or used by a patient to treat or</u>	27
<u>prevent another disease, illness, or infection.</u>	28
<u>(b) The drug is legal for use in this state.</u>	29
<u>(6) "Patient's personal representative" has the same</u>	30
<u>meaning as in section 3701.74 of the Revised Code.</u>	31
<u>(7) "Pharmacist" means an individual who holds a license</u>	32
<u>issued under section 4729.08 of the Revised Code authorizing the</u>	33
<u>individual to practice pharmacy.</u>	34
<u>(8) "Physician" means an individual licensed under Chapter</u>	35
<u>4731. of the Revised Code to practice medicine and surgery,</u>	36
<u>osteopathic medicine and surgery, or podiatric medicine and</u>	37
<u>surgery.</u>	38
<u>(9) "State agency" means any organized agency, board,</u>	39
<u>body, commission, department, institution, office, or other</u>	40
<u>entity established by the laws of the state for the exercise of</u>	41
<u>any function of state government. "State agency" does not</u>	42
<u>include a court.</u>	43
<u>(B) (1) A pharmacist shall dispense, and a hospital,</u>	44
<u>inpatient facility, outpatient health care facility, or pharmacy</u>	45
<u>shall allow the dispensing of a drug, including for off-label</u>	46

use, prescribed by a physician, to a patient except in either of
the following circumstances:

(a) As provided in section 4743.10 of the Revised Code,
the pharmacist, hospital, inpatient facility, outpatient health
care facility, or pharmacy 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 drug, there is a life-threatening contraindication or
life-threatening drug interaction for that patient, or the drug
has a high probability of causing serious disability or serious
injury to that patient.

(2) When neither exception in division (B) (1) (a) or (b) of
this section applies and a pharmacist must dispense, or a
hospital, inpatient facility, outpatient health care facility,
or pharmacy must allow the dispensing of, a drug, including for
off-label use, for a patient pursuant to this section, but the
pharmacist, hospital, inpatient facility, outpatient health care
facility, or pharmacy has an objective, good faith, and
scientific objection to the administration or dosage of the drug
for that patient or that patient's condition, then after
explaining and discussing the objection with the physician, if
it is still the clinical judgment of the physician to dispense
the drug, the pharmacist, hospital, inpatient facility,
outpatient health care facility, or pharmacy shall dispense the
drug and shall be immune from civil liability, professional
discipline, and sanctions or fines imposed by a regulatory
authority for any harm that may arise from the dispensing or
administration of the drug starting from the date of dispensing
if the pharmacist, hospital, inpatient facility, outpatient

health care facility, or pharmacy meets the following minimum 77
requirements: 78

(a) Documents in the patient's medical record that the 79
objective, good faith, and scientific objection was discussed 80
with the physician and notes the date of the discussion. The 81
objection is not required to be described in detail. 82

(b) Documents the objective, good faith, and scientific 83
objection within twenty-four hours of dispensing the drug. 84

(3) Nothing in this section prevents compliance with 85
federal laws or laws of this state governing the practice of 86
pharmacy and the dispensing or administration of drugs, but it 87
establishes that the final decision on whether a prescribed drug 88
is dispensed pursuant to division (B) (1) of this section shall 89
be made by the physician. 90

(4) In the case of a pharmacist who practices within a 91
hospital's or inpatient facility's pharmacy and where an in- 92
house physician issues a prescription for a drug, including for 93
off-label use, that is neither in stock nor listed on the 94
hospital's or facility's formulary, and the patient can obtain 95
the drug at an outpatient pharmacy, then the hospital or 96
inpatient facility must permit the drug to be brought into the 97
hospital or inpatient facility to be identified for the 98
patient's use. To be identified for the patient's use, the 99
hospital or inpatient facility must determine that the drug was 100
prescribed for the patient, is in the original manufacturer's 101
packaging or is labeled from an outpatient retail pharmacy for 102
the patient, has been approved by the physician for the 103
patient's use, and is not outside of its beyond-use or 104
expiration date. If the drug is able to be identified according 105
to the hospital or inpatient facility's drug identification 106

procedure, then the drug shall be administered to the patient in 107
the hospital or inpatient facility. 108

(5) When a hospital or inpatient facility patient or a 109
patient's personal representative wishes to try a drug to treat 110
a patient's condition, but there is no in-house physician 111
willing to prescribe the drug, the hospital or inpatient 112
facility shall not obstruct or intentionally delay the transfer 113
of that patient to another hospital, inpatient facility, or 114
hospice that is willing to accept and treat the patient, nor 115
shall the hospital or inpatient facility prevent the patient's 116
discharge if that is the wish of the patient or the patient's 117
personal representative. 118

(6) When there is a safety concern regarding a 119
prescription for a drug, including a drug for off-label use, a 120
pharmacist should discuss any prescription dosage 121
recommendations or other clinical concerns with the physician, 122
the patient, or the patient's personal representative. There 123
should be risk-benefit discussions between the physician, the 124
patient or the patient's personal representative, and other 125
inpatient and outpatient medical staff directly involved in the 126
patient's care. Outside of emergency situations, the ultimate 127
decision to take a drug, including a drug for off-label use, 128
prescribed by the physician should be made by the consenting 129
patient or the patient's personal representative. 130

(C) In an outpatient pharmacy setting, if a drug is not 131
covered by a patient's health benefit plan or the patient does 132
not want to wait for prior authorization, the physician or 133
pharmacist shall notify the patient of the option to pay for the 134
drug out of pocket. The physician or pharmacist must notify the 135
patient of the estimated out-of-pocket costs for the drug, and 136

the pharmacist must offer the drug at an upfront, out-of-pocket 137
cost to the patient. 138

(D) Except as provided in division (F) of this section, a 139
health-related licensing board, the department of health, or 140
another state agency responsible for the licensure or regulation 141
of health care professionals or health care facilities shall not 142
consider the action of prescribing, dispensing, or administering 143
a drug to a consenting patient or with the consent of the 144
patient's personal representative, including for off-label use, 145
by a physician, pharmacist, hospital, inpatient facility, 146
outpatient health care facility, or pharmacy under this section 147
to be unlawful, unethical, unauthorized, or unprofessional 148
conduct and shall not pursue professional discipline or fines or 149
other regulatory sanctions against the physician, pharmacist, 150
hospital, facility, or pharmacy except in cases where a court 151
has determined that the prescribing, dispensing, or 152
administering of the drug to that patient was done with 153
recklessness or gross negligence. This section does not provide 154
a physician immunity from civil liability. Except as provided in 155
division (B)(2) of this section, this section does not provide a 156
pharmacist, hospital, inpatient facility, outpatient health care 157
facility, or pharmacy immunity from civil liability. 158

(E) A health care professional should be free to engage 159
in scientific debate. A health-related licensing board, the 160
department of health, or other state agency responsible for the 161
licensure or regulation of health care professionals shall not 162
pursue or threaten to pursue professional discipline or fines or 163
other regulatory sanctions against a physician, pharmacist, or 164
other licensed health care professional for doing either of the 165
following: 166

(1) Publicly expressing an opinion regarding the safety, 167
risks, benefits, or efficacy of a drug approved or authorized by 168
the United States food and drug administration, including a drug 169
prescribed for off-label use, or other medical intervention 170
because that opinion does not align with the opinions of the 171
board, department, other state agency, a board of health of a 172
city or general health district, or other health authority. 173

(2) Informing a patient or a patient's personal 174
representative of safety concerns or risks that may be 175
associated with a drug, including a drug prescribed for off- 176
label use, or other medical intervention. 177

This division does not provide a health care professional 178
immunity from civil liability to a patient under the health care 179
professional's care in a private care setting. 180

(F) Except for division (E) of this section, no portion of 181
this section applies to, repeals, or supersedes existing law 182
regarding prescribing, dispensing, or administering any of the 183
following: 184

(1) Controlled substances, including opioids; 185

(2) Drugs subject to a United States food and drug 186
administration risk evaluation and mitigation strategy; 187

(3) Cross-sex hormones or puberty-blocking drugs, as 188
defined in section 3129.01 of the Revised Code, to be used in 189
violation of section 3129.02 of the Revised Code; 190

(4) Abortifacients when prescribed, dispensed, or 191
administered to patients who are believed to be pregnant; 192

(5) Drugs that are known to be used for the intent or 193
purpose of euthanasia. 194

Section 2. This act shall be known as the Jeff, Dave, and	195
Angie Patient Right to Try Act.	196