

As Introduced

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H. B. No. 12

Representatives Gross, Swearingen

Cosponsors: Representatives Barhorst, Fischer, Lorenz, Williams, Dean, Miller, K., Hall, T., Lear, King, Mullins, Creech, Ferguson, Click, Klopfenstein, Fowler Arthur, Pizzulli, Stephens, Mathews, T., Deeter, Demetriou, Newman, Teska, Ray, Miller, M., Claggett, Willis, Thomas, C., Schmidt, McClain, Thomas, D., Salvo, Workman, John, Richardson, Johnson, Holmes, Young, Mathews, A., Hiner

A BILL

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 prescriber" means a prescriber who is 13
employed or contracted by the hospital or inpatient facility 14

<u>where a patient is being treated.</u>	15
<u>(4) "Inpatient facility" means either or both of the</u>	16
<u>following:</u>	17
<u>(a) A skilled nursing facility as defined in section</u>	18
<u>5165.01 of the Revised Code;</u>	19
<u>(b) A freestanding inpatient rehabilitation facility</u>	20
<u>licensed under section 3702.30 of the Revised Code.</u>	21
<u>(5) "Off-label use" means the use of a drug that meets</u>	22
<u>both of the following:</u>	23
<u>(a) The drug is approved by the United States food and</u>	24
<u>drug administration to treat or prevent a disease, illness, or</u>	25
<u>infection, but prescribed for or used by a patient to treat or</u>	26
<u>prevent another disease, illness, or infection.</u>	27
<u>(b) The drug is legal for use in this state.</u>	28
<u>(6) "Patient's personal representative" has the same</u>	29
<u>meaning as in section 3701.74 of the Revised Code.</u>	30
<u>(7) "Pharmacist" means an individual who holds a license</u>	31
<u>issued under section 4729.08 of the Revised Code authorizing the</u>	32
<u>individual to practice pharmacy.</u>	33
<u>(8) "Prescriber" has the same meaning as in section</u>	34
<u>4729.01 of the Revised Code, except it does not include a</u>	35
<u>veterinarian licensed under Chapter 4741. of the Revised Code.</u>	36
<u>(9) "State agency" means any organized agency, board,</u>	37
<u>body, commission, department, institution, office, or other</u>	38
<u>entity established by the laws of the state for the exercise of</u>	39
<u>any function of state government. "State agency" does not</u>	40
<u>include a court.</u>	41

(B) Except as otherwise provided in Chapters 4715., 4723., 42
4725., and 4730. of the Revised Code and in compliance with 43
other state law regarding prescribing drugs, a prescriber may 44
issue for a patient a prescription for any drug, including for 45
off-label use, if the prescriber has obtained the informed 46
consent of the patient or the patient's personal representative. 47
Informed consent means communication between the patient or the 48
patient's personal representative and the prescriber that 49
results in the patient or the patient's personal representative 50
authorizing, or agreeing to accept, a specific drug. The 51
prescriber, as part of such communication, shall provide all of 52
the following information to the patient or the patient's 53
personal representative: 54

(1) The patient's diagnosis, if known; 55

(2) Information about the drug consistent with current law 56
and practices for on-label use; 57

(3) Any other available information related to the risks 58
and benefits of options pertaining to the drug's off-label uses, 59
including the option of forgoing treatment with the drug; 60

(4) Any known financial conflicts of interest the 61
prescriber may have regarding the recommended drug. 62

(C) (1) A pharmacist shall dispense, and a hospital, 63
inpatient facility, or pharmacy shall allow the dispensing of a 64
drug, including for off-label use, to a patient if a prescriber 65
has issued for the patient a prescription for the drug as 66
described in division (B) of this section, except in either of 67
the following circumstances: 68

(a) As provided in section 4743.10 of the Revised Code, 69
the pharmacist, hospital, inpatient facility, or pharmacy has a 70

moral, ethical, or religious belief or conviction that conflicts 71
with the drug's dispensing. 72

(b) The pharmacist has documented that the patient has a 73
history of a life-threatening allergic reaction to the 74
prescribed drug or there is a life-threatening contraindication 75
or life-threatening drug interaction for that patient. 76

(2) When neither exception in division (C) (1) (a) or (b) of 77
this section applies and a pharmacist must dispense, or a 78
hospital, inpatient facility, or pharmacy must allow the 79
dispensing of, a drug, including for off-label use, for a 80
patient pursuant to this section, but the pharmacist, hospital, 81
inpatient facility, or pharmacy has an objective, good faith, 82
and scientific objection to the administration or dosage of the 83
drug for that patient or that patient's condition, then after 84
explaining and discussing the objection with the prescriber, the 85
pharmacist, hospital, inpatient facility, or pharmacy shall be 86
immune from civil liability, professional discipline, and 87
sanctions or fines imposed by a regulatory authority for any 88
harm that may arise from the dispensing or use of the drug 89
starting from the date of dispensing if, as soon as practicable 90
and within twenty-four hours after dispensing, the pharmacist, 91
hospital, inpatient facility, or pharmacy documents in the 92
patient's medical record that the objection was explained and 93
discussed with the prescriber before dispensing. 94

(3) (a) In the case of a pharmacist who practices within a 95
hospital's or inpatient facility's pharmacy and where an in- 96
house prescriber issues a prescription for a drug, including for 97
off-label use, that is neither in stock nor listed on the 98
hospital's or facility's formulary, the pharmacist must document 99
in the patient's medical record that a good faith effort was 100

made to find out if the drug is available from another hospital 101
or inpatient facility or another distributor located in the 102
United States. 103

(b) If the hospital or inpatient facility pharmacist is 104
unable to obtain the drug from another hospital, inpatient 105
facility, or distributor, or if the hospital, inpatient 106
facility, or pharmacist declines to dispense the prescription 107
for the reasons provided in section 4743.10 of the Revised Code, 108
and the patient has access to the drug through a pharmacy 109
outside the hospital or inpatient facility or has the drug 110
available at home, then both of the following apply: 111

(i) The hospital or inpatient facility must permit the 112
drug to be brought into the hospital or inpatient facility to be 113
identified for the patient's use. To be identified for the 114
patient's use, the hospital or inpatient facility must determine 115
that the drug was prescribed for the patient, is in the original 116
manufacturer's packaging or is labeled from an outpatient retail 117
pharmacy for the patient, has been approved by the prescriber 118
for the patient's use, and is not outside of its beyond-use or 119
expiration date. If the drug is able to be identified according 120
to the hospital or inpatient facility's drug identification 121
procedure, then the drug shall be administered to the patient in 122
the hospital or inpatient facility. 123

(ii) If the patient's in-house prescriber is not available 124
to administer the identified drug, and the medical staff 125
employed or contracted by the hospital or inpatient facility who 126
are involved in the patient's care are, pursuant to section 127
4743.10 of the Revised Code, unwilling to administer the 128
identified drug to the patient, then the patient's prescriber 129
may designate a delegate pursuant to sections 4723.48, 4723.489, 130

4730.203, and 4731.053 of the Revised Code to administer the 131
drug. Such a delegate must meet the hospital or inpatient 132
facility's guidelines and accreditation standards for drug 133
administration. 134

(4) When the patient's in-house prescriber is absent from 135
the hospital or inpatient facility, the prescriber's orders for 136
a drug, including for off-label use, shall not be modified or 137
discontinued unless one of the following circumstances applies: 138

(a) The in-house prescriber is consulted and agrees to the 139
modification or discontinuation; 140

(b) The patient or the patient's personal representative 141
requests in writing to discontinue the drug or consents to the 142
modification; 143

(c) In an emergency when there is not time to contact the 144
in-house prescriber for consent or it is not possible to contact 145
the in-house prescriber, the hospital or inpatient facility 146
shall follow the hospital or inpatient facility's existing 147
protocol for patient care. 148

(5) When there is a disagreement between the patient's in- 149
house prescriber and other medical staff employed or contracted 150
by the hospital or inpatient facility who are involved in the 151
patient's care regarding whether to continue a drug, including 152
for off-label use, the decision to continue the use of the drug 153
shall be made by the patient or the patient's personal 154
representative after discussing the risks and benefits of 155
continuing the drug with the in-house prescriber and the other 156
medical staff involved in the patient's care and giving informed 157
consent. 158

(6) When a hospital or inpatient facility patient or a 159

patient's personal representative wishes to try a drug to treat 160
a patient's condition, but there is no in-house prescriber 161
willing to prescribe the drug, the hospital or inpatient 162
facility shall not obstruct or intentionally delay the transfer 163
of that patient to another hospital, inpatient facility, or 164
hospice that is willing to accept and treat the patient, nor 165
shall the hospital or inpatient facility prevent the patient's 166
discharge if that is the wish of the patient or the patient's 167
personal representative. 168

(7) Nothing in this section prevents a pharmacist from 169
discussing a prescription or expressing any dosage 170
recommendations or other concerns with the prescriber, the 171
patient, or the patient's personal representative. The ultimate 172
decision to accept a drug prescribed by the prescriber shall be 173
made by the patient or the patient's personal representative. 174

(D) (1) In an outpatient pharmacy setting, if a drug is not 175
covered by a patient's health benefit plan or the patient does 176
not want to wait for prior authorization, the prescriber or 177
pharmacist shall notify the patient of the option to pay for the 178
drug out of pocket. The prescriber or pharmacist must notify the 179
patient of the estimated out-of-pocket costs for the drug, and 180
the pharmacist must offer the drug at an upfront, out-of-pocket 181
cost to the patient. 182

(2) When a hospital or inpatient facility pharmacist has 183
located a drug pursuant to division (C) (3) (a) of this section, 184
but the drug is not covered by the patient's health benefit plan 185
or the patient does not want to wait for prior authorization, 186
the prescriber or pharmacist must notify the patient of the 187
estimated out-of-pocket costs for the drug, and the pharmacist 188
must offer the drug at an upfront, out-of-pocket cost to the 189

patient. The hospital or inpatient facility may require payment 190
before ordering the drug. 191

(E) Except as provided in division (G) of this section, a 192
health-related licensing board, the department of health, or 193
another state agency responsible for the licensure or regulation 194
of health care professionals or health care facilities shall not 195
consider the action of prescribing, dispensing, or administering 196
a drug to a consenting patient or with the informed consent of 197
the patient's personal representative, including for off-label 198
use, by a prescriber, pharmacist, hospital, inpatient facility, 199
or pharmacy under this section to be unlawful, unethical, 200
unauthorized, or unprofessional conduct and shall not pursue 201
professional discipline or fines or other regulatory sanctions 202
against the prescriber, pharmacist, hospital, facility, or 203
pharmacy except in cases where prescribing, dispensing, or 204
administering the drug to that patient was done with 205
recklessness or gross negligence. The prescriber is not immune 206
from civil liability if harm comes to the patient. 207

(F) Free speech is a protected right under the United 208
States and Ohio Constitutions. Health care professionals are not 209
exempt from constitutional protections. A health-related 210
licensing board, the department of health, or other state agency 211
responsible for the licensure or regulation of health care 212
professionals shall neither infringe on free speech nor pursue 213
or threaten to pursue professional discipline or fines or other 214
regulatory sanctions against a prescriber, pharmacist, or other 215
licensed health care professional for publicly or privately 216
expressing an opinion regarding the safety, risks, benefits, or 217
efficacy of a drug or other medical intervention because that 218
opinion does not align with the opinions of the board, 219
department, other state agency, a board of health of a city or 220

general health district, or other health authority. This 221
division does not limit liability for a medical act that causes 222
actual patient harm. 223

(G) Except for division (F) of this section, no portion of 224
this section applies to, repeals, or supersedes existing law 225
regarding prescribing, dispensing, or administering any of the 226
following: 227

(1) Controlled substances, including opioids; 228

(2) Drugs subject to a United States food and drug 229
administration risk evaluation and mitigation strategy; 230

(3) Cross-sex hormones or puberty-blocking drugs, as 231
defined in section 3129.01 of the Revised Code, to be used in 232
violation of section 3129.02 of the Revised Code; 233

(4) Abortifacients when prescribed, dispensed, or 234
administered to patients who are known to be pregnant; 235

(5) Drugs that are known to be used for the intent or 236
purpose of euthanasia. 237

Section 2. This act shall be known as the Jeff, Dave, and 238
Angie Patient Right to Try Act. 239