

As Reported by the House Health Committee

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Regular Session

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H. B. No. 601

Representative Ginter

A BILL

To amend sections 4723.52, 4729.45, 4729.553, 1
4730.56, and 4731.83 of the Revised Code 2
regarding administration of drugs for drug 3
addiction treatment. 4

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

Section 1. That sections 4723.52, 4729.45, 4729.553, 5
4730.56, and 4731.83 of the Revised Code be amended to read as 6
follows: 7

Sec. 4723.52. (A) As used in this section: 8

(1) "Community addiction services provider" has the same 9
meaning as in section 5119.01 of the Revised Code. 10

(2) "Medication-assisted treatment" has the same meaning 11
as in section 340.01 of the Revised Code. 12

(B) An advanced practice registered nurse shall comply 13
with section 3715.08 of the Revised Code and rules adopted under 14
section 4723.51 of the Revised Code when treating a patient for 15
addiction with medication-assisted treatment or proposing to 16
initiate such treatment. 17

(C) An advanced practice registered nurse who fails to 18

comply with this section shall treat not more than thirty 19
patients at any one time with medication-assisted treatment even 20
if the facility or location at which the treatment is provided 21
is either of the following: 22

(1) Exempted by divisions (B) (2) (a) (i) to ~~(d)~~ (iv) and 23
(vii) of section 4729.553 of the Revised Code from being 24
required to possess a category III terminal distributor of 25
dangerous drugs license with an office-based opioid treatment 26
classification; 27

(2) A community addiction services provider that provides 28
alcohol and drug addiction services that are certified by the 29
department of mental health and addiction services under section 30
5119.36 of the Revised Code. 31

Sec. 4729.45. (A) As used in this section, "physician" 32
means an individual authorized under Chapter 4731. of the 33
Revised Code to practice medicine and surgery or osteopathic 34
medicine and surgery. 35

(B) (1) Subject to division (C) of this section, a 36
pharmacist licensed under this chapter may administer by 37
injection any of the following drugs as long as the drug that is 38
to be administered has been prescribed by a physician and the 39
individual to whom the drug was prescribed has an ongoing 40
physician-patient relationship with the physician: 41

(a) ~~An opioid antagonist~~ A drug used for treatment of drug 42
addiction and administered in a long-acting or extended-release 43
form; 44

(b) An antipsychotic drug administered in a long-acting or 45
extended-release form; 46

(c) Hydroxyprogesterone caproate; 47

(d) Medroxyprogesterone acetate;	48
(e) Cobalamin.	49
(2) As part of engaging in the administration of drugs by injection pursuant to this section, a pharmacist may administer epinephrine or diphenhydramine, or both, to an individual in an emergency situation resulting from an adverse reaction to a drug administered by the pharmacist.	50 51 52 53 54
(C) To be authorized to administer drugs pursuant to this section, a pharmacist must do all of the following:	55 56
(1) Successfully complete a course in the administration of drugs that satisfies the requirements established by the state board of pharmacy in rules adopted under division (H) (1) (a) of this section;	57 58 59 60
(2) Receive and maintain certification to perform basic life-support procedures by successfully completing a basic life-support training course certified by the American red cross or American heart association;	61 62 63 64
(3) Practice in accordance with a protocol that meets the requirements of division (F) of this section.	65 66
(D) Each time a pharmacist administers a drug pursuant to this section, the pharmacist shall do all of the following:	67 68
(1) Obtain permission in accordance with the procedures specified in rules adopted under division (H) of this section and comply with the following requirements:	69 70 71
(a) Except as provided in division (D) (1) (c) of this section, for each drug administered by a pharmacist to an individual who is eighteen years of age or older, the pharmacist shall obtain permission from the individual.	72 73 74 75

(b) For each drug administered by a pharmacist to an individual who is under eighteen years of age, the pharmacist shall obtain permission from the individual's parent or other person having care or charge of the individual.

(c) For each drug administered by a pharmacist to an individual who lacks the capacity to make informed health care decisions, the pharmacist shall obtain permission from the person authorized to make such decisions on the individual's behalf.

(2) In the case of ~~an opioid antagonist~~ a drug described in division (B) (1) (a) of this section, obtain in accordance with division (E) of this section test results indicating that it is appropriate to administer the drug to the individual if either of the following is to be administered:

(a) The initial dose of the drug;

(b) Any subsequent dose, if the administration occurs more than thirty days after the previous dose of the drug was administered.

(3) Observe the individual to whom the drug is administered to determine whether the individual has an adverse reaction to the drug;

(4) Notify the physician who prescribed the drug that the drug has been administered to the individual.

(E) A pharmacist may obtain the test results described in division (D) (2) of this section in either of the following ways:

(1) From the physician;

(2) By ordering blood and urine tests for the individual to whom the ~~opioid antagonist~~ drug is to be administered.

If a pharmacist orders blood and urine tests, the 104
pharmacist shall evaluate the results of the tests to determine 105
whether they indicate that it is appropriate to administer the 106
~~opioid antagonist~~ drug. A pharmacist's authority to evaluate 107
test results under this division does not authorize the 108
pharmacist to make a diagnosis. 109

(F) All of the following apply with respect to the 110
protocol required by division (C) (3) of this section: 111

(1) The protocol must be established by a physician who 112
has a scope of practice that includes treatment of the condition 113
for which the individual has been prescribed the drug to be 114
administered. 115

(2) The protocol must satisfy the requirements established 116
in rules adopted under division (H) (1) (b) of this section. 117

(3) The protocol must do all of the following: 118

(a) Specify a definitive set of treatment guidelines; 119

(b) Specify the locations at which a pharmacist may engage 120
in the administration of drugs pursuant to this section; 121

(c) Include provisions for implementing the requirements 122
of division (D) of this section, including for purposes of 123
division (D) (3) of this section provisions specifying the length 124
of time and location at which a pharmacist must observe an 125
individual who receives a drug to determine whether the 126
individual has an adverse reaction to the drug; 127

(d) Specify procedures to be followed by a pharmacist when 128
administering epinephrine, diphenhydramine, or both, to an 129
individual who has an adverse reaction to a drug administered by 130
the pharmacist. 131

(G) A pharmacist shall not do either of the following:	132
(1) Engage in the administration of drugs pursuant to this section unless the requirements of division (C) of this section have been met;	133 134 135
(2) Delegate to any person the pharmacist's authority to engage in the administration of drugs pursuant to this section.	136 137
(H) (1) The state board of pharmacy shall adopt rules to implement this section. The rules shall be adopted in accordance with Chapter 119. of the Revised Code and include all of the following:	138 139 140 141
(a) Requirements for courses in administration of drugs;	142
(b) Requirements for protocols to be followed by pharmacists in administering drugs pursuant to this section;	143 144
(c) Procedures to be followed by a pharmacist in obtaining permission to administer a drug to an individual.	145 146
(2) The board shall consult with the state medical board before adopting rules regarding requirements for protocols under this section.	147 148 149
Sec. 4729.553. (A) As used in this section:	150
(1) <u>"Advanced practice registered nurse" has the same meaning as in section 4723.01 of the Revised Code.</u>	151 152
<u>(2) "Controlled substance" has the same meaning as in section 3719.01 of the Revised Code.</u>	153 154
(2) <u>(3) "Hospital" means a hospital registered with the department of health under section 3701.07 of the Revised Code.</u>	155 156
(3) <u>(4) "Office-based opioid treatment" means the treatment of opioid dependence or addiction using a controlled</u>	157 158

substance. 159

(5) "Physician" means an individual who is authorized 160
under Chapter 4731. of the Revised Code to practice medicine and 161
surgery or osteopathic medicine and surgery. 162

(6) "Physician assistant" means an individual who is 163
licensed under Chapter 4730. of the Revised Code. 164

(B) (1) Except as provided in division (B) (2) of this 165
section, no person shall knowingly operate a facility, clinic, 166
or other location where a prescriber provides office-based 167
opioid treatment to more than thirty patients or that meets any 168
other identifying criteria established in rules adopted under 169
division (G) of this section without holding a category III 170
terminal distributor of dangerous drugs license with an office- 171
based opioid treatment classification. 172

(2) (a) Division (B) (1) of this section does not apply to 173
any of the following: 174

~~(a)~~ (i) A hospital; 175

~~(b)~~ (ii) A facility for the treatment of opioid dependence 176
or addiction that is operated by a hospital; 177

~~(c)~~ (iii) A physician practice owned or controlled, in 178
whole or in part, by a hospital or by an entity that owns or 179
controls, in whole or in part, one or more hospitals; 180

~~(d)~~ (iv) A facility that conducts only clinical research 181
and uses controlled substances in studies approved by a 182
hospital-based institutional review board or an institutional 183
review board that is accredited by the association for the 184
accreditation of human research protection programs, inc.; 185

~~(e)~~ (v) A facility that holds a category III terminal 186

distributor of dangerous drugs license in accordance with 187
section 4729.54 of the Revised Code for the purpose of treating 188
drug dependence or addiction as part of an opioid treatment 189
program and is the subject of a current, valid certification 190
from the substance abuse and mental health services 191
administration of the United States department of health and 192
human services pursuant to 42 C.F.R. 8.11; 193

~~(f)~~ (vi) A program or facility that is licensed or 194
certified by the department of mental health and addiction 195
services under Chapter 5119. of the Revised Code; 196

(vii) A place in which patients are treated for opioid 197
dependence or addiction by direct administration by a physician, 198
physician assistant, or advanced practice registered nurse of 199
drugs that are used for addiction treatment and are not 200
dispensed to patients for self-administration. 201

(b) Patients who receive treatment for opioid drug 202
dependence or addiction by direct administration of a drug by a 203
physician, physician assistant, or advanced practice registered 204
nurse shall not be included in determining whether more than 205
thirty patients are being provided office-based opioid treatment 206
in a particular facility, clinic, or other location that is 207
subject to division (B)(1) of this section. 208

(C) To be eligible to receive a license as a category III 209
terminal distributor of dangerous drugs with an office-based 210
opioid treatment classification, an applicant shall submit 211
evidence satisfactory to the state board of pharmacy that the 212
applicant's office-based opioid treatment will be operated in 213
accordance with the requirements specified in division (D) of 214
this section and that the applicant meets any other applicable 215
requirements of this chapter. 216

If the board determines that an applicant meets all of the requirements, the board shall issue to the applicant a license as a category III terminal distributor of dangerous drugs with an office-based opioid treatment classification.

(D) The holder of a category III terminal distributor license with an office-based opioid treatment classification shall do all of the following:

(1) Be in control of a facility that is owned and operated solely by one or more physicians authorized under Chapter 4731. of the Revised Code to practice medicine and surgery or osteopathic medicine and surgery, unless the state board of pharmacy has exempted the holder from this requirement;

(2) Comply with the requirements for conducting office-based opioid treatment, as established by the state medical board in rules adopted under section 4731.056 of the Revised Code;

(3) Require any person with ownership of the facility to submit to a criminal records check in accordance with section 4776.02 of the Revised Code and send the results of the criminal records check directly to the state board of pharmacy for review and decision under section 4729.071 of the Revised Code;

(4) Require all employees of the facility to submit to a criminal records check in accordance with section 4776.02 of the Revised Code and ensure that no person is employed who has previously been convicted of, or pleaded guilty to, either of the following:

(a) A theft offense, described in division (K) (3) of section 2913.01 of the Revised Code, that would constitute a felony under the laws of this state, any other state, or the

United States;	246
(b) A felony drug offense, as defined in section 2925.01 of the Revised Code.	247 248
(5) Maintain a list of each person with ownership of the facility and notify the state board of pharmacy of any change to that list.	249 250 251
(E) No person subject to licensure as a category III terminal distributor of dangerous drugs with an office-based opioid treatment classification shall knowingly fail to remain in compliance with the requirements of division (D) of this section and any other applicable requirements of this chapter.	252 253 254 255 256
(F) The state board of pharmacy may impose a fine of not more than five thousand dollars on a person who violates division (B) or (E) of this section. A separate fine may be imposed for each day the violation continues. In imposing the fine, the board's actions shall be taken in accordance with Chapter 119. of the Revised Code.	257 258 259 260 261 262
(G) The state board of pharmacy shall adopt rules as it considers necessary to implement and administer this section. The rules shall be adopted in accordance with Chapter 119. of the Revised Code.	263 264 265 266
Sec. 4730.56. (A) As used in this section:	267
(1) "Community addiction services provider" has the same meaning as in section 5119.01 of the Revised Code.	268 269
(2) "Medication-assisted treatment" has the same meaning as in section 340.01 of the Revised Code.	270 271
(B) A physician assistant shall comply with section 3715.08 of the Revised Code and rules adopted under section	272 273

4730.55 of the Revised Code when treating a patient with 274
medication-assisted treatment or proposing to initiate such 275
treatment. 276

(C) A physician assistant who fails to comply with this 277
section shall treat not more than thirty patients at any one 278
time with medication-assisted treatment even if the facility or 279
location at which the treatment is provided is either of the 280
following: 281

(1) Exempted by divisions (B) (2) (a) (i) to ~~(d)~~ (iv) and 282
(vii) of section 4729.553 of the Revised Code from being 283
required to possess a category III terminal distributor of 284
dangerous drugs license with an office-based opioid treatment 285
classification; 286

(2) A community addiction services provider that provides 287
alcohol and drug addiction services that are certified by the 288
department of mental health and addiction services under section 289
5119.36 of the Revised Code. 290

Sec. 4731.83. (A) As used in this section: 291

(1) "Medication-assisted treatment" has the same meaning 292
as in section 340.01 of the Revised Code. 293

(2) "Physician" means an individual authorized by this 294
chapter to practice medicine and surgery or osteopathic medicine 295
and surgery. 296

(B) A physician shall comply with section 3715.08 of the 297
Revised Code and rules adopted under section 4731.056 of the 298
Revised Code when treating a patient with medication-assisted 299
treatment or proposing to initiate such treatment. 300

(C) A physician who fails to comply with this section 301

shall treat not more than thirty patients at any one time with 302
medication-assisted treatment even if the facility or location 303
at which the treatment is provided is either of the following: 304

(1) Exempted by divisions (B) (2) (a) (i) to ~~(d)~~ (iv) and 305
(vii) of section 4729.553 of the Revised Code from being 306
required to possess a category III terminal distributor of 307
dangerous drugs license with an office-based opioid treatment 308
classification; 309

(2) A community addiction services provider that provides 310
alcohol and drug addiction services that are certified by the 311
department of mental health and addiction services under section 312
5119.36 of the Revised Code. 313

Section 2. That existing sections 4723.52, 4729.45, 314
4729.553, 4730.56, and 4731.83 of the Revised Code are hereby 315
repealed. 316