

**As Introduced**

**133rd General Assembly**

**Regular Session**

**2019-2020**

**H. B. No. 341**

**Representative Ginter**

**Cosponsors: Representatives Seitz, Blair, Lightbody, Koehler**

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**A BILL**

To amend sections 4723.52, 4729.45, 4729.553, 1  
4730.56, and 4731.83 of the Revised Code 2  
regarding the administration of drugs for 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 3719.064 of the Revised Code and rules adopted 14  
under section 4723.51 of the Revised Code when treating a 15  
patient for addiction with medication-assisted treatment or 16  
proposing to 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) to (d) or (i) of 23  
section 4729.553 of the Revised Code from being required to 24  
possess a category III terminal distributor of dangerous drugs 25  
license with an office-based opioid treatment classification; 26

(2) A community addiction services provider that provides 27  
alcohol and drug addiction services that are certified by the 28  
department of mental health and addiction services under section 29  
5119.36 of the Revised Code. 30

**Sec. 4729.45.** (A) As used in this section, "physician" 31  
means an individual authorized under Chapter 4731. of the 32  
Revised Code to practice medicine and surgery or osteopathic 33  
medicine and surgery. 34

(B) (1) Subject to division (C) of this section, a 35  
pharmacist licensed under this chapter may administer by 36  
injection any of the following drugs as long as the drug that is 37  
to be administered has been prescribed by a physician and the 38  
individual to whom the drug was prescribed has an ongoing 39  
physician-patient relationship with the physician: 40

(a) ~~An opioid antagonist~~ A drug used for treatment of drug 41  
addiction and administered in a long-acting or extended-release 42  
form; 43

(b) An antipsychotic drug administered in a long-acting or 44  
extended-release form; 45

(c) Hydroxyprogesterone caproate; 46

(d) Medroxyprogesterone acetate;	47
(e) Cobalamin.	48
(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.	49 50 51 52 53
(C) To be authorized to administer drugs pursuant to this section, a pharmacist must do all of the following:	54 55
(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;	56 57 58 59
(2) Receive and maintain certification to perform basic life-support procedures by successfully completing a basic life-support training course that is certified by the American red cross or American heart association or approved by the state board of pharmacy;	60 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	72 73 74

shall obtain permission from the individual. 75

(b) For each drug administered by a pharmacist to an 76  
individual who is under eighteen years of age, the pharmacist 77  
shall obtain permission from the individual's parent or other 78  
person having care or charge of the individual. 79

(c) For each drug administered by a pharmacist to an 80  
individual who lacks the capacity to make informed health care 81  
decisions, the pharmacist shall obtain permission from the 82  
person authorized to make such decisions on the individual's 83  
behalf. 84

(2) In the case of ~~an opioid antagonist~~ a drug described 85  
in division (B) (1) (a) of this section, obtain in accordance with 86  
division (E) of this section test results indicating that it is 87  
appropriate to administer the drug to the individual if either 88  
of the following is to be administered: 89

(a) The initial dose of the drug; 90

(b) Any subsequent dose, if the administration occurs more 91  
than thirty days after the previous dose of the drug was 92  
administered. 93

(3) Observe the individual to whom the drug is 94  
administered to determine whether the individual has an adverse 95  
reaction to the drug; 96

(4) Notify the physician who prescribed the drug that the 97  
drug has been administered to the individual. 98

(E) A pharmacist may obtain the test results described in 99  
division (D) (2) of this section in either of the following ways: 100

(1) From the physician; 101

(2) By ordering blood and urine tests for the individual 102  
to whom the ~~opioid antagonist drug~~ is to be administered. 103

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 the pharmacist.	130 131
(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
<b>Sec. 4729.553.</b> (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)</u> "Controlled substance" has the same meaning as in section 3719.01 of the Revised Code.	153 154
<del>(2)</del> <u>(3)</u> "Hospital" means a hospital registered with the department of health under section 3701.07 of the Revised Code.	155 156

~~(3)~~ (4) "Office-based opioid treatment" means the treatment of opioid dependence or addiction using a controlled substance.

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

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

(B) (1) Except as provided in ~~division~~ divisions (B) (2) and (3) of this section, no person shall knowingly operate a facility, clinic, or other location where a prescriber provides office-based opioid treatment to more than thirty patients or that meets any other identifying criteria established in rules adopted under this section without holding a category III terminal distributor of dangerous drugs license with an office-based opioid treatment classification.

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

(a) A hospital;

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

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

(d) A facility that conducts only clinical research and uses controlled substances in studies approved by a hospital-based institutional review board or an institutional review board that is accredited by the association for the

accreditation of human research protection programs, inc.;	185
(e) A facility that holds a category III terminal distributor of dangerous drugs license in accordance with section 4729.54 of the Revised Code for the purpose of treating drug dependence or addiction as part of an opioid treatment program and is the subject of a current, valid certification from the substance abuse and mental health services administration of the United States department of health and human services pursuant to 42 C.F.R. 8.11;	186 187 188 189 190 191 192 193
(f) A program or facility that holds a license or certification issued by the department of mental health and addiction services under Chapter 5119. of the Revised Code if the license or certification is approved by the state board of pharmacy;	194 195 196 197 198
(g) A federally qualified health center or federally qualified health center look-alike, as defined in section 3701.047 of the Revised Code;	199 200 201
(h) A state or local correctional facility, as defined in section 5163.45 of the Revised Code;	202 203
(i) <u>A place in which patients are treated for opioid dependence or addiction through direct administration by a physician, physician assistant, or advanced practice registered nurse of drugs that are used for treatment of opioid dependence or addiction and are not dispensed to patients for self-administration;</u>	204 205 206 207 208 209
(j) <u>Any other facility specified in rules adopted under this section.</u>	210 211
(3) <u>A patient who receives treatment for opioid dependence or addiction through direct administration of a drug by a</u>	212 213

physician, physician assistant, or advanced practice registered 214  
nurse shall not be included in determining whether more than 215  
thirty patients are being provided office-based opioid treatment 216  
in a particular facility, clinic, or other location that is 217  
subject to division (B)(1) of this section. 218

(C) To be eligible to receive a license as a category III 219  
terminal distributor of dangerous drugs with an office-based 220  
opioid treatment classification, an applicant shall submit 221  
evidence satisfactory to the state board of pharmacy that the 222  
applicant's office-based opioid treatment will be operated in 223  
accordance with the requirements specified in division (D) of 224  
this section and that the applicant meets any other applicable 225  
requirements of this chapter. 226

If the board determines that an applicant meets all of the 227  
requirements, the board shall issue to the applicant a license 228  
as a category III terminal distributor of dangerous drugs with 229  
an office-based opioid treatment classification. 230

(D) The holder of a category III terminal distributor 231  
license with an office-based opioid treatment classification 232  
shall do all of the following: 233

(1) Be in control of a facility that is owned and operated 234  
solely by one or more physicians ~~authorized under Chapter 4731.~~ 235  
~~of the Revised Code to practice medicine and surgery or~~ 236  
~~osteopathic medicine and surgery,~~ unless the state board of 237  
pharmacy waives this requirement for the holder; 238

(2) Comply with the requirements for conducting office- 239  
based opioid treatment, as established by the state medical 240  
board in rules adopted under section 4731.056 of the Revised 241  
Code; 242

(3) Require any person with ownership of the facility to	243
submit to a criminal records check in accordance with section	244
4776.02 of the Revised Code and send the results of the criminal	245
records check directly to the state board of pharmacy for review	246
and decision under section 4729.071 of the Revised Code;	247
(4) Require each person employed by or seeking employment	248
with the facility to submit to a criminal records check in	249
accordance with section 4776.02 of the Revised Code;	250
(5) Ensure that a person is not employed by the facility	251
if the person, within the ten years immediately preceding the	252
date the person applied for employment, was convicted of or	253
pleaded guilty to either of the following, unless the state	254
board of pharmacy permits the person to be employed by waiving	255
this requirement for the facility:	256
(a) A theft offense, described in division (K) (3) of	257
section 2913.01 of the Revised Code, that would constitute a	258
felony under the laws of this state, any other state, or the	259
United States;	260
(b) A felony drug offense, as defined in section 2925.01	261
of the Revised Code.	262
(6) Maintain a list of each person with ownership of the	263
facility and notify the state board of pharmacy of any change to	264
that list.	265
(E) No person subject to licensure as a category III	266
terminal distributor of dangerous drugs with an office-based	267
opioid treatment classification shall knowingly fail to remain	268
in compliance with the requirements of division (D) of this	269
section and any other applicable requirements of this chapter.	270
(F) The state board of pharmacy may impose a fine of not	271

more than five thousand dollars on a person who violates 272  
division (B) or (E) of this section. A separate fine may be 273  
imposed for each day the violation continues. In imposing the 274  
fine, the board's actions shall be taken in accordance with 275  
Chapter 119. of the Revised Code. 276

(G) The state board of pharmacy shall adopt rules as it 277  
considers necessary to implement and administer this section. 278  
The rules shall be adopted in accordance with Chapter 119. of 279  
the Revised Code. 280

**Sec. 4730.56.** (A) As used in this section: 281

(1) "Community addiction services provider" has the same 282  
meaning as in section 5119.01 of the Revised Code. 283

(2) "Medication-assisted treatment" has the same meaning 284  
as in section 340.01 of the Revised Code. 285

(B) A physician assistant shall comply with section 286  
3719.064 of the Revised Code and rules adopted under section 287  
4730.55 of the Revised Code when treating a patient with 288  
medication-assisted treatment or proposing to initiate such 289  
treatment. 290

(C) A physician assistant who fails to comply with this 291  
section shall treat not more than thirty patients at any one 292  
time with medication-assisted treatment even if the facility or 293  
location at which the treatment is provided is either of the 294  
following: 295

(1) Exempted by divisions (B) (2) (a) to (d) or (i) of 296  
section 4729.553 of the Revised Code from being required to 297  
possess a category III terminal distributor of dangerous drugs 298  
license with an office-based opioid treatment classification; 299

(2) A community addiction services provider that provides 300  
alcohol and drug addiction services that are certified by the 301  
department of mental health and addiction services under section 302  
5119.36 of the Revised Code. 303

**Sec. 4731.83.** (A) As used in this section: 304

(1) "Medication-assisted treatment" has the same meaning 305  
as in section 340.01 of the Revised Code. 306

(2) "Physician" means an individual authorized by this 307  
chapter to practice medicine and surgery or osteopathic medicine 308  
and surgery. 309

(B) A physician shall comply with section 3719.064 of the 310  
Revised Code and rules adopted under section 4731.056 of the 311  
Revised Code when treating a patient with medication-assisted 312  
treatment or proposing to initiate such treatment. 313

(C) A physician who fails to comply with this section 314  
shall treat not more than thirty patients at any one time with 315  
medication-assisted treatment even if the facility or location 316  
at which the treatment is provided is either of the following: 317

(1) Exempted by divisions (B) (2) (a) to (d) or (i) of 318  
section 4729.553 of the Revised Code from being required to 319  
possess a category III terminal distributor of dangerous drugs 320  
license with an office-based opioid treatment classification; 321

(2) A community addiction services provider that provides 322  
alcohol and drug addiction services that are certified by the 323  
department of mental health and addiction services under section 324  
5119.36 of the Revised Code. 325

**Section 2.** That existing sections 4723.52, 4729.45, 326  
4729.553, 4730.56, and 4731.83 of the Revised Code are hereby 327

repealed. 328

**Section 3.** Section 4729.553 of the Revised Code is 329  
presented in this act as a composite of the section as amended 330  
by both Sub. H.B. 101 and Sub. S.B. 229 of the 132nd General 331  
Assembly. The General Assembly, applying the principle stated in 332  
division (B) of section 1.52 of the Revised Code that amendments 333  
are to be harmonized if reasonably capable of simultaneous 334  
operation, finds that the composite is the resulting version of 335  
the section in effect prior to the effective date of the section 336  
as presented in this act. 337