As Reported by the House Health Committee

133rd General Assembly

Regular Session 2019-2020

Sub. H. B. No. 341

Representative Ginter

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

A BILL

То	amend sections 4723.52, 4729.45, 4729.553,	1
	4729.80, 4730.56, and 4731.83 of the Revised	2
	Code regarding the administration of addiction	3
	treatment drugs and federal agency access to the	4
	Ohio Automated Rx Reporting System.	5

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

Section 1 . That sections 4723.52, 4729.45, 4729.553,	6
4729.80, 4730.56, and 4731.83 of the Revised Code be amended to	7
read as follows:	8
Sec. 4723.52. (A) As used in this section:	9
(1) "Community addiction services provider" has the same	10
meaning as in section 5119.01 of the Revised Code.	11
(2) "Medication-assisted treatment" has the same meaning	12
as in section 340.01 of the Revised Code.	13
(B) An advanced practice registered nurse shall comply	14
with section 3719.064 of the Revised Code and rules adopted	15
under section 4723.51 of the Revised Code when treating a	16
patient for addiction with medication-assisted treatment or	17

(a) Except as provided in division (D)(1)(c) of this

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division (D)(2) of this section in either of the following ways:	102
(1) From the physician;	103
(2) By ordering blood and urine tests for the individual	104
to whom the opioid antagonist drug is to be administered.	105
If a pharmacist orders blood and urine tests, the	106
pharmacist shall evaluate the results of the tests to determine	107
whether they indicate that it is appropriate to administer the	108
opioid antagonist drug. A pharmacist's authority to evaluate	109
test results under this division does not authorize the	110
pharmacist to make a diagnosis.	111
(F) All of the following apply with respect to the	112
protocol required by division (C)(3) of this section:	113
(1) The protocol must be established by a physician who	114
has a scope of practice that includes treatment of the condition	115
for which the individual has been prescribed the drug to be	116
administered.	117
(2) The protocol must satisfy the requirements established	118
in rules adopted under division (H)(1)(b) of this section.	119
(3) The protocol must do all of the following:	120
(a) Specify a definitive set of treatment guidelines;	121
(b) Specify the locations at which a pharmacist may engage	122
in the administration of drugs pursuant to this section;	123
(c) Include provisions for implementing the requirements	124
of division (D) of this section, including for purposes of	125
division (D)(3) of this section provisions specifying the length	126
of time and location at which a pharmacist must observe an	127
individual who receives a drug to determine whether the	128

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(d) A facility that conducts only clinical research and	183
uses controlled substances in studies approved by a hospital-	184
based institutional review board or an institutional review	185
board that is accredited by the association for the	186
accreditation of human research protection programs, inc.;	187
(e) A facility that holds a category III terminal	188
distributor of dangerous drugs license in accordance with	189
section 4729.54 of the Revised Code for the purpose of treating	190
drug dependence or addiction as part of an opioid treatment	191
program and is the subject of a current, valid certification	192
from the substance abuse and mental health services	193
administration of the United States department of health and	194
human services pursuant to 42 C.F.R. 8.11;	195
(f) A program or facility that holds a license or	196
certification issued by the department of mental health and	197
addiction services under Chapter 5119. of the Revised Code if	198
the license or certification is approved by the state board of	199
pharmacy;	200
(g) A federally qualified health center or federally	201
qualified health center look-alike, as defined in section	202
3701.047 of the Revised Code;	203
(h) A state or local correctional facility, as defined in	204
section 5163.45 of the Revised Code;	205
(i) A facility in which patients are treated on-site for	206
opioid dependence or addiction exclusively through direct	207
administration by a physician, physician assistant, or advanced	208
practice registered nurse of drugs that are used for treatment	209
of opioid dependence or addiction and are neither dispensed nor	210
personally furnished to patients for off-site self-	211

administration;	212
(j) Any other facility specified in rules adopted under	213
this section.	214
(3) A patient who receives treatment on-site for opioid	215
dependence or addiction through direct administration of a drug	216
by a physician, physician assistant, or advanced practice	217
registered nurse shall not be included in determining whether	218
more than thirty patients are being provided office-based opioid	219
treatment in a particular facility, clinic, or other location	220
that is subject to division (B)(1) of this section.	221
(C) To be eligible to receive a license as a category III	222
terminal distributor of dangerous drugs with an office-based	223
opioid treatment classification, an applicant shall submit	224
evidence satisfactory to the state board of pharmacy that the	225
applicant's office-based opioid treatment will be operated in	226
accordance with the requirements specified in division (D) of	227
this section and that the applicant meets any other applicable	228
requirements of this chapter.	229
If the board determines that an applicant meets all of the	230
requirements, the board shall issue to the applicant a license	231
as a category III terminal distributor of dangerous drugs with	232
an office-based opioid treatment classification.	233
(D) The holder of a category III terminal distributor	234
license with an office-based opioid treatment classification	235
shall do all of the following:	236
(1) Be in control of a facility that is owned and operated	237
solely by one or more physicians—authorized under Chapter 4731.	238
of the Revised Code to practice medicine and surgery or	239
osteopathic medicine and surgery, unless the state board of	240

pharmacy waives this requirement for the holder;	241
(2) Comply with the requirements for conducting office-	242
based opioid treatment, as established by the state medical	243
board in rules adopted under section 4731.056 of the Revised	244
Code;	245
(3) Require any person with ownership of the facility to	246
submit to a criminal records check in accordance with section	247
4776.02 of the Revised Code and send the results of the criminal	248
records check directly to the state board of pharmacy for review	249
and decision under section 4729.071 of the Revised Code;	250
(4) Require each person employed by or seeking employment	251
with the facility to submit to a criminal records check in	252
accordance with section 4776.02 of the Revised Code;	253
(5) Ensure that a person is not employed by the facility	254
if the person, within the ten years immediately preceding the	255
date the person applied for employment, was convicted of or	256
pleaded guilty to either of the following, unless the state	257
board of pharmacy permits the person to be employed by waiving	258
this requirement for the facility:	259
(a) A theft offense, described in division (K)(3) of	260
section 2913.01 of the Revised Code, that would constitute a	261
felony under the laws of this state, any other state, or the	262
United States;	263
(b) A felony drug offense, as defined in section 2925.01	264
of the Revised Code.	265
(6) Maintain a list of each person with ownership of the	266
facility and notify the state board of pharmacy of any change to	267
that list.	268

investigation.

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(E) No person subject to licensure as a category III	269
terminal distributor of dangerous drugs with an office-based	270
opioid treatment classification shall knowingly fail to remain	271
in compliance with the requirements of division (D) of this	272
section and any other applicable requirements of this chapter.	273
(F) The state board of pharmacy may impose a fine of not	274
more than five thousand dollars on a person who violates	275
division (B) or (E) of this section. A separate fine may be	276
imposed for each day the violation continues. In imposing the	277
fine, the board's actions shall be taken in accordance with	278
	279
Chapter 119. of the Revised Code.	
(G) The state board of pharmacy shall adopt rules as it	280
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(2) On receipt of a request from a federal officer, or a	298
state or local officer of this or any other state, whose duties	299
include enforcing laws relating to drugs, the board shall	300
provide to the officer information from the database relating to	301
the person who is the subject of an active investigation of a	302
drug abuse offense, as defined in section 2925.01 of the Revised	303
Code, being conducted by the officer's employing government	304
entity.	305
(3) Pursuant to a subpoena issued by a grand jury, the	306
board shall provide to the grand jury information from the	307
database relating to the person who is the subject of an	308
investigation being conducted by the grand jury.	309
(4) Pursuant to a subpoena, search warrant, or court order	310
in connection with the investigation or prosecution of a	311
possible or alleged criminal offense, the board shall provide	312
information from the database as necessary to comply with the	313
subpoena, search warrant, or court order.	314
(5) On receipt of a request from a prescriber or the	315
prescriber's delegate approved by the board, the board shall	316
provide to the prescriber a report of information from the	317
database relating to a patient who is either a current patient	318
of the prescriber or a potential patient of the prescriber based	319
on a referral of the patient to the prescriber, if all of the	320
following conditions are met:	321
(a) The prescriber certifies in a form specified by the	322

board that it is for the purpose of providing medical treatment

(b) The prescriber has not been denied access to the

to the patient who is the subject of the request;

database by the board.

- (6) On receipt of a request from a pharmacist or the 327 pharmacist's delegate approved by the board, the board shall 328 provide to the pharmacist information from the database relating 329 to a current patient of the pharmacist, if the pharmacist 330 certifies in a form specified by the board that it is for the 3.31 purpose of the pharmacist's practice of pharmacy involving the 332 patient who is the subject of the request and the pharmacist has 333 not been denied access to the database by the board. 334
- (7) On receipt of a request from an individual seeking the 335 individual's own database information in accordance with the 336 procedure established in rules adopted under section 4729.84 of 337 the Revised Code, the board may provide to the individual the 338 individual's own prescription history. 339
- (8) On receipt of a request from a medical director or a 340 pharmacy director of a managed care organization that has 341 entered into a contract with the department of medicaid under 342 section 5167.10 of the Revised Code and a data security 343 agreement with the board required by section 5167.14 of the 344 Revised Code, the board shall provide to the medical director or 345 the pharmacy director information from the database relating to 346 a medicaid recipient enrolled in the managed care organization, 347 including information in the database related to prescriptions 348 for the recipient that were not covered or reimbursed under a 349 program administered by the department of medicaid. 350
- (9) On receipt of a request from the medicaid director,

 the board shall provide to the director information from the

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 database relating to a recipient of a program administered by

 the department of medicaid, including information in the

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 database related to prescriptions for the recipient that were

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 not covered or paid by a program administered by the department.

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(10) On receipt of a request from a medical director of a	357
managed care organization that has entered into a contract with	358
the administrator of workers' compensation under division (B)(4)	359
of section 4121.44 of the Revised Code and a data security	360
agreement with the board required by section 4121.447 of the	361
Revised Code, the board shall provide to the medical director	362
information from the database relating to a claimant under	363
Chapter 4121., 4123., 4127., or 4131. of the Revised Code	364
assigned to the managed care organization, including information	365
in the database related to prescriptions for the claimant that	366
were not covered or reimbursed under Chapter 4121., 4123.,	367
4127., or 4131. of the Revised Code, if the administrator of	368
workers' compensation confirms, upon request from the board,	369
that the claimant is assigned to the managed care organization.	370

- (11) On receipt of a request from the administrator of 371 workers' compensation, the board shall provide to the 372 administrator information from the database relating to a 373 claimant under Chapter 4121., 4123., 4127., or 4131. of the 374 Revised Code, including information in the database related to 375 prescriptions for the claimant that were not covered or 376 reimbursed under Chapter 4121., 4123., 4127., or 4131. of the 377 Revised Code. 378
- (12) On receipt of a request from a prescriber or the 379 prescriber's delegate approved by the board, the board shall 380 provide to the prescriber information from the database relating 381 to a patient's mother, if the prescriber certifies in a form 382 specified by the board that it is for the purpose of providing 383 medical treatment to a newborn or infant patient diagnosed as 384 opioid dependent and the prescriber has not been denied access 385 to the database by the board. 386

(13) On receipt of a request from the director of health,	387
the board shall provide to the director information from the	388
database relating to the duties of the director or the	389
department of health in implementing the Ohio violent death	390
reporting system established under section 3701.93 of the	391
Revised Code.	392
(14) On receipt of a request from a requestor described in	393
division (A)(1), (2), (5), or (6) of this section who is from or	394
participating with another state's prescription monitoring	395
program, the board may provide to the requestor information from	396
the database, but only if there is a written agreement under	397
which the information is to be used and disseminated according	398
to the laws of this state.	399
(15) On receipt of a request from a delegate of a retail	400
dispensary licensed under Chapter 3796. of the Revised Code who	400
is approved by the board to serve as the dispensary's delegate,	402
the board shall provide to the delegate a report of information	403
from the database pertaining only to a patient's use of medical	404
marijuana, if both of the following conditions are met:	405
marijuana, ir both or the fortowing conditions are met.	100
(a) The delegate certifies in a form specified by the	406
board that it is for the purpose of dispensing medical marijuana	407
for use in accordance with Chapter 3796. of the Revised Code.	408
(b) The retail dispensary or delegate has not been denied	409
access to the database by the board.	410
(16) On receipt of a request from a judge of a program	411
certified by the Ohio supreme court as a specialized docket	412
program for drugs, the board shall provide to the judge, or an	412
employee of the program who is designated by the judge to	413
receive the information, information from the database that	415
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relates specifically to a current or prospective program	416
participant.	417
(17) On receipt of a request from a coroner, deputy	418
coroner, or coroner's delegate approved by the board, the board	419
shall provide to the requestor information from the database	420
relating to a deceased person about whom the coroner is	421
conducting or has conducted an autopsy or investigation.	422
(18) On receipt of a request from a prescriber, the board	423
may provide to the prescriber a summary of the prescriber's	424
prescribing record if such a record is created by the board.	425
Information in the summary is subject to the confidentiality	426
requirements of this chapter.	427
(19)(a) On receipt of a request from a pharmacy's	428
responsible person, the board may provide to the responsible	429
person a summary of the pharmacy's dispensing record if such a	430
record is created by the board. Information in the summary is	431
subject to the confidentiality requirements of this chapter.	432
(b) As used in division (A)(19)(a) of this section,	433
"responsible person" has the same meaning as in rules adopted by	434
the board under section 4729.26 of the Revised Code.	435
(20) The board may provide information from the database	436
without request to a prescriber or pharmacist who is authorized	437
to use the database pursuant to this chapter.	438
(21)(a) On receipt of a request from a prescriber or	439
pharmacist, or the prescriber's or pharmacist's delegate, who is	440
a designated representative of a peer review committee, the	441
board shall provide to the committee information from the	442
database relating to a prescriber who is subject to the	443
committee's evaluation, supervision, or discipline if the	444

enforcement outcomes.

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information is to be used for one of those purposes. The board	445
shall provide only information that it determines, in accordance	446
with rules adopted under section 4729.84 of the Revised Code, is	447
appropriate to be provided to the committee.	448
(b) As used in division (A)(21)(a) of this section, "peer	449
review committee" has the same meaning as in section 2305.25 of	450
the Revised Code, except that it includes only a peer review	451
committee of a hospital or a peer review committee of a	452
nonprofit health care corporation that is a member of the	453
hospital or of which the hospital is a member.	454
(22) On receipt of a request from a requestor described in	455
division (A)(5) or (6) of this section who is from or	456
participating with a prescription monitoring program that is	457
operated by a federal agency and approved by the board, the	458
board may provide to the requestor information from the	459
database, but only if there is a written agreement under which	460
the information is to be used and disseminated according to the	461
laws of this state.	462
(23) Any personal health information submitted to the	463
board pursuant to section 4729.772 of the Revised Code may be	464
provided by the board only as authorized by the submitter of the	465
information and in accordance with rules adopted under section	466
4729.84 of the Revised Code.	467
(B) The state board of pharmacy shall maintain a record of	468
each individual or entity that requests information from the	469
database pursuant to this section. In accordance with rules	470
adopted under section 4729.84 of the Revised Code, the board may	471
use the records to document and report statistics and law	472

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The board may provide records of an individual's requests 474 for database information only to the following: 475 (1) A designated representative of a government entity 476 that is responsible for the licensure, regulation, or discipline 477 of health care professionals with authority to prescribe, 478 administer, or dispense drugs who is involved in an active 479 criminal or disciplinary investigation being conducted by the 480 government entity of the individual who submitted the requests 481 for database information; 482 (2) A federal officer, or a state or local officer of this 483 or any other state, whose duties include enforcing laws relating 484 to drugs and who is involved in an active investigation being 485 conducted by the officer's employing government entity of the 486 individual who submitted the requests for database information; 487 (3) A designated representative of the department of 488 medicaid regarding a prescriber who is treating or has treated a 489 recipient of a program administered by the department and who 490 submitted the requests for database information. 491 (C) Information contained in the database and any 492 information obtained from it is confidential and is not a public 493 record. Information contained in the records of requests for 494 information from the database is confidential and is not a 495 public record. Information contained in the database that does 496 not identify a person, including any licensee or registrant of 497 the board or other entity, may be released in summary, 498 statistical, or aggregate form. 499 (D) A pharmacist or prescriber shall not be held liable in 500 damages to any person in any civil action for injury, death, or 501

loss to person or property on the basis that the pharmacist or

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(2) "Physician" means an individual authorized by this	531
chapter to practice medicine and surgery or osteopathic medicine	532
and surgery.	533
(B) A physician shall comply with section 3719.064 of the	534
Revised Code and rules adopted under section 4731.056 of the	535
Revised Code when treating a patient with medication-assisted	536
treatment or proposing to initiate such treatment.	537
(C) A physician who fails to comply with this section	538
shall treat not more than thirty patients at any one time with	539
medication-assisted treatment even if the facility or location	540
at which the treatment is provided is either of the following:	541
(1) Exempted by divisions (B)(2)(a) to (d) or (i) of	542
section 4729.553 of the Revised Code from being required to	543
possess a category III terminal distributor of dangerous drugs	544
license with an office-based opioid treatment classification;	545
(2) A community addiction services provider that provides	546
alcohol and drug addiction services that are certified by the	547
department of mental health and addiction services under section	548
5119.36 of the Revised Code.	549
Section 2. That existing sections 4723.52, 4729.45,	550
4729.553, 4729.80, 4730.56, and 4731.83 of the Revised Code are	551
hereby repealed.	552
Section 3. Section 4729.553 of the Revised Code is	553
presented in this act as a composite of the section as amended	554
by both Sub. H.B. 101 and Sub. S.B. 229 of the 132nd General	555
Assembly. The General Assembly, applying the principle stated in	556
division (B) of section 1.52 of the Revised Code that amendments	557
are to be harmonized if reasonably capable of simultaneous	558
operation, finds that the composite is the resulting version of	559

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the section in effect prior to the effective date of the section	560
as presented in this act.	561