### As Introduced

**131st General Assembly** 

**Regular Session** 

2015-2016

Representatives Sprague, Anielski Cosponsors: Representatives Blessing, Dever, Grossman, Hackett, Henne, Rezabek, Romanchuk, Thompson

# A BILL

To amend sections 1739.05, 4729.291, 4729.51,	1
4729.57, 4731.22, and 4731.227 and to enact	2
sections 1751.671, 3923.851, 4729.88, 4729.89,	3
and 4731.96 of the Revised Code to permit a	4
physician to treat a terminally ill patient with	5
a drug that is not approved by the United States	6
Food and Drug Administration and permit a drug	7
manufacturer to provide such a drug to the	8
patient or physician.	9

H. B. No. 290

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

Section 1. That sections 1739.05, 4729.291, 4729.51,	10
4729.57, 4731.22, and 4731.227 be amended and sections 1751.671,	11
3923.851, 4729.88, 4729.89, and 4731.96 of the Revised Code be	12
enacted to read as follows:	13
Sec. 1739.05. (A) A multiple employer welfare arrangement	14
that is created pursuant to sections 1739.01 to 1739.22 of the	15
Revised Code and that operates a group self-insurance program	16
may be established only if any of the following applies:	17
(1) The arrangement has and maintains a minimum enrollment	18

of three hundred employees of two or more employers.

(2) The arrangement has and maintains a minimum enrollment20of three hundred self-employed individuals.21

(3) The arrangement has and maintains a minimum enrollment
(2) of three hundred employees or self-employed individuals in any
(3) The arrangement has and maintains a minimum enrollment
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(2) of three hundred enrollment
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(3) The arrangement has and maintains a minimum enrollment
(4) (1) and (2) of this section.

25 (B) A multiple employer welfare arrangement that is created pursuant to sections 1739.01 to 1739.22 of the Revised 26 Code and that operates a group self-insurance program shall 27 comply with all laws applicable to self-funded programs in this 28 state, including sections 3901.04, 3901.041, 3901.19 to 3901.26, 29 3901.38, 3901.381 to 3901.3814, 3901.40, 3901.45, 3901.46, 30 3902.01 to 3902.14, 3923.24, 3923.282, 3923.30, 3923.301, 31 3923.38, 3923.581, 3923.63, 3923.80, 3923.85, <u>3923.851</u>, 32 3924.031, 3924.032, and 3924.27 of the Revised Code. 33

(C) A multiple employer welfare arrangement created
pursuant to sections 1739.01 to 1739.22 of the Revised Code
shall solicit enrollments only through agents or solicitors
licensed pursuant to Chapter 3905. of the Revised Code to sell
or solicit sickness and accident insurance.

(D) A multiple employer welfare arrangement created 39 pursuant to sections 1739.01 to 1739.22 of the Revised Code 40 shall provide benefits only to individuals who are members, 41 employees of members, or the dependents of members or employees, 42 or are eligible for continuation of coverage under section 43 1751.53 or 3923.38 of the Revised Code or under Title X of the 44 "Consolidated Omnibus Budget Reconciliation Act of 1985," 100 45 Stat. 227, 29 U.S.C.A. 1161, as amended. 46

Sec. 1751.671. (A) As used in this section:

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(1) "Investigational drug, product, or device" has the	48
same meaning as under section 4731.96 of the Revised Code.	49
(2) "Investigational drug, product, or device recipient"	50
	51
means an individual receiving an investigational drug, product,	
or device under sections 4729.88 and 4731.96 of the Revised	52
Code.	53
(B) An individual or group health policy, contract, or	54
agreement issued by a health insuring corporation may exclude	55
coverage in relation to an investigational drug, product, or	56
device according to both of the following:	57
(1) The policy, contract, or agreement may exclude	58
coverage for the cost of an investigational drug, product, or	59
device provided under sections 4729.88 and 4731.96 of the	60
Revised Code;	61
(2)(a) The policy, contract, or agreement may exclude	62
coverage for an investigational drug, product, or device	63
recipient beginning on the date that the investigational drug,	64
product, or device is first dispensed to the recipient.	65
(b) The exclusion prescribed in division (B)(2)(a) of this	66
section is subject to the following:	67
(i) The exclusion shall not last for a period of more than	68
six months.	69
(ii) The exclusion shall not include conditions that	70
existed prior to the start date of the exclusion.	71
(iii) The exclusion shall not include benefits that	72
commenced prior to the start date of the exclusion.	73
<u>(C) If an investigational drug, product, or device</u>	74
recipient dies while being treated with an investigational drug,	75

product, or device, the recipient's estate, devisees, and heirs	76
shall not be liable for any outstanding costs related to	77
treating the recipient or the recipient's lack of health	78
insurance coverage under division (B) of this section.	79
Sec. 3923.851. (A) As used in this section:	80
(1) "Investigational drug, product, or device" has the	81
same meaning as under section 4731.96 of the Revised Code.	82
(2) "Investigational drug, product, or device recipient"	83
means an individual receiving an investigational drug, product,	84
or device under sections 4729.88 and 4731.96 of the Revised	85
<u>Code.</u>	86
(B) An individual or group policy of sickness and accident	87
insurance that is delivered, issued for delivery, or renewed in	88
this state, or a public employee benefit plan that is	89
established or modified in this state, may exclude coverage in	90
relation to an investigational drug, product, or device	91
according to both of the following:	92
(1) The policy or plan may exclude coverage for the cost	93
of an investigational drug, product, or device provided under	94
sections 4729.88 and 4731.96 of the Revised Code;	95
(2)(a) The policy or plan may exclude coverage for an	96
investigational drug, product, or device recipient beginning on	97
the date that the investigational drug, product, or device is	98
first dispensed to the recipient.	99
(b) The exclusion prescribed in division (B)(2)(a) of this	100
section is subject to the following:	101
(i) The exclusion shall not last for a period of more than	102
six months.	103

(ii) The exclusion shall not include conditions that	104
existed prior to the start date of the exclusion.	105
(iii) The exclusion shall not include benefits that	106
commenced prior to the start date of the exclusion.	107
Some of the state date of the chordstone	107
(C) If an investigational drug, product, or device	108
recipient dies while being treated with an investigational drug,	109
product, or device, the recipient's estate, devisees, and heirs	110
shall not be liable for any outstanding costs related to	111
treating the recipient or to the recipient's lack of health	112
insurance coverage under division (B) of this section.	113
Sec. 4729.291. (A) When Except when provided under section	114
4731.96 of the Revised Code, when a licensed health professional	115
authorized to prescribe drugs personally furnishes drugs to a	116
patient pursuant to division (B) of section 4729.29 of the	117
Revised Code, the prescriber shall ensure that the drugs are	118
labeled and packaged in accordance with state and federal drug	119
laws and any rules and regulations adopted pursuant to those	120
laws. Records of purchase and disposition of all drugs	121
personally furnished to patients shall be maintained by the	122
prescriber in accordance with state and federal drug statutes	123
and any rules adopted pursuant to those statutes.	124
(B) When personally furnishing to a patient RU-486	125
(mifepristone), a prescriber is subject to section 2919.123 of	126
the Revised Code. A prescription for RU-486 (mifepristone) shall	127
be in writing and in accordance with section 2919.123 of the	128
Revised Code.	129
(C)(1) Except as provided in division (D) of this section,	130
no prescriber shall do either of the following:	131
(a) In any thirty-day pariod paraonally furnish to ar for	130

(a) In any thirty-day period, personally furnish to or for 132

patients, taken as a whole, controlled substances in an amount 133 that exceeds a total of two thousand five hundred dosage units; 134 (b) In any seventy-two-hour period, personally furnish to 135 or for a patient an amount of a controlled substance that 136 exceeds the amount necessary for the patient's use in a seventy-137 two-hour period. 138 (2) The state board of pharmacy may impose a fine of not 139 more than five thousand dollars on a prescriber who fails to 140 comply with the limits established under division (C)(1) of this 141 section. A separate fine may be imposed for each instance of 142 failing to comply with the limits. In imposing the fine, the 143 board's actions shall be taken in accordance with Chapter 119. 144 of the Revised Code. 145 (D)(1) None of the following shall be counted in 146 determining whether the amounts specified in division (C)(1) of 147 this section have been exceeded: 148 (a) Methadone provided to patients for the purpose of 149 treating drug dependence or addiction, if the prescriber meets 150 the conditions specified in 21 C.F.R. 1306.07; 151 (b) Buprenorphine provided to patients for the purpose of 152

(b) Suprenorphille provided to patients for the purpose of152treating drug dependence or addiction as part of an opioid153treatment program that is the subject of a current, valid154certification from the substance abuse and mental health155services administration of the United States department of156health and human services pursuant to 42 C.F.R. 8.11 and157distributes both buprenorphine and methadone;158

(c) Controlled substances provided to research subjects by
 a facility conducting clinical research in studies approved by a
 hospital-based institutional review board or an institutional
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review board accredited by the association for the accreditation 162 of human research protection programs. 163 (2) Division (C)(1) of this section does not apply to a 164 prescriber who is a veterinarian. 165 **Sec. 4729.51.** (A) (1) Except as provided in division (A) (2) 166 of this section, no person other than a registered wholesale 167 distributor of dangerous drugs shall possess for sale, sell, 168 distribute, or deliver, at wholesale, dangerous drugs, except as 169 follows: 170 (a) A pharmacist who is a licensed terminal distributor of 171 dangerous drugs or who is employed by a licensed terminal 172 distributor of dangerous drugs may make occasional sales of 173 dangerous drugs at wholesale; 174 (b) A licensed terminal distributor of dangerous drugs 175 having more than one establishment or place may transfer or 176 deliver dangerous drugs from one establishment or place for 177 which a license has been issued to the terminal distributor to 178 another establishment or place for which a license has been 179 issued to the terminal distributor if the license issued for 180 each establishment or place is in effect at the time of the 181 transfer or delivery. 182 183 (2) A manufacturer of dangerous drugs may donate epinephrine autoinjectors to any of the following: 184 (a) The board of education of a city, local, exempted 185 village, or joint vocational school district; 186 (b) A community school established under Chapter 3314. of 187 the Revised Code; 188 (c) A STEM school established under Chapter 3326. of the 189

Revised Code; 190 (d) A college-preparatory boarding school established 191 under Chapter 3328. of the Revised Code; 192 (e) A chartered or nonchartered nonpublic school. 193 (B) (1) No registered wholesale distributor of dangerous 194 drugs shall possess for sale, or sell, at wholesale, dangerous 195 drugs to any person other than the following: 196 (a) Except as provided in division (B)(2)(a) of this 197 section, a licensed health professional authorized to prescribe 198 drugs; 199 (b) An optometrist licensed under Chapter 4725. of the 200 Revised Code who holds a topical ocular pharmaceutical agents 201 certificate; 202 (c) A registered wholesale distributor of dangerous drugs; 203 (d) A manufacturer of dangerous drugs; 204 (e) Subject to division (B) (3) of this section, a licensed 205 terminal distributor of dangerous drugs; 206 (f) Carriers or warehouses for the purpose of carriage or 207 storage; 208 (g) Terminal or wholesale distributors of dangerous drugs 209 who are not engaged in the sale of dangerous drugs within this 210 state; 211 (h) An individual who holds a current license, 212 certificate, or registration issued under Title XLVII of the 213

Revised Code and has been certified to conduct diabetes214education by a national certifying body specified in rules215adopted by the state board of pharmacy under section 4729.68 of216

the Revised Code, but only with respect to insulin that will be217used for the purpose of diabetes education and only if diabetes218education is within the individual's scope of practice under219statutes and rules regulating the individual's profession;220

(i) An individual who holds a valid certificate issued by
a nationally recognized S.C.U.B.A. diving certifying
organization approved by the state board of pharmacy in rule,
but only with respect to medical oxygen that will be used for
the purpose of emergency care or treatment at the scene of a
diving emergency;

(j) Except as provided in division (B)(2)(b) of this 227 section, a business entity that is a corporation formed under 228 division (B) of section 1701.03 of the Revised Code, a limited 229 liability company formed under Chapter 1705. of the Revised 230 Code, or a professional association formed under Chapter 1785. 231 of the Revised Code if the entity has a sole shareholder who is 232 a licensed health professional authorized to prescribe drugs and 233 is authorized to provide the professional services being offered 234 235 by the entity;

(k) Except as provided in division (B)(2)(c) of this 236 section, a business entity that is a corporation formed under 237 division (B) of section 1701.03 of the Revised Code, a limited 238 liability company formed under Chapter 1705. of the Revised 239 Code, a partnership or a limited liability partnership formed 240 under Chapter 1775. of the Revised Code, or a professional 241 association formed under Chapter 1785. of the Revised Code, if, 242 to be a shareholder, member, or partner, an individual is 243 required to be licensed, certified, or otherwise legally 244 authorized under Title XLVII of the Revised Code to perform the 245 professional service provided by the entity and each such 246

Page 10

individual is a licensed health professional authorized to 247 prescribe drugs; 248 (1) With respect to epinephrine autoinjectors that may be 249 possessed under section 3313.7110, 3313.7111, 3314.143, 3326.28, 250 or 3328.29 of the Revised Code, any of the following: the board 251 of education of a city, local, exempted village, or joint 252 vocational school district; a chartered or nonchartered 253 nonpublic school; a community school established under Chapter 254 3314. of the Revised Code; a STEM school established under 255 Chapter 3326. of the Revised Code; or a college-preparatory 256 boarding school established under Chapter 3328. of the Revised 257 Code; 258 (m) With respect to epinephrine autoinjectors that may be 259 possessed under section 5101.76 of the Revised Code, any of the 260 following: a residential camp, as defined in section 2151.011 of 261 the Revised Code; a child day camp, as defined in section 262 5104.01 of the Revised Code; or a child day camp operated by any 263 county, township, municipal corporation, township park district 264 created under section 511.18 of the Revised Code, park district 265

created under section 1545.04 of the Revised Code, or joint 266 recreation district established under section 755.14 of the 267 Revised Code; 268

(n) With respect to naloxone that may be possessed under 269 section 2925.61 of the Revised Code, a law enforcement agency 270 and its peace officers. 271

(2) No registered wholesale distributor of dangerous drugs 272 shall possess for sale, or sell, at wholesale, dangerous drugs 273 to any of the following: 274

(a) A prescriber who is employed by a pain management

clinic that is not licensed as a terminal distributor of276dangerous drugs with a pain management clinic classification277issued under section 4729.552 of the Revised Code;278

(b) A business entity described in division (B) (1) (j) of 279
this section that is, or is operating, a pain management clinic 280
without a license as a terminal distributor of dangerous drugs 281
with a pain management clinic classification issued under 282
section 4729.552 of the Revised Code; 283

(c) A business entity described in division (B) (1) (k) of
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this section that is, or is operating, a pain management clinic
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without a license as a terminal distributor of dangerous drugs
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with a pain management clinic classification issued under
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section 4729.552 of the Revised Code.

(3) No registered wholesale distributor of dangerous drugs
(3) No registered wholesale distributor of dangerous drugs for sale at wholesale, or sell
(3) such drugs at wholesale, to a licensed terminal distributor of
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(a) In the case of a terminal distributor with a category 293
I license, only dangerous drugs described in category I, as 294
defined in division (A) (1) of section 4729.54 of the Revised 295
Code; 296

(b) In the case of a terminal distributor with a category 297
II license, only dangerous drugs described in category I and 298
category II, as defined in divisions (A) (1) and (2) of section 299
4729.54 of the Revised Code; 300

(c) In the case of a terminal distributor with a category
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III license, dangerous drugs described in category I, category
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II, and category III, as defined in divisions (A) (1), (2), and
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(3) of section 4729.54 of the Revised Code;
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(d) In the case of a terminal distributor with a limited 305 category I, II, or III license, only the dangerous drugs 306 specified in the certificate furnished by the terminal 307 distributor in accordance with section 4729.60 of the Revised 308 Code. 309

(C)(1) Except as provided in division (C)(4) of this 310 section, no person shall sell, at retail, dangerous drugs. 311

(2) Except as provided in division (C)(4) of this section, 312 no person shall possess for sale, at retail, dangerous drugs. 313

(3) Except as provided in division (C)(4) of this section, 314 315 no person shall possess dangerous drugs.

(4) Divisions (C)(1), (2), and (3) of this section do not 316 apply to a registered wholesale distributor of dangerous drugs, 317 a licensed terminal distributor of dangerous drugs, or a person 318 who possesses, or possesses for sale or sells, at retail, a 319 dangerous drug in accordance with Chapters 3719., 4715., 4723., 320 4725., 4729., 4730., 4731., and 4741. of the Revised Code. 321

Divisions (C)(1), (2), and (3) of this section do not 322 apply to an individual who holds a current license, certificate, 323 or registration issued under Title XLVII of the Revised Code and 324 has been certified to conduct diabetes education by a national 325 certifying body specified in rules adopted by the state board of 326 pharmacy under section 4729.68 of the Revised Code, but only to 327 the extent that the individual possesses insulin or personally 328 supplies insulin solely for the purpose of diabetes education 329 and only if diabetes education is within the individual's scope 330 of practice under statutes and rules regulating the individual's 331 profession. 332

Divisions (C)(1), (2), and (3) of this section do not

apply to an individual who holds a valid certificate issued by a334nationally recognized S.C.U.B.A. diving certifying organization335approved by the state board of pharmacy in rule, but only to the336extent that the individual possesses medical oxygen or337personally supplies medical oxygen for the purpose of emergency338care or treatment at the scene of a diving emergency.339

Division (C)(3) of this section does not apply to the 340 board of education of a city, local, exempted village, or joint 341 vocational school district, a school building operated by a 342 school district board of education, a chartered or nonchartered 343 nonpublic school, a community school, a STEM school, or a 344 college-preparatory boarding school for the purpose of 345 possessing epinephrine autoinjectors under section 3313.7110, 346 3313.7111, 3314.143, 3326.28, or 3328.29 of the Revised Code. 347

Division (C) (3) of this section does not apply to a 348 residential camp, as defined in section 2151.011 of the Revised 349 Code, a child day camp, as defined in section 5104.01 of the 350 Revised Code, or a child day camp operated by any county, 351 township, municipal corporation, township park district created 352 under section 511.18 of the Revised Code, park district created 353 under section 1545.04 of the Revised Code, or joint recreation 354 district established under section 755.14 of the Revised Code 355 for the purpose of possessing epinephrine autoinjectors under 356 section 5101.76 of the Revised Code. 357

Division (C)(3) of this section does not apply to a law 358 enforcement agency or the agency's peace officers if the agency 359 or officers possess naloxone for administration to individuals 360 who are apparently experiencing opioid-related overdoses. 361

Divisions (C) (1), (2), and (3) of this section do not362apply to a manufacturer of dangerous drugs that provides an363

investigational drug, product, or device to an eligible patient	364
under section 4729.88 of the Revised Code or to the patient's	365
treating physician as defined in section 4731.96 of the Revised	366
Code.	367
(D) No licensed terminal distributor of dangerous drugs	368
shall purchase for the purpose of resale dangerous drugs from	369
any person other than a registered wholesale distributor of	370
dangerous drugs, except as follows:	371
(1) A licensed terminal distributor of dangerous drugs may	372
make occasional purchases of dangerous drugs for resale from a	373
pharmacist who is a licensed terminal distributor of dangerous	374
drugs or who is employed by a licensed terminal distributor of	375
dangerous drugs;	376
(2) A licensed terminal distributor of dangerous drugs	377
having more than one establishment or place may transfer or	378
receive dangerous drugs from one establishment or place for	379
which a license has been issued to the terminal distributor to	380
another establishment or place for which a license has been	381
issued to the terminal distributor if the license issued for	382
each establishment or place is in effect at the time of the	383
transfer or receipt.	384
(E) No licensed terminal distributor of dangerous drugs	385
shall engage in the sale or other distribution of dangerous	386
drugs at retail or maintain possession, custody, or control of	387
dangerous drugs for any purpose other than the distributor's	388
personal use or consumption, at any establishment or place other	389
than that or those described in the license issued by the state	390
board of pharmacy to such terminal distributor.	391

(F) Nothing in this section shall be construed to

interfere with the performance of official duties by any law 393
enforcement official authorized by municipal, county, state, or 394
federal law to collect samples of any drug, regardless of its 395
nature or in whose possession it may be. 396

(G) Notwithstanding anything to the contrary in this
section, the board of education of a city, local, exempted
village, or joint vocational school district may deliver
epinephrine autoinjectors to a school under its control for the
purpose of possessing epinephrine autoinjectors under section
3313.7110 of the Revised Code.

Sec. 4729.57. (A) The state board of pharmacy may suspend, 403 revoke, or refuse to grant or renew any license as a terminal 404 distributor of dangerous drugs, or may impose a monetary penalty 405 or forfeiture not to exceed in severity any fine designated 406 under the Revised Code for a similar offense or one thousand 407 dollars if the acts committed have not been classified as an 408 offense by the Revised Code, for any of the following causes: 409

(1) Making any false material statements in an applicationfor a license as a terminal distributor of dangerous drugs;411

(2) Violating any rule of the board;

(3) Violating any provision of this chapter;

(4) Violating Except as provided in section 4729.88 of the
Revised Code, violating any provision of the "Federal Food,
Drug, and Cosmetic Act," 52 Stat. 1040 (1938), 21 U.S.C.A. 301,
or Chapter 3715. of the Revised Code;

(5) Violating any provision of the federal drug abusecontrol laws or Chapter 2925. or 3719. of the Revised Code;419

(6) Falsely or fraudulently promoting to the public a 420

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dangerous drug, except that nothing in this division prohibits a421terminal distributor of dangerous drugs from furnishing422information concerning a dangerous drug to a health care423provider or another licensed terminal distributor;424

(7) Ceasing to satisfy the qualifications of a terminal
distributor of dangerous drugs set forth in section 4729.55 of
the Revised Code;

(8) Except as provided in division (B) of this section: 428

(a) Waiving the payment of all or any part of a deductible 429 or copayment that an individual, pursuant to a health insurance 430 or health care policy, contract, or plan that covers the 431 services provided by a terminal distributor of dangerous drugs, 432 would otherwise be required to pay for the services if the 433 waiver is used as an enticement to a patient or group of 434 patients to receive pharmacy services from that terminal 435 distributor; 436

(b) Advertising that the terminal distributor will waive
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the payment of all or any part of a deductible or copayment that
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an individual, pursuant to a health insurance or health care
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policy, contract, or plan that covers the pharmaceutical
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services, would otherwise be required to pay for the services.

(B) Sanctions shall not be imposed under division (A) (8)
of this section against any terminal distributor of dangerous
drugs that waives deductibles and copayments as follows:
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(1) In compliance with a health benefit plan that
expressly allows such a practice. Waiver of the deductibles or
copayments shall be made only with the full knowledge and
consent of the plan purchaser, payer, and third-party
administrator. Documentation of the consent shall be made
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available to the board on request.

(2) For professional services rendered to any other person
licensed pursuant to this chapter to the extent allowed by this
chapter and the rules of the board.
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(C) (1) Upon the suspension or revocation of a license
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issued to a terminal distributor of dangerous drugs or the
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refusal by the board to renew such a license, the distributor
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shall immediately surrender the license to the board.
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(2) The board may place under seal all dangerous drugs 458 that are owned by or in the possession, custody, or control of a 459 460 terminal distributor at the time the license is suspended or revoked or at the time the board refuses to renew the license. 461 Except as otherwise provided in this division, dangerous drugs 462 so sealed shall not be disposed of until appeal rights under 463 Chapter 119. of the Revised Code have expired or an appeal filed 464 pursuant to that chapter has been determined. 465

The court involved in an appeal filed pursuant to Chapter 466 119. of the Revised Code may order the board, during the 467 pendency of the appeal, to sell sealed dangerous drugs that are 468 perishable. The proceeds of such a sale shall be deposited with 469 that court. 470

Sec. 4729.88. (A) As used in this section and section4714729.89 of the Revised Code, "eligible patient,"472"investigational drug, product, or device," "terminal illness,"473and "treating physician" have the same meanings as in section4744731.96 of the Revised Code.475

(B) A manufacturer of dangerous drugs may, in accordance476with section 4731.96 of the Revised Code, provide an477investigational drug, product, or device for treatment of a478

terminal illness to an eligible patient or to the treating	479
physician treating the eligible patient's terminal illness.	480
The manufacturer may do all of the following:	481
(1) Provide the investigational drug, product, or device	482
to the patient or treating physician directly or through a	483
terminal distributor of dangerous drugs;	484
(2) Provide the investigational drug, product, or device	485
without charge or charge for the costs associated with	486
manufacturing and providing the investigational drug, product,	487
<u>or device;</u>	488
(3) Require the eligible patient to participate in data	489
collection relating to use of the investigational drug, product,	490
<u>or device.</u>	491
(C) Except for actions or omissions constituting willful	492
or wanton misconduct:	493
(1) A manufacturer or terminal distributor of dangerous	494
drugs that provides or distributes an investigational drug,	495
product, or device pursuant to this section and section 4731.96	496
of the Revised Code is not liable for or subject to damages in	497
any civil action or prosecution in any criminal proceeding for	498
actions or omissions related to providing or distributing the	499
investigational drug, product, or device.	500
(2) A terminal distributor of dangerous drugs that	501
distributes an investigational drug, product, or device pursuant	502
to this section and section 4731.96 of the Revised Code is not	503
subject to any action related to its license under Chapter 4729.	504
of the Revised Code for actions or omissions related to	505
distributing the investigationalinvestgational drug, product, or	506
device.	507

(D) Nothing in this section shall be interpreted as	508
requiring a manufacturer or terminal distributor to provide an	509
investigational drug, product, or device to a patient or the	510
patient's treating physician.	511
Sec. 4729.89. No official, employee, or agent of the state	512
shall prevent or attempt to prevent access by an eligible	513
patient or eligible patient's treating physician to an	514
investigational drug, product, or device that is being provided	515
or is to be provided in accordance with section 4729.88 or	516
4731.96 of the Revised Code.	517
Sec. 4731.22. (A) The state medical board, by an	518
affirmative vote of not fewer than six of its members, may	519
limit, revoke, or suspend an individual's certificate to	520
practice, refuse to grant a certificate to an individual, refuse	521
to register an individual, refuse to reinstate a certificate, or	522
reprimand or place on probation the holder of a certificate if	523
the individual or certificate holder is found by the board to	524
have committed fraud during the administration of the	525
examination for a certificate to practice or to have committed	526
fraud, misrepresentation, or deception in applying for or	527
securing any certificate to practice or certificate of	528
registration issued by the board.	529
(B) The board, by an affirmative vote of not fewer than	530
six members, shall, to the extent permitted by law, limit,	531

six members, shall, to the extent permitted by law, limit, 531 revoke, or suspend an individual's certificate to practice, 532 refuse to register an individual, refuse to reinstate a 533 certificate, or reprimand or place on probation the holder of a 534 certificate for one or more of the following reasons: 535

(1) Permitting one's name or one's certificate to practiceor certificate of registration to be used by a person, group, or537

corporation when the individual concerned is not actually 538 directing the treatment given; 539 (2) Failure to maintain minimal standards applicable to 540 the selection or administration of drugs, or failure to employ 541 acceptable scientific methods in the selection of drugs or other 542 modalities for treatment of disease: 543 (3) - Selling Except as provided in section 4731.96 of the 544 <u>Revised Code, selling</u>, giving away, personally furnishing, 545 prescribing, or administering drugs for other than legal and 546 legitimate therapeutic purposes or a plea of quilty to, a 547 judicial finding of guilt of, or a judicial finding of 548 eligibility for intervention in lieu of conviction of, a 549 violation of any federal or state law regulating the possession, 550 distribution, or use of any drug; 551 (4) Willfully betraying a professional confidence. 552 For purposes of this division, "willfully betraying a 553

professional confidence" does not include providing any 554 information, documents, or reports to a child fatality review 555 board under sections 307.621 to 307.629 of the Revised Code and 556 does not include the making of a report of an employee's use of 557 a drug of abuse, or a report of a condition of an employee other 558 than one involving the use of a drug of abuse, to the employer 559 of the employee as described in division (B) of section 2305.33 560 of the Revised Code. Nothing in this division affects the 561 immunity from civil liability conferred by that section upon a 562 physician who makes either type of report in accordance with 563 division (B) of that section. As used in this division, 564 "employee," "employer," and "physician" have the same meanings 565 as in section 2305.33 of the Revised Code. 566

(5) Making a false, fraudulent, deceptive, or misleading
statement in the solicitation of or advertising for patients; in
relation to the practice of medicine and surgery, osteopathic
medicine and surgery, podiatric medicine and surgery, or a
limited branch of medicine; or in securing or attempting to
secure any certificate to practice or certificate of
registration issued by the board.

As used in this division, "false, fraudulent, deceptive, 574 or misleading statement" means a statement that includes a 575 misrepresentation of fact, is likely to mislead or deceive 576 because of a failure to disclose material facts, is intended or 577 is likely to create false or unjustified expectations of 578 favorable results, or includes representations or implications 579 that in reasonable probability will cause an ordinarily prudent 580 person to misunderstand or be deceived. 581

(6) A departure from, or the failure to conform to,
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minimal standards of care of similar practitioners under the
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same or similar circumstances, whether or not actual injury to a
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patient is established;
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(7) Representing, with the purpose of obtaining
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compensation or other advantage as personal gain or for any
other person, that an incurable disease or injury, or other
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incurable condition, can be permanently cured;
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(8) The obtaining of, or attempting to obtain, money or
anything of value by fraudulent misrepresentations in the course
of practice;

(9) A plea of guilty to, a judicial finding of guilt of,
or a judicial finding of eligibility for intervention in lieu of
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conviction for, a felony;
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(10) Commission of an act that constitutes a felony in	596
this state, regardless of the jurisdiction in which the act was	597
committed;	598
(11) A plea of guilty to, a judicial finding of guilt of,	599
or a judicial finding of eligibility for intervention in lieu of	600
conviction for, a misdemeanor committed in the course of	601
practice;	602
(12) Commission of an act in the course of practice that	603
constitutes a misdemeanor in this state, regardless of the	604
jurisdiction in which the act was committed;	605
(13) A plea of guilty to, a judicial finding of guilt of,	606
or a judicial finding of eligibility for intervention in lieu of	607
conviction for, a misdemeanor involving moral turpitude;	608
(14) Commission of an act involving moral turpitude that	609
constitutes a misdemeanor in this state, regardless of the	610
jurisdiction in which the act was committed;	611
(15) Violation of the conditions of limitation placed by	612
the board upon a certificate to practice;	613
(16) Failure to pay license renewal fees specified in this	614
chapter;	615
(17) Except as authorized in section 4731.31 of the	616
Revised Code, engaging in the division of fees for referral of	617
patients, or the receiving of a thing of value in return for a	618
specific referral of a patient to utilize a particular service	619
or business;	620
(18) Subject to section 4731.226 of the Revised Code,	621
violation of any provision of a code of ethics of the American	622
medical association, the American osteopathic association, the	623

American podiatric medical association, or any other national 624 professional organizations that the board specifies by rule. The 625 state medical board shall obtain and keep on file current copies 626 of the codes of ethics of the various national professional 627 organizations. The individual whose certificate is being 628 suspended or revoked shall not be found to have violated any 629 provision of a code of ethics of an organization not appropriate 630 to the individual's profession. 631

For purposes of this division, a "provision of a code of 632 ethics of a national professional organization" does not include 633 any provision that would preclude the making of a report by a 634 physician of an employee's use of a drug of abuse, or of a 635 condition of an employee other than one involving the use of a 636 drug of abuse, to the employer of the employee as described in 637 division (B) of section 2305.33 of the Revised Code. Nothing in 638 this division affects the immunity from civil liability 639 conferred by that section upon a physician who makes either type 640 of report in accordance with division (B) of that section. As 641 used in this division, "employee," "employer," and "physician" 642 have the same meanings as in section 2305.33 of the Revised 643 Code. 644

(19) Inability to practice according to acceptable and prevailing standards of care by reason of mental illness or physical illness, including, but not limited to, physical deterioration that adversely affects cognitive, motor, or perceptive skills.

In enforcing this division, the board, upon a showing of a 650 possible violation, may compel any individual authorized to 651 practice by this chapter or who has submitted an application 652 pursuant to this chapter to submit to a mental examination, 653

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physical examination, including an HIV test, or both a mental 654 and a physical examination. The expense of the examination is 655 the responsibility of the individual compelled to be examined. 656 Failure to submit to a mental or physical examination or consent 657 to an HIV test ordered by the board constitutes an admission of 658 the allegations against the individual unless the failure is due 659 to circumstances beyond the individual's control, and a default 660 and final order may be entered without the taking of testimony 661 or presentation of evidence. If the board finds an individual 662 unable to practice because of the reasons set forth in this 663 division, the board shall require the individual to submit to 664 care, counseling, or treatment by physicians approved or 665 designated by the board, as a condition for initial, continued, 666 reinstated, or renewed authority to practice. An individual 667 affected under this division shall be afforded an opportunity to 668 demonstrate to the board the ability to resume practice in 669 compliance with acceptable and prevailing standards under the 670 provisions of the individual's certificate. For the purpose of 671 this division, any individual who applies for or receives a 672 certificate to practice under this chapter accepts the privilege 673 of practicing in this state and, by so doing, shall be deemed to 674 have given consent to submit to a mental or physical examination 675 when directed to do so in writing by the board, and to have 676 waived all objections to the admissibility of testimony or 677 examination reports that constitute a privileged communication. 678

(20) Except when civil penalties are imposed under section
4731.225 or 4731.281 of the Revised Code, and subject to section
4731.226 of the Revised Code, violating or attempting to
681 violate, directly or indirectly, or assisting in or abetting the
682 violation of, or conspiring to violate, any provisions of this
683 chapter or any rule promulgated by the board.

This division does not apply to a violation or attempted 685 violation of, assisting in or abetting the violation of, or a 686 conspiracy to violate, any provision of this chapter or any rule 687 adopted by the board that would preclude the making of a report 688 by a physician of an employee's use of a drug of abuse, or of a 689 condition of an employee other than one involving the use of a 690 drug of abuse, to the employer of the employee as described in 691 division (B) of section 2305.33 of the Revised Code. Nothing in 692 this division affects the immunity from civil liability 693 conferred by that section upon a physician who makes either type 694 of report in accordance with division (B) of that section. As 695 used in this division, "employee," "employer," and "physician" 696 have the same meanings as in section 2305.33 of the Revised 697 Code. 698

(21) The violation of section 3701.79 of the Revised Code
or of any abortion rule adopted by the public health council
pursuant to section 3701.341 of the Revised Code;
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(22) Any of the following actions taken by an agency 702 responsible for authorizing, certifying, or regulating an 703 individual to practice a health care occupation or provide 704 health care services in this state or another jurisdiction, for 705 any reason other than the nonpayment of fees: the limitation, 706 revocation, or suspension of an individual's license to 707 practice; acceptance of an individual's license surrender; 708 denial of a license; refusal to renew or reinstate a license; 709 imposition of probation; or issuance of an order of censure or 710 other reprimand; 711

(23) The violation of section 2919.12 of the Revised Code
or the performance or inducement of an abortion upon a pregnant
woman with actual knowledge that the conditions specified in
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division (B) of section 2317.56 of the Revised Code have not715been satisfied or with a heedless indifference as to whether716those conditions have been satisfied, unless an affirmative717defense as specified in division (H) (2) of that section would718apply in a civil action authorized by division (H) (1) of that719section;720

(24) The revocation, suspension, restriction, reduction, 721 or termination of clinical privileges by the United States 722 department of defense or department of veterans affairs or the 723 termination or suspension of a certificate of registration to 724 prescribe drugs by the drug enforcement administration of the 725 United States department of justice; 726

(25) Termination or suspension from participation in the
medicare or medicaid programs by the department of health and
human services or other responsible agency for any act or acts
that also would constitute a violation of division (B) (2), (3),
(6), (8), or (19) of this section;

(26) Impairment of ability to practice according to
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acceptable and prevailing standards of care because of habitual
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or excessive use or abuse of drugs, alcohol, or other substances
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that impair ability to practice.
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For the purposes of this division, any individual 736 authorized to practice by this chapter accepts the privilege of 737 practicing in this state subject to supervision by the board. By 738 filing an application for or holding a certificate to practice 739 under this chapter, an individual shall be deemed to have given 740 consent to submit to a mental or physical examination when 741 ordered to do so by the board in writing, and to have waived all 742 objections to the admissibility of testimony or examination 743 reports that constitute privileged communications. 744

If it has reason to believe that any individual authorized 745 to practice by this chapter or any applicant for certification 746 to practice suffers such impairment, the board may compel the 747 individual to submit to a mental or physical examination, or 748 both. The expense of the examination is the responsibility of 749 the individual compelled to be examined. Any mental or physical 750 examination required under this division shall be undertaken by 751 a treatment provider or physician who is qualified to conduct 752 the examination and who is chosen by the board. 753

Failure to submit to a mental or physical examination 754 ordered by the board constitutes an admission of the allegations 755 against the individual unless the failure is due to 756 circumstances beyond the individual's control, and a default and 757 final order may be entered without the taking of testimony or 758 presentation of evidence. If the board determines that the 759 individual's ability to practice is impaired, the board shall 760 suspend the individual's certificate or deny the individual's 761 application and shall require the individual, as a condition for 762 initial, continued, reinstated, or renewed certification to 763 practice, to submit to treatment. 764

Before being eligible to apply for reinstatement of a765certificate suspended under this division, the impaired766practitioner shall demonstrate to the board the ability to767resume practice in compliance with acceptable and prevailing768standards of care under the provisions of the practitioner's769certificate. The demonstration shall include, but shall not be770limited to, the following:771

(a) Certification from a treatment provider approved under
section 4731.25 of the Revised Code that the individual has
successfully completed any required inpatient treatment;
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(b) Evidence of continuing full compliance with an 775 776 aftercare contract or consent agreement; (c) Two written reports indicating that the individual's 777 ability to practice has been assessed and that the individual 778 has been found capable of practicing according to acceptable and 779 prevailing standards of care. The reports shall be made by 780 individuals or providers approved by the board for making the 781 assessments and shall describe the basis for their 782 determination. 783 The board may reinstate a certificate suspended under this 784 division after that demonstration and after the individual has 785 entered into a written consent agreement. 786 When the impaired practitioner resumes practice, the board 787 shall require continued monitoring of the individual. The 788 monitoring shall include, but not be limited to, compliance with 789 the written consent agreement entered into before reinstatement 790 or with conditions imposed by board order after a hearing, and, 791

upon termination of the consent agreement, submission to the792board for at least two years of annual written progress reports793made under penalty of perjury stating whether the individual has794maintained sobriety.795

(27) A second or subsequent violation of section 4731.66 796
or 4731.69 of the Revised Code; 797

(28) Except as provided in division (N) of this section: 798

(a) Waiving the payment of all or any part of a deductible
or copayment that a patient, pursuant to a health insurance or
health care policy, contract, or plan that covers the
individual's services, otherwise would be required to pay if the
waiver is used as an enticement to a patient or group of

patients to receive health care services from that individual;	804
(b) Advertising that the individual will waive the payment	805
of all or any part of a deductible or copayment that a patient,	806
pursuant to a health insurance or health care policy, contract,	807
or plan that covers the individual's services, otherwise would	808
be required to pay.	809
(29) Failure to use universal blood and body fluid	810
precautions established by rules adopted under section 4731.051	811
of the Revised Code;	812
(30) Failure to provide notice to, and receive	813
acknowledgment of the notice from, a patient when required by	814
section 4731.143 of the Revised Code prior to providing	815
nonemergency professional services, or failure to maintain that	816
notice in the patient's file;	817
(31) Failure of a physician supervising a physician	818
assistant to maintain supervision in accordance with the	819
requirements of Chapter 4730. of the Revised Code and the rules	820
adopted under that chapter;	821
(32) Failure of a physician or podiatrist to enter into a	822
standard care arrangement with a clinical nurse specialist,	823
certified nurse-midwife, or certified nurse practitioner with	824
whom the physician or podiatrist is in collaboration pursuant to	825
section 4731.27 of the Revised Code or failure to fulfill the	826
responsibilities of collaboration after entering into a standard	827
care arrangement;	828
(33) Failure to comply with the terms of a consult	829
agreement entered into with a pharmacist pursuant to section	830
4729.39 of the Revised Code;	831
(24) Esilves to according to in an investigation conducted by	030

(34) Failure to cooperate in an investigation conducted by 832

the board under division (F) of this section, including failure 833 to comply with a subpoena or order issued by the board or 834 failure to answer truthfully a question presented by the board 835 in an investigative interview, an investigative office 836 conference, at a deposition, or in written interrogatories, 8.37 except that failure to cooperate with an investigation shall not 838 constitute grounds for discipline under this section if a court 839 of competent jurisdiction has issued an order that either 840 quashes a subpoena or permits the individual to withhold the 841 842 testimony or evidence in issue; (35) Failure to supervise an oriental medicine 843 practitioner or acupuncturist in accordance with Chapter 4762. 844 of the Revised Code and the board's rules for providing that 845 supervision; 846 (36) Failure to supervise an anesthesiologist assistant in 847 accordance with Chapter 4760. of the Revised Code and the 848 board's rules for supervision of an anesthesiologist assistant; 849 (37) Assisting suicide as defined in section 3795.01 of 850 the Revised Code: 851 (38) Failure to comply with the requirements of section 852 2317.561 of the Revised Code; 853 854 (39) Failure to supervise a radiologist assistant in accordance with Chapter 4774. of the Revised Code and the 855 board's rules for supervision of radiologist assistants; 856 (40) Performing or inducing an abortion at an office or 857

(40) Performing or inducing an abortion at an office or 857 facility with knowledge that the office or facility fails to 858 post the notice required under section 3701.791 of the Revised 859 Code; 860

(41) Failure to comply with the standards and procedures 861

established in rules under section 4731.054 of the Revised Code 862 for the operation of or the provision of care at a pain 863 management clinic; 864

(42) Failure to comply with the standards and procedures
established in rules under section 4731.054 of the Revised Code
for providing supervision, direction, and control of individuals
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at a pain management clinic;

(43) Failure to comply with the requirements of section
4729.79 or 4731.055 of the Revised Code, unless the state board
670 of pharmacy no longer maintains a drug database pursuant to
871 section 4729.75 of the Revised Code;
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(44) Failure to comply with the requirements of section
2919.171 of the Revised Code or failure to submit to the
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department of health in accordance with a court order a complete
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report as described in section 2919.171 of the Revised Code;
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(45) Practicing at a facility that is subject to licensure 877 as a category III terminal distributor of dangerous drugs with a 878 pain management clinic classification unless the person 879 operating the facility has obtained and maintains the license 880 with the classification; 881

(46) Owning a facility that is subject to licensure as a 882 category III terminal distributor of dangerous drugs with a pain 883 management clinic classification unless the facility is licensed 884 with the classification; 885

(47) Failure to comply with the requirement regarding
maintaining notes described in division (B) of section 2919.191
of the Revised Code or failure to satisfy the requirements of
section 2919.191 of the Revised Code prior to performing or
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inducing an abortion upon a pregnant woman;

(48) Failure to comply with the requirements in section
3719.061 of the Revised Code before issuing to a minor a
prescription for a controlled substance containing an opioid.
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(C) Disciplinary actions taken by the board under 894 divisions (A) and (B) of this section shall be taken pursuant to 895 an adjudication under Chapter 119. of the Revised Code, except 896 that in lieu of an adjudication, the board may enter into a 897 consent agreement with an individual to resolve an allegation of 898 a violation of this chapter or any rule adopted under it. A 899 consent agreement, when ratified by an affirmative vote of not 900 fewer than six members of the board, shall constitute the 901 findings and order of the board with respect to the matter 902 addressed in the agreement. If the board refuses to ratify a 903 consent agreement, the admissions and findings contained in the 904 consent agreement shall be of no force or effect. 905

A telephone conference call may be utilized for 906 ratification of a consent agreement that revokes or suspends an 907 individual's certificate to practice. The telephone conference 908 call shall be considered a special meeting under division (F) of 909 section 121.22 of the Revised Code. 910

If the board takes disciplinary action against an 911 individual under division (B) of this section for a second or 912 subsequent plea of quilty to, or judicial finding of quilt of, a 913 violation of section 2919.123 of the Revised Code, the 914 disciplinary action shall consist of a suspension of the 915 individual's certificate to practice for a period of at least 916 one year or, if determined appropriate by the board, a more 917 serious sanction involving the individual's certificate to 918 practice. Any consent agreement entered into under this division 919 with an individual that pertains to a second or subsequent plea 920

of guilty to, or judicial finding of guilt of, a violation of921that section shall provide for a suspension of the individual's922certificate to practice for a period of at least one year or, if923determined appropriate by the board, a more serious sanction924involving the individual's certificate to practice.925

(D) For purposes of divisions (B)(10), (12), and (14) of 926 this section, the commission of the act may be established by a 927 finding by the board, pursuant to an adjudication under Chapter 928 119. of the Revised Code, that the individual committed the act. 929 The board does not have jurisdiction under those divisions if 930 the trial court renders a final judgment in the individual's 931 favor and that judgment is based upon an adjudication on the 932 merits. The board has jurisdiction under those divisions if the 933 trial court issues an order of dismissal upon technical or 934 procedural grounds. 935

(E) The sealing of conviction records by any court shall 936 have no effect upon a prior board order entered under this 937 section or upon the board's jurisdiction to take action under 938 this section if, based upon a plea of guilty, a judicial finding 939 of guilt, or a judicial finding of eligibility for intervention 940 in lieu of conviction, the board issued a notice of opportunity 941 for a hearing prior to the court's order to seal the records. 942 The board shall not be required to seal, destroy, redact, or 943 otherwise modify its records to reflect the court's sealing of 944 conviction records. 945

(F) (1) The board shall investigate evidence that appears
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to show that a person has violated any provision of this chapter
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or any rule adopted under it. Any person may report to the board
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in a signed writing any information that the person may have
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that appears to show a violation of any provision of this
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chapter or any rule adopted under it. In the absence of bad 951 faith, any person who reports information of that nature or who 952 testifies before the board in any adjudication conducted under 953 Chapter 119. of the Revised Code shall not be liable in damages 954 in a civil action as a result of the report or testimony. Each 955 complaint or allegation of a violation received by the board 956 shall be assigned a case number and shall be recorded by the 957 board. 958

(2) Investigations of alleged violations of this chapter 959 960 or any rule adopted under it shall be supervised by the supervising member elected by the board in accordance with 961 section 4731.02 of the Revised Code and by the secretary as 962 provided in section 4731.39 of the Revised Code. The president 963 may designate another member of the board to supervise the 964 investigation in place of the supervising member. No member of 965 the board who supervises the investigation of a case shall 966 participate in further adjudication of the case. 967

(3) In investigating a possible violation of this chapter 968 or any rule adopted under this chapter, or in conducting an 969 inspection under division (E) of section 4731.054 of the Revised 970 Code, the board may question witnesses, conduct interviews, 971 administer oaths, order the taking of depositions, inspect and 972 copy any books, accounts, papers, records, or documents, issue 973 subpoenas, and compel the attendance of witnesses and production 974 of books, accounts, papers, records, documents, and testimony, 975 except that a subpoena for patient record information shall not 976 be issued without consultation with the attorney general's 977 office and approval of the secretary and supervising member of 978 the board. 979

(a) Before issuance of a subpoena for patient record

information, the secretary and supervising member shall

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 determine whether there is probable cause to believe that the
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 complaint filed alleges a violation of this chapter or any rule
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 adopted under it and that the records sought are relevant to the
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 alleged violation and material to the investigation. The
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 subpoena may apply only to records that cover a reasonable
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 period of time surrounding the alleged violation.
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(b) On failure to comply with any subpoena issued by the
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board and after reasonable notice to the person being
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subpoenaed, the board may move for an order compelling the
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production of persons or records pursuant to the Rules of Civil
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Procedure.

993 (c) A subpoena issued by the board may be served by a sheriff, the sheriff's deputy, or a board employee designated by 994 the board. Service of a subpoena issued by the board may be made 995 996 by delivering a copy of the subpoena to the person named therein, reading it to the person, or leaving it at the person's 997 usual place of residence, usual place of business, or address on 998 file with the board. When serving a subpoena to an applicant for 999 or the holder of a certificate issued under this chapter, 1000 service of the subpoena may be made by certified mail, return 1001 receipt requested, and the subpoena shall be deemed served on 1002 the date delivery is made or the date the person refuses to 1003 accept delivery. If the person being served refuses to accept 1004 the subpoena or is not located, service may be made to an 1005 attorney who notifies the board that the attorney is 1006 representing the person. 1007

(d) A sheriff's deputy who serves a subpoena shall receive
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the same fees as a sheriff. Each witness who appears before the
board in obedience to a subpoena shall receive the fees and
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mileage provided for under section 119.094 of the Revised Code. 1011

(4) All hearings, investigations, and inspections of the 1012 board shall be considered civil actions for the purposes of 1013 section 2305.252 of the Revised Code. 1014

(5) A report required to be submitted to the board under 1015 this chapter, a complaint, or information received by the board 1016 pursuant to an investigation or pursuant to an inspection under 1017 division (E) of section 4731.054 of the Revised Code is 1018 confidential and not subject to discovery in any civil action. 1019

The board shall conduct all investigations or inspections 1020 and proceedings in a manner that protects the confidentiality of 1021 patients and persons who file complaints with the board. The 1022 board shall not make public the names or any other identifying 1023 information about patients or complainants unless proper consent 1024 is given or, in the case of a patient, a waiver of the patient 1025 privilege exists under division (B) of section 2317.02 of the 1026 Revised Code, except that consent or a waiver of that nature is 1027 not required if the board possesses reliable and substantial 1028 evidence that no bona fide physician-patient relationship 1029 exists. 1030

The board may share any information it receives pursuant 1031 to an investigation or inspection, including patient records and 1032 patient record information, with law enforcement agencies, other 1033 licensing boards, and other governmental agencies that are 1034 prosecuting, adjudicating, or investigating alleged violations 1035 of statutes or administrative rules. An agency or board that 1036 receives the information shall comply with the same requirements 1037 regarding confidentiality as those with which the state medical 1038 board must comply, notwithstanding any conflicting provision of 1039 the Revised Code or procedure of the agency or board that 1040

applies when it is dealing with other information in its 1041 possession. In a judicial proceeding, the information may be 1042 admitted into evidence only in accordance with the Rules of 1043 Evidence, but the court shall require that appropriate measures 1044 are taken to ensure that confidentiality is maintained with 1045 respect to any part of the information that contains names or 1046 other identifying information about patients or complainants 1047 whose confidentiality was protected by the state medical board 1048 when the information was in the board's possession. Measures to 1049 ensure confidentiality that may be taken by the court include 1050 sealing its records or deleting specific information from its 1051 records. 1052 (6) On a quarterly basis, the board shall prepare a report 1053 that documents the disposition of all cases during the preceding 1054 three months. The report shall contain the following information 1055 for each case with which the board has completed its activities: 1056 (a) The case number assigned to the complaint or alleged 1057 violation; 1058 (b) The type of certificate to practice, if any, held by 1059 the individual against whom the complaint is directed; 1060 (c) A description of the allegations contained in the 1061 1062 complaint; (d) The disposition of the case. 1063 The report shall state how many cases are still pending 1064 and shall be prepared in a manner that protects the identity of 1065 each person involved in each case. The report shall be a public 1066 record under section 149.43 of the Revised Code. 1067

(G) If the secretary and supervising member determine bothof the following, they may recommend that the board suspend an1069

individual's certificate to practice without a prior hearing: 1070 (1) That there is clear and convincing evidence that an 1071 individual has violated division (B) of this section; 1072 (2) That the individual's continued practice presents a 1073 danger of immediate and serious harm to the public. 1074 Written allegations shall be prepared for consideration by 1075 the board. The board, upon review of those allegations and by an 1076 affirmative vote of not fewer than six of its members, excluding 1077 the secretary and supervising member, may suspend a certificate 1078 without a prior hearing. A telephone conference call may be 1079 utilized for reviewing the allegations and taking the vote on 1080 the summary suspension. 1081 The board shall issue a written order of suspension by 1082 certified mail or in person in accordance with section 119.07 of 1083 the Revised Code. The order shall not be subject to suspension 1084 by the court during pendency of any appeal filed under section 1085 119.12 of the Revised Code. If the individual subject to the 1086 summary suspension requests an adjudicatory hearing by the 1087 board, the date set for the hearing shall be within fifteen 1088

days, but not earlier than seven days, after the individual1089requests the hearing, unless otherwise agreed to by both the1090board and the individual.1091

Any summary suspension imposed under this division shall1092remain in effect, unless reversed on appeal, until a final1093adjudicative order issued by the board pursuant to this section1094and Chapter 119. of the Revised Code becomes effective. The1095board shall issue its final adjudicative order within seventy-1096five days after completion of its hearing. A failure to issue1097the order within seventy-five days shall result in dissolution1098

of the summary suspension order but shall not invalidate any 1099 subsequent, final adjudicative order. 1100

(H) If the board takes action under division (B) (9), (11), 1101 or (13) of this section and the judicial finding of guilt, 1102 guilty plea, or judicial finding of eligibility for intervention 1103 in lieu of conviction is overturned on appeal, upon exhaustion 1104 of the criminal appeal, a petition for reconsideration of the 1105 order may be filed with the board along with appropriate court 1106 documents. Upon receipt of a petition of that nature and 1107 supporting court documents, the board shall reinstate the 1108 individual's certificate to practice. The board may then hold an 1109 adjudication under Chapter 119. of the Revised Code to determine 1110 whether the individual committed the act in question. Notice of 1111 an opportunity for a hearing shall be given in accordance with 1112 Chapter 119. of the Revised Code. If the board finds, pursuant 1113 to an adjudication held under this division, that the individual 1114 committed the act or if no hearing is requested, the board may 1115 order any of the sanctions identified under division (B) of this 1116 section. 1117

1118 (I) The certificate to practice issued to an individual under this chapter and the individual's practice in this state 1119 are automatically suspended as of the date of the individual's 1120 second or subsequent plea of guilty to, or judicial finding of 1121 quilt of, a violation of section 2919.123 of the Revised Code, 1122 or the date the individual pleads guilty to, is found by a judge 1123 or jury to be guilty of, or is subject to a judicial finding of 1124 eligibility for intervention in lieu of conviction in this state 1125 or treatment or intervention in lieu of conviction in another 1126 jurisdiction for any of the following criminal offenses in this 1127 state or a substantially equivalent criminal offense in another 1128 jurisdiction: aggravated murder, murder, voluntary manslaughter, 1129

## H. B. No. 290 As Introduced

felonious assault, kidnapping, rape, sexual battery, gross1130sexual imposition, aggravated arson, aggravated robbery, or1131aggravated burglary. Continued practice after suspension shall1132be considered practicing without a certificate.1133

The board shall notify the individual subject to the 1134 suspension by certified mail or in person in accordance with 1135 section 119.07 of the Revised Code. If an individual whose 1136 certificate is automatically suspended under this division fails 1137 to make a timely request for an adjudication under Chapter 119. 1138 of the Revised Code, the board shall do whichever of the 1139 following is applicable: 1140

(1) If the automatic suspension under this division is for 1141 a second or subsequent plea of guilty to, or judicial finding of 1142 guilt of, a violation of section 2919.123 of the Revised Code, 1143 the board shall enter an order suspending the individual's 1144 certificate to practice for a period of at least one year or, if 1145 determined appropriate by the board, imposing a more serious 1146 sanction involving the individual's certificate to practice. 1147

(2) In all circumstances in which division (I) (1) of this
section does not apply, enter a final order permanently revoking
the individual's certificate to practice.
1150

(J) If the board is required by Chapter 119. of the 1151 Revised Code to give notice of an opportunity for a hearing and 1152 if the individual subject to the notice does not timely request 1153 a hearing in accordance with section 119.07 of the Revised Code, 1154 the board is not required to hold a hearing, but may adopt, by 1155 an affirmative vote of not fewer than six of its members, a 1156 final order that contains the board's findings. In that final 1157 order, the board may order any of the sanctions identified under 1158 division (A) or (B) of this section. 1159

(K) Any action taken by the board under division (B) of 1160 this section resulting in a suspension from practice shall be 1161 accompanied by a written statement of the conditions under which 1162 the individual's certificate to practice may be reinstated. The 1163 board shall adopt rules governing conditions to be imposed for 1164 reinstatement. Reinstatement of a certificate suspended pursuant 1165 to division (B) of this section requires an affirmative vote of 1166 not fewer than six members of the board. 1167

(L) When the board refuses to grant a certificate to an 1168 applicant, revokes an individual's certificate to practice, 1169 refuses to register an applicant, or refuses to reinstate an 1170 individual's certificate to practice, the board may specify that 1171 its action is permanent. An individual subject to a permanent 1172 action taken by the board is forever thereafter ineligible to 1173 hold a certificate to practice and the board shall not accept an 1174 application for reinstatement of the certificate or for issuance 1175 of a new certificate. 1176

(M) Notwithstanding any other provision of the RevisedCode, all of the following apply:1178

(1) The surrender of a certificate issued under this 1179 chapter shall not be effective unless or until accepted by the 1180 board. A telephone conference call may be utilized for 1181 acceptance of the surrender of an individual's certificate to 1182 practice. The telephone conference call shall be considered a 1183 special meeting under division (F) of section 121.22 of the 1184 Revised Code. Reinstatement of a certificate surrendered to the 1185 board requires an affirmative vote of not fewer than six members 1186 of the board. 1187

(2) An application for a certificate made under theprovisions of this chapter may not be withdrawn without approval1189

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of the board.	1190
(3) Failure by an individual to renew a certificate of	1191
registration in accordance with this chapter shall not remove or	1192
limit the board's jurisdiction to take any disciplinary action	1193
under this section against the individual.	1194
(4) At the request of the board, a certificate holder	1195
shall immediately surrender to the board a certificate that the	1196
board has suspended, revoked, or permanently revoked.	1197
(N) Sanctions shall not be imposed under division (B)(28)	1198
of this section against any person who waives deductibles and	1199
copayments as follows:	1200
(1) In compliance with the health benefit plan that	1201
expressly allows such a practice. Waiver of the deductibles or	1202
copayments shall be made only with the full knowledge and	1203
consent of the plan purchaser, payer, and third-party	1204
administrator. Documentation of the consent shall be made	1205
available to the board upon request.	1206
(2) For professional services rendered to any other person	1207
authorized to practice pursuant to this chapter, to the extent	1208
allowed by this chapter and rules adopted by the board.	1209
(O) Under the board's investigative duties described in	1210
this costion and subject to division $(\mathbf{F})$ of this costion the	1211

this section and subject to division (F) of this section, the 1211 board shall develop and implement a quality intervention program 1212 designed to improve through remedial education the clinical and 1213 communication skills of individuals authorized under this 1214 chapter to practice medicine and surgery, osteopathic medicine 1215 and surgery, and podiatric medicine and surgery. In developing 1216 and implementing the quality intervention program, the board may 1217 do all of the following: 1218

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(1) Offer in appropriate cases as determined by the board	1219
an educational and assessment program pursuant to an	1220
investigation the board conducts under this section;	1221
(2) Select providers of educational and assessment	1222
services, including a quality intervention program panel of case	1223
reviewers;	1224
(3) Make referrals to educational and assessment service	1225
providers and approve individual educational programs	1226
recommended by those providers. The board shall monitor the	1227
progress of each individual undertaking a recommended individual	1228
educational program.	1229
(4) Determine what constitutes successful completion of an	1230
individual educational program and require further monitoring of	1231
the individual who completed the program or other action that	1232
the board determines to be appropriate;	1233
(5) Adopt rules in accordance with Chapter 119. of the	1234
Revised Code to further implement the quality intervention	1235
program.	1236
An individual who participates in an individual	1237
educational program pursuant to this division shall pay the	1238
financial obligations arising from that educational program.	1239
Sec. 4731.227. An individual authorized to practice	1240
medicine and surgery or osteopathic medicine and surgery may use	1241
alternative medical treatments if the individual has provided	1242
the information necessary to obtain informed consent from the	1243
patient and the treatment meets the standards enforced by the	1244
state medical board pursuant to section 4731.22 of the Revised	1245
Code and any rules adopted by the board.	1246
As used in this section, "alternative medical treatment"	1247

means care that is complementary to or different from	1248
conventional medical care but is reasonable when the benefits	1249
and risks of the alternative medical treatment and the	1250
conventional medical care are compared. <u>Alternative medical</u>	1251
treatment does not include treatment with an investigational	1252
drug, product, or device under section 4731.96 of the Revised	1253
Code.	1254
Sec. 4731.96. (A) As used in this section:	1255
(1) "Drug" has the same meaning as in section 4729.01 of	1256
the Revised Code.	1257
(2) "Investigational drug, product, or device" means a	1258
drug, product, or device that has successfully completed phase	1259
one of United States food and drug administration clinical	1260
trials and remains under clinical trial, but has not been	1261
approved for general use by the United States food and drug	1262
administration. "Investigational drug, product, or device" does	1263
not include controlled substances in schedule I, as established	1264
pursuant to section 3719.41 of the Revised Code, and as amended.	1265
(3) "Product" means a biological product, other than a	1266
drug, that is made from a natural human, animal, or	1267
microorganism source and is intended to treat a disease or	1268
medical condition.	1269
(4) "Device" means a medical device that is intended for	1270
use in the diagnosis or treatment of a disease or medical	1271
condition.	1272
(5) "Terminal illness" means a condition that satisfies	1273
all of the following criteria:	1274
(a) The condition is caused by a disease, illness, or	1275
injury from which an individual is unlikely to recover if left	1276

1277 <u>untreated;</u> (b) The condition is irreversible and incurable through a 1278 method of treatment approved by the United States food and drug 1279 administration; 1280 (c) In accordance with reasonable medical standards and a 1281 reasonable degree of medical certainty, it appears that the 1282 1283 condition is likely to cause death within twelve months. (6) "Treating physician" means the physician or physicians 1284 primarily responsible for providing medical care and treating an 1285 eligible patient's terminal illness. "Treating physician" does 1286 not include the patient's primary care physician unless that 1287 physician is treating the patient's terminal illness and no 1288 other physician is primarily responsible for treating the 1289 terminal illness. 1290 (B) An individual is an eligible patient if all of the 1291 following conditions are met: 1292 (1) The individual has a terminal illness. 1293 (2) The individual, as determined by the individual's 1294 treating physician, has considered all treatment options for the 1295 1296 terminal illness that are approved by the United States food and drug administration and determined that there are no 1297 satisfactory or comparable approved treatments and that the risk 1298 from the investigational drug, product, or device is no greater 1299 than the probable risk from not treating the terminal illness. 1300 (3) The individual's treating physician recommends the use 1301 of the investigational drug, product, or device and agrees to 1302 either administer or personally furnish it or has issued a 1303 prescription to the individual for the investigational drug, 1304 1305 product, or device.

(4) The treating physician includes documentation in the 1306 patient's medical record that all of the foregoing conditions 1307 have been met. 1308 (C) (1) A treating physician may treat an eligible patient 1309 with an investigational drug, product, or device after securing 1310 the patient's informed consent in a signed statement. If the 1311 patient is a minor or lacks the capacity to consent, the 1312 informed consent must be obtained from a parent, quardian, or 1313 other person legally responsible for the patient. 1314 (2) To secure informed consent, the treating physician 1315 must do all of the following: 1316 (a) Record all of the following in the document that is to 1317 be signed: 1318 (i) An explanation of the approved treatment options for 1319 the terminal illness from which the patient suffers; 1320 (ii) The specific proposed investigational drug, product, 1321 1322 or device; (iii) The potentially best and worst outcomes of using the 1323 investigational drug, product, or device with a realistic 1324 description of the most likely outcome, including the 1325 possibility that new, unanticipated, different, or worse 1326 symptoms might result, and that death could be hastened by the 1327 investigational drug, product, or device; 1328 (iv) An explanation that the manufacturer of the 1329 investigational drug, product, or device may hold the patient 1330 liable for all expenses that arise from the patient's use of the 1331 investigational drug, product, or device. 1332

(b) Have the individual giving consent sign the document 1333

in the conscious presence of a competent witness;	1334
(c) Have the witness also sign the document and attest	1335
that the individual giving consent appeared to do all of the	1336
following:	1337
(i) Concur with the treating physician in believing that	1338
all approved treatment options would be unlikely to prolong the	1339
patient's life;	1340
(ii) Understand the risks involved with using the	1341
investigational drug, product, or device;	1342
(iii) Willingly desire to use the investigational drug,	1343
product, or device to treat the terminal illness.	1344
(D) Except for actions constituting willful or wanton	1345
misconduct, a physician who recommends or treats an eligible	1346
patient with an investigational drug, product, or device in	1347
compliance with this section is not liable for or subject to any	1348
of the following for an action or omission related to treatment	1349
with the investigational drug, product, or device: damages in	1350
any civil action, prosecution in any criminal proceeding, or	1351
professional disciplinary action.	1352
(E) Nothing in this section shall be interpreted as	1353
requiring any insurer, government health care program, or other	1354
provider of health care coverage to provide coverage for charges	1355
incurred from the use of any investigational drug, product, or	1356
device.	1357
Section 2. That existing sections 1739.05, 4729.291,	1358
4729.51, 4729.57, 4731.22, and 4731.227 of the Revised Code are	1359
hereby repealed.	1360
Section 3. Sections 1739.05 and 1751.691 of the Revised	1361

Code, as amended or enacted by this act, apply only to policies, 1362 contracts, and agreements that are delivered, issued for 1363 delivery, or renewed in this state on or after January 1, 2016. 1364 Section 3923.851 of the Revised Code, as enacted by this act, 1365 applies only to policies of sickness and accident insurance 1366 delivered, issued for delivery, or renewed in this state and to 1367 public employee benefit plans that are established or modified 1368 in this state, on or after January 1, 2016. 1369