

As Passed by the House

131st General Assembly

Regular Session

2015-2016

Am. H. B. No. 188

Representatives Manning, Huffman

Cosponsors: Representatives Maag, Rezabek, Gonzales, Amstutz, Anielski, Antonio, Baker, Blessing, Boyce, Boyd, Buchy, Burkley, Conditt, Craig, Derickson, Dever, Dovilla, Gerberry, Ginter, Green, Hackett, Hall, Hambley, Hayes, Howse, Kraus, Kuhns, Leland, McClain, O'Brien, M., Patterson, Pelanda, Perales, Ramos, Reece, Retherford, Rogers, Ryan, Schaffer, Scherer, Sears, Sheehy, Slaby, Smith, R., Stinziano, Strahorn, Terhar, Young, Speaker Rosenberger

A BILL

To amend sections 4729.01, 4729.281, and 4729.39 of 1
the Revised Code to revise the laws governing 2
pharmacist consult agreements and the laws 3
governing the circumstances under which a 4
pharmacist may dispense or sell a drug without a 5
prescription. 6

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

Section 1. That sections 4729.01, 4729.281, and 4729.39 of 7
the Revised Code be amended to read as follows: 8

Sec. 4729.01. As used in this chapter: 9

(A) "Pharmacy," except when used in a context that refers 10
to the practice of pharmacy, means any area, room, rooms, place 11
of business, department, or portion of any of the foregoing 12
where the practice of pharmacy is conducted. 13

(B) "Practice of pharmacy" means providing pharmacist care 14

requiring specialized knowledge, judgment, and skill derived 15
from the principles of biological, chemical, behavioral, social, 16
pharmaceutical, and clinical sciences. As used in this division, 17
"pharmacist care" includes the following: 18

- (1) Interpreting prescriptions; 19
- (2) Dispensing drugs and drug therapy related devices; 20
- (3) Compounding drugs; 21
- (4) Counseling individuals with regard to their drug 22
therapy, recommending drug therapy related devices, and 23
assisting in the selection of drugs and appliances for treatment 24
of common diseases and injuries and providing instruction in the 25
proper use of the drugs and appliances; 26
- (5) Performing drug regimen reviews with individuals by 27
discussing all of the drugs that the individual is taking and 28
explaining the interactions of the drugs; 29
- (6) Performing drug utilization reviews with licensed 30
health professionals authorized to prescribe drugs when the 31
pharmacist determines that an individual with a prescription has 32
a drug regimen that warrants additional discussion with the 33
prescriber; 34
- (7) Advising an individual and the health care 35
professionals treating an individual with regard to the 36
individual's drug therapy; 37
- (8) Acting pursuant to a consult agreement with ~~a~~ 38
~~physician~~ one or more physicians authorized under Chapter 4731. 39
of the Revised Code to practice medicine and surgery or 40
osteopathic medicine and surgery, if an agreement has been 41
established ~~with the physician~~; 42

(9) Engaging in the administration of immunizations to the extent authorized by section 4729.41 of the Revised Code. 43
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(C) "Compounding" means the preparation, mixing, assembling, packaging, and labeling of one or more drugs in any of the following circumstances: 45
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(1) Pursuant to a prescription issued by a licensed health professional authorized to prescribe drugs; 48
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(2) Pursuant to the modification of a prescription made in accordance with a consult agreement; 50
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(3) As an incident to research, teaching activities, or chemical analysis; 52
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(4) In anticipation of orders for drugs pursuant to prescriptions, based on routine, regularly observed dispensing patterns; 54
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(5) Pursuant to a request made by a licensed health professional authorized to prescribe drugs for a drug that is to be used by the professional for the purpose of direct administration to patients in the course of the professional's practice, if all of the following apply: 57
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(a) At the time the request is made, the drug is not commercially available regardless of the reason that the drug is not available, including the absence of a manufacturer for the drug or the lack of a readily available supply of the drug from a manufacturer. 62
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(b) A limited quantity of the drug is compounded and provided to the professional. 67
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(c) The drug is compounded and provided to the professional as an occasional exception to the normal practice 69
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of dispensing drugs pursuant to patient-specific prescriptions. 71

(D) "Consult agreement" means an agreement ~~to manage an~~ 72
~~individual's drug therapy that has been entered into by a~~ 73
~~pharmacist and a physician authorized under Chapter 4731. of the~~ 74
~~Revised Code to practice medicine and surgery or osteopathic~~ 75
~~medicine and surgery~~under section 4729.39 of the Revised Code. 76

(E) "Drug" means: 77

(1) Any article recognized in the United States 78
pharmacopoeia and national formulary, or any supplement to them, 79
intended for use in the diagnosis, cure, mitigation, treatment, 80
or prevention of disease in humans or animals; 81

(2) Any other article intended for use in the diagnosis, 82
cure, mitigation, treatment, or prevention of disease in humans 83
or animals; 84

(3) Any article, other than food, intended to affect the 85
structure or any function of the body of humans or animals; 86

(4) Any article intended for use as a component of any 87
article specified in division (E) (1), (2), or (3) of this 88
section; but does not include devices or their components, 89
parts, or accessories. 90

(F) "Dangerous drug" means any of the following: 91

(1) Any drug to which either of the following applies: 92

(a) Under the "Federal Food, Drug, and Cosmetic Act," 52 93
Stat. 1040 (1938), 21 U.S.C.A. 301, as amended, the drug is 94
required to bear a label containing the legend "Caution: Federal 95
law prohibits dispensing without prescription" or "Caution: 96
Federal law restricts this drug to use by or on the order of a 97
licensed veterinarian" or any similar restrictive statement, or 98

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| the drug may be dispensed only upon a prescription; | 99 |
| (b) Under Chapter 3715. or 3719. of the Revised Code, the drug may be dispensed only upon a prescription. | 100 101 |
| (2) Any drug that contains a schedule V controlled substance and that is exempt from Chapter 3719. of the Revised Code or to which that chapter does not apply; | 102 103 104 |
| (3) Any drug intended for administration by injection into the human body other than through a natural orifice of the human body. | 105 106 107 |
| (G) "Federal drug abuse control laws" has the same meaning as in section 3719.01 of the Revised Code. | 108 109 |
| (H) "Prescription" means a written, electronic, or oral order for drugs or combinations or mixtures of drugs to be used by a particular individual or for treating a particular animal, issued by a licensed health professional authorized to prescribe drugs. | 110 111 112 113 114 |
| (I) "Licensed health professional authorized to prescribe drugs" or "prescriber" means an individual who is authorized by law to prescribe drugs or dangerous drugs or drug therapy related devices in the course of the individual's professional practice, including only the following: | 115 116 117 118 119 |
| (1) A dentist licensed under Chapter 4715. of the Revised Code; | 120 121 |
| (2) A clinical nurse specialist, certified nurse-midwife, or certified nurse practitioner who holds a certificate to prescribe issued under section 4723.48 of the Revised Code; | 122 123 124 |
| (3) An optometrist licensed under Chapter 4725. of the Revised Code to practice optometry under a therapeutic | 125 126 |

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| pharmaceutical agents certificate; | 127 |
| (4) A physician authorized under Chapter 4731. of the Revised Code to practice medicine and surgery, osteopathic medicine and surgery, or podiatric medicine and surgery; | 128 129 130 |
| (5) A physician assistant who holds a certificate to prescribe issued under Chapter 4730. of the Revised Code; | 131 132 |
| (6) A veterinarian licensed under Chapter 4741. of the Revised Code. | 133 134 |
| (J) "Sale" and "sell" include delivery, transfer, barter, exchange, or gift, or offer therefor, and each such transaction made by any person, whether as principal proprietor, agent, or employee. | 135 136 137 138 |
| (K) "Wholesale sale" and "sale at wholesale" mean any sale in which the purpose of the purchaser is to resell the article purchased or received by the purchaser. | 139 140 141 |
| (L) "Retail sale" and "sale at retail" mean any sale other than a wholesale sale or sale at wholesale. | 142 143 |
| (M) "Retail seller" means any person that sells any dangerous drug to consumers without assuming control over and responsibility for its administration. Mere advice or instructions regarding administration do not constitute control or establish responsibility. | 144 145 146 147 148 |
| (N) "Price information" means the price charged for a prescription for a particular drug product and, in an easily understandable manner, all of the following: | 149 150 151 |
| (1) The proprietary name of the drug product; | 152 |
| (2) The established (generic) name of the drug product; | 153 |

(3) The strength of the drug product if the product 154
contains a single active ingredient or if the drug product 155
contains more than one active ingredient and a relevant strength 156
can be associated with the product without indicating each 157
active ingredient. The established name and quantity of each 158
active ingredient are required if such a relevant strength 159
cannot be so associated with a drug product containing more than 160
one ingredient. 161

(4) The dosage form; 162

(5) The price charged for a specific quantity of the drug 163
product. The stated price shall include all charges to the 164
consumer, including, but not limited to, the cost of the drug 165
product, professional fees, handling fees, if any, and a 166
statement identifying professional services routinely furnished 167
by the pharmacy. Any mailing fees and delivery fees may be 168
stated separately without repetition. The information shall not 169
be false or misleading. 170

(O) "Wholesale distributor of dangerous drugs" means a 171
person engaged in the sale of dangerous drugs at wholesale and 172
includes any agent or employee of such a person authorized by 173
the person to engage in the sale of dangerous drugs at 174
wholesale. 175

(P) "Manufacturer of dangerous drugs" means a person, 176
other than a pharmacist, who manufactures dangerous drugs and 177
who is engaged in the sale of those dangerous drugs within this 178
state. 179

(Q) "Terminal distributor of dangerous drugs" means a 180
person who is engaged in the sale of dangerous drugs at retail, 181
or any person, other than a wholesale distributor or a 182

pharmacist, who has possession, custody, or control of dangerous 183
drugs for any purpose other than for that person's own use and 184
consumption, and includes pharmacies, hospitals, nursing homes, 185
and laboratories and all other persons who procure dangerous 186
drugs for sale or other distribution by or under the supervision 187
of a pharmacist or licensed health professional authorized to 188
prescribe drugs. 189

(R) "Promote to the public" means disseminating a 190
representation to the public in any manner or by any means, 191
other than by labeling, for the purpose of inducing, or that is 192
likely to induce, directly or indirectly, the purchase of a 193
dangerous drug at retail. 194

(S) "Person" includes any individual, partnership, 195
association, limited liability company, or corporation, the 196
state, any political subdivision of the state, and any district, 197
department, or agency of the state or its political 198
subdivisions. 199

(T) "Finished dosage form" has the same meaning as in 200
section 3715.01 of the Revised Code. 201

(U) "Generically equivalent drug" has the same meaning as 202
in section 3715.01 of the Revised Code. 203

(V) "Animal shelter" means a facility operated by a humane 204
society or any society organized under Chapter 1717. of the 205
Revised Code or a dog pound operated pursuant to Chapter 955. of 206
the Revised Code. 207

(W) "Food" has the same meaning as in section 3715.01 of 208
the Revised Code. 209

(X) "Pain management clinic" has the same meaning as in 210
section 4731.054 of the Revised Code. 211

Sec. 4729.281. (A) A pharmacist may dispense or sell a dangerous drug, other than a schedule II controlled substance as defined in section 3719.01 of the Revised Code, without a written or oral prescription from a licensed health professional authorized to prescribe drugs if all of the following conditions are met:

(1) The pharmacy at which the pharmacist works has a record of a prescription for the drug in the name of the patient who is requesting it, but the prescription does not provide for a refill or the time permitted by rules adopted by the state board of pharmacy for providing refills has elapsed.

(2) The pharmacist is unable to obtain authorization to refill the prescription from the health care professional who issued the prescription or another health professional responsible for the patient's care.

(3) In the exercise of the pharmacist's professional judgment:

(a) The drug is essential to sustain the life of the patient or continue therapy for a chronic condition of the patient.

(b) Failure to dispense or sell the drug to the patient could result in harm to the health of the patient.

~~(4) The (a) Except as provided in division (A) (4) (b) of this section, the amount of the drug that is dispensed or sold under this section does not exceed a seventy-two-hour supply as provided in the prescription.~~

(b) (i) Subject to division (A) (4) (b) (ii) of this section, if the drug dispensed or sold under this section is not a controlled substance and the patient has been on a consistent

drug therapy as demonstrated by records maintained by a 241
pharmacy, the amount of the drug dispensed or sold does not 242
exceed a thirty-day supply as provided in the prescription or, 243
if the standard unit of dispensing for the drug exceeds a 244
thirty-day supply, the amount of the drug dispensed or sold does 245
not exceed the standard unit of dispensing. The pharmacist shall 246
exercise professional judgment in determining the amount of the 247
drug to be dispensed or sold. 248

(ii) A pharmacist shall not dispense or sell a particular 249
drug to the same patient in an amount described in division (A) 250
(4)(b)(i) of this section more than once in any twelve-month 251
period. 252

(B) A pharmacist who dispenses or sells a drug under this 253
section shall do all of the following: 254

(1) For one year after the date of dispensing or sale, 255
maintain a record in accordance with this chapter of the drug 256
dispensed or sold, including the name and address of the patient 257
and the individual receiving the drug, if the individual 258
receiving the drug is not the patient, the amount dispensed or 259
sold, and the original prescription number; 260

(2) Notify the health professional who issued the 261
prescription described in division (A)(1) of this section or 262
another health professional responsible for the patient's care 263
not later than seventy-two hours after the drug is sold or 264
dispensed; 265

(3) If applicable, obtain authorization for additional 266
dispensing from one of the health professionals described in 267
division (B)(2) of this section. 268

(C) A pharmacist who dispenses or sells a drug under this 269

section may do so once for each prescription described in 270
division (A) (1) of this section. 271

Sec. 4729.39. (A) ~~A pharmacist~~ One or more pharmacists may 272
enter into a consult agreement with ~~a physician~~ one or more 273
physicians authorized under Chapter 4731. of the Revised Code to 274
practice medicine and surgery or osteopathic medicine and 275
surgery if all of the following conditions are met: 276

(1) Each physician has an ongoing physician-patient 277
relationship with each patient whose drug therapy is being 278
managed. 279

(2) The diagnosis for which each patient has been 280
prescribed drug therapy is within the scope of each physician's 281
practice. 282

(3) Each pharmacist has training and experience related to 283
the particular diagnosis for which drug therapy is prescribed. 284

~~Under~~ (B) With respect to consult agreements, all of the 285
following apply: 286

(1) Under a consult agreement, a pharmacist is authorized 287
to manage an individual's drug therapy ~~do both of the following,~~ 288
but only to the extent specified in the agreement, this section, 289
and the rules adopted under this section; 290

(a) Manage drug therapy for treatment of specified 291
diagnoses or diseases for each patient who is subject to the 292
agreement, including all of the following: 293

(i) Changing the duration of treatment for the current 294
drug therapy; 295

(ii) Adjusting a drug's strength, dose, dosage form, 296
frequency of administration, or route of administration; 297

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| <u>(iii) Discontinuing the use of a drug;</u> | 298 |
| <u>(iv) Administering a drug;</u> | 299 |
| <u>(v) Notwithstanding the definition of "licensed health professional authorized to prescribe drugs" in section 4729.01 of the Revised Code, adding a drug to the patient's drug therapy.</u> | 300 301 302 303 |
| <u>(b) (i) Order blood and urine tests and evaluate results related to the drug therapy being managed.</u> | 304 305 |
| <u>(ii) A pharmacist's authority to evaluate blood and urine tests under division (B) (1) (b) (i) of this section does not authorize the pharmacist to make a diagnosis.</u> | 306 307 308 |
| (B) All of the following apply to a consult agreement that authorizes a pharmacist to manage the drug therapy of an individual who is not a patient of a hospital, as defined in section 3727.01 of the Revised Code, or a resident in a long-term care facility, as defined in section 3729.01 of the Revised Code: | 309 310 311 312 313 314 |
| (1) A separate consult agreement must be entered into for each individual whose drug therapy is to be managed by a pharmacist. A consult agreement applies only to the particular diagnosis for which a physician prescribed an individual's drug therapy. If a different diagnosis is made for the individual, the pharmacist and physician must enter into a new or additional consult agreement. | 315 316 317 318 319 320 321 |
| (2) Management of an individual's drug therapy by a pharmacist under a consult agreement may include monitoring and modifying a prescription that has been issued for the individual. Except as provided in section 4729.38 of the Revised Code for the selection of generically equivalent drugs, | 322 323 324 325 326 |

~~management of an individual's drug therapy by a pharmacist under
a consult agreement shall not include dispensing a drug that has
not been prescribed by the physician.~~ 327
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~~(3) Each consult agreement shall be in writing, except
that a consult agreement may be entered into verbally if it is
immediately reduced to writing.~~ 330
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~~(4) A physician entering into a consult agreement shall
specify in the agreement the extent to which the pharmacist is
authorized to manage the drug therapy of the individual
specified in the agreement.~~ 333
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~~(5) A physician entering into a consult agreement may
specify one other physician who has agreed to serve as an
alternate physician in the event that the primary physician is
unavailable to consult directly with the pharmacist. The
pharmacist may specify one other pharmacist who has agreed to
serve as an alternate pharmacist in the event that the primary
pharmacist is unavailable to consult directly with the
physician.~~ 337
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~~(6) A consult agreement may not be implemented until it
has been signed by the primary pharmacist, the primary
physician, and the individual whose drug therapy will be managed
or another person who has the authority to provide consent to
treatment on behalf of the individual. Once the agreement is
signed by all required parties, the physician shall include in
the individual's medical record the fact that a consult
agreement has been entered into with a pharmacist.~~ 345
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~~(7) Prior to commencing any action to manage an
individual's drug therapy under a consult agreement, the
pharmacist shall make reasonable attempts to contact and confer-~~ 353
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~~with the physician who entered into the consult agreement with
the pharmacist. A pharmacist may commence an action to manage an
individual's drug therapy prior to conferring with the physician
or the physician's alternate, but shall immediately cease the
action that was commenced if the pharmacist has not conferred
with either physician within forty eight hours.~~

~~A pharmacist acting under a consult agreement shall
maintain a record of each action taken to manage an individual's
drug therapy. The pharmacist shall send to the individual's
physician a written report of all actions taken to manage the
individual's drug therapy at intervals the physician shall
specify when entering into the agreement. The physician shall
include the pharmacist's report in the medical records the
physician maintains for the individual.~~

~~(8)-(2) (a) A consult agreement, or the portion of the
agreement that applies to a particular patient, may be
terminated by either the any of the following:~~

~~(i) A pharmacist ~~or~~ who entered into the agreement;~~

~~(ii) A physician who entered into the agreement. By
withdrawing consent, the individual;~~

~~(iii) A patient whose drug therapy is being managed ~~or~~
the;~~

~~(iv) An individual who consented to the treatment on
behalf of the individual may terminate a consult agreement a
patient or an individual authorized to act on behalf of a
patient.~~

~~The (b) The pharmacist or physician who receives the
individual's withdrawal of consent notice of a patient's
termination of the agreement shall provide written notice to the~~

~~opposite party~~every other pharmacist or physician who is a party 385
to the agreement. A pharmacist or physician who terminates a 386
consult agreement with regard to one or more patients shall 387
provide written notice to ~~the opposite party~~ all other 388
pharmacists and physicians who entered into the agreement and to 389
~~the~~ each individual who consented to treatment under the 390
agreement. The termination of a consult agreement with regard to 391
one or more patients shall be recorded by the pharmacist and 392
physician in the medical records ~~they maintain on the individual~~ 393
~~being treated~~of each patient to whom the termination applies. 394

~~(9) Except as described in division (B) (5) of this~~ 395
~~section, the authority of a pharmacist to manage an individual's~~ 396
~~drug therapy under a consult agreement does not permit the~~ 397
~~pharmacist to manage drug therapy prescribed by any other~~ 398
~~physician.~~ 399

~~(C) All of the following apply to a consult agreement that~~ 400
~~authorizes a pharmacist to manage the drug therapy of an~~ 401
~~individual who is a patient of a hospital, as defined in section~~ 402
~~3727.01 of the Revised Code, or a resident in a long term care~~ 403
~~facility, as defined in section 3729.01 of the Revised Code:~~ 404

~~(1) Before a consult agreement may be entered into and~~ 405
~~implemented, a hospital or long term care facility shall adopt a~~ 406
~~policy for consult agreements. For any period of time during~~ 407
~~which a pharmacist or physician acting under a consult agreement~~ 408
~~is not physically present and available at the hospital or~~ 409
~~facility, the policy shall require that another pharmacist and~~ 410
~~physician be available at the hospital or facility.~~ 411

~~(2) The~~ (3) A consult agreement shall be made in writing 412
and shall ~~comply with the hospital's or facility's policy on~~ 413
~~consult agreements~~include all of the following: 414

(a) The diagnoses and diseases being managed under the 415
agreement, including whether each disease is primary or 416
comorbid; 417

(b) A description of the drugs or drug categories the 418
agreement involves; 419

(c) A description of the procedures, decision criteria, 420
and plan the pharmacist is to follow in acting under a consult 421
agreement; 422

(d) A description of how the pharmacist is to comply with 423
divisions (B) (5) and (6) of this section. 424

~~(3)~~ (4) The content of the a consult agreement shall be 425
communicated to the individual each patient whose drug therapy 426
will be is managed in a manner consistent with the hospital's or 427
facility's policy on consult agreements under the agreement. 428

~~(4)~~ (5) A pharmacist acting under a consult agreement 429
shall maintain in the individual's medical record a record of 430
each action taken for each patient whose drug therapy is managed 431
under the agreement. 432

~~(5)~~ (6) Communication between a pharmacist and physician 433
acting under the a consult agreement shall take place at regular 434
intervals specified by the primary physician acting under the 435
agreement. The agreement may include a requirement that a 436
pharmacist send a consult report to each consulting physician. 437

~~(6) A consult agreement may be terminated by the~~ 438
~~individual, a person authorized to act on behalf of the~~ 439
~~individual, the primary physician acting under the agreement, or~~ 440
~~the primary pharmacist acting under the agreement. When a~~ 441
~~consult agreement is terminated, all parties to the agreement~~ 442
~~shall be notified and the termination shall be recorded in the~~ 443

~~individual's medical record.~~ 444

~~(7) The authority of a pharmacist acting under a A consult agreement is effective for two years and may be renewed if the conditions specified in division (A) of this section are met.~~ 445
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~~(8) A consult agreement does not permit ~~the a~~ pharmacist to act under the agreement in a hospital long term care facility at which the pharmacist is not authorized to practice manage drug therapy prescribed by a physician who has not entered into the agreement.~~ 448
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~~(D)~~ (C) The state board of pharmacy, in consultation with the state medical board, shall adopt rules to be followed by pharmacists, and the state medical board, in consultation with the state board of pharmacy, shall adopt rules to be followed by physicians, that establish standards and procedures for entering into a consult agreement and managing ~~an individual's a~~ patient's drug therapy under a consult agreement. The boards shall specify in the rules any categories of drugs or types of diseases for which a consult agreement may not be established. Either board may adopt any other rules it considers necessary for the implementation and administration of this section. All rules adopted under this division shall be adopted in accordance with Chapter 119. of the Revised Code. 453
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(D) (1) Subject to division (D) (2) of this section, both of the following apply: 466
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(a) A pharmacist acting in accordance with a consult agreement regarding a physician's change in a drug for a patient whose drug therapy the pharmacist is managing under the agreement is not liable in damages in a tort or other civil action for injury or loss to person or property allegedly 468
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arising from the change. 473

(b) A physician acting in accordance with a consult 474
agreement regarding a pharmacist's change in a drug for a 475
patient whose drug therapy the pharmacist is managing under a 476
consult agreement is not liable in damages in a tort or other 477
civil action for injury or loss to person or property allegedly 478
arising from the change unless the physician authorized the 479
specific change. 480

(2) Division (D)(1) of this section does not limit a 481
physician's or pharmacist's liability in damages in a tort or 482
other civil action for injury or loss to person or property 483
allegedly arising from actions that are not related to the 484
physician's or pharmacist's change in a drug for a patient whose 485
drug therapy is being managed under a consult agreement. 486

Section 2. That existing sections 4729.01, 4729.281, and 487
4729.39 of the Revised Code are hereby repealed. 488