

As Reported by the Senate Health and Human Services Committee

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Representatives Huffman, Pelanda

Cosponsors: Representatives Becker, Johnson, T., Sprague, Ginter, Barnes, Brown, Butler, Schuring, Amstutz, Anielski, Antonio, Baker, Burkley, Dovilla, Gonzales, Green, Grossman, McClain, O'Brien, S., Rogers, Sears, Smith, R., Sweeney

Senators Gardner, Jones, Cafaro, Brown, Beagle, Tavares

A BILL

To amend sections 1751.04, 1751.72, 3715.01, 1
3715.64, 3923.041, 4729.01, 4729.38, 4729.99, 2
and 5160.34 and to enact section 3715.011 of the 3
Revised Code to regulate biological products and 4
the substitution of interchangeable biological 5
products, to revise certain deadlines related to 6
prior authorization requirements, to establish 7
an exemption from the laws governing health 8
insuring corporations, to delay the expiration 9
of certain supervision agreements between 10
physicians and physician assistants, and to 11
declare an emergency. 12

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

Section 1. That sections 1751.04, 1751.72, 3715.01, 13
3715.64, 3923.041, 4729.01, 4729.38, 4729.99, and 5160.34 of the 14
Revised Code be amended and section 3715.011 of the Revised Code 15

be enacted to read as follows: 16

Sec. 1751.04. (A) Except as provided by division (D) of 17
this section, upon the receipt by the superintendent of 18
insurance of a complete application for a certificate of 19
authority to establish or operate a health insuring corporation, 20
which application sets forth or is accompanied by the 21
information and documents required by division (A) of section 22
1751.03 of the Revised Code, the superintendent shall review the 23
application and accompanying documents and make findings as to 24
whether the applicant for a certificate of authority has done 25
all of the following with respect to any basic health care 26
services and supplemental health care services to be furnished: 27

(1) Demonstrated the willingness and potential ability to 28
ensure that all basic health care services and supplemental 29
health care services described in the evidence of coverage will 30
be provided to all its enrollees as promptly as is appropriate 31
and in a manner that assures continuity; 32

(2) Made effective arrangements to ensure that its 33
enrollees have reliable access to qualified providers in those 34
specialties that are generally available in the geographic area 35
or areas to be served by the applicant and that are necessary to 36
provide all basic health care services and supplemental health 37
care services described in the evidence of coverage; 38

(3) Made appropriate arrangements for the availability of 39
short-term health care services in emergencies within the 40
geographic area or areas to be served by the applicant, twenty- 41
four hours per day, seven days per week, and for the provision 42
of adequate coverage whenever an out-of-area emergency arises; 43

(4) Made appropriate arrangements for an ongoing 44

evaluation and assurance of the quality of health care services 45
provided to enrollees, including, if applicable, the development 46
of a quality assurance program complying with the requirements 47
of sections 1751.73 to 1751.75 of the Revised Code, and the 48
adequacy of the personnel, facilities, and equipment by or 49
through which the services are rendered; 50

(5) Developed a procedure to gather and report statistics 51
relating to the cost and effectiveness of its operations, the 52
pattern of utilization of its services, and the quality, 53
availability, and accessibility of its services. 54

(B) Based upon the information provided in the application 55
for issuance of a certificate of authority, the superintendent 56
shall determine whether or not the applicant meets the 57
requirements of division (A) of this section. If the 58
superintendent determines that the applicant does not meet these 59
requirements, the superintendent shall specify in what respects 60
it is deficient. However, the superintendent shall not deny an 61
application because the requirements of this section are not met 62
unless the applicant has been given an opportunity for a hearing 63
on that issue. 64

(C) If the applicant requests a hearing, the 65
superintendent shall hold a hearing before denying an 66
application because the applicant does not meet the requirements 67
of this section. The hearing shall be held in accordance with 68
Chapter 119. of the Revised Code. 69

(D) Nothing in this section requires the superintendent to 70
review or make findings with regard to an application and 71
accompanying documents to establish or operate any of the 72
following: 73

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| (1) A health insuring corporation to cover solely medicaid recipients; | 74 75 |
| (2) A health insuring corporation to cover solely medicare beneficiaries; | 76 77 |
| (3) A health insuring corporation to cover solely medicaid recipients and medicare beneficiaries; | 78 79 |
| <u>(4) A health insuring corporation to cover solely federal employees and other individuals eligible for coverage in the federal employees health benefits program pursuant to 5 U.S.C. 8905.</u> | 80 81 82 83 |
| Sec. 1751.72. (A) As used in this section: | 84 |
| (1) "Chronic condition" means a medical condition that has persisted after reasonable efforts have been made to relieve or cure its cause and has continued, either continuously or episodically, for longer than six continuous months. | 85 86 87 88 |
| (2) "Clinical peer" means a health care practitioner in the same, or in a similar, specialty that typically manages the medical condition, procedure, or treatment under review. | 89 90 91 |
| (3) "Covered person" means a person receiving coverage for health services under a policy, contract, or agreement issued by a health insuring corporation. | 92 93 94 |
| (4) "Emergency services" has the same meaning as in section 1753.28 of the Revised Code. | 95 96 |
| (5) "Fraudulent or materially incorrect information" means any type of intentional deception or misrepresentation made by a person with the knowledge that the deception could result in some unauthorized benefit to the covered person in question. | 97 98 99 100 |

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| (6) "Health care practitioner" has the same meaning as in | 101 |
| section 3701.74 of the Revised Code. | 102 |
| (7) "NCPDP SCRIPT standard" means the national council for | 103 |
| prescription drug programs SCRIPT standard version 201310 or the | 104 |
| most recent standard adopted by the the United States department | 105 |
| of health and human services. | 106 |
| (8) "Prior authorization requirement" means any practice | 107 |
| implemented by a health insuring corporation in which coverage | 108 |
| of a health care service, device, or drug is dependent upon a | 109 |
| covered person or a health care practitioner obtaining approval | 110 |
| from the health insuring corporation prior to the service, | 111 |
| device, or drug being performed, received, or prescribed, as | 112 |
| applicable. "Prior authorization" includes prospective or | 113 |
| utilization review procedures conducted prior to providing a | 114 |
| health care service, device, or drug. | 115 |
| (9) "Urgent care services" means a medical care or other | 116 |
| service for a condition where application of the timeframe for | 117 |
| making routine or non-life threatening care determinations is | 118 |
| either of the following: | 119 |
| (a) Could seriously jeopardize the life, health, or safety | 120 |
| of the patient or others due to the patient's psychological | 121 |
| state; | 122 |
| (b) In the opinion of a practitioner with knowledge of the | 123 |
| patient's medical or behavioral condition, would subject the | 124 |
| patient to adverse health consequences without the care or | 125 |
| treatment that is the subject of the request. | 126 |
| (10) "Utilization review" and "utilization review | 127 |
| organization" have the same meanings as in section 1751.77 of | 128 |
| the Revised Code. | 129 |

(B) If a policy, contract, or agreement issued by a health insuring corporation contains a prior authorization requirement, then all of the following apply:

(1) On or before January 1, 2018, the health insuring corporation shall permit health care practitioners to access the prior authorization form through the applicable electronic software system.

(2) (a) For policies issued on or after January 1, 2018, the health insuring corporation or other payer acting on behalf of the health insuring corporation, shall accept prior authorization requests through a secure electronic transmission.

(b) For policies issued on or after January 1, 2018, the health insuring corporation, a pharmacy benefit manager responsible for handling prior authorization requests, or other payer acting on behalf of the health insuring corporation shall accept and respond to prior prescription benefit authorization requests through a secure electronic transmission using NCPDP SCRIPT standard ePA transactions, and for prior medical benefit authorization requests through a secure electronic transmission using standards established by the council for affordable quality health care on operating rules for information exchange or its successor.

(c) For purposes of division (B) (2) of this section, neither of the following shall be considered a secure electronic transmission:

(i) A facsimile;

(ii) A proprietary payer portal for prescription drug requests that does not use NCPDP SCRIPT standard.

(3) For policies issued on or after January 1, 2018, a

health care practitioner and health insuring corporation may 159
enter into a contractual arrangement under which the health 160
insuring corporation agrees to process prior authorization 161
requests that are not submitted electronically because of the 162
financial hardship that electronic submission of prior 163
authorization requests would create for the health care 164
practitioner or if internet connectivity is limited or 165
unavailable where the health care practitioner is located. 166

(4) (a) For policies issued on or after January 1, 2018, if 167
the health care practitioner submits the request for prior 168
authorization as described in divisions (B) (1) and (2) of this 169
section, the health insuring corporation shall respond to all 170
prior authorization requests within forty-eight hours for urgent 171
care services, or ten calendar days for any prior ~~approval~~ 172
authorization request that is not for an urgent care service, of 173
the time the request is received by the health insuring 174
corporation ~~with all information necessary to support the prior~~ 175
~~authorization request~~. Division (B) (4) of this section does not 176
apply to emergency services. 177

(b) ~~(i)~~ The response required under division (B) (4) (a) of 178
this section shall indicate whether the request is approved, or 179
denied, ~~or incomplete~~. If the prior authorization is denied, the 180
health insuring corporation shall provide the specific reason 181
for the denial. 182

(c) If the prior authorization request is incomplete, the 183
health insuring corporation shall indicate the specific 184
additional information that is required to process the request. 185

~~(ii) For a response that is considered incomplete, the~~ 186
~~health care practitioner shall provide the additional~~ 187
~~information requested under division (B) (4) (b) (i) of this~~ 188

~~section within seventy two hours of the time the request is~~ 189
~~received by the practitioner.~~ 190

(5) (a) For policies issued on or after January 1, 2018, if 191
a health care practitioner submits a prior authorization request 192
as described in divisions (B) (1) and (2) of this section, the 193
health insuring corporation shall provide an electronic receipt 194
to the health care practitioner acknowledging that the prior 195
authorization request was received. 196

(b) For policies issued on or after January 1, 2018, if a 197
health insuring corporation requests additional information that 198
is required to process a prior authorization request as 199
described in division (B) (4) ~~(b) (i)~~ (c) of this section, the 200
health care practitioner shall provide an electronic receipt to 201
the health insuring corporation acknowledging that the request 202
for additional information was received. 203

(6) (a) For policies issued on or after January 1, 2017, 204
for a prior approval related to a chronic condition, the health 205
insuring corporation shall honor a prior authorization approval 206
for an approved drug for the lesser of the following from the 207
date of the approval: 208

(i) Twelve months; 209

(ii) The last day of the covered person's eligibility 210
under the policy, contract, or agreement. 211

(b) The duration of all other prior authorization 212
approvals shall be dictated by the policy, contract, or 213
agreement issued by the health insuring corporation. 214

(c) A health insuring corporation may, in relation to a 215
prior approval under division (B) (6) (a) of this section, require 216
a health care practitioner to submit information to the health 217

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| insuring corporation indicating that the patient's chronic | 218 |
| condition has not changed. | 219 |
| (i) The request for information by the health insuring | 220 |
| corporation and the response by the health care practitioner | 221 |
| shall be in an electronic format, which may be by electronic | 222 |
| mail or other electronic communication. | 223 |
| (ii) The frequency of the submission of requested | 224 |
| information shall be consistent with medical or scientific | 225 |
| evidence as defined in section 3922.01 of the Revised Code, but | 226 |
| shall not be required more frequently than quarterly. | 227 |
| (iii) If the health care practitioner does not respond | 228 |
| within five calendar days from the date the request was | 229 |
| received, the health insuring corporation may terminate the | 230 |
| twelve-month approval. | 231 |
| (d) A year-long <u>twelve-month</u> approval provided under | 232 |
| division (B) (6) (a) of this section is no longer valid and | 233 |
| automatically terminates if there are changes to federal or | 234 |
| state laws or federal regulatory guidance or compliance | 235 |
| information prescribing that the drug in question is no longer | 236 |
| approved or safe for the intended purpose. | 237 |
| (e) A twelve-month approval provided under division (B) (6) | 238 |
| (a) of this section does not apply to and is not required for | 239 |
| any of the following: | 240 |
| (i) Medications that are prescribed for a non-maintenance | 241 |
| condition; | 242 |
| (ii) Medications that have a typical treatment of less | 243 |
| than one year; | 244 |
| (iii) Medications that require an initial trial period to | 245 |

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| determine effectiveness and tolerability, beyond which a one- | 246 |
| year, or greater, prior authorization period will be given; | 247 |
| (iv) Medications where there is medical or scientific | 248 |
| evidence as defined in section 3922.01 of the Revised Code that | 249 |
| do not support a twelve-month prior approval; | 250 |
| (v) Medications that are a schedule I or II controlled | 251 |
| substance or any opioid analgesic or benzodiazepine, as defined | 252 |
| in section 3719.01 of the Revised Code; | 253 |
| (vi) Medications that are not prescribed by an in-network | 254 |
| provider as part of a care management program. | 255 |
| (7) For policies issued on or after January 1, 2017, a | 256 |
| health insuring corporation may, but is not required to, provide | 257 |
| the twelve-month approval prescribed in division (B) (6) (a) of | 258 |
| this section for a prescription drug that meets either of the | 259 |
| following: | 260 |
| (a) The drug is prescribed or administered to treat a rare | 261 |
| medical condition and pursuant to medical or scientific evidence | 262 |
| as defined in section 3922.01 of the Revised Code. | 263 |
| (b) Medications that are controlled substances not | 264 |
| included in division (B) (6) (e) (v) of this section. | 265 |
| For purposes of division (B) (7) of this section, "rare | 266 |
| medical condition" means any disease or condition that affects | 267 |
| fewer than two hundred thousand individuals in the United | 268 |
| States. | 269 |
| (8) Nothing in division (B) (6) or (7) of this section | 270 |
| prohibits the substitution, <u>in accordance with section 4729.38</u> | 271 |
| <u>of the Revised Code,</u> of any drug that has received a twelve- | 272 |
| month approval under division (B) (6) (a) of this section when | 273 |

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| there is a release of a <u>either of the following:</u> | 274 |
| <u>(a) A United States food and drug administration approved</u> | 275 |
| comparable brand product or a generic counterpart of a brand | 276 |
| product that is listed as therapeutically equivalent in the | 277 |
| United States food and drug administration's publication titled | 278 |
| approved drug products with therapeutic equivalence evaluations; | 279 |
| <u>(b) An interchangeable biological product, as defined in</u> | 280 |
| <u>section 3715.01 of the Revised Code.</u> | 281 |
| (9) (a) For policies issued on or after January 1, 2017, | 282 |
| upon written request, a health insuring corporation shall permit | 283 |
| a retrospective review for a claim that is submitted for a | 284 |
| service where prior authorization was required but not obtained | 285 |
| if the service in question meets all of the following: | 286 |
| (i) The service is directly related to another service for | 287 |
| which prior approval has already been obtained and that has | 288 |
| already been performed. | 289 |
| (ii) The new service was not known to be needed at the | 290 |
| time the original prior authorized service was performed. | 291 |
| (iii) The need for the new service was revealed at the | 292 |
| time the original authorized service was performed. | 293 |
| (b) Once the written request and all necessary information | 294 |
| is received, the health insuring corporation shall review the | 295 |
| claim for coverage and medical necessity. The health insuring | 296 |
| corporation shall not deny a claim for such a new service based | 297 |
| solely on the fact that a prior authorization approval was not | 298 |
| received for the new service in question. | 299 |
| (10) (a) For policies issued on or after January 1, 2017, | 300 |
| the health insuring corporation shall disclose to all | 301 |

participating health care practitioners any new prior 302
authorization requirement at least thirty days prior to the 303
effective date of the new requirement. 304

(b) The notice may be sent via electronic mail or standard 305
mail and shall be conspicuously entitled "Notice of Changes to 306
Prior Authorization Requirements." The notice is not required to 307
contain a complete listing of all changes made to the prior 308
authorization requirements, but shall include specific 309
information on where the health care practitioner may locate the 310
information on the health insuring corporation's web site or, if 311
applicable, the health insuring corporation's portal. 312

(c) All participating health care practitioners shall 313
promptly notify the health insuring corporation of any changes 314
to the health care practitioner's electronic mail or standard 315
mail address. 316

(11) (a) For policies issued on or after January 1, 2017, 317
the health insuring corporation shall make available to all 318
participating health care practitioners on its web site or 319
provider portal a listing of its prior authorization 320
requirements, including specific information or documentation 321
that a ~~provider-practitioner~~ must submit in order for the prior 322
authorization request to be considered complete. 323

(b) The health insuring corporation shall make available 324
on its web site information about the policies, contracts, or 325
agreements offered by the health insuring corporation that 326
clearly identifies specific services, drugs, or devices to which 327
a prior authorization requirement exists. 328

(12) For policies issued on or after January 1, 2018, the 329
health insuring corporation shall establish a streamlined appeal 330

process relating to adverse prior authorization ~~decision~~ 331
determinations that shall include all of the following: 332

(a) For urgent care services, the appeal shall be 333
considered within forty-eight hours after the health insuring 334
corporation receives the appeal. 335

(b) For all other matters, the appeal shall be considered 336
within ten calendar days after the health insuring corporation 337
receives the appeal. 338

(c) The appeal shall be between the health care 339
practitioner requesting the service in question and a clinical 340
peer. 341

(d) If the appeal does not resolve the disagreement, 342
either the covered person or an authorized representative as 343
defined in section 3922.01 of the Revised Code may request an 344
external review under Chapter 3922. of the Revised Code to the 345
extent Chapter 3922. of the Revised Code is applicable. 346

(C) For policies issued on or after January 1, 2017, 347
except in cases of fraudulent or materially incorrect 348
information, a health insuring corporation shall not 349
retroactively deny a prior authorization for a health care 350
service, drug, or device when all of the following are met: 351

(1) The health care practitioner submits a prior 352
authorization request to the health insuring corporation for a 353
health care service, drug, or device. 354

(2) The health insuring corporation approves the prior 355
authorization request after determining that all of the 356
following are true: 357

(a) The patient is eligible under the health benefit plan. 358

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| (b) The health care service, drug, or device is covered under the patient's health benefit plan. | 359 360 |
| (c) The health care service, drug, or device meets the health insuring corporation's standards for medical necessity and prior authorization. | 361 362 363 |
| (3) The health care practitioner renders the health care service, drug, or device pursuant to the approved prior authorization request and all of the terms and conditions of the health care practitioner's contract with the health insuring corporation. | 364 365 366 367 368 |
| (4) On the date the health care practitioner renders the prior approved health care service, drug, or device, all of the following are true: | 369 370 371 |
| (a) The patient is eligible under the health benefit plan. | 372 |
| (b) The patient's condition or circumstances related to the patient's care has not changed. | 373 374 |
| (c) The health care practitioner submits an accurate claim that matches the information submitted by the health care practitioner in the approved prior authorization request. | 375 376 377 |
| (5) If the health care practitioner submits a claim that includes an unintentional error and the error results in a claim that does not match the information originally submitted by the health care practitioner in the approved prior authorization request, upon receiving a denial of services from the health insuring corporation, the health care practitioner may resubmit the claim pursuant to division (C) of this section with the information that matches the information included in the approved prior authorization. | 378 379 380 381 382 383 384 385 386 |

(D) Any provision of a contractual arrangement entered 387
into between a health insuring corporation and a health care 388
practitioner or beneficiary that is contrary to divisions (A) to 389
(C) of this section is unenforceable. 390

(E) For policies issued on or after January 1, 2017, 391
committing a series of violations of this section that, taken 392
together, constitute a practice or pattern shall be considered 393
an unfair and deceptive practice under sections 3901.19 to 394
3901.26 of the Revised Code. 395

(F) The superintendent of insurance may adopt rules in 396
accordance with Chapter 119. of the Revised Code as necessary to 397
implement the provisions of this section. 398

(G) This section does not apply to any of the following 399
types of coverage: a policy, contract, certificate, or agreement 400
that covers only a specified accident, accident only, credit, 401
dental, disability income, long-term care, hospital indemnity, 402
supplemental coverage as described in section 3923.37 of the 403
Revised Code, specified disease, or vision care; coverage issued 404
as a supplement to liability insurance; insurance arising out of 405
workers' compensation or similar law; automobile medical payment 406
insurance; insurance under which benefits are payable with or 407
without regard to fault and which is statutorily required to be 408
contained in any liability insurance policy or equivalent self- 409
insurance; a medicare supplement policy of insurance as defined 410
by the superintendent of insurance by rule; coverage under a 411
plan through medicare or the federal employees benefit program; 412
or any coverage issued under Chapter 55 of Title 10 of the 413
United States Code and any coverage issued as a supplement to 414
that coverage. 415

Sec. 3715.01. (A) As used in this chapter: 416

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| (1) "Person" means an individual, partnership, | 417 |
| corporation, or association. | 418 |
| (2) "Food" means: | 419 |
| (a) Articles used for food or drink for humans or animals; | 420 |
| (b) Chewing gum; | 421 |
| (c) Articles used for components of any such articles. | 422 |
| (3) "Drug" means: | 423 |
| (a) Articles recognized in the United States pharmacopoeia | 424 |
| and national formulary, or any supplement to them; | 425 |
| (b) Articles intended for use in the diagnosis, cure, | 426 |
| mitigation, treatment, or prevention of disease in humans or | 427 |
| animals; | 428 |
| (c) Articles, other than food, intended to affect the | 429 |
| structure or any function of the body of humans or other | 430 |
| animals; | 431 |
| (d) Articles intended for use as a component of any of the | 432 |
| foregoing articles, other than devices or their components, | 433 |
| parts, or accessories. | 434 |
| (4) "Device," except when used in division (B) (1) of this | 435 |
| section and in division (A) (10) of section 3715.52, division (F) | 436 |
| of section 3715.60, division (A) (5) of section 3715.64, and | 437 |
| division (C) of section 3715.67 of the Revised Code, means any | 438 |
| instrument, apparatus, implement, machine, contrivance, implant, | 439 |
| in vitro reagent, or other similar or related article, including | 440 |
| any component, part, or accessory, that is any of the following: | 441 |
| (a) Recognized in the United States pharmacopoeia and | 442 |
| national formulary, or any supplement to them; | 443 |

(b) Intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease in humans or animals;

(c) Intended to affect the structure or any function of the body of humans or animals, and that does not achieve any of its principal intended purposes through chemical action within or on the body of humans or animals and is not dependent upon being metabolized for the achievement of any of its principal intended purposes.

(5) "Cosmetic" means:

(a) Articles intended to be rubbed, poured, sprinkled, or sprayed on, introduced into, or otherwise applied to the human body or any part thereof for cleansing, beautifying, promoting attractiveness, or altering the appearance;

(b) Articles intended for use as a component of any such article, except that "cosmetic" does not include soap.

(6) "Label" means a display of written, printed, or graphic matter upon the immediate container, exclusive of package liners, of any article.

Any word, statement, or other information required by this chapter to appear on the label must appear on the outside container or wrapper, if any, of the retail package of the article, or the label must be easily legible through the outside container or wrapper.

(7) "Labeling" means all labels and other written, printed, or graphic matter:

(a) Upon an article or any of its containers or wrappers;

(b) Accompanying such article.

(8) "Advertisement" means all representations disseminated 472
in any manner or by any means, other than by labeling, for the 473
purpose of inducing, or that are likely to induce, directly or 474
indirectly, the purchase of food, drugs, devices, or cosmetics. 475

(9) "New drug" means: 476

(a) Any drug the composition of which is such that the 477
drug is not generally recognized among experts qualified by 478
scientific training and experience to evaluate the safety of 479
drugs, as safe for use under the conditions prescribed, 480
recommended, or suggested in the labeling thereof; 481

(b) Any drug the composition of which is such that the 482
drug, as a result of investigation to determine its safety for 483
use under such conditions, has become so recognized, but that 484
has not, other than in an investigation, been used to a material 485
extent or for a material time under such conditions. 486

(10) "Contaminated with filth" applies to any food, drug, 487
device, or cosmetic that has not been protected as far as may be 488
necessary by all reasonable means from dust, dirt, and all 489
foreign or injurious substances. 490

(11) "Honey" means the nectar and saccharine exudation of 491
plants that has been gathered, modified, and stored in a 492
honeycomb by honeybees. 493

(12) "Finished dosage form" means the form of a drug that 494
is, or is intended to be, dispensed or administered to humans or 495
animals and requires no further manufacturing or processing 496
other than packaging, reconstituting, or labeling. 497

(13) (a) "Manufacture" means the planting, cultivating, 498
harvesting, processing, making, preparing, or otherwise engaging 499
in any part of the production of a drug by propagating, 500

compounding, converting, or processing, either directly or 501
indirectly by extracting from substances of natural origin, or 502
independently by means of chemical synthesis, or by a 503
combination of extraction and chemical synthesis, and includes 504
the following: 505

(i) Any packaging or repackaging of the drug or labeling 506
or relabeling of its container, the promotion and marketing of 507
the drug, and other activities incident to production; 508

(ii) The preparation and promotion of commercially 509
available products from bulk compounds for resale by pharmacies, 510
licensed health professionals authorized to prescribe drugs, or 511
other persons. 512

(b) "Manufacture" does not include the preparation, 513
compounding, packaging, or labeling of a drug by a pharmacist as 514
an incident to either of the following: 515

(i) Dispensing a drug in the usual course of professional 516
practice; 517

(ii) Providing a licensed health professional authorized 518
to prescribe drugs with a drug for the purpose of administering 519
to patients or for using the drug in treating patients in the 520
professional's office. 521

(14) "Dangerous drug" has the same meaning as in section 522
4729.01 of the Revised Code. 523

(15) "Generically equivalent drug" means a drug that 524
contains identical amounts of the identical active ingredients, 525
but not necessarily containing the same inactive ingredients, 526
that meets the identical compendial or other applicable standard 527
of identity, strength, quality, and purity, including potency, 528
and where applicable, content uniformity, disintegration times, 529

or dissolution rates, as the prescribed brand name drug and the 530
manufacturer or distributor holds, if applicable, either an 531
approved new drug application or an approved abbreviated new 532
drug application unless other approval by law or from the 533
federal food and drug administration is required. 534

No drug shall be considered a generically equivalent drug 535
for the purposes of this chapter if it has been listed by the 536
federal food and drug administration as having proven 537
bioequivalence problems. 538

(16) "Licensed health professional authorized to prescribe 539
drugs" and "prescriber" have the same meanings as in section 540
4729.01 of the Revised Code. 541

(17) "Home" means the primary residence occupied by the 542
residence's owner, on the condition that the residence contains 543
only one stove or oven used for cooking, which may be a double 544
oven, designed for common residence usage and not for commercial 545
usage, and that the stove or oven be operated in an ordinary 546
kitchen within the residence. 547

(18) "Potentially hazardous food" means a food that is 548
natural or synthetic, to which any of the following apply: 549

(a) It has a pH level greater than 4.6 when measured at 550
seventy-five degrees fahrenheit or twenty-four degrees celsius. 551

(b) It has a water activity value greater than 0.85. 552

(c) It requires temperature control because it is in a 553
form capable of supporting the rapid and progressive growth of 554
infectious or toxigenic microorganisms, the growth and toxin 555
production of clostridium botulinum, or in the case of raw 556
shell eggs, the growth of salmonella enteritidis. 557

(19) "Cottage food production operation" means a person 558
who, in the person's home, produces food items that are not 559
potentially hazardous foods, including bakery products, jams, 560
jellies, candy, fruit butter, and similar products specified in 561
rules adopted pursuant to section 3715.025 of the Revised Code. 562

(20) "Biological product" means, except as provided in 563
section 3715.011 of the Revised Code, a drug that is a 564
biological product, as defined on the effective date of this 565
amendment in subsection (i) of section 351 of the "Public Health 566
Service Act," 42 U.S.C. 262(i). 567

(21) "Interchangeable biological product" means, except as 568
provided in section 3715.011 of the Revised Code, both of the 569
following: 570

(a) A biological product that, on the effective date of 571
this amendment, has been determined by the United States food 572
and drug administration to meet the standards for 573
interchangeability set forth in subsection (k) of section 351 of 574
the "Public Health Service Act," 42 U.S.C. 262(k), as amended, 575
and has been licensed under that subsection; 576

(b) A biological product that, prior to the effective date 577
of this amendment, was determined by the United States food and 578
drug administration to be therapeutically equivalent as set 579
forth in its publication titled "Approved Drug Products with 580
Therapeutic Equivalence Evaluations." 581

(B) For the purposes of sections 3715.52 to 3715.72 of the 582
Revised Code: 583

(1) If an article is alleged to be misbranded because the 584
labeling is misleading, or if an advertisement is alleged to be 585
false because it is misleading, then in determining whether the 586

labeling or advertisement is misleading, there shall be taken 587
into account, among other things, not only representations made 588
or suggested by statement, word, design, device, sound, or in 589
any combination thereof, but also the extent to which the 590
labeling or advertisement fails to reveal facts material in the 591
light of such representations or material with respect to 592
consequence which may result from the use of the article to 593
which the labeling or advertisement relates under the conditions 594
of use prescribed in the labeling or advertisement thereof or 595
under such conditions of use as are customary or usual. 596

(2) The provisions regarding the selling of food, drugs, 597
devices, or cosmetics include the manufacture, production, 598
processing, packing, exposure, offer, possession, and holding of 599
any such article for sale; and the sale, dispensing, and giving 600
of any such article, and the supplying or applying of any such 601
articles in the conduct of any food, drug, or cosmetic 602
establishment. The provisions do not prohibit a licensed health 603
professional authorized to prescribe drugs from administering or 604
personally furnishing a drug or device to a patient. 605

(3) The representation of a drug, in its labeling or 606
advertisement, as an antiseptic is a representation that it is a 607
germicide, except in the case of a drug purporting to be, or 608
represented as, an antiseptic for inhibitory use as a wet 609
dressing, ointment, dusting powder, or other use that involves 610
prolonged contact with the body. 611

(4) Whenever jurisdiction is vested in the director of 612
agriculture or the state board of pharmacy, the jurisdiction of 613
the board shall be limited to the sale, offering for sale, 614
giving away, delivery, or dispensing in any manner of drugs at 615
the wholesale and retail levels or to the consumer and shall be 616

exclusive in the case of such sale, offering for sale, giving 617
away, delivery, or dispensing in any manner of drugs at the 618
wholesale and retail levels or to the consumer in any place 619
where prescriptions are dispensed or compounded. 620

(5) To assist in effectuating the provisions of those 621
sections, the director of agriculture or state board of pharmacy 622
may request assistance or data from any government or private 623
agency or individual. 624

Sec. 3715.011. (A) When one of the following changes 625
occurs under federal law with respect to a biological product or 626
interchangeable biological product, the change is automatically 627
effected under this chapter and Chapter 4729. of the Revised 628
Code, subject to any rule adopted under division (B) of this 629
section to the contrary: 630

(1) An article is added to or removed from the definition 631
of biological product in subsection (i) of section 351 of the 632
"Public Health Service Act," 42 U.S.C. 262(i). 633

(2) The United States food and drug administration 634
determines that a biological product meets the standards for 635
interchangeability set forth in section 351 of the "Public 636
Health Service Act," 42 U.S.C. 262(k), and the product is 637
licensed under that subsection. 638

(3) The United States food and drug administration 639
determines that a biological product no longer meets the 640
standards for interchangeability set forth in section 351 of the 641
"Public Health Service Act," 42 U.S.C. 262(k), and the product's 642
license under that subsection is suspended or revoked. 643

(B) The state board of pharmacy may adopt rules that 644
exclude a biological product or interchangeable biological 645

product that, pursuant to division (A) of this section, would 646
otherwise be included under this chapter and Chapter 4729. of 647
the Revised Code. The board's rules shall establish criteria to 648
be used in determining whether a product is to be excluded. 649

All rules adopted under this division shall be adopted in 650
accordance with Chapter 119. of the Revised Code. 651

Sec. 3715.64. (A) A drug or device is misbranded within 652
the meaning of sections 3715.01 and 3715.52 to 3715.72 of the 653
Revised Code, if: 654

(1) Its labeling is false or misleading in any particular. 655

(2) It is in package form and does not bear a label 656
containing both of the following: 657

(a) In clearly legible form, the name and place of 658
business of the manufacturer, packer, or distributor; 659

(b) An accurate statement of the quantity of the contents 660
in terms of weight, measure, or numerical count; but reasonable 661
variations shall be permitted, and exemptions as to small 662
packages shall apply as established by rules adopted by the 663
director of agriculture or state board of pharmacy. 664

(3) It is a dangerous drug and does not bear a label 665
containing in clearly legible form the name and place of 666
business of the manufacturer of the finished dosage form and, if 667
different, the packer or distributor. 668

(4) It is a dangerous drug in finished solid oral dosage 669
form and it does not have clearly and prominently marked or 670
imprinted on it an individual symbol, company name, national 671
drug code number or other number, words, letters, or any 672
combination thereof, identifying the drug and its manufacturer 673

or distributor. This requirement does not apply to drugs that 674
are compounded by a licensed pharmacist. The manufacturer or 675
distributor of each such drug shall make available to the state 676
board of pharmacy descriptive material identifying the mark or 677
imprint used by the manufacturer or distributor. The board shall 678
provide this information to all poison control centers in this 679
state. Upon application by a manufacturer or distributor, the 680
board may exempt a drug from the requirements of this division 681
on the grounds that marking or imprinting the drug is not 682
feasible because of its size, texture, or other unique 683
characteristic. 684

(5) Any word, statement, or other information that is 685
required by or under authority of sections 3715.01 and 3715.52 686
to 3715.72 of the Revised Code to appear on the label or 687
labeling is not prominently placed on the label or labeling in a 688
conspicuous manner, as compared with other words, statements, 689
designs, or devices on the label or labeling, and in terms that 690
render it likely to be read and understood by the ordinary 691
individual under customary conditions of purchase and use. 692

(6) It is a drug and it is not designated solely by a name 693
recognized in the United States pharmacopoeia and national 694
formulary, or any supplement to them, unless its label bears: 695

(a) The common or usual name of the drug, if any; 696

(b) In case it is fabricated from two or more ingredients, 697
the common or usual name of each active ingredient the drug 698
contains, including the kind and quantity or proportion of any 699
alcohol, and also including whether active or not, the name and 700
quantity or proportion of any bromides, ether, chloroform, 701
acetanalid, acetophenetidin, aminopyrine, atropine, hyoscine, 702
hyoscyamine, arsenic, digitalis, digitalis glycosides, mercury, 703

ouabain, strophanthin, strychnine, thyroid, or any derivative or 704
preparation of any such substances; but to the extent that 705
compliance with these requirements is impracticable, exemptions 706
shall apply as established by rules adopted by the director of 707
agriculture or state board of pharmacy. 708

(7) Its labeling does not bear the following: 709

(a) Adequate directions for use of the drug or device, 710
except that when compliance with this requirement is not 711
necessary for a particular drug or device to protect the public 712
health, the director shall adopt rules exempting the drug or 713
device from the requirement; 714

(b) Adequate warnings against use in those pathological 715
conditions or by children when its use may be dangerous to 716
health, or against unsafe dosage or methods or duration of 717
administration or application, presented in a manner and form as 718
necessary for the protection of users. 719

(8) It purports to be a drug the name of which is 720
recognized in the United States pharmacopoeia and national 721
formulary, or any supplement to them, and it is not packaged and 722
labeled as prescribed in those compendiums, except that the 723
method of packing may be modified with the consent of the 724
director of agriculture. Whenever a drug is recognized in both 725
the homoeopathic pharmacopoeia of the United States and in the 726
United States pharmacopoeia and national formulary, including 727
their supplements, it shall be subject to the requirements of 728
the United States pharmacopoeia and national formulary with 729
respect to packaging and labeling unless it is labeled and 730
offered for sale as a homoeopathic drug, in which case it shall 731
be subject to the provisions of the homoeopathic pharmacopoeia 732
of the United States and not to those of the United States 733

pharmacopoeia and national formulary. 734

(9) It has been found by the director of agriculture to be 735
a drug liable to deterioration, unless it is packaged in the 736
form and manner, and its label bears a statement of precautions, 737
as required by rules adopted by the director as necessary for 738
the protection of public health. No rule shall be established 739
for any drug recognized in the United States pharmacopoeia and 740
national formulary, or any supplements to them, until the 741
director has informed the appropriate bodies charged with the 742
revision of those compendiums of the need for packaging or 743
labeling requirements and those bodies have failed within a 744
reasonable time to prescribe such requirements. 745

(10) (a) It is a drug and its container is so made, formed, 746
or filled as to be misleading. 747

(b) It is an imitation of another drug. 748

(c) It is offered for sale under the name of another drug. 749

(d) The drug sold or dispensed is not the brand or drug 750
specifically prescribed or ordered or, when dispensed by a 751
pharmacist upon prescription, the drug is neither the brand or 752
drug prescribed nor a generically equivalent drug or, in the 753
case of a drug that is a biological product, is neither the 754
brand or biological product prescribed nor an interchangeable 755
biological product. 756

(11) It is dangerous to health when used in the dosage, or 757
with the frequency or duration prescribed, recommended, or 758
suggested in its labeling. 759

(12) It is a drug intended for human use to which the 760
following apply: 761

(a) Because of its toxicity or other potentiality for harmful effect, the method of its use, or the collateral measures necessary to its use, the drug is not safe for use except under the supervision of a licensed health professional authorized to prescribe drugs;

(b) The drug is limited by an effective application under section 505 of the "Federal Food, Drug, and Cosmetic Act," 52 Stat. 1040 (1938), 21 U.S.C.A. 301, as amended, to use under professional supervision by a licensed health professional authorized to prescribe drugs, unless it is dispensed only:

(i) Upon a written or electronic prescription;

(ii) Upon an oral prescription, which is reduced promptly to writing by the pharmacist;

(iii) By refilling a prescription if refilling is authorized by the prescriber either in the original prescription or by oral order, which is promptly reduced to writing by the pharmacist.

(B) (1) Any drug dispensed pursuant to a written, electronic, or oral prescription of a licensed health professional authorized to prescribe drugs shall be exempt from the requirements of division (A) of this section, except divisions (A) (1) and (10) of this section, if the drug bears a label containing the name and address of the dispenser, the serial number and the date the prescription is dispensed, the name of the prescriber, the name of the patient, and, if stated in the prescription, the directions for use and cautionary statements. ~~Unless~~

(2) Unless the prescription directions prohibit labeling ~~prescriber instructs otherwise~~, the label for the

dispensed drug shall include information that meets the 791
following requirements, using abbreviations as necessary: 792

(a) Except as provided in divisions (B)(2)(b) and (c) of 793
this section, the label shall include the dispensed drug's brand 794
name of the drug dispensed. If 795

(b) If the drug dispensed has no brand name and is a 796
generically equivalent drug, the label shall include the generic 797
name of the drug and the distributor of the finished dosage form 798
shall be included. 799

(c) If the drug dispensed has no brand name and is an 800
interchangeable biological product, the label shall include the 801
name of the interchangeable biological product, the 802
manufacturer, and if the distributor is not the same as the 803
manufacturer, the distributor of the finished dosage form. 804

Sec. 3923.041. (A) As used in this section: 805

(1) "Chronic condition" means a medical condition that has 806
persisted after reasonable efforts have been made to relieve or 807
cure its cause and has continued, either continuously or 808
episodically, for longer than six continuous months. 809

(2) "Clinical peer" means a health care practitioner in 810
the same or in a similar, specialty that typically manages the 811
medical condition, procedure, or treatment under review. 812

(3) "Covered person" means a person receiving coverage for 813
health services under a policy of sickness and accident 814
insurance or a public employee benefit plan. 815

(4) "Emergency service" has the same meaning as in section 816
1753.28 of the Revised Code. 817

(5) "Fraudulent or materially incorrect information" means 818

any type of intentional deception or misrepresentation made by a 819
person with the knowledge that the deception could result in 820
some unauthorized benefit to the covered person in question. 821

(6) "Health care practitioner" has the same meaning as in 822
section 3701.74 of the Revised Code. 823

(7) "NCPDP SCRIPT standard" means the national council for 824
prescription drug programs SCRIPT standard version 201310 or the 825
most recent standard adopted by the United States department of 826
health and human services. 827

(8) "Prior authorization requirement" means any practice 828
implemented by either a sickness and accident insurer or a 829
public employee benefit plan in which coverage of a health care 830
service, device, or drug is dependent upon a covered person or a 831
health care practitioner obtaining approval from the insurer or 832
plan prior to the service, device, or drug being performed, 833
received, or prescribed, as applicable. "Prior authorization" 834
includes prospective or utilization review procedures conducted 835
prior to providing a health care service, device, or drug. 836

(9) "Urgent care services" means a medical care or other 837
service for a condition where application of the timeframe for 838
making routine or non-life threatening care determinations is 839
either of the following: 840

(a) Could seriously jeopardize the life, health, or safety 841
of the patient or others due to the patient's psychological 842
state; 843

(b) In the opinion of a practitioner with knowledge of the 844
patient's medical or behavioral condition, would subject the 845
patient to adverse health consequences without the care or 846
treatment that is the subject of the request. 847

(10) "Utilization review" and "utilization review organization" have the same meanings as in section 1751.77 of the Revised Code. 848
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(B) If a policy issued by a sickness and accident insurer or a public employee benefit plan contains a prior authorization requirement, then all of the following apply: 851
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(1) For policies issued on or after January 1, 2018, the insurer or plan shall permit health care practitioners to access the prior authorization form through the applicable electronic software system. 854
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(2) (a) For policies issued on or after January 1, 2018, the insurer or plan, or other payer acting on behalf of the insurer or plan, to accept prior authorization requests through a secure electronic transmission. 858
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(b) For policies issued on or after January 1, 2018, the insurer or plan, a pharmacy benefit manager responsible for handling prior authorization requests, or other payer acting on behalf of the insurer or plan shall accept and respond to prior prescription benefit authorization requests through a secure electronic transmission using NCPDP SCRIPT standard ePA transactions, and for prior medical benefit authorization requests through a secure electronic transmission using standards established by the council for affordable quality health care on operating rules for information exchange or its successor. 862
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(c) For purposes of division (B) (2) of this section, neither of the following shall be considered a secure electronic transmission: 873
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(i) A facsimile; 876

(ii) A proprietary payer portal for prescription drug requests that does not use NCPDP SCRIPT standard. 877
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(3) For policies issued on or after January 1, 2018, a health care practitioner and an insurer or plan may enter into a contractual arrangement under which the insurer or plan agrees to process prior authorization requests that are not submitted electronically because of the financial hardship that electronic submission of prior authorization requests would create for the health care practitioner or if internet connectivity is limited or unavailable where the health care practitioner is located. 879
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(4) (a) For policies issued on or after January 1, 2018, if the health care practitioner submits the request for prior authorization electronically as described in divisions (B) (1) and (2) of this section, the insurer or plan shall respond to all prior authorization requests within forty-eight hours for urgent care services, or ten calendar days for any prior ~~approval authorization request~~ that is not for an urgent care service, of the time the request is received by the insurer or plan ~~with all information necessary to support the prior authorization request~~. Division (B) (4) of this section does not apply to emergency services. 887
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(b) ~~(i)~~ The response required under division (B) (4) (a) of this section shall indicate whether the request is approved, or denied, ~~or incomplete~~. If the prior authorization is denied, the insurer or plan shall provide the specific reason for the denial. 898
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(c) If the prior authorization request is incomplete, the insurer or plan shall indicate the specific additional information that is required to process the request. 903
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~~(ii) For a response that is considered incomplete, the health care practitioner shall provide the additional information requested under division (B) (4) (b) (i) of this section within seventy two hours of the time the request is received by the practitioner.~~

(5) (a) For policies issued on or after January 1, 2018, if a health care practitioner submits a prior authorization request as described in divisions (B) (1) and (2) of this section, the insurer or plan shall provide an electronic receipt to the health care practitioner acknowledging that the prior authorization request was received.

(b) For policies issued on or after January 1, 2018, if an issuer or plan requests additional information that is required to process a prior authorization request as described in division (B) (4) ~~(b) (i)~~ (c) of this section, the health care practitioner shall provide an electronic receipt to the issuer or plan acknowledging that the request for additional information was received.

(6) (a) For policies issued on or after January 1, 2017, for a prior approval related to a chronic condition, the insurer or plan shall honor a prior authorization approval for an approved drug for the lesser of the following from the date of the approval:

(i) Twelve months;

(ii) The last day of the covered person's eligibility under the policy or plan.

(b) The duration of all other prior authorization approvals shall be dictated by the policy or plan.

(c) An insurer or plan, in relation to prior approval

under division (B) (6) (a) of this section, may require a health 935
care practitioner to submit information to the insurer or plan 936
indicating that the patient's chronic condition has not changed. 937

(i) The request for information by the insurer or plan and 938
the response by the health care practitioner shall be in an 939
electronic format, which may be by ~~traditional~~ electronic mail 940
or other electronic communication. 941

(ii) The frequency of the submission of requested 942
information shall be consistent with medical or scientific 943
evidence, as defined in section 3922.01 of the Revised Code, but 944
shall not be required more frequently than quarterly. 945

(iii) If the health care practitioner does not respond 946
within five calendar days from the date the request was 947
received, the insurer or plan may terminate the twelve-month 948
approval. 949

(d) A ~~year-long twelve-month~~ approval provided under 950
division (B) (6) (a) of this section is no longer valid and 951
automatically terminates if there are changes to federal or 952
state laws or federal regulatory guidance or compliance 953
information prescribing that the drug in question is no longer 954
approved or safe for the intended purpose. 955

(e) A twelve-month approval provided under division (B) (6) 956
(a) of this section does not apply to and is not required for 957
any of the following: 958

(i) Medications that are prescribed for a non-maintenance 959
condition; 960

(ii) Medications that have a typical treatment of less 961
than one year; 962

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|---|-----|
| (iii) Medications that require an initial trial period to determine effectiveness and tolerability, beyond which a one-year, or greater, prior authorization period will be given; | 963 |
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| (iv) Medications where there is medical or scientific evidence as defined in section 3922.01 of the Revised Code that do not support a twelve-month prior approval; | 966 |
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| (v) Medications that are a schedule I or II controlled substance or any opioid analgesic or benzodiazepine, as defined in section 3719.01 of the Revised Code; | 969 |
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| (vi) Medications that are not prescribed by an in-network provider as part of the care management program. | 972 |
| | 973 |
| (7) For policies issued on or after January 1, 2017, an insurer or plan may, but is not required to, provide the twelve-month approval prescribed in division (B) (6) (a) of this section for a prescription drug that meets either of the following: | 974 |
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| (a) The drug is prescribed or administered to treat a rare medical condition and pursuant to medical or scientific evidence as defined in section 3922.01 of the Revised Code. | 978 |
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| (b) Medications that are controlled substances not included in division (B) (6) (e) (v) of this section. | 981 |
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| For purposes of division (B) (7) of this section, "rare medical condition" means any disease or condition that affects fewer than two hundred thousand individuals in the United States. | 983 |
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| (8) Nothing in division (B) (6) or (7) of this section prohibits the substitution, <u>in accordance with section 4729.38 of the Revised Code,</u> of any drug that has received a twelve-month approval under division (B) (6) (a) of this section when | 987 |
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there is a release of ~~a~~either of the following: 991

(a) A United States food and drug administration approved 992
comparable brand product or a generic counterpart of a brand 993
product that is listed as therapeutically equivalent in the 994
United States food and drug administration's publication titled 995
approved drug products with therapeutic equivalence evaluations; 996

(b) An interchangeable biological product, as defined in 997
section 3715.01 of the Revised Code. 998

(9) (a) For policies issued on or after January 1, 2017, 999
upon written request, an insurer or plan shall permit a 1000
retrospective review for a claim that is submitted for a service 1001
where prior authorization was required but not obtained if the 1002
service in question meets all of the following: 1003

(i) The service is directly related to another service for 1004
which prior approval has already been obtained and that has 1005
already been performed. 1006

(ii) The new service was not known to be needed at the 1007
time the original prior authorized service was performed. 1008

(iii) The need for the new service was revealed at the 1009
time the original authorized service was performed. 1010

(b) Once the written request and all necessary information 1011
is received, the insurer or plan shall review the claim for 1012
coverage and medical necessity. The insurer or plan shall not 1013
deny a claim for such a new service based solely on the fact 1014
that a prior authorization approval was not received for the new 1015
service in question. 1016

(10) (a) For policies issued on or after January 1, 2017, 1017
the insurer or plan shall disclose to all participating health 1018

care practitioners any new prior authorization requirement at 1019
least thirty days prior to the effective date of the new 1020
requirement. 1021

(b) The notice may be sent via electronic mail or standard 1022
mail and shall be conspicuously entitled "Notice of Changes to 1023
Prior Authorization Requirements." The notice is not required to 1024
contain a complete listing of all changes made to the prior 1025
authorization requirements, but shall include specific 1026
information on where the health care practitioner may locate the 1027
information on the insurer or plan's web site or, if applicable, 1028
the insurer's or plan's portal. 1029

(c) All participating health care practitioners shall 1030
promptly notify the insurer or plan of any changes to the health 1031
care practitioner's electronic mail or standard mail address. 1032

(11) (a) For policies issued on or after January 1, 2017, 1033
the insurer or plan shall make available to all participating 1034
health care practitioners on its web site or provider portal a 1035
listing of its prior authorization requirements, including 1036
specific information or documentation that a ~~provider~~ 1037
practitioner must submit in order for the prior authorization 1038
request to be considered complete. 1039

(b) The insurer or plan shall make available on its web 1040
site information about the policies, contracts, or agreements 1041
offered by the insurer or plan that clearly identifies specific 1042
services, drugs, or devices to which a prior authorization 1043
requirement exists. 1044

(12) For policies issued on or after January 1, 2018, the 1045
insurer or plan shall establish a streamlined appeal process 1046
relating to adverse prior authorization determinations that 1047

shall include all of the following: 1048

(a) For urgent care services, the appeal shall be 1049
considered within forty-eight hours after the insurer or plan 1050
receives the appeal. 1051

(b) For all other matters, the appeal shall be considered 1052
within ten calendar days after the insurer or plan receives the 1053
appeal. 1054

(c) The appeal shall be between the health care 1055
practitioner requesting the service in question and a clinical 1056
peer. 1057

(d) If the appeal does not resolve the disagreement, 1058
either the covered person or an authorized representative as 1059
defined in section 3922.01 of the Revised Code may request an 1060
external review under Chapter 3922. of the Revised Code to the 1061
extent Chapter 3922. of the Revised Code is applicable. 1062

(C) For policies issued on or after January 1, 2017, 1063
except in cases of fraudulent or materially incorrect 1064
information, an insurer or plan shall not retroactively deny a 1065
prior authorization for a health care service, drug, or device 1066
when all of the following are met: 1067

(1) The health care practitioner submits a prior 1068
authorization request to the insurer or plan for a health care 1069
service, drug, or device; 1070

(2) The insurer or plan approves the prior authorization 1071
request after determining that all of the following are true: 1072

(a) The patient is eligible under the health benefit plan. 1073

(b) The health care service, drug, or device is covered 1074
under the patient's health benefit plan. 1075

(c) The health care service, drug, or device meets the insurer's or plan's standards for medical necessity and prior authorization. 1076
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(3) The health care practitioner renders the health care service, drug, or device pursuant to the approved prior authorization request and all of the terms and conditions of the health care practitioner's contract with the insurer or plan; 1079
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(4) On the date the health care practitioner renders the prior approved health care service, drug, or device, all of the following are true: 1083
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(a) The patient is eligible under the health benefit plan. 1086

(b) The patient's condition or circumstances related to the patient's care has not changed. 1087
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(c) The health care practitioner submits an accurate claim that matches the information submitted by the health care practitioner in the approved prior authorization request. 1089
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(5) If the health care practitioner submits a claim that includes an unintentional error and the error results in a claim that does not match the information originally submitted by the health care practitioner in the approved prior authorization request, upon receiving a denial of services from the insurer or plan, the health care practitioner may resubmit the claim pursuant to division (C) of this section with the information that matches the information included in the approved prior authorization. 1092
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(D) Any provision of a contractual arrangement entered into between an insurer or plan and a health care practitioner or beneficiary that is contrary to divisions (A) to (C) of this section is unenforceable. 1101
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(E) For policies issued on or after January 1, 2017, 1105
committing a series of violations of this section that, taken 1106
together, constitute a practice or pattern shall be considered 1107
an unfair and deceptive practice under sections 3901.19 to 1108
3901.26 of the Revised Code. 1109

(F) The superintendent of insurance may adopt rules in 1110
accordance with Chapter 119. of the Revised Code as necessary to 1111
implement the provisions of this section. 1112

(G) This section does not apply to any of the following 1113
types of coverage: a policy, contract, certificate, or agreement 1114
that covers only a specified accident, accident only, credit, 1115
dental, disability income, long-term care, hospital indemnity, 1116
supplemental coverage as described in section 3923.37 of the 1117
Revised Code, specified disease, or vision care; coverage issued 1118
as a supplement to liability insurance; insurance arising out of 1119
workers' compensation or similar law; automobile medical payment 1120
insurance; insurance under which benefits are payable with or 1121
without regard to fault and which is statutorily required to be 1122
contained in any liability insurance policy or equivalent self- 1123
insurance; a medicare supplement policy of insurance as defined 1124
by the superintendent of insurance by rule; coverage under a 1125
plan through medicare or the federal employees benefit program; 1126
or any coverage issued under Chapter 55 of Title 10 of the 1127
United States Code and any coverage issued as a supplement to 1128
that coverage. 1129

Sec. 4729.01. As used in this chapter: 1130

(A) "Pharmacy," except when used in a context that refers 1131
to the practice of pharmacy, means any area, room, rooms, place 1132
of business, department, or portion of any of the foregoing 1133
where the practice of pharmacy is conducted. 1134

(B) "Practice of pharmacy" means providing pharmacist care 1135
requiring specialized knowledge, judgment, and skill derived 1136
from the principles of biological, chemical, behavioral, social, 1137
pharmaceutical, and clinical sciences. As used in this division, 1138
"pharmacist care" includes the following: 1139

(1) Interpreting prescriptions; 1140

(2) Dispensing drugs and drug therapy related devices; 1141

(3) Compounding drugs; 1142

(4) Counseling individuals with regard to their drug 1143
therapy, recommending drug therapy related devices, and 1144
assisting in the selection of drugs and appliances for treatment 1145
of common diseases and injuries and providing instruction in the 1146
proper use of the drugs and appliances; 1147

(5) Performing drug regimen reviews with individuals by 1148
discussing all of the drugs that the individual is taking and 1149
explaining the interactions of the drugs; 1150

(6) Performing drug utilization reviews with licensed 1151
health professionals authorized to prescribe drugs when the 1152
pharmacist determines that an individual with a prescription has 1153
a drug regimen that warrants additional discussion with the 1154
prescriber; 1155

(7) Advising an individual and the health care 1156
professionals treating an individual with regard to the 1157
individual's drug therapy; 1158

(8) Acting pursuant to a consult agreement with one or 1159
more physicians authorized under Chapter 4731. of the Revised 1160
Code to practice medicine and surgery or osteopathic medicine 1161
and surgery, if an agreement has been established; 1162

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| (9) Engaging in the administration of immunizations to the extent authorized by section 4729.41 of the Revised Code. | 1163 1164 |
| (C) "Compounding" means the preparation, mixing, assembling, packaging, and labeling of one or more drugs in any of the following circumstances: | 1165 1166 1167 |
| (1) Pursuant to a prescription issued by a licensed health professional authorized to prescribe drugs; | 1168 1169 |
| (2) Pursuant to the modification of a prescription made in accordance with a consult agreement; | 1170 1171 |
| (3) As an incident to research, teaching activities, or chemical analysis; | 1172 1173 |
| (4) In anticipation of orders for drugs pursuant to prescriptions, based on routine, regularly observed dispensing patterns; | 1174 1175 1176 |
| (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: | 1177 1178 1179 1180 1181 |
| (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. | 1182 1183 1184 1185 1186 |
| (b) A limited quantity of the drug is compounded and provided to the professional. | 1187 1188 |
| (c) The drug is compounded and provided to the professional as an occasional exception to the normal practice | 1189 1190 |

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| of dispensing drugs pursuant to patient-specific prescriptions. | 1191 |
| (D) "Consult agreement" means an agreement that has been entered into under section 4729.39 of the Revised Code. | 1192 1193 |
| (E) "Drug" means: | 1194 |
| (1) Any article recognized in the United States pharmacopoeia and national formulary, or any supplement to them, intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in humans or animals; | 1195 1196 1197 1198 |
| (2) Any other article intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in humans or animals; | 1199 1200 1201 |
| (3) Any article, other than food, intended to affect the structure or any function of the body of humans or animals; | 1202 1203 |
| (4) Any article intended for use as a component of any article specified in division (E) (1), (2), or (3) of this section; but does not include devices or their components, parts, or accessories. | 1204 1205 1206 1207 |
| (F) "Dangerous drug" means any of the following: | 1208 |
| (1) Any drug to which either of the following applies: | 1209 |
| (a) Under the "Federal Food, Drug, and Cosmetic Act," 52 Stat. 1040 (1938), 21 U.S.C.A. 301, as amended, the drug is required to bear a label containing the legend "Caution: Federal law prohibits dispensing without prescription" or "Caution: Federal law restricts this drug to use by or on the order of a licensed veterinarian" or any similar restrictive statement, or the drug may be dispensed only upon a prescription; | 1210 1211 1212 1213 1214 1215 1216 |
| (b) Under Chapter 3715. or 3719. of the Revised Code, the | 1217 |

drug may be dispensed only upon a prescription. 1218

(2) Any drug that contains a schedule V controlled 1219
substance and that is exempt from Chapter 3719. of the Revised 1220
Code or to which that chapter does not apply; 1221

(3) Any drug intended for administration by injection into 1222
the human body other than through a natural orifice of the human 1223
body; 1224

(4) Any drug that is a biological product, as defined in 1225
section 3715.01 of the Revised Code. 1226

(G) "Federal drug abuse control laws" has the same meaning 1227
as in section 3719.01 of the Revised Code. 1228

(H) "Prescription" means all of the following: 1229

(1) A written, electronic, or oral order for drugs or 1230
combinations or mixtures of drugs to be used by a particular 1231
individual or for treating a particular animal, issued by a 1232
licensed health professional authorized to prescribe drugs; 1233

(2) For purposes of sections 2925.61, 4723.488, 4729.44, 1234
4730.431, and 4731.94 of the Revised Code, a written, 1235
electronic, or oral order for naloxone issued to and in the name 1236
of a family member, friend, or other individual in a position to 1237
assist an individual who there is reason to believe is at risk 1238
of experiencing an opioid-related overdose. 1239

(3) For purposes of sections 4723.4810, 4729.282, 1240
4730.432, and 4731.93 of the Revised Code, a written, 1241
electronic, or oral order for a drug to treat chlamydia, 1242
gonorrhoea, or trichomoniasis issued to and in the name of a 1243
patient who is not the intended user of the drug but is the 1244
sexual partner of the intended user; 1245

(4) For purposes of sections 3313.7110, 3313.7111, 1246
3314.143, 3326.28, 3328.29, 4723.483, 4729.88, 4730.433, 1247
4731.96, and 5101.76 of the Revised Code, a written, electronic, 1248
or oral order for an epinephrine autoinjector issued to and in 1249
the name of a school, school district, or camp; 1250

(5) For purposes of Chapter 3728. and sections 4723.483, 1251
4729.88, 4730.433, and 4731.96 of the Revised Code, a written, 1252
electronic, or oral order for an epinephrine autoinjector issued 1253
to and in the name of a qualified entity, as defined in section 1254
3728.01 of the Revised Code. 1255

(I) "Licensed health professional authorized to prescribe 1256
drugs" or "prescriber" means an individual who is authorized by 1257
law to prescribe drugs or dangerous drugs or drug therapy 1258
related devices in the course of the individual's professional 1259
practice, including only the following: 1260

(1) A dentist licensed under Chapter 4715. of the Revised 1261
Code; 1262

(2) A clinical nurse specialist, certified nurse-midwife, 1263
or certified nurse practitioner who holds a certificate to 1264
prescribe issued under section 4723.48 of the Revised Code; 1265

(3) An optometrist licensed under Chapter 4725. of the 1266
Revised Code to practice optometry under a therapeutic 1267
pharmaceutical agents certificate; 1268

(4) A physician authorized under Chapter 4731. of the 1269
Revised Code to practice medicine and surgery, osteopathic 1270
medicine and surgery, or podiatric medicine and surgery; 1271

(5) A physician assistant who holds a license to practice 1272
as a physician assistant issued under Chapter 4730. of the 1273
Revised Code, holds a valid prescriber number issued by the 1274

state medical board, and has been granted physician-delegated prescriptive authority;

(6) A veterinarian licensed under Chapter 4741. of the Revised Code.

(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.

(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.

(L) "Retail sale" and "sale at retail" mean any sale other than a wholesale sale or sale at wholesale.

(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.

(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:

(1) The proprietary name of the drug product;

(2) The established (generic) name of the drug product;

(3) The strength of the drug product if the product contains a single active ingredient or if the drug product contains more than one active ingredient and a relevant strength can be associated with the product without indicating each active ingredient. The established name and quantity of each

active ingredient are required if such a relevant strength 1303
cannot be so associated with a drug product containing more than 1304
one ingredient. 1305

(4) The dosage form; 1306

(5) The price charged for a specific quantity of the drug 1307
product. The stated price shall include all charges to the 1308
consumer, including, but not limited to, the cost of the drug 1309
product, professional fees, handling fees, if any, and a 1310
statement identifying professional services routinely furnished 1311
by the pharmacy. Any mailing fees and delivery fees may be 1312
stated separately without repetition. The information shall not 1313
be false or misleading. 1314

(O) "Wholesale distributor of dangerous drugs" means a 1315
person engaged in the sale of dangerous drugs at wholesale and 1316
includes any agent or employee of such a person authorized by 1317
the person to engage in the sale of dangerous drugs at 1318
wholesale. 1319

(P) "Manufacturer of dangerous drugs" means a person, 1320
other than a pharmacist, who manufactures dangerous drugs and 1321
who is engaged in the sale of those dangerous drugs within this 1322
state. 1323

(Q) "Terminal distributor of dangerous drugs" means a 1324
person who is engaged in the sale of dangerous drugs at retail, 1325
or any person, other than a wholesale distributor or a 1326
pharmacist, who has possession, custody, or control of dangerous 1327
drugs for any purpose other than for that person's own use and 1328
consumption, and includes pharmacies, hospitals, nursing homes, 1329
and laboratories and all other persons who procure dangerous 1330
drugs for sale or other distribution by or under the supervision 1331

of a pharmacist or licensed health professional authorized to 1332
prescribe drugs. 1333

(R) "Promote to the public" means disseminating a 1334
representation to the public in any manner or by any means, 1335
other than by labeling, for the purpose of inducing, or that is 1336
likely to induce, directly or indirectly, the purchase of a 1337
dangerous drug at retail. 1338

(S) "Person" includes any individual, partnership, 1339
association, limited liability company, or corporation, the 1340
state, any political subdivision of the state, and any district, 1341
department, or agency of the state or its political 1342
subdivisions. 1343

~~(T) "Finished dosage form" has the same meaning as in~~ 1344
~~section 3715.01 of the Revised Code.~~ 1345

~~(U) "Generically equivalent drug" has the same meaning as~~ 1346
~~in section 3715.01 of the Revised Code.~~ 1347

~~(V) "Animal shelter" means a facility operated by a humane~~ 1348
~~society or any society organized under Chapter 1717. of the~~ 1349
~~Revised Code or a dog pound operated pursuant to Chapter 955. of~~ 1350
~~the Revised Code.~~ 1351

~~(W)~~ (U) "Food" has the same meaning as in section 3715.01 1352
of the Revised Code. 1353

~~(X)~~ (V) "Pain management clinic" has the same meaning as 1354
in section 4731.054 of the Revised Code. 1355

Sec. 4729.38. (A) As used in this section, "biological 1356
product," "finished dosage form," "generically equivalent drug," 1357
and "interchangeable biological product" have the same meanings 1358
as in section 3715.01 of the Revised Code. 1359

(B) Unless instructed otherwise by the person receiving 1360
the drug pursuant to the prescription, a pharmacist filling a 1361
prescription for a drug prescribed by its brand name may, 1362
subject to the following conditions, select a generically 1363
equivalent drug, ~~as defined in section 3715.01 of the Revised~~ 1364
Code, subject to the following conditions or, in the case of a 1365
drug that is a biological product, select an interchangeable 1366
biological product: 1367

(1) The pharmacist shall not select a generically 1368
equivalent drug or interchangeable biological product if the 1369
prescriber either of the following applies: 1370

(a) In the case of a written or electronic prescription, 1371
including a computer-generated prescription, the prescriber 1372
handwrites or actively causes to display on the prescription 1373
"dispense as written," or "D.A.W.," on the written prescription, 1374
or, when ordering a prescription electronically or orally, the 1375
prescriber "do not substitute," "brand medically necessary," or 1376
any other statement or numerical code that indicates the 1377
prescriber's intent to prevent substitution. Such a designation 1378
shall not be preprinted or stamped on the prescription, but a 1379
reminder to the prescriber of the designation procedure may be 1380
preprinted or displayed on the prescription form or electronic 1381
system the prescriber uses to issue the prescription. 1382

(b) In the case of an oral prescription, the prescriber 1383
specifies that the ~~prescribed~~ drug as prescribed is medically 1384
necessary or otherwise indicates the prescriber's intent to 1385
prevent substitution. ~~These designations shall not be preprinted~~ 1386
or stamped on the prescription. ~~Division (A) (1) of this section~~ 1387
does not preclude a reminder of the procedure required to 1388
prohibit the selection of a generically equivalent drug from 1389

~~being preprinted on the prescription.~~ 1390

(2) The pharmacist shall not select a generically 1391
equivalent drug or interchangeable biological product unless its 1392
price to the patient is less than or equal to the price of the 1393
~~prescribed drug as prescribed.~~ 1394

(3) The pharmacist~~7~~ or the pharmacist's agent, assistant, 1395
or employee shall inform the patient or the patient's agent if a 1396
generically equivalent drug or interchangeable biological 1397
product is available at a lower or equal cost~~7~~ and of the 1398
person's right to refuse the drug selected. Division ~~(A)~~(B) (3) 1399
of this section does not apply to any: 1400

(a) Prescription that is billed to any agency, division, 1401
or department of this state which will reimburse the pharmacy; 1402

(b) Prescriptions for patients of a hospital, nursing 1403
home, or similar patient care facility. 1404

~~(B)~~(C) (1) Unless the prescriber instructs otherwise, the 1405
label for every drug dispensed shall include information that 1406
meets the following requirements, using abbreviations as 1407
necessary: 1408

(a) Except as provided in divisions (C) (1) (b) and (c) of 1409
this section, the label shall include the dispensed drug's brand 1410
name, if any, or its generic name and the name of the. 1411

(b) If the drug dispensed has no brand name and is a 1412
generically equivalent drug, the label shall include the generic 1413
name of the drug and the distributor, using abbreviations if 1414
necessary of the finished dosage form. 1415

(c) If the drug dispensed has no brand name and is an 1416
interchangeable biological product, the label shall include the 1417

name of the interchangeable biological product, the 1418
manufacturer, and if the distributor is not the same as the 1419
manufacturer, the distributor of the finished dosage form. 1420

(2) When dispensing at retail a drug that is a generically 1421
equivalent drug or interchangeable biological product for the 1422
brand name a drug prescribed by its brand name, the pharmacist 1423
shall indicate on the drug's label or container that a ~~generic~~ 1424
substitution was made. ~~The~~ 1425

(3) The labeling requirements established by this division 1426
divisions (C) (1) and (2) of this section are in addition to all 1427
other labeling requirements of Chapter 3715. of the Revised 1428
Code. 1429

~~(C)~~ (D) A pharmacist who selects a drug that is a 1430
generically equivalent drug or interchangeable biological 1431
product pursuant to this section assumes no greater liability 1432
for selecting the dispensed drug than would be incurred in 1433
filling a prescription for a drug prescribed by its brand name. 1434

~~(D)~~ (E) The failure of a prescriber to restrict a 1435
prescription by ~~specifying "dispense as written," or "D.A.W.,"~~ 1436
indicating an intent to prevent substitution pursuant to 1437
division ~~(A)~~ (B) (1) of this section shall not constitute evidence 1438
of the prescriber's negligence unless the prescriber had 1439
reasonable cause to believe that the health condition of the 1440
patient for whom the drug was intended warranted the 1441
prescription of a specific brand name drug and no other. No 1442
prescriber shall be liable for civil damages or in any criminal 1443
prosecution arising from the ~~interchange~~ substitution of a 1444
generically equivalent drug or interchangeable biological 1445
product for a prescribed brand name drug by a pharmacist, unless 1446
the prescribed brand name drug would have reasonably caused the 1447

same loss, damage, injury, or death. 1448

(F) (1) (a) Except as provided in division (F) (1) (b) of this 1449
section, not later than five business days after a pharmacist 1450
dispenses a drug for which an interchangeable biological product 1451
is available, regardless of whether a substitution is made, the 1452
pharmacist or an individual designated by the pharmacist shall 1453
communicate to the prescriber information identifying the 1454
specific biological product that was dispensed, including the 1455
name of the biological product and its manufacturer. 1456

(b) Communication of the information is not required when 1457
a biological product is dispensed by refilling a prescription 1458
and the product that is dispensed is the same product that was 1459
dispensed when the same prescription was last filled or 1460
refilled. 1461

(2) When possible, communication of the information shall 1462
be conveyed by entering the information into a recordkeeping 1463
system that can reasonably be presumed to be electronically 1464
accessible to the prescriber. Such a system may include any of 1465
the following: 1466

(a) An interoperable electronic medical records system; 1467

(b) An electronic prescribing system; 1468

(c) An electronic pharmacy benefit management system; 1469

(d) An electronic pharmacy record system. 1470

(3) Entering the complete information into one of the 1471
recordkeeping systems listed in division (F) (2) of this section 1472
is presumed to provide notice to the prescriber. 1473

(4) When it is not possible to communicate the information 1474
by using one of the recordkeeping systems listed in division (F) 1475

(2) of this section, communication of the information shall be 1476
conveyed by telephone, facsimile, another form of electronic 1477
communication, or any other prevailing means of communication. 1478

(G) No pharmacist shall knowingly engage in conduct that 1479
is prohibited by division (B) or (C) of this section. 1480

Sec. 4729.99. (A) Whoever violates section 4729.16, 1481
division ~~(A) or (B)~~ (G) of section 4729.38, or section 4729.57 1482
of the Revised Code is guilty of a minor misdemeanor. Each day's 1483
violation constitutes a separate offense. 1484

(B) Whoever violates section 4729.27, 4729.28, or 4729.36 1485
of the Revised Code is guilty of a misdemeanor of the third 1486
degree. Each day's violation constitutes a separate offense. If 1487
the offender previously has been convicted of or pleaded guilty 1488
to a violation of this chapter, that person is guilty of a 1489
misdemeanor of the second degree. 1490

(C) Whoever violates section 4729.32, 4729.33, or 4729.34 1491
of the Revised Code is guilty of a misdemeanor. 1492

(D) Whoever violates division (A), (B), (D), or (E) of 1493
section 4729.51 of the Revised Code is guilty of a misdemeanor 1494
of the first degree. 1495

(E) (1) Whoever violates section 4729.37, division (C) (2) 1496
of section 4729.51, division (J) of section 4729.54, or section 1497
4729.61 of the Revised Code is guilty of a felony of the fifth 1498
degree. If the offender previously has been convicted of or 1499
pleaded guilty to a violation of this chapter or a violation of 1500
Chapter 2925. or 3719. of the Revised Code, that person is 1501
guilty of a felony of the fourth degree. 1502

(2) If an offender is convicted of or pleads guilty to a 1503
violation of section 4729.37, division (C) of section 4729.51, 1504

division (J) of section 4729.54, or section 4729.61 of the Revised Code, if the violation involves the sale, offer to sell, or possession of a schedule I or II controlled substance, with the exception of marihuana, and if the court imposing sentence upon the offender finds that the offender as a result of the violation is a major drug offender, as defined in section 2929.01 of the Revised Code, and is guilty of a specification of the type described in section 2941.1410 of the Revised Code, the court, in lieu of the prison term authorized or required by division (E) (1) of this section and sections 2929.13 and 2929.14 of the Revised Code and in addition to any other sanction imposed for the offense under sections 2929.11 to 2929.18 of the Revised Code, shall impose upon the offender, in accordance with division (B) (3) of section 2929.14 of the Revised Code, the mandatory prison term specified in that division.

(3) Notwithstanding any contrary provision of section 3719.21 of the Revised Code, the clerk of court shall pay any fine imposed for a violation of section 4729.37, division (C) of section 4729.51, division (J) of section 4729.54, or section 4729.61 of the Revised Code pursuant to division (A) of section 2929.18 of the Revised Code in accordance with and subject to the requirements of division (F) of section 2925.03 of the Revised Code. The agency that receives the fine shall use the fine as specified in division (F) of section 2925.03 of the Revised Code.

(F) Whoever violates section 4729.531 of the Revised Code or any rule adopted thereunder or section 4729.532 of the Revised Code is guilty of a misdemeanor of the first degree.

(G) Whoever violates division (C) (1) of section 4729.51 of the Revised Code is guilty of a felony of the fourth degree. If

the offender has previously been convicted of or pleaded guilty 1535
to a violation of this chapter, or of a violation of Chapter 1536
2925. or 3719. of the Revised Code, that person is guilty of a 1537
felony of the third degree. 1538

(H) Whoever violates division (C) (3) of section 4729.51 of 1539
the Revised Code is guilty of a misdemeanor of the first degree. 1540
If the offender has previously been convicted of or pleaded 1541
guilty to a violation of this chapter, or of a violation of 1542
Chapter 2925. or 3719. of the Revised Code, that person is 1543
guilty of a felony of the fifth degree. 1544

(I) (1) Whoever violates division (B) of section 4729.42 of 1545
the Revised Code is guilty of unauthorized pharmacy-related drug 1546
conduct. Except as otherwise provided in this section, 1547
unauthorized pharmacy-related drug conduct is a misdemeanor of 1548
the second degree. If the offender previously has been convicted 1549
of or pleaded guilty to a violation of division (B), (C), (D), 1550
or (E) of that section, unauthorized pharmacy-related drug 1551
conduct is a misdemeanor of the first degree on a second offense 1552
and a felony of the fifth degree on a third or subsequent 1553
offense. 1554

(2) Whoever violates division (C) or (D) of section 1555
4729.42 of the Revised Code is guilty of permitting unauthorized 1556
pharmacy-related drug conduct. Except as otherwise provided in 1557
this section, permitting unauthorized pharmacy-related drug 1558
conduct is a misdemeanor of the second degree. If the offender 1559
previously has been convicted of or pleaded guilty to a 1560
violation of division (B), (C), (D), or (E) of that section, 1561
permitting unauthorized pharmacy-related drug conduct is a 1562
misdemeanor of the first degree on a second offense and a felony 1563
of the fifth degree on a third or subsequent offense. 1564

(3) Whoever violates division (E) of section 4729.42 of the Revised Code is guilty of the offense of falsification under section 2921.13 of the Revised Code. In addition to any other sanction imposed for the violation, the offender is forever disqualified from engaging in any activity specified in division (B) (1), (2), or (3) of section 4729.42 of the Revised Code and from performing any function as a health care professional or health care worker. As used in this division, "health care professional" and "health care worker" have the same meanings as in section 2305.234 of the Revised Code.

(4) Notwithstanding any contrary provision of section 3719.21 of the Revised Code or any other provision of law that governs the distribution of fines, the clerk of the court shall pay any fine imposed pursuant to division (I) (1), (2), or (3) of this section to the state board of pharmacy if the board has adopted a written internal control policy under division (F) (2) of section 2925.03 of the Revised Code that addresses fine moneys that it receives under Chapter 2925. of the Revised Code and if the policy also addresses fine moneys paid under this division. The state board of pharmacy shall use the fines so paid in accordance with the written internal control policy to subsidize the board's law enforcement efforts that pertain to drug offenses.

(J) (1) Whoever violates division (A) (1) of section 4729.86 of the Revised Code is guilty of a misdemeanor of the third degree. If the offender has previously been convicted of or pleaded guilty to a violation of division (A) (1), (2), or (3) of section 4729.86 of the Revised Code, that person is guilty of a misdemeanor of the first degree.

(2) Whoever violates division (A) (2) of section 4729.86 of

the Revised Code is guilty of a misdemeanor of the first degree. 1595
If the offender has previously been convicted of or pleaded 1596
guilty to a violation of division (A) (1), (2), or (3) of section 1597
4729.86 of the Revised Code, that person is guilty of a felony 1598
of the fifth degree. 1599

(3) Whoever violates division (A) (3) of section 4729.86 of 1600
the Revised Code is guilty of a felony of the fifth degree. If 1601
the offender has previously been convicted of or pleaded guilty 1602
to a violation of division (A) (1), (2), or (3) of section 1603
4729.86 of the Revised Code, that person is guilty of a felony 1604
of the fourth degree. 1605

(K) A person who violates division (C) of section 4729.552 1606
of the Revised Code is guilty of a misdemeanor of the first 1607
degree. If the person previously has been convicted of or 1608
pleaded guilty to a violation of division (C) of section 1609
4729.552 of the Revised Code, that person is guilty of a felony 1610
of the fifth degree. 1611

Sec. 5160.34. (A) As used in this section: 1612

(1) "Chronic condition" means a medical condition that has 1613
persisted after reasonable efforts have been made to relieve or 1614
cure its cause and has continued, either continuously or 1615
episodically, for longer than six continuous months. 1616

(2) "Clinical peer" means a ~~medical~~ health care provider 1617
in the same, or in a similar, specialty that typically manages 1618
the medical condition, procedure, or treatment under review. 1619

(3) "Emergency services" has the same meaning as in 1620
section 1753.28 of the Revised Code. 1621

(4) "Prior authorization requirement" means any practice 1622
implemented by a medical assistance program in which coverage of 1623

a health care service, device, or drug is dependent upon a 1624
medical assistance recipient or a health care provider, 1625
receiving approval from the department of medicaid or its 1626
designee, including a medicaid managed care organization, prior 1627
to the service, device, or drug being performed, received, or 1628
prescribed, as applicable. "Prior authorization" includes 1629
prospective or utilization review procedures conducted prior to 1630
providing a health care service, device, or drug. 1631

(5) "Urgent care services" means a medical care or other 1632
service for a condition where application of the timeframe for 1633
making routine or non-life threatening care determinations is 1634
either of the following: 1635

(a) Could seriously jeopardize the life, health, or safety 1636
of the recipient or others due to the recipient's psychological 1637
state; 1638

(b) In the opinion of a practitioner with knowledge of the 1639
recipient's medical or behavioral condition, would subject the 1640
recipient to adverse health consequences without the care or 1641
treatment that is the subject of the request. 1642

(6) "Utilization review" and "utilization review 1643
organization" have the same meanings as in section 1751.77 of 1644
the Revised Code. 1645

(B) If a medical assistance program has a prior 1646
authorization requirement, the department of medicaid or its 1647
designee, including a medicaid managed care organization, shall 1648
do all of the following: 1649

(1) On or before January 1, 2018, permit a health care 1650
provider to access the prior authorization form through the 1651
applicable electronic software system. 1652

(2) (a) On or before January 1, 2018, permit the department 1653
or its designee to accept and respond to prior prescription 1654
benefit authorization requests through a secure electronic 1655
transmission. 1656

(b) On or before January 1, 2018, the department or its 1657
designee shall accept and respond to prior prescription benefit 1658
authorization requests through a secure electronic transmission 1659
using NCPDP SCRIPT standard ePA transactions, and for prior 1660
medical benefit authorization requests through a secure 1661
electronic transmission using standards established by the 1662
council for affordable quality health care on operating rules 1663
for information exchange or its successor. 1664

(c) For purposes of division (B) (2) of this section, 1665
neither of the following shall be considered a secure electronic 1666
transmission: 1667

(i) A facsimile; 1668

(ii) A proprietary payer portal for prescription drug 1669
requests that does not use NCPDP SCRIPT standard. 1670

(3) On or before January 1, 2018, a health care provider 1671
and the department of medicaid or its designee may enter into a 1672
contractual arrangement under which the department or its 1673
designee agrees to process prior authorization requests that are 1674
not submitted electronically because of the financial hardship 1675
that electronic submission of prior authorization requests would 1676
create for the provider or if internet connectivity is limited 1677
or unavailable where the provider is located. 1678

(4) (a) On or before January 1, 2018, if the health care 1679
provider submits the request for prior authorization 1680
electronically as described in divisions (B) (1) and (2) of this 1681

section, respond to all prior authorization requests within 1682
forty-eight hours for urgent care services, or ten calendar days 1683
for any prior ~~approval~~ authorization request that is not for an 1684
urgent care service, of the time the request is received by the 1685
department or its designee ~~with all information necessary to~~ 1686
~~support the prior authorization request.~~ Division (B) ~~(5)~~ (4) of 1687
this section does not apply to emergency services. 1688

(b) ~~(i)~~ The response required under division (B) (4) (a) of 1689
this section shall indicate whether the request is approved, or 1690
~~denied, or incomplete.~~ If the prior authorization is denied, the 1691
department or its designee shall provide the specific reason for 1692
the denial. 1693

(c) If the prior authorization request is incomplete, the 1694
department or its designee shall indicate the specific 1695
additional information that is required to process the request. 1696

~~(ii) For a response that is considered incomplete, the~~ 1697
~~health care provider shall provide the additional information~~ 1698
~~requested under division (B) (4) (b) (i) of this section within~~ 1699
~~seventy-two hours of the time the request is received by the~~ 1700
~~provider.~~ 1701

(5) (a) On or before January 1, 2018, if a health care 1702
provider submits a prior authorization request as described in 1703
divisions (B) (1) and (2) of this section, the department or its 1704
designee shall provide an electronic receipt to the health care 1705
provider acknowledging that the prior authorization request was 1706
received. 1707

(b) On or before January 1, 2018, if the department or its 1708
designee requests additional information that is required to 1709
process a prior authorization request as described in division 1710

(B) (4) ~~(b) (i)~~ (c) of this section, the health care provider shall 1711
provide an electronic receipt to the department or its designee 1712
acknowledging that the request for additional information was 1713
received. 1714

(6) (a) On or before January 1, 2017, honor a prior 1715
authorization approval for an approved drug for the lesser of 1716
the following from the date of approval: 1717

(i) Twelve months; 1718

(ii) The last day of the medical assistance recipient's 1719
eligibility for the medical assistance program. 1720

(b) The duration of all other prior authorization 1721
approvals shall be dictated by the medical assistance program. 1722

(c) The department or its designee, in relation to prior 1723
approval under division (B) (6) (a) of this section, may require a 1724
health care provider to submit information to the department or 1725
its designee indicating that the patient's chronic condition has 1726
not changed. 1727

(i) The request for information by the department or its 1728
designee and the response by the health care provider shall be 1729
in an electronic format, which may be by ~~traditional~~ electronic 1730
mail or other electronic communication. 1731

(ii) The frequency of the submission of requested 1732
information shall be consistent with medical or scientific 1733
evidence as defined in section 3922.01 of the Revised Code, but 1734
shall not be required more frequently than quarterly. 1735

(iii) If the health care provider does not respond within 1736
five calendar days from the date the request was received, the 1737
insurer or plan may terminate the twelve-month approval. 1738

(d) A ~~year-long~~ twelve-month approval provided under 1739
division (B) (6) (a) of this section is no longer valid and 1740
automatically terminates if there are changes to federal or 1741
state laws or federal regulatory guidance or compliance 1742
information prescribing that the drug in question is no longer 1743
approved or safe for the intended purpose. 1744

(e) A twelve-month approval provided under division (B) (6) 1745
(a) of this section does not apply to and is not required for 1746
any of the following: 1747

(i) Medications that are prescribed for a non-maintenance 1748
condition; 1749

(ii) Medications that have a typical treatment of less 1750
than one year; 1751

(iii) Medications that require an initial trial period to 1752
determine effectiveness and tolerability, beyond which a one- 1753
year, or greater, prior authorization period will be given; 1754

(iv) Medications where there is medical or scientific 1755
evidence as defined in section 3922.01 of the Revised Code that 1756
do not support a twelve-month prior approval; 1757

(v) Medications that are a schedule I or II controlled 1758
substance or any opioid analgesic or benzodiazepine, as defined 1759
in section 3719.01 of the Revised Code; 1760

(vi) Medications that are not prescribed by an in-network 1761
provider as part of a care management program. 1762

(7) On or before January 1, 2017, the department or its 1763
designee may, but is not required to, provide the twelve-month 1764
approval prescribed in division (B) (6) (a) of this section for a 1765
prescription drug that meets either of the following: 1766

(a) The drug is prescribed or administered to treat a rare 1767
medical condition and pursuant to medical or scientific evidence 1768
as defined in section 3922.01 of the Revised Code. 1769

(b) Medications that are controlled substances not 1770
included in division (B) (6) (e) (v) of this section. 1771

For purposes of division (B) (7) of this section, "rare 1772
medical condition" means any disease or condition that affects 1773
fewer than two-hundred thousand individuals in the United 1774
States. 1775

(8) Nothing in division (B) (6) or (7) of this section 1776
prohibits the substitution, in accordance with section 4729.38 1777
of the Revised Code, of any drug that has received a twelve- 1778
month approval under division (B) (6) (a) of this section when 1779
there is a release of ~~a~~ either of the following: 1780

(a) A United States food and drug administration approved 1781
comparable brand product or a generic counterpart of a brand 1782
product that is listed as therapeutically equivalent in the 1783
United States food and drug administration's publication titled 1784
approved drug products with therapeutic equivalence evaluations; 1785

(b) An interchangeable biological product, as defined in 1786
section 3715.01 of the Revised Code. 1787

(9) (a) On or after January 1, 2017, upon written request, 1788
the department or its designee shall permit a retrospective 1789
review for a claim that is submitted for a service where prior 1790
authorization was required, but not obtained if the service in 1791
question meets all of the following: 1792

(i) The service is directly related to another service for 1793
which prior approval has already been obtained and that has 1794
already been performed. 1795

(ii) The new service was not known to be needed at the 1796
time the original prior authorized service was performed. 1797

(iii) The need for the new service was revealed at the 1798
time the original authorized service was performed. 1799

(b) Once the written request and all necessary information 1800
is received, the department or its designee shall review the 1801
claim for coverage and medical necessity. The department or its 1802
designee shall not deny a claim for such a new service based 1803
solely on the fact that a prior authorization approval was not 1804
received for the new service in question. 1805

(10) (a) On or before January 1, 2017, disclose to all 1806
participating health care providers any new prior authorization 1807
requirement at least thirty days prior to the effective date of 1808
the new requirement. 1809

(b) The notice may be sent via electronic mail or standard 1810
mail and shall be conspicuously entitled "Notice of Changes to 1811
Prior Authorization Requirements." The notice is not required to 1812
contain a complete listing of all changes made to the prior 1813
authorization requirements, but shall include specific 1814
information on where the health care ~~practitioner~~ provider may 1815
locate the information on the department's or its designee's web 1816
site or, if applicable, the department's or its designee's 1817
portal. 1818

(c) All participating health care providers shall promptly 1819
notify the department or its designee of any changes to the 1820
health care provider's electronic mail or standard mail address. 1821

(11) (a) On or before January 1, 2017, make available to 1822
all participating health care providers on its web site or 1823
provider portal a listing of its prior authorization 1824

requirements, including specific information or documentation 1825
that a provider must submit in order for the prior authorization 1826
request to be considered complete. 1827

(b) Make available on its web site information about the 1828
medical assistance programs offered in this state that clearly 1829
identifies specific services, drugs, or devices to which a prior 1830
authorization requirement exists. 1831

(12) On or before January 1, 2018, establish a streamlined 1832
appeal process relating to adverse prior authorization 1833
determinations that shall include all of the following: 1834

(a) For urgent care services, the appeal shall be 1835
considered within forty-eight hours after the department or its 1836
designee receives the appeal. 1837

(b) For all other matters, the appeal shall be considered 1838
within ten calendar days after the department or its designee 1839
receives the appeal. 1840

(c) The appeal shall be between the health care provider 1841
requesting the service in question and a clinical peer appointed 1842
by or contracted by the department or the department's designee. 1843

(d) If the appeal does not resolve the disagreement, the 1844
appeal procedures shall permit the recipient to further appeal 1845
in accordance with section 5160.31 of the Revised Code. 1846

(C) Beginning January 1, 2017, except in cases of 1847
fraudulent or materially incorrect information, the department 1848
or its designee shall not retroactively deny a prior 1849
authorization for a health care service, drug, or device when 1850
all of the following are met: 1851

(1) The health care provider submits a prior authorization 1852

request to the department or its designee for a health care service, drug, or device. 1853
1854

(2) The department or its designee approves the prior authorization request after determining that all of the following are true: 1855
1856
1857

(a) The recipient is eligible for the health care service, drug, or device under the medical assistance program. 1858
1859

(b) The health care service, drug, or device is covered by the medical assistance program. 1860
1861

(c) The health care service, drug, or device meets the department's standards for medical necessity and prior authorization. 1862
1863
1864

(3) The health care provider renders the health care service, drug, or device pursuant to the approved prior authorization request and all of the terms and conditions of the health care provider's contract with the department or the department's designee. 1865
1866
1867
1868
1869

(4) On the date the health care provider renders the prior approved health care service, drug, or device, all of the following are true: 1870
1871
1872

(a) The recipient is eligible for the medical assistance program. 1873
1874

(b) The recipient's condition or circumstances related to the recipient's care has not changed. 1875
1876

(c) The health care provider submits an accurate claim that matches the information submitted by the health care provider in the approved prior authorization request. 1877
1878
1879

(5) If the health care provider submits a claim that 1880
includes an unintentional error and the error results in a claim 1881
that does not match the information originally submitted by the 1882
health care provider in the approved prior authorization 1883
request, upon receiving a denial of services from the department 1884
or its designee, the health care ~~practitioner~~ provider may 1885
resubmit the claim pursuant to division (C) of this section with 1886
the information that matches the information included in the 1887
approved prior authorization. 1888

(D) Any provision of a contractual arrangement entered 1889
into between the department or its designee and a health care 1890
provider or recipient that is contrary to divisions (A) to (C) 1891
of this section is unenforceable. 1892

(E) The director of medicaid may adopt rules in accordance 1893
with Chapter 119. of the Revised Code as necessary to implement 1894
the provisions of this section. 1895

Section 2. That existing sections 1751.04, 1751.72, 1896
3715.01, 3715.64, 3923.041, 4729.01, 4729.38, 4729.99, and 1897
5160.34 of the Revised Code are hereby repealed. 1898

Section 3. (A) This section applies to supervision 1899
agreements that, in accordance with section 4730.19 of the 1900
Revised Code, would expire on January 31, 2017. 1901

(B) Notwithstanding section 4730.19 of the Revised Code, a 1902
supervision agreement described in division (A) of this section 1903
is valid until February 1, 2018. Beginning August 1, 2017, such 1904
a supervision agreement may be renewed in accordance with 1905
section 4730.19 of the Revised Code. 1906

Section 4. Sections 1 and 2 of this act take effect on the 1907
ninety-first day after the effective date of this act. 1908

Section 5. This act is hereby declared to be an emergency 1909
measure necessary for the immediate preservation of the public 1910
peace, health, and safety. The reason for the necessity is that 1911
immediate action is needed to address in a timely manner issues 1912
related to the oversight of supervision agreements between 1913
physicians and physician assistants. Therefore, this act shall 1914
go into immediate effect. 1915