

As Introduced

**132nd General Assembly
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S. B. No. 56

Senators Lehner, Tavares

Cosponsors: Senators Thomas, Beagle, Brown, Terhar, Williams, Schiavoni, Yuko

A BILL

To amend section 5167.12 and to enact sections 1
3901.82, 3901.821, 3901.822, 3901.823, 2
5164.7512, 5164.7513, and 5164.7514 of the 3
Revised Code to adopt requirements related to 4
step therapy protocols implemented by health 5
plan issuers and the Department of Medicaid. 6

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

Section 1. That section 5167.12 be amended and sections 7
3901.82, 3901.821, 3901.822, 3901.823, 5164.7512, 5164.7513, and 8
5164.7514 of the Revised Code be enacted to read as follows: 9

Sec. 3901.82. As used in sections 3901.82 to 3901.823 of 10
the Revised Code: 11

(A) "Clinical practice guidelines" means a systematically 12
developed statement to assist health care provider and patient 13
decisions with regard to appropriate health care for specific 14
clinical circumstances and conditions. 15

(B) "Clinical review criteria" means the written screening 16
procedures, decision abstracts, clinical protocols, and clinical 17
practice guidelines used by a health plan issuer or utilization 18

review organization to determine whether or not health care 19
services or drugs are appropriate and medically necessary. 20

(C) "Health benefit plan" and "health plan issuer" have 21
the same meanings as in section 3922.01 of the Revised Code. 22

(D) "Medically necessary" means a determination that a 23
health care service or drug is, under the applicable standard of 24
care, appropriate for any of the following: 25

(1) To improve or preserve health, life, or function; 26

(2) To slow the deterioration of health, life, or 27
function; 28

(3) For the screening, prevention, evaluation, diagnosis, 29
or treatment of a disease, condition, illness, or injury. 30

(E) "Step therapy exemption" means an overriding of a step 31
therapy protocol in favor of immediate coverage of the health 32
care provider's selected prescription drug. 33

(F) "Step therapy protocol" means a protocol or program 34
that establishes a specific sequence in which prescription drugs 35
that are for a specified medical condition and that are 36
medically necessary for a particular patient are covered, under 37
either a medical or prescription drug benefit, by a health 38
benefit plan, including both self-administered and physician- 39
administered drugs. 40

(G) "Utilization review organization" has the same meaning 41
as in section 1751.77 of the Revised Code. 42

Sec. 3901.821. (A) If a health plan issuer or a 43
utilization review organization implements a step therapy 44
protocol, that protocol shall be implemented via clinical review 45
criteria that are based on clinical practice guidelines that 46

<u>meet all of the following:</u>	47
<u>(1) Recommend that the prescription drugs be taken in the</u>	48
<u>specific sequence required by the step therapy protocol;</u>	49
<u>(2) Are developed and endorsed by a multidisciplinary</u>	50
<u>panel of experts that manage conflicts of interest of the</u>	51
<u>writing and review groups by implementing all of the following:</u>	52
<u>(a) A requirement that each member disclose any potential</u>	53
<u>conflict of interest with entities, including health plan</u>	54
<u>issuers and pharmaceutical manufacturers, and recuse the</u>	55
<u>member's self from voting if the member has a conflict of</u>	56
<u>interest;</u>	57
<u>(b) The use of a methodologist to work with writing groups</u>	58
<u>to provide objectivity in data analysis and ranking of evidence</u>	59
<u>through the preparation of evidence tables and facilitating</u>	60
<u>consensus;</u>	61
<u>(c) A requirement that the public be offered opportunity</u>	62
<u>for review and comment.</u>	63
<u>(3) Are based on high quality studies, research, and</u>	64
<u>medical practice;</u>	65
<u>(4) Are created by an explicit and transparent process</u>	66
<u>that does all of the following:</u>	67
<u>(a) Minimizes bias and conflicts of interest;</u>	68
<u>(b) Explains the relationship between treatment options</u>	69
<u>and outcomes;</u>	70
<u>(c) Rates the quality of the evidence supporting</u>	71
<u>recommendations;</u>	72
<u>(d) Considers relevant patient subgroups and preferences.</u>	73

(5) Are continually updated through a review of new evidence, research, and newly developed treatments. 74
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(B) In the absence of clinical practice guidelines that meet the requirements of division (A) of this section, peer-reviewed publications may be used instead. 76
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(C) When establishing a step therapy protocol, a health plan issuer and a utilization review organization shall also take into account the needs of atypical patient populations and diagnoses when establishing clinical review criteria. 79
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(D) This section shall not be construed as requiring either a health plan issuer or the state to set up a new entity to develop clinical review criteria for step therapy protocols. 83
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(E) A health plan issuer or utilization review organization shall certify, annually in rate filing documents submitted to the superintendent of insurance, that the clinical review criteria used in step therapy protocols for prescription drugs are based on clinical practice guidelines that meet the requirements set forth in division (A) of this section. 86
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(F) A health plan issuer or utilization review organization shall submit proposed clinical review criteria in relation to each step therapy protocol that the health plan issuer or utilization review organization seeks to implement to the superintendent of insurance for review and shall not implement those criteria prior to receiving approval or accreditation from the superintendent. 92
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Sec. 3901.822. (A) (1) (a) When coverage of a prescription drug for the treatment of any medical condition is restricted for use by a health plan issuer or utilization review organization through the use of a step therapy protocol, the 99
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health plan issuer or utilization review organization shall 103
provide the patient and prescribing practitioner access to a 104
clear, easily accessible, and convenient process to request a 105
step therapy exemption. 106

(b) A step therapy exemption request shall include 107
supporting documentation and rationale. 108

(2) A covered individual may appeal a step therapy 109
exemption request that is denied. 110

(3) A health plan issuer or utilization review 111
organization may use its existing adverse benefit determination 112
process provided for under Chapter 3922. of the Revised Code to 113
provide for step therapy exemption requests and appeals. 114

(4) The health plan issuer or utilization review 115
organization shall make the process easily accessible on the 116
health plan issuer or utilization review organization's web 117
site. 118

(B) A health plan issuer or utilization review 119
organization shall expeditiously grant a step therapy exemption 120
if any of the following are met: 121

(1) The required prescription drug is contraindicated or 122
will likely cause an adverse reaction by, or physical or mental 123
harm to, the patient. 124

(2) The required prescription drug is expected to be 125
ineffective based on the known clinical characteristics of the 126
patient and the known characteristics of the prescription drug 127
regimen. 128

(3) The patient has tried the required prescription drug 129
while under their current, or a previous, health benefit plan, 130

or another prescription drug in the same pharmacologic class or 131
with the same mechanism of action, and such prescription drug 132
was discontinued due to lack of efficacy or effectiveness, 133
diminished effect, or an adverse event. 134

(4) The required prescription drug is not in the best 135
interest of the patient, based on medical necessity. 136

(5) The patient is stable on a prescription drug selected 137
by their health care provider for the medical condition under 138
consideration, regardless of whether or not the drug was 139
prescribed when the patient was covered under the current or a 140
previous health benefit plan. 141

(C) Upon the granting of a step therapy exemption, the 142
health plan issuer or utilization review organization shall 143
authorize coverage for the prescription drug prescribed by the 144
patient's treating health care provider. 145

(D) (1) (a) A health plan issuer or utilization review 146
organization shall respond to a step therapy exemption request 147
or an appeal within seventy-two hours of receipt. 148

(b) In cases where exigent circumstances exist, a health 149
plan issuer or a utilization review organization shall respond 150
within twenty-four hours of receipt. 151

(2) Should a response by a health plan issuer or a 152
utilization review organization not be received within this 153
time, the exception or appeal shall be deemed granted. 154

(E) This section shall not be construed to prevent either 155
of the following: 156

(1) A health plan issuer or utilization review 157
organization from requiring a patient to try an AB-rated generic 158

equivalent prior to providing coverage for the equivalent 159
branded prescription drug; 160

(2) A health care provider from prescribing a prescription 161
drug that is determined to be medically necessary. 162

Sec. 3901.823. The superintendent of insurance shall adopt 163
rules as necessary to enforce sections 3901.82 to 3901.823 of 164
the Revised Code. 165

Sec. 5164.7512. (A) As used in sections 5164.7512 to 166
5164.7514 of the Revised Code: 167

(1) "Clinical practice guidelines" means a systematically 168
developed statement to assist providers and medicaid recipients 169
in making decisions about appropriate health care for specific 170
clinical circumstances and conditions. 171

(2) "Clinical review criteria" means the written screening 172
procedures, decision abstracts, clinical protocols, and clinical 173
practice guidelines used by the medicaid program to determine 174
whether or not a health care service or drug is appropriate and 175
medically necessary. 176

(3) "Health plan issuer" has the same meaning as in 177
section 3922.01 of the Revised Code. 178

(4) "Medically necessary" means a determination that a 179
prescribed health care service or drug is, under the applicable 180
standard of care, appropriate for any of the following: 181

(a) To improve or preserve health, life, or function; 182

(b) To slow the deterioration of health, life, or 183
function; 184

(c) For the screening, prevention, evaluation, diagnosis, 185

or treatment of a disease, condition, illness, or injury. 186

(5) "Step therapy protocol" means a protocol under which 187
it is determined through a specific sequence whether the 188
medicaid program, under either a pharmacy or medical benefit, 189
will pay for a medically necessary prescribed drug that a 190
medicaid provider prescribes for a medicaid recipient's 191
specified medical condition, including both self-administered 192
and physician-administered drugs. 193

(B) If the department of medicaid utilizes a step therapy 194
protocol for the medicaid program under which it is recommended 195
that prescribed drugs be taken in a specific sequence, the 196
department shall do both of the following: 197

(1) Implement that step therapy program using clinical 198
review criteria that are based on clinical practice guidelines 199
that meet the requirements of section 5164.7513 of the Revised 200
Code; 201

(2) In a manner consistent with section 5164.7514 of the 202
Revised Code, establish and implement a step therapy exemption 203
process under which medicaid recipients and medicaid providers 204
who prescribe prescribed drugs for medicaid recipients may 205
request and receive a step therapy exemption under division (A) 206
(4) of section 5164.7514 of the Revised Code. 207

Sec. 5164.7513. All of the following shall apply to 208
clinical practice guidelines used to develop a step therapy 209
program by the department of medicaid pursuant to division (B) 210
(1) of section 5164.7512 of the Revised Code: 211

(A) The guidelines shall recommend that the prescription 212
drugs be taken in the specific sequence required by the step 213
therapy protocol; 214

(B) The guidelines shall be developed and endorsed by a multidisciplinary panel of experts not affiliated with the medicaid program that manage conflicts of interest of the writing and review groups by implementing all of the following: 215
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(1) A requirement that members disclose any potential conflict of interest with entities, including the department, health plan issuers, and pharmaceutical manufacturers, and recuse the member's self from voting if the member has a conflict of interest; 219
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(2) The use of a methodologist to work with writing groups to provide objectivity in data analysis and ranking of evidence through the preparation of evidence tables and facilitating consensus; 224
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(3) A requirement that the public be allowed to review the guidelines and provide comments. 228
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(C) The criteria shall be based on high quality studies, research, and medical practice. 230
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(D) The criteria shall be created by an explicit and transparent process that does all of the following: 232
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(1) Minimizes bias and conflicts of interest; 234

(2) Explains the relationship between treatment options and outcomes; 235
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(3) Rates the quality of the evidence supporting recommendations; 237
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(4) Considers relevant medicaid recipient subgroups and preferences. 239
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(E) The criteria shall be continually updated through a 241

<u>review of new evidence, research, and newly developed</u>	242
<u>treatments.</u>	243
<u>(F) In the absence of guidelines that meet the</u>	244
<u>requirements of divisions (A) to (E) of this section, the</u>	245
<u>department may use peer-reviewed publications instead.</u>	246
<u>(G) This section shall not be construed as requiring the</u>	247
<u>department to set up a new entity to develop clinical review</u>	248
<u>criteria for step therapy protocols.</u>	249
<u>Sec. 5164.7514.</u> (A) <u>All of the following shall apply to</u>	250
<u>the step therapy exemption process established and implemented</u>	251
<u>by the department of medicaid pursuant to division (B)(2) of</u>	252
<u>section 5164.7512 of the Revised Code:</u>	253
<u>(1) The process shall be clear and convenient.</u>	254
<u>(2) The process shall be easily accessible on the</u>	255
<u>department's web site.</u>	256
<u>(3) The process shall require that supporting rationale</u>	257
<u>and documentation be submitted with each request for an</u>	258
<u>exemption.</u>	259
<u>(4) The process shall require the department to</u>	260
<u>expeditiously grant an exemption if either of the following</u>	261
<u>applies:</u>	262
<u>(a) Any of the following apply to the prescribed drug that</u>	263
<u>would otherwise have to be used under the step therapy protocol:</u>	264
<u>(i) It is contraindicated or will likely cause an adverse</u>	265
<u>reaction by, or physical or mental harm to, the medicaid</u>	266
<u>recipient.</u>	267
<u>(ii) It is expected to be ineffective based on the known</u>	268

relevant clinical characteristics of the medicaid recipient and 269
the known characteristics of the prescribed drug regimen. 270

(iii) The medicaid recipient tried it while enrolled in 271
medicaid or other health care coverage, or another prescribed 272
drug in the same pharmacologic class or with the same mechanism 273
of action, and it or the other prescribed drug was discontinued 274
due to lack of efficacy or effectiveness, diminished effect, or 275
an adverse event. 276

(iv) It is not in the best interest of the medicaid 277
recipient, based on medical necessity. 278

(b) The medicaid recipient is stable on the prescribed 279
drug selected by the recipient's medicaid provider for the 280
medical condition under consideration, regardless of whether or 281
not the drug was prescribed while the individual in question was 282
a medicaid recipient. 283

(5) On granting an exemption, the department shall 284
authorize payment for the prescribed drug prescribed by the 285
medicaid recipient's medicaid provider. 286

(B) (1) (a) The department shall respond to a step therapy 287
exemption request or an appeal within seventy-two hours of 288
receipt. 289

(b) In cases where exigent circumstances exist, the 290
department shall respond within twenty-four hours of receipt. 291

(2) Should a response by the department not be received 292
within this time, the exemption or appeal shall be deemed 293
granted. 294

(C) Any step therapy exemption request that is denied 295
shall be eligible for appeal by a medicaid recipient. 296

(D) This section shall not be construed to prevent either 297
of the following: 298

(1) The department from requiring a medicaid recipient to 299
try an AB-rated generic equivalent before authorizing a medicaid 300
payment for the equivalent branded prescribed drug; 301

(2) A medicaid provider from prescribing a prescribed drug 302
that is determined to be medically appropriate. 303

Sec. 5167.12. (A) When contracting under section 5167.10 304
of the Revised Code with a managed care organization that is a 305
health insuring corporation, the department of medicaid shall 306
require the health insuring corporation to provide coverage of 307
prescribed drugs for medicaid recipients enrolled in the health 308
insuring corporation. In providing the required coverage, the 309
health insuring corporation may use strategies for the 310
management of drug utilization, but any such strategies are 311
subject to ~~divisions (B) and (E)~~ the limitations and 312
requirements of this section and the department's approval. 313

(B) The department shall not permit a health insuring 314
corporation to impose a prior authorization requirement in the 315
case of a drug to which all of the following apply: 316

(1) The drug is an antidepressant or antipsychotic. 317

(2) The drug is administered or dispensed in a standard 318
tablet or capsule form, except that in the case of an 319
antipsychotic, the drug also may be administered or dispensed in 320
a long-acting injectable form. 321

(3) The drug is prescribed by either of the following: 322

(a) A physician whom the health insuring corporation, 323
pursuant to division (C) of section 5167.10 of the Revised Code, 324

has credentialed to provide care as a psychiatrist; 325

(b) A psychiatrist practicing at a community mental health 326
services provider whose mental health services are certified by 327
the department of mental health and addiction services under 328
section 5119.36 of the Revised Code. 329

(4) The drug is prescribed for a use that is indicated on 330
the drug's labeling, as approved by the federal food and drug 331
administration. 332

(C) Subject to division (E) of this section, the 333
department shall authorize a health insuring corporation to 334
develop and implement a pharmacy utilization management program 335
under which prior authorization through the program is 336
established as a condition of obtaining a controlled substance 337
pursuant to a prescription. 338

(D) The department shall require a health insuring 339
corporation to comply with ~~section~~ sections 5164.091, 5164.7511, 340
5164.7512, 5164.7513, and 5164.7514 of the Revised Code ~~with~~ 341
~~respect to medication synchronization as if the health insuring~~ 342
corporation were the department. 343

~~(E) The department shall require a health insuring~~ 344
~~corporation to comply with section 5164.091 of the Revised Code~~ 345
~~as if the health insuring corporation were the department.~~ 346

Section 2. That existing section 5167.12 of the Revised 347
Code is hereby repealed. 348

Section 3. (A) The Ohio General Assembly finds all of the 349
following: 350

(1) That health plan issuers and Medicaid are increasingly 351
making use of step therapy protocols under which patients are 352

required to try one or more prescription drugs before coverage 353
is provided for a drug selected by the patient's health care 354
provider. 355

(2) That such step therapy protocols, when they are based 356
on well-developed scientific standards and administered in a 357
flexible manner that takes into account the individual needs of 358
patients, can play an important role in controlling health care 359
costs. 360

(3) That, in some cases, requiring a patient to follow a 361
step therapy protocol may have adverse and even dangerous 362
consequences for the patient who may either not realize a 363
benefit from taking a prescription drug or may suffer harm from 364
taking an inappropriate drug. 365

(4) That, without uniform policies in the state for step 366
therapy protocols, patients may not receive the best and most 367
appropriate treatment. 368

(5) That it is imperative that step therapy protocols in 369
the state preserve the health care provider's right to make 370
treatment decisions in the best interest of the patient. 371

(B) Therefore, the General Assembly declares its intent in 372
relation to the enactment of this act and the implementation of 373
step therapy protocols all of the following: 374

(1) That the Department of Medicaid, health plan issuers, 375
and other related organizations that use step therapy protocols 376
make coverage or benefits determinations based on appropriate 377
clinical practice guidelines or published, peer-reviewed data 378
developed by independent experts with knowledge of the condition 379
or conditions under consideration; 380

(2) That patients be exempt from step therapy protocols 381

when those protocols are inappropriate or otherwise not in the 382
best interest of the patients; 383

(3) That patients have access to a fair, transparent, and 384
independent process for requesting an exemption to a step 385
therapy protocol when the patient's physician considers 386
appropriate. 387

Section 4. This act shall apply to health benefits plans, 388
as defined in section 3922.01 of the Revised Code, delivered, 389
issued for delivery, modified, or renewed on or after January 1, 390
2018. This act shall apply to the Medicaid program's coverage of 391
prescribed drugs on and after January 1, 2018. 392