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Sub. S. B. No. 56

Senators Lehner, Tavares

Cosponsors: Senators Thomas, Beagle, Brown, Terhar, Williams, Schiavoni, Yuko, Hottinger, Gardner, Sykes, Burke, Eklund, Hackett, Hoagland, Kunze, LaRose, Manning, O'Brien, Skindell, Uecker, Wilson

A BILL

То	amend section 5167.12 and to enact sections	1
	3901.83, 3901.831, 3901.832, 3901.833,	2
	5164.7512, and 5164.7514 of the Revised Code to	3
	adopt requirements related to step therapy	4
	protocols implemented by health plan issuers and	5
	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
3901.83, 3901.831, 3901.832, 3901.833, 5164.7512, and 5164.7514	8
of the Revised Code be enacted to read as follows:	9
Sec. 3901.83. As used in sections 3901.83 to 3901.833 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 consistent with medical or	20
<u>scientific evidence.</u>	21
(C) "Health benefit plan" and "health plan issuer" have	22
the same meanings as in section 3922.01 of the Revised Code.	23
(D) "Medical or scientific evidence" has the same meaning	24
as in section 3922.01 of the Revised Code.	25
(E) "Step therapy exemption" means an overriding of a step_	26
therapy protocol in favor of immediate coverage of the health	27
care provider's selected prescription drug.	28
(F) "Step therapy protocol" means a protocol or program	29
that establishes a specific sequence in which prescription drugs	30
that are for a specified medical condition and that are	31
consistent with medical or scientific evidence for a particular	32
patient are covered, under either a medical or prescription drug	33
benefit, by a health benefit plan, including both self-	34
administered and physician-administered drugs.	35
(G) "Urgent care services" has the same meaning as in	36
section 3923.041 of the Revised Code.	37
(H) "Utilization review organization" has the same meaning	38
as in section 1751.77 of the Revised Code.	39
Sec. 3901.831. (A) If a health plan issuer or a	40
utilization review organization implements a step therapy	41
protocol, that protocol shall be implemented via clinical review	42
criteria that are based on clinical practice guidelines or	43
<u>medical or scientific evidence.</u>	44

(B) When establishing a step therapy protocol, a health	45
plan issuer and a utilization review organization shall also	46
take into account the needs of atypical patient populations and	47
diagnoses when establishing clinical review criteria.	48
(C) This section shall not be construed as requiring	49
(C) This section shall not be construed as requiring	-
either a health plan issuer or the state to set up a new entity	50
to develop clinical review criteria for step therapy protocols.	51
Sec. 3901.832. (A)(1)(a) When coverage of a prescription	52
drug for the treatment of any medical condition is restricted	53
for use by a health plan issuer or utilization review	54
organization through the use of a step therapy protocol, the	55
health plan issuer or utilization review organization shall	56
provide the prescribing health care provider access to a clear,	57
easily accessible, and convenient process to request a step	58
therapy exemption on behalf of a covered individual. A health	59
plan issuer or utilization review organization may use its	60
existing medical exceptions process to satisfy this requirement.	61
(b) A step therapy exemption request shall include_	62
supporting documentation and rationale.	63
supporting documentation and factonate.	00
(2)(a) A health plan issuer shall make available, to all	64
health care providers, a list of all drugs covered by the issuer	65
that are subject to a step therapy protocol. If the health plan	66
issuer offers more than one health benefit plan, and the covered	67
drugs subject to a step therapy protocol vary from one plan to	68
another, then the health plan issuer shall issue a separate list	69
for each plan.	70
(b) Along with the information required under division (A)	71
(2) (a) of this section, a health plan issuer shall indicate what	72
information or documentation must be provided to the issuer or	73
information of accumentation made be provided to the install of	, 5

organization for a step therapy exemption request to be_	74
considered complete. Such information shall be provided for each	75
drug, if the requirements vary according to the drug, plan, or	76
protocol in question.	77
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(3) (a) The list required under division (A) (2) (a) of this	78
section, along with the required information or documentation	79
described in division (A)(2)(b) of this section, shall be made	80
available on the issuer's web site or provider portal.	81
(b) A utilization review organization shall, for each	82
health benefit plan it oversees that implements a step therapy	83
protocol, similarly make the list and information required under	84
divisions (A)(2)(a) and (b) of this section available on its web	85
<u>site or provider portal.</u>	86
(4) From the time a step therapy exemption request is	87
received by a health plan issuer or utilization review	88
organization, the issuer or organization shall either grant or	89
deny the request within the following time frames:	90
<u>(a) Forty-eight hours for a request related to urgent care</u>	91
services;	92
(b) Ten calendar days for all other requests.	93
(5)(a) A provider may, on behalf of the covered	94
individual, appeal any exemption request that is denied.	95
(b) From the time an appeal is received by a health plan	96
issuer or utilization review organization, the issuer or	97
organization shall either grant or deny the appeal within the	98
following time frames:	99
(i) Forty-eight hours for appeals related to urgent care	100
services;	101

(ii) Ten calendar days for all other appeals.	102
(c) The appeal shall be between the health care provider	103
requesting the service in question and a clinical peer, as	104
defined in section 3923.041 of the Revised Code.	105
(d)(i) The appeal shall be considered an internal appeal	106
for purposes of section 3922.03 of the Revised Code.	107
(ii) A health plan issuer shall not impose a step therapy	108
exemption appeal as an additional level of appeal beyond what is	109
required under section 3922.03 of the Revised Code, unless	110
otherwise permitted by law.	111
(e)(i) If the appeal does not resolve the disagreement,	112
the covered individual, or the covered individual's authorized	113
representative, may request an external review under Chapter	114
3922. of the Revised Code to the extent Chapter 3922. of the	115
Revised Code is applicable.	116
(ii) As used in division (A)(5)(e) of this section,	117
"authorized representative" has the same meaning as in section	118
3922.01 of the Revised Code.	119
(6) If a health plan issuer or utilization review	120
organization does not either grant or deny an exemption request	121
or an appeal within the time frames prescribed in division (A)	122
(4) or (5) of this section, then such an exemption request or	123
appeal shall be deemed to be granted.	124
(B) Pursuant to a step therapy exemption request initiated	125
under division (A)(1) of this section or an appeal made under	126
division (A)(5) of this section, a health plan issuer or	127
utilization review organization shall grant a step therapy	128
exemption if any of the following are met:	129

(1) The required prescription drug is contraindicated for	130
that specific patient, pursuant to the drug's United States food	131
and drug administration prescribing information.	132
(2) The patient has tried the required prescription drug	133
while under their current, or a previous, health benefit plan,	134
or another United States food and drug administration approved	135
AB-rated prescription drug, and such prescription drug was	136
discontinued due to lack of efficacy or effectiveness,	137
diminished effect, or an adverse event.	138
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(3) The patient is stable on a prescription drug selected	139
by the patient's health care provider for the medical condition	140
under consideration, regardless of whether or not the drug was	141
prescribed when the patient was covered under the current or a	142
previous health benefit plan, or has already gone through a step	143
therapy protocol. However, a health benefit plan may require a	144
stable patient to try a pharmaceutical alternative, per the	145
federal food and drug administration's orange book, purple book,	146
or their successors, prior to providing coverage for the	147
prescribed drug.	148
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(C) Upon the granting of a step therapy exemption, the	149
health plan issuer or utilization review organization shall	150
authorize coverage for the prescription drug prescribed by the	151
patient's treating health care provider.	152
(D) This section shall not be construed to prevent either	153
of the following:	154
(1) A health plan issuer or utilization review	155
organization from requiring a patient to try any new or existing	156
pharmaceutical alternative, per the federal food and drug	157
administration's orange book, purple book, or their successors,	158

prior to providing or renewing coverage for the prescribed drug;	159
(2) A health care provider from prescribing a prescription	160
drug, consistent with medical or scientific evidence.	161
(E) Committing a series of violations of this section	162
that, taken together, constitute a practice or pattern shall be	163
considered an unfair and deceptive practice under sections	164
3901.19 to 3901.26 of the Revised Code.	165
Sec. 3901.833. The superintendent of insurance may adopt_	166
rules as necessary to enforce sections 3901.83 to 3901.833 of	167
the Revised Code.	168
Sec. 5164.7512. (A) As used in sections 5164.7512 to	169
5164.7514 of the Revised Code:	170
(1) "Clinical practice guidelines" means a systematically	171
developed statement to assist providers and medicaid recipients	172
in making decisions about appropriate health care for specific	173
clinical circumstances and conditions.	174
(2) "Clinical review criteria" means the written screening	175
procedures, decision abstracts, clinical protocols, and clinical	176
practice guidelines used by the medicaid program to determine	177
whether or not a health care service or drug is appropriate and	178
consistent with medical or scientific evidence.	179
(3) "Medical or scientific evidence" has the same meaning	180
as in section 3922.01 of the Revised Code.	181
(4) "Step therapy exemption" means an overriding of a step	182
therapy protocol in favor of immediate coverage of a medicaid	183
provider's selected prescription drug.	184
(5) "Step therapy protocol" means a protocol under which	185
it is determined through a specific sequence whether the	186

medicaid program, under either a pharmacy or medical benefit,	187
will pay for a prescribed drug that a medicaid provider,	188
consistent with medical or scientific evidence, prescribes for a	189
medicaid recipient's specified medical condition, including both	190
self-administered and physician-administered drugs.	191
(6) "Urgent care services" has the same meaning as in	192
section 3922.041 of the Revised Code.	192
Section 3522.011 of the Revised code.	195
(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 all of the following:	197
(1) Implement that step therapy protocol using clinical	198
review criteria that are based on clinical practice guidelines	199
or medical or scientific evidence. The department shall take	200
into account the needs of atypical patient populations and	201
diagnoses when establishing clinical review criteria.	202
(2) In a manner consistent with section 5164.7514 of the	203
Revised Code, establish and implement a step therapy exemption	204
process under which medicaid recipients and medicaid providers	205
who prescribe prescribed drugs for medicaid recipients may	206
request and receive a step therapy exemption;	200
request and receive a step therapy exemption,	207
(3)(a) Make available, to all medicaid providers, a list	208
of all drugs covered by the medicaid program that are subject to	209
<u>a step therapy protocol;</u>	210
(b) Along with the information required under division (B)	211
(3)(a) of this section, the department of medicaid shall	212
indicate what information or documentation must be provided to	213
the department for a step therapy exemption request to be	214
considered complete. Such information shall be provided for each	215

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drug, if the requirements vary according to the drug or protocol	216
in question.	217
(c) The list required under division (B)(3)(a) of this	218
section, along with all of the required information or	219
documentation described in division (B)(3)(b) of this section,	220
shall be made available on the department of medicaid's web site	221
<u>or provider portal.</u>	222
(C) This section shall not be construed as requiring the	223
department to set up a new entity to develop clinical review	224
criteria for step therapy protocols.	225
Sec. 5164.7514. (A) All of the following shall apply to	226

Sec. 5164.7514. (A) All of the the step therapy exemption process established and implemented 227 by the department of medicaid pursuant to division (B)(2) of 228 section 5164.7512 of the Revised Code: 229 (1) The process shall be clear and convenient. 230 (2) The process shall be easily accessible on the 231 department's web site. 232

(3) The process shall require that a medicaid provider initiate a step therapy exemption request on behalf of a medicaid recipient.

(4) The process shall require supporting documentation and 236 rationale be submitted with each request for a step therapy 237 238 exemption.

(5) The process shall, pursuant to a step therapy 239 exemption request made under division (B)(2) of section 240 5164.7512 of the Revised Code or an appeal made under division 241 (B) (2) of this section, require the department to grant a step 242 therapy exemption if either of the following applies: 243

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(a) Either of the following apply to the prescribed drug	244
that would otherwise have to be used under the step therapy	245
protocol:	246
(i) The required prescription drug is contraindicated for	247
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that specific medicaid recipient, pursuant to the drug's United	-
States food and drug administration prescribing information.	249
(ii) The medicaid recipient tried the required	250
prescription drug while enrolled in medicaid or other health	251
care coverage, or another United States food and drug	252
administration approved AB-rated prescription drug, and such	253
prescription drug was discontinued due to lack of efficacy or	254
effectiveness, diminished effect, or an adverse event.	255
(b) The medicaid recipient is stable on the prescribed	256
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drug selected by the recipient's medicaid provider for the	-
medical condition under consideration, regardless of whether or	258
not the drug was prescribed while the individual in question was	259
<u>a medicaid recipient, or has already gone through a step therapy</u>	260
protocol. However, the department may require a stable medicaid	261
recipient to try a pharmaceutical alternative, per the federal	262
food and drug administration's orange book, purple book, or	263
their successors, prior to providing coverage for the prescribed	264
drug.	265
(6) On granting a step therapy exemption, the department	266
shall authorize payment for the prescribed drug prescribed by	267
the medicaid recipient's medicaid provider.	268
(B)(1) From the time a step therapy exemption request is	269
received, the department shall either grant or deny the request	270
within the following time frames:	271
(a) Forty-eight hours for requests related to urgent care	272

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<u>services;</u>	273
(b) Ten calendar days for all other requests.	274
(2)(a) If an exemption request is denied, a medicaid	275
provider may appeal the denial on behalf of the medicaid	276
recipient.	277
(b) From the time a step therapy appeal is received, the	278
department shall either grant or deny the appeal within the	279
following time frames:	280
(i) Forty-eight hours for appeals related to urgent care	281
<u>services;</u>	282
(ii) Ten calendar days for all other appeals.	283
(3) The appeal shall be between the medicaid provider	284
making the appeal and a clinical peer appointed by or contracted	285
by the department or the department's designee.	286
(4) If the department does not either grant or deny an	287
exemption request or an appeal within the time frames prescribed	288
in division (B)(1) or (2) of this section, then such an	289
exemption request or appeal shall be deemed to be granted.	290
(C) If an appeal is rejected, the medicaid recipient in	291
question may make a further appeal in accordance with section	292
5160.31 of the Revised Code.	293
(D) This section shall not be construed to prevent either	294
of the following:	295
(1) The department from requiring a medicaid recipient to	296
try any new or existing pharmaceutical alternative, per the	297
federal food and drug administration's orange book, purple book,	298
or their successors, before authorizing a medicaid payment for	299

the prescribed drug;

(2) A medicaid provider from prescribing a prescribed drug	301
that is determined to be consistent with medical or scientific	302
evidence.	303

304 Sec. 5167.12. (A) When contracting under section 5167.10 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 <u>requirements</u> of this section and the department's approval. 313

(B) The department shall not permit a health insuring
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corporation to impose a prior authorization requirement in the
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case of a drug to which all of the following apply:
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(1) The drug is an antidepressant or antipsychotic. 317

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

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

(a) A physician who is allowed by the health insuring
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corporation to provide care as a psychiatrist through its
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credentialing process, as described in division (C) of section
5167.10 of the Revised Code;
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(b) A psychiatrist who is practicing at a location on 327

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behalf of a community mental health services provider whose328mental health services are certified by the department of mental329health and addiction services under section 5119.36 of the330Revised Code;331

(c) A certified nurse practitioner, as defined in section
4723.01 of the Revised Code, who is certified in psychiatric
mental health by a national certifying organization approved by
the board of nursing under section 4723.46 of the Revised Code;
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(d) A clinical nurse specialist, as defined in section
4723.01 of the Revised Code, who is certified in psychiatric
mental health by a national certifying organization approved by
the board of nursing under section 4723.46 of the Revised Code.
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(4) The drug is prescribed for a use that is indicated on
(4) The drug is prescribed for a use that is indicated on
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the drug's labeling, as approved by the federal food and drug
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administration.

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

(D) The department shall require a health insuring 349
corporation to comply with section sections 5164.091, 5164.7511, 350
5164.7512, and 5164.7514 of the Revised Code with respect to 351
medication synchronization, as if the health insuring 352
corporation were the department. 353

(E) The department shall require a health insuring354corporation to comply with section 5164.091 of the Revised Code355as if the health insuring corporation were the department.356

Section 2. That existing section 5167.12 of the Revised	357
Code is hereby repealed.	358
Section 3. This act shall apply to health benefit plans,	359
as defined in section 3922.01 of the Revised Code, delivered,	360
issued for delivery, modified, or renewed on or after January 1,	361
2020. Not later than ninety days after the effective date of	362
this act, the Medicaid Director shall submit to the United	363
States Secretary of Health and Human Services a Medicaid state	364
plan amendment as necessary for the implementation of this act.	365