

FIRST REGULAR SESSION

# HOUSE BILL NO. 751

101ST GENERAL ASSEMBLY

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INTRODUCED BY REPRESENTATIVE STEPHENS (128).

1390H.011

DANA RADEMAN MILLER, Chief Clerk

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## AN ACT

To repeal sections 376.2030, 376.2034, and 376.2036, RSMo, and to enact in lieu thereof five new sections relating to step therapy protocols.

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*Be it enacted by the General Assembly of the state of Missouri, as follows:*

Section A. Sections 376.2030, 376.2034, and 376.2036, RSMo, are repealed and five new sections enacted in lieu thereof, to be known as sections 376.2030, 376.2032, 376.2036, 376.2038, and 376.2039, to read as follows:

376.2030. As used in sections 376.2030 to ~~376.2036~~ **376.2039**, the following terms mean:

(1) **"Clinical practice guidelines"**, systematically developed protocols to assist decision-making by health care providers and patients in specific clinical circumstances and conditions;

(2) **"Clinical review criteria"**, the written screening procedures, decision abstracts, clinical protocols, and practice guidelines used by a health benefit plan, health carrier, or utilization review organization to determine the medical necessity and appropriateness of health care services;

(3) **"Health benefit plan"**, the same meaning as such term is defined in section 376.1350;

~~(2)~~ (4) **"Health care provider"**, the same meaning as such term is defined in section 376.1350;

~~(3)~~ (5) **"Health carrier"**, the same meaning as such term is defined in section 376.1350;

~~(4)~~ (6) **"Medical necessity"**, health services and supplies that are appropriate under the applicable standard of care to:

(a) **Improve or preserve health, life, or function;**

EXPLANATION — Matter enclosed in bold-faced brackets [thus] in the above bill is not enacted and is intended to be omitted from the law. Matter in **bold-face** type in the above bill is proposed language.

- 17           **(b) Slow the deterioration of health, life, or function; or**  
18           **(c) Facilitate the early screening, prevention, evaluation, diagnosis, or treatment**  
19 **of a disease, condition, illness, or injury;**  
20           **(7) "Pharmacy benefits manager", the same meaning given to the term in section**  
21 **376.388;**  
22           **(8) "Step therapy override exception determination", a determination as to whether a step**  
23 **therapy protocol should apply in a particular situation, or whether the step therapy protocol**  
24 **should be overridden in favor of immediate coverage of the health care provider's preferred**  
25 **prescription drug. This determination is based on a review of the patient's health care provider's**  
26 **request for an override, along with supporting rationale and documentation;**  
27           ~~[(5) "Step therapy override exception request", a written request from the patient's health~~  
28 ~~care provider for the step therapy protocol to be overridden in favor of immediate coverage of~~  
29 ~~the health care provider's preferred prescription drug. The manner and form of the written~~  
30 ~~request shall be disclosed to the patient and the health care provider as described in subsection~~  
31 ~~1 of section 376.2034;~~  
32           ~~—(6)]~~ **(9) "Step therapy protocol", a protocol or program that establishes the specific**  
33 **sequence in which prescription drugs for a specified medical condition and medically appropriate**  
34 **for a particular patient are to be prescribed and covered by a health carrier or health benefit plan;**  
35           ~~[(7)]~~ **(10) "Utilization review organization", an entity that conducts utilization review**  
36 **other than an insurer or health carrier performing utilization review for its own health benefit**  
37 **plans.**

**376.2032. 1. Clinical review criteria used to establish a step therapy protocol shall**  
2 **be based on clinical practice guidelines that:**

- 3           **(1) Recommend that prescription drugs be taken in the specific sequence required**  
4 **by the step therapy protocol;**  
5           **(2) Are developed and endorsed by a multidisciplinary panel of experts that**  
6 **manages conflicts of interest among members by:**  
7           **(a) Requiring members to disclose any potential conflicts of interest with any**  
8 **relevant entities including, but not limited to, health benefit plans, health carriers, and**  
9 **pharmaceutical manufacturers;**  
10           **(b) Requiring members to recuse themselves from any vote in which they have a**  
11 **conflict of interest;**  
12           **(c) Using a methodologist to work with writing groups to provide objectivity in data**  
13 **analysis and ranking of evidence through preparing evidence tables and facilitating**  
14 **consensus; and**  
15           **(d) Offering opportunity for public comment and review;**

- 16           **(3) Are based on high-quality studies, research, and medical practices;**  
17           **(4) Are created by an explicit and transparent process that:**  
18           **(a) Minimizes biases and conflicts of interest;**  
19           **(b) Explains the relationship between treatment options and outcomes;**  
20           **(c) Rates the quality of the evidence supporting recommendations;**  
21           **(d) Considers relevant patient subgroups and preferences; and**  
22           **(e) Considers the needs of atypical patient populations and diagnoses when**  
23 **establishing clinical review criteria; and**  
24           **(5) Are continually updated through a review of new evidence, research, and newly**  
25 **developed treatments.**

26           **2. In the absence of clinical practice guidelines that meet the requirements in**  
27 **subdivision (2) of subsection 1 of this section, clinical practice guidelines may be**  
28 **established using criteria that appear in a peer-reviewed publication.**

29           **3. A health carrier, pharmacy benefits manager, or utilization review organization**  
30 **shall:**

31           **(1) Upon written request, provide all specific written clinical review criteria**  
32 **relating to a particular condition or disease, including clinical review criteria relating to**  
33 **a step therapy override exception determination; and**

34           **(2) Make available such clinical review criteria and other clinical information on**  
35 **its website and to a health care provider on behalf of an insured upon written request.**

36           **4. This section shall not require health carriers, health benefit plans, or the**  
37 **department of commerce and insurance to establish a new entity to develop clinical review**  
38 **criteria for step therapy protocols.**

376.2036. Notwithstanding any law to the contrary, the department of commerce and  
2 insurance shall enforce sections 376.2030 to ~~[376.2036]~~ **376.2039**. The provisions of sections  
3 376.2030 to ~~[376.2036]~~ **376.2039** shall apply to health insurance and health benefit plans  
4 delivered, issued for delivery, or renewed on or after ~~[January 1, 2018]~~ **August 28, 2021**.

**376.2038. 1. If coverage of a prescription drug for the treatment of any medical**  
2 **condition is restricted by a health carrier, health benefit plan, or utilization review**  
3 **organization through the use of a step therapy protocol, the health carrier, health benefit**  
4 **plan, or utilization review organization shall provide the patient and health care provider**  
5 **the option to request a step therapy override exception determination. A health carrier,**  
6 **health benefit plan, or utilization review organization may use an existing medical**  
7 **exceptions process to satisfy this requirement, but the process shall be easily accessible on**  
8 **the website of the health carrier, health benefit plan, or utilization review organization.**  
9 **A health carrier, health benefit plan, or utilization review organization shall disclose all**

10 rules and criteria related to the step therapy protocol upon request to all prescribing health  
11 care providers, including the specific information and documentation that shall be  
12 submitted by a prescribing health care provider or patient to be considered a complete  
13 request for a step therapy override exception determination.

14       2. A request for a step therapy override exception made under subsection 1 of this  
15 section shall be granted if:

16       (1) The prescription drug required by the step therapy protocol is contraindicated  
17 or is likely to cause an adverse reaction or physical or mental harm to the patient;

18       (2) The prescription drug required by the step therapy protocol is expected to be  
19 ineffective based on the known clinical characteristics of the patient and the prescription  
20 drug regimen;

21       (3) The patient has tried the prescription drug required by the step therapy  
22 protocol, a drug in the same pharmacologic class, or a drug with the same mechanism of  
23 action previously and the prescription drug was discontinued due to lack of effectiveness,  
24 diminished effect, or an adverse event;

25       (4) The prescription drug required by the step therapy protocol is not in the best  
26 interest of the patient, based on medical necessity; or

27       (5) The patient is stable on a prescription drug selected by his or her health care  
28 provider for the medical condition under consideration while on a current or previous  
29 health benefit plan.

30       3. Upon granting a step therapy override exception request, the health carrier,  
31 health benefit plan, or utilization review organization shall authorize coverage for the  
32 prescription drug prescribed by the patient's health care provider.

33       4. The health carrier, health benefit plan, or utilization review organization shall  
34 grant or deny a step therapy override exception request or an appeal of a step therapy  
35 override exception request denial made under subsection 5 of this section within seventy-  
36 two hours of receipt. If exigent circumstances exist, the health carrier, health benefit plan,  
37 or utilization review organization shall grant or deny the step therapy override exception  
38 request or the appeal of a step therapy override exception request denial made under  
39 subsection 5 of this section within twenty-four hours of receipt. If a step therapy override  
40 exception request is incomplete or additional clinically relevant information is required,  
41 the health carrier, health benefit plan, or utilization review organization shall notify the  
42 prescribing health care provider within seventy-two hours of submission, or within twenty-  
43 four hours of submission in exigent circumstances, of the additional or clinically relevant  
44 information required in order to grant or deny the request or appeal in accordance with  
45 the criteria disclosed in subsection 1 of this section. Once the requested information is

46 submitted, the applicable time period to grant or deny a step therapy override exception  
47 request or appeal shall apply. If a determination or a request for additional or clinically  
48 relevant information by a health carrier, health benefit plan, or utilization review  
49 organization is not received by the prescribing health care provider within the time  
50 allotted, the exception request or appeal shall be deemed granted.

51 **5. Any step therapy override exception determination made under this section shall**  
52 **be eligible for appeal by a patient.**

53 **6. This section shall not prevent:**

54 **(1) A health carrier, health benefit plan, or utilization review organization from,**  
55 **prior to providing coverage for a branded prescription drug, requiring a patient to try an**  
56 **AB-rated generic equivalent or interchangeable biological product, as described in 42**  
57 **U.S.C. Section 262(i)(3), unless such a requirement meets any of the criteria in subsection**  
58 **2 of this section under a step therapy override exception request submitted under**  
59 **subsection 1 of this section; or**

60 **(2) A health care provider from prescribing a prescription drug that is determined**  
61 **to be medically appropriate.**

**376.2039. Annually, a health carrier, health benefit plan, or utilization review**  
2 **organization shall report to the department of commerce and insurance, in a format**  
3 **prescribed by the department, the following:**

4 **(1) The number of step therapy override exception requests received by exception,**  
5 **as detailed under subsection 2 of section 376.2038;**

6 **(2) The type of health care providers or the medical specialties of the health care**  
7 **providers submitting step therapy override exception requests;**

8 **(3) The number of step therapy override exception requests by exception, as**  
9 **detailed under subsection 2 of section 376.2038, that were denied and the reasons for the**  
10 **denials;**

11 **(4) The number of step therapy override exception requests by exception, as**  
12 **detailed under subsection 2 of section 376.2038, that were approved;**

13 **(5) The number of step therapy override exception requests by exception, as**  
14 **detailed under subsection 2 of section 376.2038, that were initially denied and then**  
15 **appealed;**

16 **(6) The number of step therapy override exception requests by exception, as**  
17 **detailed under subsection 2 of section 376.2038, that were initially denied and then**  
18 **subsequently reversed by internal appeals or external reviews; and**

19           **(7) The medical conditions for which patients are granted exceptions due to the**  
 20 **likelihood that switching from the prescription drug will cause an adverse reaction by or**  
 21 **physical or mental harm to the insured.**

2                   ~~[376.2034. 1. If coverage of a prescription drug for the treatment of any~~  
 3 ~~medical condition is restricted for use by a health carrier, health benefit plan, or~~  
 4 ~~utilization review organization via a step therapy protocol, a patient, through his~~  
 5 ~~or her health care provider, shall have access to a clear, convenient, and readily~~  
 6 ~~accessible process to request a step therapy override exception determination. A~~  
 7 ~~health carrier, health benefit plan, or utilization review organization may use its~~  
 8 ~~existing medical exceptions process to satisfy this requirement. The process shall~~  
 9 ~~be disclosed to the patient and health care provider, which shall include the~~  
 10 ~~necessary documentation needed to process such request and be made available~~  
 11 ~~on the health carrier plan or health benefit plan website.~~

12                   ~~2. A step therapy override exception determination shall be granted if the~~  
 13 ~~patient has tried the step therapy required prescription drugs while under his or~~  
 14 ~~her current or previous health insurance or health benefit plan, and such~~  
 15 ~~prescription drugs were discontinued due to lack of efficacy or effectiveness,~~  
 16 ~~diminished effect, or an adverse event. Pharmacy drug samples shall not be~~  
 17 ~~considered trial and failure of a preferred prescription drug in lieu of trying the~~  
 18 ~~step therapy required prescription drug.~~

19                   ~~3. The health carrier, health benefit plan, or utilization review~~  
 20 ~~organization may request relevant documentation from the patient or provider to~~  
 21 ~~support the override exception request.~~

22                   ~~4. Upon the granting of a step therapy override exception request, the~~  
 23 ~~health carrier, health benefit plan, or utilization review organization shall~~  
 24 ~~authorize dispensation of and coverage for the prescription drug prescribed by the~~  
 25 ~~patient's treating health care provider, provided such drug is a covered drug under~~  
 26 ~~such policy or contract.~~

27                   ~~5. This section shall not be construed to prevent:~~

28                   ~~(1) A health carrier, health benefit plan, or utilization review organization~~  
 29 ~~from requiring a patient to try a generic equivalent or other brand name drug prior~~  
 30 ~~to providing coverage for the requested prescription drug; or~~

31                   ~~(2) A health care provider from prescribing a prescription drug he or she~~  
 determines is medically appropriate.]

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