

SECOND REGULAR SESSION

[PERFECTED]

HOUSE COMMITTEE SUBSTITUTE FOR

HOUSE BILL NO. 2029

98TH GENERAL ASSEMBLY

5403H.02P

D. ADAM CRUMBLISS, Chief Clerk

AN ACT

To amend chapter 376, RSMo, by adding thereto four new sections relating to step therapy for prescription drugs.

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

Section A. Chapter 376, RSMo, is amended by adding thereto four new sections, to be known as sections 376.2029, 376.2030, 376.2034, and 376.2036, to read as follows:

376.2029. The legislature declares it a matter of public interest:

(1) That patients be exempt from step therapy protocols if inappropriate or otherwise not in the best interest of the patient;

(2) That patients have access to a fair, transparent, and independent process for requesting an exception to a step therapy protocol if the patient's health care provider deems such exception appropriate; and

(3) That patients and health care providers receive a timely determination from health carriers and benefit plans on requests for an exception to a step therapy protocol.

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

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

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

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

(4) "Medical necessity", health services or supplies that under the applicable standard of care are appropriate:

(a) To 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.

- 10 **(b) To slow the deterioration of health, life, or function; or**
11 **(c) For the early screening, prevention, evaluation, diagnosis, or treatment of a**
12 **disease, condition, illness, or injury;**
- 13 **(5) "Step therapy override exception determination", a determination as to whether**
14 **a step therapy protocol should apply in a particular situation, or whether the step therapy**
15 **protocol should be overridden in favor of immediate coverage of the prescriber's preferred**
16 **prescription drug. This determination is based on a review of the patient's or prescriber's**
17 **request for an override, along with supporting rationale and documentation;**
- 18 **(6) "Step therapy override exception request", a request for the step therapy**
19 **protocol to be overridden in favor of immediate coverage of the prescriber's preferred**
20 **prescription drug;**
- 21 **(7) "Step therapy protocol", a protocol or program that establishes the specific**
22 **sequence in which prescription drugs for a specified medical condition and medically**
23 **appropriate for a particular patient are to be prescribed and paid for by a health carrier**
24 **or health benefit plan;**
- 25 **(8) "Utilization review organization", an entity that conducts utilization review**
26 **other than an insurer or health carrier performing utilization review for its own health**
27 **benefit plans.**

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

10 **2. A step therapy override exception request shall be expeditiously granted if:**

- 11 **(1) The required prescription drug is contraindicated or will likely cause an**
12 **adverse reaction by or physical or mental harm to the patient;**
- 13 **(2) The required prescription drug is expected to be ineffective based on the known**
14 **clinical characteristics of the patient and the known characteristics of the prescription drug**
15 **regimen;**
- 16 **(3) The patient has tried the step therapy-required prescription drug while under**
17 **his or her current or previous health insurance or health benefit plan and such**

18 prescription drug was discontinued due to lack of efficacy or effectiveness, diminished
19 effect, or an adverse event; or

20 (4) The step therapy-required prescription drug is not in the best interest of the
21 patient based on medical necessity.

22 3. The health carrier, health benefit plan, or utilization review organization may
23 request relevant documentation from the patient or provider to support the override
24 exception request.

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

29 5. (1) The health carrier, health benefit plan, or utilization review organization
30 shall:

31 (a) Acknowledge receipt of a step therapy override exception request or an appeal
32 related to such request and indicate if relevant supporting documentation is needed within
33 thirty-six hours of receipt; and

34 (b) Grant or deny the step therapy override exception request or an appeal related
35 to such request within three business days of receipt of the request or appeal or receipt of
36 the supporting documentation.

37 (2) If exigent circumstances exist, a health carrier, health benefit plan, or utilization
38 review organization shall:

39 (a) Acknowledge receipt of a step therapy override exception request or an appeal
40 related to such request and indicate if relevant supporting documentation is needed within
41 twelve hours of receipt; and

42 (b) Grant or deny the step therapy override exception request or an appeal within
43 one business day of receipt of the request or appeal or receipt of the supporting
44 documentation.

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46 If an insurer, health plan, or utilization review organization does not grant or deny the step
47 therapy override exception or the appeal related to such request within the time allotted
48 under this subsection, the step therapy override exception request or the appeal related to
49 such request shall be deemed granted.

50 6. This section shall not be construed to prevent:

51 (1) A health carrier, health benefit plan, or utilization review organization from
52 requiring a patient to try a generic equivalent, as permitted under section 338.056, prior
53 to providing coverage for the equivalent branded prescription drug; or

54 **(2) A health care provider from prescribing a prescription drug he or she**
55 **determines is medically appropriate.**

376.2036. 1. Notwithstanding any law to the contrary, the department of insurance,
2 **financial institutions and professional registration shall enforce sections 376.2030 to**
3 **376.2036.**

4 **2. The provisions of sections 376.2030 to 376.2036 shall apply only to health**
5 **insurance and health benefit plans delivered, issued for delivery, or renewed on or after**
6 **January 1, 2017.**

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