

SECOND REGULAR SESSION
HOUSE COMMITTEE SUBSTITUTE FOR
HOUSE BILL NO. 2029
98TH GENERAL ASSEMBLY

5403H.02C

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;**
 - (b) To slow the deterioration of health, life, or function; or**

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.

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 an insurer or
24 health 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, or another
18 prescription drug in the same pharmacologic class or with the same mechanism of action,

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

21 (4) The patient is stable on a prescription drug selected by his or her health care
22 provider for the medical condition under consideration; or

23 (5) The step therapy-required prescription drug is not in the best interest of the
24 patient based on medical necessity.

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

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

32 5. The health carrier, health benefit plan, or utilization review organization shall
33 respond to a step therapy override exception request or an appeal related to such request
34 within seventy-two hours of receipt. If exigent circumstances exist, a health carrier, health
35 benefit plan, or utilization review organization shall respond within twenty-four hours of
36 receipt. If an insurer, health plan, or utilization review organization does not respond
37 within the time allotted under this subsection, the step therapy override exception request
38 or the appeal related to such request shall be deemed granted.

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

40 (1) A health carrier, health benefit plan, or utilization review organization from
41 requiring a patient to try an AB-rated generic equivalent prior to providing coverage for
42 the equivalent branded prescription drug; or

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

376.2036. 1. Notwithstanding any law to the contrary, the department of insurance,
2 financial institutions and professional registration shall promulgate any regulations
3 necessary to enforce sections 376.2030 to 376.2036. Any rule or portion of a rule, as that
4 term is defined in section 536.010, that is created under the authority delegated in this
5 section shall become effective only if it complies with and is subject to all of the provisions
6 of chapter 536 and, if applicable, section 536.028. This section and chapter 536 are
7 nonseverable, and if any of the powers vested with the general assembly pursuant to
8 chapter 536 to review, to delay the effective date, or to disapprove and annul a rule are
9 subsequently held unconstitutional, then the grant of rulemaking authority and any rule
10 proposed or adopted after August 28, 2016, shall be invalid and void.

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

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