SECOND REGULAR SESSION

HOUSE BILL NO. 2571

100TH GENERAL ASSEMBLY

INTRODUCED BY REPRESENTATIVE STEPHENS (128).

5572H.01I DANA RADEMAN MILLER, Chief Clerk

AN ACT

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

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Section A. Sections 376.2030, 376.2034, and 376.2036, RSMo, are repealed and four new sections enacted in lieu thereof, to be known as sections 376.2030, 376.2032, 376.2036, and 376.2038, to read as follows:

376.2030. As used in sections 376.2030 to **[**~~376.2036~~**] 376.2038**, 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;

(6) "Medically necessary", 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.

(b) Slow the deterioration of health, life, or function; or

(c) Facilitate the early screening, prevention, evaluation, diagnosis, or treatment of a disease, condition, illness, or injury;

[~~(4)~~**] (7)** "Step therapy override exception determination", a determination as to whether a step therapy protocol should apply in a particular situation, or whether the step therapy protocol should be overridden in favor of immediate coverage of the health care provider's preferred prescription drug. This determination is based on a review of the patient's health care provider's request for an override, along with supporting rationale and documentation;

[~~(5) "Step therapy override exception request", a written request from the patient's health care provider for the step therapy protocol to be overridden in favor of immediate coverage of the health care provider's preferred prescription drug. The manner and form of the written request shall be disclosed to the patient and the health care provider as described in subsection 1 of section 376.2034;~~

~~(6)~~**] (8)** "Step therapy protocol", a protocol or program that establishes the specific sequence in which prescription drugs for a specified medical condition and medically appropriate for a particular patient are to be prescribed and covered by a health carrier or health benefit plan;

[~~(7)~~**] (9)** "Utilization review organization", an entity that conducts utilization review other than an insurer or health carrier performing utilization review for its own health benefit plans.

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

(1) Recommend that prescription drugs be taken in the specific sequence required by the step therapy protocol;

(2) Are developed and endorsed by a multidisciplinary panel of experts that manages conflicts of interest among members by:

(a) Requiring members to disclose any potential conflicts of interest with any relevant entities including, but not limited to, health benefit plans, health carriers, and pharmaceutical manufacturers;

(b) Requiring members to recuse themselves from any vote in which they have a conflict of interest;

(c) Using a methodologist to work with writing groups to provide objectivity in data analysis and ranking of evidence through preparing evidence tables and facilitating consensus; and

(d) Offering opportunity for public comment and review;

(3) Are based on high quality studies, research, and medical practices;

(4) Are created by an explicit and transparent process that:

(a) Minimizes biases and conflicts of interest;

(b) Explains the relationship between treatment options and outcomes;

(c) Rates the quality of the evidence supporting recommendations;

(d) Considers relevant patient subgroups and preferences; and

(e) Considers the needs of atypical patient populations and diagnoses when establishing clinical review criteria; and

(5) Are continually updated through a review of new evidence, research, and newly developed treatments.

2. Notwithstanding the provisions of subsection 1 of this section, clinical practice guidelines may also be established using criteria that appear in a peer-reviewed publication.

3. This section shall not require health carriers, health benefit plans, or the department of commerce and insurance to establish an entity to develop clinical review criteria for step therapy protocols.

376.2036. Notwithstanding any law to the contrary, the department of commerce and insurance shall enforce sections 376.2030 to **[**~~376.2036~~**] 376.2038**. The provisions of sections 376.2030 to **[**~~376.2036~~**] 376.2038** shall apply to health insurance and health benefit plans delivered, issued for delivery, or renewed on or after January 1, **[**~~2018~~**] 2021**.

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

2. A step therapy override exception determination shall be granted if:

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

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

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

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

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

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

4. The health carrier, health benefit plan, or utilization review organization shall respond to a step therapy override exception request within seventy-two hours of receipt. If exigent circumstances exist, a health carrier, health benefit plan, or utilization review organization shall respond within twenty-four hours of receipt. If a health carrier, health benefit plan, or utilization review organization does not respond within the time allotted, the exception request shall be deemed granted.

5. Any step therapy override exception determination under this subsection shall be eligible for appeal by a patient.

6. This section shall not prevent:

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

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

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

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

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

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

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

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

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

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