SECOND REGULAR SESSION

HOUSE BILL NO. 2029

98TH GENERAL ASSEMBLY

INTRODUCED BY REPRESENTATIVE HOSKINS.

5403H.01I D. ADAM CRUMBLISS, Chief Clerk

AN ACT

To amend chapter 376, RSMo, by adding thereto five 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 five new sections, to be known as sections 376.2029, 376.2030, 376.2032, 376.2034, and 376.2036, to read as follows:

376.2029. 1. The legislature finds that health insurance plans are increasingly making use of step therapy protocols, under which patients are required to try one or more prescription drugs before coverage is provided for a drug selected by the patient's health care provider.

2. The legislature finds that such step therapy protocols, if based on well-developed scientific standards and administered in a flexible manner that takes into account the individual needs of patients, can play an important role in controlling health care costs.

3. The legislature finds that, in some cases, requiring a patient to follow a step therapy protocol may have adverse and even dangerous consequences for the patient who either may not realize a benefit from taking the prescription drug required by the step therapy protocol or may suffer harm from taking an inappropriate drug that was so required.

4. The legislature finds that, without uniform policies in the state for step therapy protocols, all patients may not receive the equivalent or most appropriate treatment.

5. The legislature finds that it is imperative that step therapy protocols in the state preserve the health care provider's right to make treatment decisions in the best interest of the patient.

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.

6. Based on its findings in this section, the legislature declares it a matter of public interest:

(a) That it require health insurers to base step therapy protocols on appropriate clinical practice guidelines or published peer-reviewed data developed by independent experts with knowledge of the condition or conditions under consideration;

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

(c) 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.

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

(1) "Clinical practice guidelines", a systematically developed statement to assist practitioner and patient decisions about appropriate health care for specific clinical circumstances;

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

(3) "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

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

(4) "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 prescriber's preferred prescription drug. This determination is based on a review of the patient's or prescriber's request for an override, along with supporting rationale and documentation;

(5) "Step therapy override exception request", a request for the step therapy protocol to be overridden in favor of immediate coverage of the prescriber's preferred prescription drug;

(6) "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 paid for by an insurer or health plan;

(7) "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 step therapy protocols shall be based on clinical practice guidelines:

(1) That recommend drugs be taken in the specific sequence required by the step therapy protocol;

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

(a) Requiring members to disclose any potential conflict of interest with any entity, including any insurer, health plan, or pharmaceutical manufacturer, and recuse themselves from any vote on the panel if they have a conflict of interest;

(b) Using a methodologist to work with the panel to facilitate consensus and provide objectivity in data analysis and ranking of evidence through the preparation of evidence tables; and

(c) Offering opportunities for public review and comment;

(3) That are based on high-quality studies, research, and medical practice;

(4) That are created through 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 the recommendations; and

(d) Considers relevant patient subgroups and preferences; and

(5) That are continually updated through a review of new evidence, research, and treatments.

2. In the absence of clinical practice guidelines described in subsection 1 of this section, clinical review criteria used to establish step therapy protocols may be based instead on peer-reviewed publications.

3. An insurer, health plan, or utilization review organization shall certify, annually in rate filing documents submitted to the department of insurance, financial institutions and professional registration, that the clinical review criteria used in step therapy programs for pharmaceuticals meet the requirements set forth in this section.

4. Proposed clinical review criteria shall be submitted to the department of insurance, financial institutions and professional registration for review and shall receive approval or accreditation prior to implementation. Notwithstanding the above, this subsection applies only if the department of insurance, financial institutions and professional registration is equipped to conduct such review.

5. This section shall not be construed to require the state or any insurer or health plan to set up a new entity to develop clinical review criteria.

376.2034. 1. If coverage of a prescription drug for the treatment of any medical condition is restricted for use by an insurer, health plan, or utilization review organization via a step therapy protocol, the patient and prescribing practitioner shall have access to a clear, convenient, and readily accessible process to request a step therapy override exception determination. An insurer, health 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 providers and shall be made easily accessible on the website of the insurer, health plan, or utilization review organization.

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

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

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

(3) The patient has tried the step therapy-required prescription drug while under his or her current or previous health insurance or health benefit plan, or another prescription drug in the same pharmacologic class or with the same mechanism of action, and such prescription drug was discontinued due to lack of efficacy or effectiveness, diminished effect, or an adverse event;

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

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

3. Upon the granting of a step therapy override exception request, the insurer, health 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.

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

5. This section shall not be construed to prevent:

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

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

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

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

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