FIRST REGULAR SESSION

HOUSE BILL NO. 932

98TH GENERAL ASSEMBLY

INTRODUCED BY REPRESENTATIVE ALLEN.

2012H.01I 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 376.2030, 376.2032, 376.2034, 376.2036, to read as follows:

376.2030. As used in sections 376.2030 to 376.2036, the following terms shall 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 or health plan to determine the medical necessity and appropriateness of health care services;

(3) "Step therapy override determination", a determination as to whether step therapy should apply in a particular situation, or whether the step therapy protocol should be overridden in favor of immediate coverage of the patient's or prescriber's preferred 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;

(4) "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 a health plan;

(5) "Utilization review organization", an entity that conducts utilization review other than a health carrier performing utilization review for its own health benefit plans.

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.

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

(1) Independently developed by a professional medical society with expertise in the medical condition, or conditions, for which coverage decisions said criteria will be applied; and

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

2. 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 are based on clinical practice guidelines independently developed by a professional medical society with expertise in the medical condition, or conditions, for which coverage decisions said criteria will be applied.

3. Proposed clinical review criteria will be submitted to the department of insurance, financial institutions and professional registration for review and shall receive approval or accreditation prior to implementation.

376.2034. 1. If coverage of medications 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 and convenient process to request a step therapy 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, including documenting and making easily accessible on the insurer's or health plan's website.

2. An exception request shall be expeditiously granted if:

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

(2) The required drug is expected to be ineffective based on the known relevant physical or mental characteristics of the patient and the known characteristics of the drug regimen;

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

(4) The patient is stable on a drug recommended by his or her health care provider for the medical condition under consideration based on, but not limited to, a trial with medication samples or a prescription filled at a pharmacy; or

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

3. Upon the granting of an exception request, the insurer, health plan, utilization review organization, or other entity shall authorize dispensation of and coverage for the drug prescribed by the patient's treating health care provider, provided such drug is a covered drug under such policy or contract.

4. 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 reimbursement for the equivalent branded drug; or

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

5. Each health insurer shall maintain written or electronic records and data sufficient to demonstrate compliance with the requirements of this section and on an annual basis submit to the department of insurance, financial institutions and professional registration the following information with respect to requests for exceptions made under this section:

(1) The total number of requests received;

(2) The number of requests approved and denied; and

(3) Any other information the department of insurance, financial institutions and professional registration may request.

376.2036. 1. Notwithstanding any other provision of state or federal law, an entity licensed in this state to sell a health insurance or health benefit plan directly to a consumer shall ensure that if step therapy protocols are used to impose clinical prerequisites for coverage of prescription drugs, such drugs shall be available to the consumer at the preferred cost-sharing level for the item once the clinical prerequisites have been satisfied.

2. This section shall not be construed to prevent insurers from using tiered co-payment structures.

3. Notwithstanding any law to the contrary, the department of insurance, financial institutions and professional registration shall promulgate any regulations necessary to enforce this section. 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, 2015, shall be invalid and void.

4. The provisions of this section shall apply only to a health insurance or health benefit plan delivered, issued for delivery, or renewed on or after January 1, 2016.

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