SENATE FLOOR VERSION
April 1, 2019

ENGROSSED HOUSE
BILL NO. 2638

By: Munson, Echols, Bush, Fetgatter, Frix, Wallace, Kannady, Dunnington, Dollens, McEntire, Mize, Bennett, Caldwell (Trey), Moore, Roberts (Dustin), Blancett, Miller, Sneed, Perryman, Hill, Humphrey, Lawson and **West (Josh)** of the House

and

Rader, **Smalley**, **Young**, **Simpson**, **Daniels**, **Kidd**, **Rosino and Hicks** of the Senate

An Act relating to insurance; providing for step therapy reform; defining terms; directing providers to establish guidelines; providing for exceptions; providing for response to requests; directing Insurance Department to promulgate rules; providing for codification; and providing an effective date.

BE IT ENACTED BY THE PEOPLE OF THE STATE OF OKLAHOMA:

SECTION 1. NEW LAW A new section of law to be codified in the Oklahoma Statutes as Section 1-2610 of Title 63, unless there is created a duplication in numbering, reads as follows:

A. As used in this section:

1. "Clinical practice guidelines" means a systematically developed statement to assist decision-making by health care providers and patients about appropriate health care or specific clinical circumstances and conditions;

2. "Clinical review criteria" means 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. "Health insurance plan" means any individual or group health insurance policy, medical service plan, contract, hospital service corporation contract, hospital and medical service corporation contract, fraternal benefit society, health maintenance organization, municipal group-funded pool, the Oklahoma Medicaid program and state health care benefits plan that provides medical, surgical or hospital expense coverage. For purposes of this section, "health insurance plan" also includes any utilization review organization that contracts with a health insurance plan provider;

4. "Medical necessity" means that, under the applicable standard of care, a health service or supply is appropriate to improve or preserve health, life or function to slow the deterioration of health, life or function or for the early

screening, prevention, evaluation, diagnosis or treatment of a disease, condition, illness or injury;

5. "Step therapy protocol" means a protocol or program that establishes a specific sequence in which prescription drugs for a specified medical condition that are medically appropriate for a particular patient are covered by a health insurance plan;

6. "Step therapy exception" means a process by which a step therapy protocol is overridden in favor of immediate coverage of the health care provider's selected prescription drug; and

7. "Utilization review organization" means an entity that conducts utilization review, not including a health insurance plan provider performing utilization review for the provider's own health insurance plan.

B. For any health insurance plan that is delivered, issued for delivery, amended or renewed on or after January 1, 2020, that utilizes a step therapy protocol, the health insurance plan provider shall establish guidelines governing the use of the step therapy protocol using clinical review criteria based on clinical practice guidelines, subject to the following requirements:

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

a. recommend prescription drugs be taken in the specific sequence required by the step therapy protocol,

1 b. are developed and endorsed by a multidisciplinary
2 panel of experts that manages conflicts of interest
3 among the panel's members of the writing and review
4 groups by:
5 (1) requiring members to disclose any potential
6 conflicts of interest with entities, including
7 health insurance plan providers and
8 pharmaceutical manufacturers, and to recuse
9 themselves from voting on any matter in which a
10 member has such a conflict,
11 (2) using a methodologist to work with writing groups
12 to provide objectivity in data analysis and
13 evidence ranking by preparing evidence tables and
14 facilitating consensus, and
15 (3) offering opportunities for public review and
16 comment,
17 c. are based on high-quality studies, research and
18 medical practice,
19 d. are created by an explicit and transparent process
20 that:
21 (1) minimizes biases and conflicts of interest,
22 (2) explains the relationship between treatment
23 options and outcomes,
24

(3) rates the quality of evidence supporting recommendations, and

(4) considers relevant patient subgroups and preferences, and

e. are continually updated through review of new evidence, research and newly developed treatments;

2. In the absence of clinical guidelines that meet the requirements of subparagraph b of paragraph 1 of this subsection, peer-reviewed publications may be substituted;

3. When establishing clinical review criteria for a step therapy protocol, a utilization review agent shall also account for the needs of atypical patient populations and diagnoses; and

4. Nothing in this subsection shall be construed to require a health insurance plan provider to establish a new entity to develop clinical review criteria used for a step therapy protocol.

C. 1. For any health insurance plan that is delivered, issued for delivery, amended or renewed on or after January 1, 2020, that restricts coverage of a prescription drug for the treatment of any medical condition pursuant to a step therapy protocol, the health insurance plan provider shall provide to the prescribing health care provider and patient access to a clear, convenient and readily accessible process to request a step therapy exception. Any health insurance plan provider that utilizes a step therapy protocol shall

1 make such process to request a step therapy exception accessible on
2 the health insurance plan provider's website.

3 2. A health insurance plan shall grant a requested step therapy
4 exemption if:

5 a. the required prescription drug is contraindicated or
6 will likely cause an adverse reaction by or physical
7 or mental harm to the patient,

8 b. the required prescription drug is expected to be
9 ineffective based on the known clinical
10 characteristics of the patient and the known
11 characteristics of the prescription drug,

12 c. the patient has tried the required prescription drug
13 while under the patient's current or a previous health
14 insurance plan or another prescription drug in the
15 same pharmacologic class or with the same mechanism of
16 action and such prescription drug was discontinued due
17 to lack of efficacy or effectiveness, diminished
18 effect or an adverse event,

19 d. the required prescription drug is not in the best
20 interest of the patient based on medical necessity, or

21 e. the patient is stable on a prescription drug selected
22 by the patient's health care provider for the medical
23 condition under consideration while on the patient's
24 current or a previous health insurance plan.

3. A health insurance plan provider shall permit a patient to appeal any decision rendered on a request for a step therapy exception.

D. A health insurance plan provider shall respond to a request for a step therapy exception, or any appeal therefor, within seventy-two (72) hours of receipt of the request or appeal. If a patient's prescribing health care provider indicates that exigent circumstances exist, the health insurance plan provider shall respond to such a request or appeal within twenty-four (24) hours of receipt of the request or appeal. If the health insurance plan provider fails to respond within the required time, the step therapy exception or appeal shall be deemed granted. Upon granting a step therapy exception, the health insurance plan provider shall authorize coverage for and dispensation of the prescription drug prescribed by the patient's health care provider.

E. This section shall not be construed to prevent a health care provider from prescribing a prescription drug that is determined to be medically appropriate.

F. The Insurance Department and the Oklahoma Health Care Authority shall adopt rules and regulations as may be necessary to implement and administer this section prior to January 1, 2020.

SECTION 2. This act shall become effective November 1, 2019.

COMMITTEE REPORT BY: COMMITTEE ON HEALTH AND HUMAN SERVICES
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