

STATE OF OKLAHOMA

1st Session of the 57th Legislature (2019)

HOUSE BILL 2638

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AS INTRODUCED

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;

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

6 3. "Health insurance plan" means any individual or group health
7 insurance policy, medical service plan, contract, hospital service
8 corporation contract, hospital and medical service corporation
9 contract, fraternal benefit society, health maintenance
10 organization, municipal group-funded pool, the Oklahoma Medicaid
11 program and state health care benefits plan that provides medical,
12 surgical or hospital expense coverage. For purposes of this
13 section, "health insurance plan" also includes any utilization
14 review organization that contracts with a health insurance plan
15 provider;

16 4. "Medical necessity" means that, under the applicable
17 standard of care, a health service or supply is appropriate to
18 improve or preserve health, life or function to slow the
19 deterioration of health, life or function or for the early
20 screening, prevention, evaluation, diagnosis or treatment of a
21 disease, condition, illness or injury;

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

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

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

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

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

- 18 a. recommend prescription drugs be taken in the specific
19 sequence required by the step therapy protocol,
- 20 b. are developed and endorsed by a multidisciplinary
21 panel of experts that manages conflicts of interest
22 among the panel's members of the writing and review
23 groups by:

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1 (1) requiring members to disclose any potential
2 conflicts of interest with entities, including
3 health insurance plan providers and
4 pharmaceutical manufacturers, and to recuse
5 themselves from voting on any matter in which a
6 member has such a conflict,

7 (2) using a methodologist to work with writing groups
8 to provide objectivity in data analysis and
9 evidence ranking by preparing evidence tables and
10 facilitating consensus, and

11 (3) offering opportunities for public review and
12 comment,

13 c. are based on high-quality studies, research and
14 medical practice,

15 d. are created by an explicit and transparent process
16 that:

17 (1) minimizes biases and conflicts of interest,

18 (2) explains the relationship between treatment
19 options and outcomes,

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

22 (4) considers relevant patient subgroups and
23 preferences, and
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1 e. are continually updated through review of new
2 evidence, research and newly developed treatments;

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

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

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

12 C. 1. For any health insurance plan that is delivered, issued
13 for delivery, amended or renewed on or after January 1, 2020, that
14 restricts coverage of a prescription drug for the treatment of any
15 medical condition pursuant to a step therapy protocol, the health
16 insurance plan provider shall provide to the prescribing health care
17 provider and patient access to a clear, convenient and readily
18 accessible process to request a step therapy exception. Any health
19 insurance plan provider that utilizes a step therapy protocol shall
20 make such process to request a step therapy exception accessible on
21 the health insurance plan provider's website.

22 2. A health insurance plan shall grant a requested step therapy
23 exemption if:

- a. the required prescription drug is contraindicated or will likely cause an adverse reaction by or physical or mental harm to the patient,
- b. 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,
- c. the patient has tried the required prescription drug while under the patient's current or a previous health insurance 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,
- d. the required prescription drug is not in the best interest of the patient based on medical necessity, or
- e. the patient is stable on a prescription drug selected by the patient's health care provider for the medical condition under consideration while on the patient's 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.

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

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

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

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

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