

1 ENGROSSED HOUSE
2 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
and Lawson of the House

and

Rader of the Senate

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

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

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

21 A. As used in this section:

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

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

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

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

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

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

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

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

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

- 20 a. recommend prescription drugs be taken in the specific
21 sequence required by the step therapy protocol,
- 22 b. are developed and endorsed by a multidisciplinary
23 panel of experts that manages conflicts of interest

1 among the panel's members of the writing and review
2 groups by:

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

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

13 (3) offering opportunities for public review and
14 comment,

15 c. are based on high-quality studies, research and
16 medical practice,

17 d. are created by an explicit and transparent process
18 that:

19 (1) minimizes biases and conflicts of interest,

20 (2) explains the relationship between treatment
21 options and outcomes,

22 (3) rates the quality of evidence supporting
23 recommendations, and
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1 (4) considers relevant patient subgroups and
2 preferences, and

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

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

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

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

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

- 1 2. A health insurance plan shall grant a requested step therapy
2 exemption if:
- 3 a. the required prescription drug is contraindicated or
4 will likely cause an adverse reaction by or physical
5 or mental harm to the patient,
 - 6 b. the required prescription drug is expected to be
7 ineffective based on the known clinical
8 characteristics of the patient and the known
9 characteristics of the prescription drug,
 - 10 c. the patient has tried the required prescription drug
11 while under the patient's current or a previous health
12 insurance plan or another prescription drug in the
13 same pharmacologic class or with the same mechanism of
14 action and such prescription drug was discontinued due
15 to lack of efficacy or effectiveness, diminished
16 effect or an adverse event,
 - 17 d. the required prescription drug is not in the best
18 interest of the patient based on medical necessity, or
 - 19 e. the patient is stable on a prescription drug selected
20 by the patient's health care provider for the medical
21 condition under consideration while on the patient's
22 current or a previous health insurance plan.

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

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

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

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

22 SECTION 2. This act shall become effective November 1, 2019.
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1 Passed the House of Representatives the 12th day of March, 2019.

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4 Presiding Officer of the House
of Representatives

5 Passed the Senate the ____ day of _____, 2019.

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9 Presiding Officer of the Senate