

1 **SENATE FLOOR VERSION**

2 February 18, 2019

3 SENATE BILL NO. 509

4 By: Rader, Smalley, Simpson,
5 Young, Daniels, Hicks,
6 McCortney, Floyd, Rosino
7 and David

8 An Act relating to health insurance; defining terms;
9 requiring guidelines for step therapy protocol for
10 certain health insurance plans; requiring guidelines
11 be based upon certain criteria; authorizing certain
12 substitution; requiring insurers to provide process
13 to request a step therapy exception; requiring
14 insurer to grant step therapy exception in certain
15 circumstances; requiring insurers to permit certain
16 appeals; establishing timeline for response to step
17 therapy exception; granting exception in certain
18 circumstances; requiring insurer to authorize certain
19 coverage in certain situations; providing construing
20 provision; authorizing Insurance Department and
21 Health Care Authority to promulgate rules; providing
22 for codification; and providing an effective date.

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

24 SECTION 1. NEW LAW A new section of law to be codified
in the Oklahoma Statutes as Section 7310 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 healthcare

1 providers and patients about appropriate healthcare 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 healthcare 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 or health maintenance
12 organization, municipal group-funded pool, the Oklahoma Medicaid
13 Program and the state health care benefits plan that provides
14 medical, surgical or hospital expense coverage. For purposes of
15 this 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;

24

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 healthcare 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, and 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 that the prescription drugs be taken in the
21 specific sequence required by the step therapy
22 protocol,

23 b. are developed and endorsed by a multidisciplinary
24 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 from
7 voting on any matter in which the member has such
8 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
24

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 subsection B of
7 this section, 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, and
16 that restricts coverage of a prescription drug for the treatment of
17 any medical condition pursuant to a step therapy protocol, the
18 health insurance plan provider shall provide to the prescribing
19 healthcare provider and patient access to a clear, convenient and
20 readily accessible process to request a step therapy exception. Any
21 health insurance plan provider that utilizes a step therapy protocol
22 shall make such process to request a step therapy exception
23 accessible on the health insurance plan provider's website.

1 2. A health insurance plan shall grant a requested step therapy
2 exception 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
15 due 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,
19 or

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

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 healthcare 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 healthcare provider.

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

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

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

23 COMMITTEE REPORT BY: COMMITTEE ON HEALTH AND HUMAN SERVICES
24 February 18, 2019 - DO PASS