

1 STATE OF OKLAHOMA

2 1st Session of the 60th Legislature (2025)

3 SENATE BILL 1064

By: Rosino

6 AS INTRODUCED

7 An Act relating to health insurance; amending 63 O.S.
8 2021, Section 7310, which relates to step therapy
9 protocol; establishing guidelines for step therapy
protocol; and providing an effective date.

10
11 BE IT ENACTED BY THE PEOPLE OF THE STATE OF OKLAHOMA:

12 SECTION 1. AMENDATORY 63 O.S. 2021, Section 7310, is
13 amended to read as follows:

14 Section 7310. A. As used in this section:

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

19
20 2. "Health insurance plan" means any individual or group health
21 insurance policy, medical service plan, contract, hospital service
22 corporation contract, hospital and medical service corporation
23 contract, fraternal benefit society or health maintenance
24 organization, municipal group-funded pool, the Oklahoma Medicaid

1 Program and the state health care benefits plan that provides
2 medical, surgical or hospital expense coverage. For purposes of
3 this section, "health insurance plan" also includes any utilization
4 review organization that contracts with a health insurance plan
5 provider;

6 3. "Medical necessity" means that, under the applicable
7 standard of care, a health service or supply is appropriate to
8 improve or preserve health, life or function, to slow the
9 deterioration of health, life or function or for the early
10 screening, prevention, evaluation, diagnosis or treatment of a
11 disease, condition, illness or injury;

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

16 5. "Step therapy exception" means a process by which a step
17 therapy protocol is overridden in favor of immediate coverage of the
18 healthcare provider's selected prescription drug;

19 6. "Utilization review organization" means an entity that
20 conducts utilization review, not including a health insurance plan
21 provider performing utilization review for the provider's own health
22 insurance plan; and

1 7. "Pharmaceutical sample" means a unit of a prescription drug
2 that is not intended to be sold and is intended to promote the sale
3 of the drug.

4 B. For any health insurance plan that is delivered, issued for
5 delivery, amended or renewed on or after January 1, 2020, and that
6 utilizes a step therapy protocol, a health carrier, health benefit
7 plan or utilization review organization shall use recognized,
8 evidence-based and peer-reviewed clinical practice guidelines when
9 establishing any step therapy protocol, when such guidelines are
10 available. When peer-reviewed clinical guidelines are not
11 available, decisions shall default to the United States Food and
12 Drug Administration label as the authoritative reference.

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

23 2. A health insurance plan shall grant a requested step therapy
24 exception if the submitted justification of the prescribing provider

1 and supporting clinical documentation, if needed, is completed and
2 supports the statement of the provider that:

- 3 a. the required prescription drug is contraindicated or
4 will likely cause an adverse reaction or physical or
5 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 and such prescription drug was
13 discontinued due to lack of efficacy or effectiveness,
14 diminished effect or an adverse event,
- 15 d. the required prescription drug is not in the best
16 interest of the patient, based on medical necessity,
17 or
- 18 e. the patient is stable on a prescription drug selected
19 by the patient's healthcare provider for the medical
20 condition under consideration while on the patient's
21 current or a previous health insurance plan.

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

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

16 F. Nothing in this section shall be construed to authorize the
17 use of a pharmaceutical sample for the sole purpose of meeting the
18 requirements for a step therapy exception.

19 G. Nothing in this section shall be construed to prevent the
20 substitution of a drug in accordance with current statutes and
21 regulations of this state.

22 H. If the prescription drug that is subject to step therapy
23 protocol is approved by the FDA for the treatment of a rare disease
24 pursuant to Section 360bb of Title 21 of the United States Code, and

1 no clinical practice guidelines are available for the rare disease,
2 any restrictions imposed by the step therapy protocol shall not be
3 any more restrictive than in accordance with the conditions of use
4 included in the FDA required labeling for the prescription drug.

5 I. The Oklahoma Insurance Department and the Oklahoma Health
6 Care Authority shall adopt rules necessary to implement and
7 administer this act prior to January 1, 2020.

8 SECTION 2. This act shall become effective November 1, 2025.

10 60-1-760 CAD 1/16/2025 3:02:42 PM