

1 **SENATE FLOOR VERSION**

2 February 24, 2025

3 **AS AMENDED**

4 SENATE BILL NO. 1064

5 By: Rosino of the Senate

6 and

7 Stinson of the House

8 **[health insurance - step therapy protocol -**
9 **guidelines - 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 2. "Health insurance plan" means any individual or group health
20 insurance policy, medical service plan, contract, hospital service
21 corporation contract, hospital and medical service corporation
22 contract, fraternal benefit society or health maintenance
23 organization, municipal group-funded pool, the Oklahoma Medicaid
24 Program and the state health care benefits plan that provides

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

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

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

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

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

22 7. "Pharmaceutical sample" means a unit of a prescription drug
23 that is not intended to be sold and is intended to promote the sale
24 of the drug.

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

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

20 2. A health insurance plan shall grant a requested step therapy
21 exception if the submitted justification of the prescribing provider
22 and supporting clinical documentation, if needed, is completed and
23 supports the statement of the provider that:

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

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

23 D. A health insurance plan provider shall respond to a request
24 for a step therapy exception, or any appeal therefor, within

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

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

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

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

20 H. If the prescription drug that is subject to step therapy
21 protocol is approved by the FDA for the treatment of a rare disease
22 pursuant to Section 360bb of Title 21 of the United States Code, and
23 no clinical practice guidelines are available for the rare disease,
24 any restrictions imposed by the step therapy protocol shall not be

1 any more restrictive than in accordance with the conditions of use
2 included in the FDA required labeling for the prescription drug.

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

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

7 COMMITTEE REPORT BY: COMMITTEE ON HEALTH AND HUMAN SERVICES
8 February 24, 2025 - DO PASS AS AMENDED
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