

# An Act

ENROLLED SENATE  
BILL NO. 509

By: Rader, Smalley, Simpson,  
Young, Daniels, Hicks,  
McCortney, Floyd, Rosino,  
David and Kidd of the  
Senate

and

Munson, Dunnington, Roberts  
(Dustin), Mize, Bush,  
McEntire, Wallace, Echols,  
Blancett, Hilbert, Davis,  
Kannady, Conley, Miller,  
Caldwell (Trey), Dollens,  
Perryman, Bennett,  
Fetgatter, Frix, Dills,  
Lawson, Moore and Hasenbeck  
of the House

An Act relating to health insurance; defining terms; requiring insurers to use clinical practice guidelines for developing step therapy protocol; requiring insurers to provide process to request a step therapy exception; requiring step therapy exception process be posted online; requiring insurer to grant step therapy exception in certain circumstances; requiring insurers to permit appeal of step therapy exception decision; establishing timeline for response to step therapy exception; authorizing automatic granting of exception in certain circumstances; requiring insurer to authorize coverage and dispensation of drugs in certain situations; providing construing provisions; authorizing Insurance Department and Health Care Authority to promulgate rules; providing for codification; and providing an effective date.

SUBJECT: Health insurance

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 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 providers and patients about appropriate healthcare or specific clinical circumstances and conditions;

2. "Health insurance plan" means any individual or group health insurance policy, medical service plan, contract, hospital service corporation contract, hospital and medical service corporation contract, fraternal benefit society or health maintenance organization, municipal group-funded pool, the Oklahoma Medicaid Program and the state health care benefits plan that provides medical, surgical or hospital expense coverage. For purposes of this section, "health insurance plan" also includes any utilization review organization that contracts with a health insurance plan provider;

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

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

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

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

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

B. For any health insurance plan that is delivered, issued for delivery, amended or renewed on or after January 1, 2020, and that utilizes a step therapy protocol, a health carrier, health benefit plan or utilization review organization shall use recognized, evidence-based and peer-reviewed clinical practice guidelines when establishing any step therapy protocol, when such guidelines are available.

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

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

- a. the required prescription drug is contraindicated or will likely cause an adverse reaction 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 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 healthcare 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.

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

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

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

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

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

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

Passed the Senate the 12th day of March, 2019.

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Presiding Officer of the Senate

Passed the House of Representatives the 10th day of April, 2019.

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Presiding Officer of the House  
of Representatives

OFFICE OF THE GOVERNOR

Received by the Office of the Governor this \_\_\_\_\_

day of \_\_\_\_\_, 20\_\_\_\_\_, at \_\_\_\_\_ o'clock \_\_\_\_\_ M.

By: \_\_\_\_\_

Approved by the Governor of the State of Oklahoma this \_\_\_\_\_

day of \_\_\_\_\_, 20\_\_\_\_\_, at \_\_\_\_\_ o'clock \_\_\_\_\_ M.

\_\_\_\_\_  
Governor of the State of Oklahoma

OFFICE OF THE SECRETARY OF STATE

Received by the Office of the Secretary of State this \_\_\_\_\_

day of \_\_\_\_\_, 20\_\_\_\_\_, at \_\_\_\_\_ o'clock \_\_\_\_\_ M.

By: \_\_\_\_\_