AN ACT concerning health and healthcare; relating to health insurance plans; prescription medication; step therapy protocols.

Be it enacted by the Legislature of the State of Kansas:

Section 1. (a) As used in this section:

(1) "Clinical practice guidelines" means a systematically developed statement to assist healthcare providers and patients in making decisions about appropriate healthcare services for specific clinical circumstances and conditions developed independently of a health insurance plan, pharmaceutical manufacturer or any entity with a conflict of interest.

(2) "Clinical review criteria" means the written screening procedures, decision abstracts, clinical protocols and clinical practice guidelines used by a health insurance plan to determine the medical necessity and appropriateness of healthcare services.

(3) "Health insurance plan" means any individual or group 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 and the state healthcare benefits plan that provides medical, surgical or hospital expense coverage. For purposes of this section, "health insurance plan" also includes a utilization review organization that contracts with a health insurance plan provider.

(4) "Patient" means a member, policyholder, subscriber, enrollee, beneficiary, dependent or other individual participating in a health insurance plan who has been prescribed prescription medication subject to a step therapy protocol.

(5) "Prescriber" means the same as that term is defined in K.S.A. 65-4101, and amendments thereto.

(6) "Step therapy exception" means a process by which a step therapy protocol is overridden in favor of coverage of the selected prescription drug of the prescriber because at least one of the conditions in subsection (c) exists.

(7) "Step therapy protocol" means a protocol or program that establishes the specific sequence in which prescription drugs for a specified medical condition, including self-administered and physician-administered drugs, are medically appropriate for a particular patient and
are covered under a health insurance plan.

(b) A health insurance plan shall consider available recognized evidence-based and peer-reviewed clinical practice guidelines when establishing a step therapy protocol. Upon the written request of a patient, a health insurance plan shall provide any clinical review criteria applicable to a specific prescription drug covered by the health insurance plan.

(c) (1) When coverage of a prescription drug for the treatment of a medical condition is restricted for use by a health insurance plan through the use of a step therapy protocol, patients and prescribers shall have access to a clear, readily accessible and convenient process to request a step therapy exception. The process shall be made easily accessible on the health insurer's internet website. A health insurance plan shall grant an override to the step therapy protocol if at least one of the following conditions exist:

(A) The prescription drug required under the step therapy protocol is contraindicated pursuant to the pharmaceutical manufacturer's prescribing information for the drug or, due to a documented adverse event with a previous use or a documented medicated condition, including a comorbid condition, is likely to do any of the following:

   (i) Cause an adverse reaction to the patient;
   (ii) decrease the ability of the patient to achieve or maintain reasonable functional ability in performing daily activities; or
   (iii) cause physical or mental harm to the patient;

(B) the patient has had a trial of the required prescription drug covered by the patient's current or previous health insurance plan or another prescription drug in the same pharmacologic class or with the same mechanism of action, and was adherent during such trial for a period of time sufficient to allow for a positive treatment outcome, and the prescription drug was discontinued by the patient's prescriber due to lack of effectiveness or an adverse event. This subparagraph does not prohibit a health insurance plan from requiring a patient to try another drug in the same pharmacologic class or with the same mechanism of action if that therapy sequence is supported by the evidence-based and peer-reviewed clinical practice guidelines, United States food and drug administration label or pharmaceutical manufacturer's prescribing information; or

(C) the patient is currently receiving a positive therapeutic outcome on a prescription drug for the medical condition under consideration if, while on the patient's current health insurance plan or the immediately preceding health plan, the patient received coverage for the prescription drug and the patient's prescriber provides documentation to the health insurance plan that the change in prescription drug required by the step therapy protocol is expected to be ineffective or cause harm to the patient based on the known characteristics of the specific patient and the known
characteristics of the required prescription drug.

(2) Upon granting a step therapy exception, a health insurance plan shall authorize coverage for the prescription drug if the prescription drug is a covered prescription drug under the patient's health insurance plan.

(3) The patient, or the prescriber, if designated by the patient, may appeal the denial of a step therapy exception by a health insurance plan using the health insurance plan's designated complaint procedure.

(4) In a denial of a step therapy exception request and any subsequent appeal, a health insurance plan's decision shall specifically state why the step therapy exception request did not meet the condition under subsection (c) cited by the prescriber in requesting the step therapy exception and provide information regarding the procedure to request external review of the denial pursuant to K.S.A. 40-22a15, and amendments thereto. A denial of a request for a step therapy exception that is upheld on appeal is a final adverse determination.

(5) A health insurance plan shall respond to a request for a step therapy exception, or any appeal therefor, within 72 hours of receipt of the request or appeal. If a patient's prescriber indicates that exigent circumstances exist, the health insurance plan shall respond to such a request or appeal within 24 hours of receipt of the request or appeal. If the health insurance plan 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 shall authorize coverage for and dispensation of the prescription drug prescribed by the patient's prescriber.

(6) Step therapy exception requests shall be accessible to and submitted by prescribers and accepted by group purchasers electronically through secure electronic transmission.

(d) Nothing in this section shall be construed to prevent a health insurance plan from:

(1) Requesting relevant documentation from a patient's medical record in support of a step therapy exception request; or

(2) requiring a patient to try a generic equivalent drug or biosimilar, as defined under 42 U.S.C. § 262(i)(2), prior to providing coverage for the equivalent branded prescription drug.

(e) Nothing in this section shall be construed to:

(1) Allow the use of a pharmaceutical sample for the primary purpose of meeting the requirements of a step therapy exception; or

(2) mandate coverage for prescription medication if such coverage is not already a covered benefit by the patient's health insurance plan.

(f) The provisions of K.S.A. 40-2248 and 40-2249a, and amendments thereto, shall not apply to this section.

(g) This section shall take effect on and after January 1, 2020.
Sec. 2. The insurance department shall adopt such rules and regulations as may be necessary to implement and administer the provisions of section 1, and amendments thereto, prior to January 1, 2020.

Sec. 3. This act shall take effect and be in force from and after its publication in the statute book.