SENATE BILL NO. ____

AN ACT concerning health and healthcare; relating to health insurnace; 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 decision making by healthcare providers and patients about appropriate healthcare or specific clinical circumstances and conditions.

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

(3) "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 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.

(4) "Medically appropriate" 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.

(5) "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.

(6) "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.

(7) "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.

(b) For any health insurance plan that is delivered, issued for delivery, amended or renewed on or after January 1, 2019, and that utilizes a step therapy protocol, the health insurance plan provider shall establish guidelines governing the use of the step therapy protocol using clinical review criteria based on clinical practice guidelines, subject to the following requirements:

(1) Clinical review criteria used to establish a step therapy protocol shall be based on clinical practice guidelines that:

(A) Recommend that the prescription drugs be taken in the specific sequence required by the step therapy protocol;

(B) are developed and endorsed by a multidisciplinary panel of experts that manages conflicts of interest among the panel's members of the writing and review groups by:

(i) Requiring members to disclose any potential conflicts of interest with entities, including health insurance plan providers and pharmaceutical manufacturers and to recuse from voting on any matter in which the member has such a conflict;

(ii) using a methodologist to work with writing groups to provide objectivity in data

analysis and evidence ranking by preparing evidence tables and facilitating consensus; and

(iii) offering opportunities for public review and comment;

(C) are based on high-quality studies, research and medical practice;

(D) are created by an explicit and transparent process that:

(i) Minimizes biases and conflicts of interest;

(ii) explains the relationship between treatment options and outcomes;

(iii) rates the quality of evidence supporting recommendations; and

(iv) considers relevant patient subgroups and preferences; and

(E) are continually updated through review of new evidence, research and newly-developed treatments.

(2) In the absence of clinical guidelines that meet the requirements of subsection (b)(1)(B), peer-reviewed publications may be substituted.

(3) When establishing clinical review criteria for a step therapy protocol, a utilization review agent shall also account for the needs of atypical patient populations and diagnoses.

(4) Nothing in this subsection shall be construed to require a health insurance plan provider to establish a new entity to develop clinical review criteria used for a step therapy protocol.

(c) (1) For any health insurance plan that is delivered, issued for delivery, amended or renewed on or after January 1, 2019, 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 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 provider's website.

(2) A health insurance plan shall grant a requested step therapy exception if:

(A) The required prescription drug is contraindicated or will likely cause an adverse reaction by 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, or another prescription drug int he same pharmacologic class or with the same mechanism of action, 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 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 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:

(1) A health insurance plan provider from requiring a patient to try an AB-rated generic equivalent prescription drug prior to providing coverage for a requested brand-name prescription drug; or

(2) a healthcare provider from prescribing a prescription drug that is determined to be medically appropriate.

(f) The department of insurance shall adopt rules and regulations as may be necessary to implement and administer this section prior to January 1, 2019.

Sec. 2. This act shall take effect and be in force from and after its publication in the statute book.