

**SENATE BILL No. 304**

By Committee on Public Health and Welfare

1-22

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

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

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

6 (1) "Clinical practice guidelines" means a systematically developed  
7 statement to assist decision-making by healthcare providers and patients  
8 about appropriate healthcare or specific clinical circumstances and  
9 conditions.

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

14 (3) "Health insurance plan" means any individual or group health  
15 insurance policy, medical service plan, contract, hospital service  
16 corporation contract, hospital and medical service corporation contract,  
17 fraternal benefit society or health maintenance organization, municipal  
18 group-funded pool and the state health care benefits plan that provides  
19 medical, surgical or hospital expense coverage. For purposes of this  
20 section, "health insurance plan" also includes any utilization review  
21 organization that contracts with a health insurance plan provider.

22 (4) "Medical necessity" means that, under the applicable standard of  
23 care, a health service or supply is appropriate to improve or preserve  
24 health, life or function, to slow the deterioration of health, life or function  
25 or for the early screening, prevention, evaluation, diagnosis or treatment of  
26 a disease, condition, illness or injury.

27 (5) "Step therapy protocol" means a protocol or program that  
28 establishes a specific sequence in which prescription drugs for a specified  
29 medical condition that are medically appropriate for a particular patient are  
30 covered by a health insurance plan.

31 (6) "Step therapy exception" means a process by which a step therapy  
32 protocol is overridden in favor of immediate coverage of the healthcare  
33 provider's selected prescription drug.

34 (7) "Utilization review organization" means an entity that conducts  
35 utilization review, not including a health insurance plan provider  
36 performing utilization review for the provider's own health insurance plan.

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

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

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

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

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

18 (ii) using a methodologist to work with writing groups to provide  
19 objectivity in data analysis and evidence ranking by preparing evidence  
20 tables and facilitating consensus; and

21 (iii) offering opportunities for public review and comment;

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

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

24 (i) Minimizes biases and conflicts of interest;

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

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

28 (iv) considers relevant patient subgroups and preferences; and

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

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

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

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

39 (c) (1) For any health insurance plan that is delivered, issued for  
40 delivery, amended or renewed on or after January 1, 2019, and that  
41 restricts coverage of a prescription drug for the treatment of any medical  
42 condition pursuant to a step therapy protocol, the health insurance plan  
43 provider shall provide to the prescribing healthcare provider and patient

1 access to a clear, convenient and readily accessible process to request a  
2 step therapy exception. Any health insurance plan provider that utilizes a  
3 step therapy protocol shall make such process to request a step therapy  
4 exception accessible on the health insurance plan provider's website.

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

7 (A) The required prescription drug is contraindicated or will likely  
8 cause an adverse reaction by or physical or mental harm to the patient;

9 (B) the required prescription drug is expected to be ineffective based  
10 on the known clinical characteristics of the patient and the known  
11 characteristics of the prescription drug;

12 (C) the patient has tried the required prescription drug while under  
13 the patient's current or a previous health insurance plan, or another  
14 prescription drug in the same pharmacologic class or with the same  
15 mechanism of action, and such prescription drug was discontinued due to  
16 lack of efficacy or effectiveness, diminished effect or an adverse event;

17 (D) the required prescription drug is not in the best interest of the  
18 patient, based on medical necessity; or

19 (E) the patient is stable on a prescription drug selected by the patient's  
20 healthcare provider for the medical condition under consideration while on  
21 the patient's current or a previous health insurance plan.

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

24 (d) A health insurance plan provider shall respond to a request for a  
25 step therapy exception, or any appeal therefor, within 72 hours of receipt  
26 of the request or appeal. If a patient's prescribing healthcare provider  
27 indicates that exigent circumstances exist, the health insurance plan  
28 provider shall respond to such a request or appeal within 24 hours of  
29 receipt of the request or appeal. If the health insurance plan provider fails  
30 to respond within the required time, the step therapy exception or appeal  
31 shall be deemed granted. Upon granting a step therapy exception, the  
32 health insurance plan provider shall authorize coverage for and  
33 dispensation of the prescription drug prescribed by the patient's healthcare  
34 provider.

35 (e) This section shall not be construed to prevent:

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

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

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

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