

**SENATE BILL No. 82**

By Committee on Public Health and Welfare

1-25

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

3  
4 WHEREAS, The legislature finds that health insurance plans are  
5 increasingly making use of step therapy protocols under which patients are  
6 required to try one or more prescription drugs before coverage is provided  
7 for a drug selected by the patient's healthcare provider; and

8 WHEREAS, The legislature further finds that such step therapy  
9 protocols, where they are based on well-developed scientific standards and  
10 administered in a flexible manner that takes into account the individual  
11 needs of patients, can play an important role in controlling healthcare  
12 costs; and

13 WHEREAS, The legislature further finds that, in some cases, requiring  
14 a patient to follow a step therapy protocol may have adverse and even  
15 dangerous consequences for the patient who may either not realize a  
16 benefit from taking a prescription drug or may suffer harm from taking an  
17 inappropriate drug; and

18 WHEREAS, The legislature further finds that, without uniform policies  
19 in the state for step therapy protocols, all patients may not receive the  
20 equivalent or most appropriate treatment; and

21 WHEREAS, The legislature further finds that it is imperative that step  
22 therapy protocols in the state preserve the healthcare provider's right to  
23 make treatment decisions in the best interest of the patient; and

24 WHEREAS, The legislature declares it a matter of public interest that  
25 health insurers base step therapy protocols on appropriate clinical practice  
26 guidelines or published peer review data developed by independent experts  
27 with knowledge of the condition or conditions under consideration; that  
28 patients be exempt from step therapy protocols when inappropriate or  
29 otherwise not in the best interest of the patient; and that patients have  
30 access to a fair, transparent and independent process for requesting an  
31 exception to a step therapy protocol when the patients physician deems  
32 appropriate.

33 Now, therefore:

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

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

36 (1) "Clinical practice guidelines" means a systematically developed

1 statement to assist healthcare provider decision-making and patient  
2 decisions about appropriate healthcare for specific clinical circumstances  
3 and conditions.

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

8 (3) "Health insurance plan" includes any individual or group health  
9 insurance policy, medical service plan, contract, hospital service  
10 corporation contract, hospital and medical service corporation contract,  
11 fraternal benefit society or health maintenance organization, municipal  
12 group-funded pool and the state health care benefits plan that provides  
13 medical, surgical or hospital expense coverage. For purposes of this  
14 section, health insurance plan also includes any third-party entity that  
15 conducts utilization review pursuant to a contract with a health insurance  
16 plan provider.

17 (4) "Step therapy protocol" means a protocol or program that  
18 establishes a specific sequence in which prescription drugs that are  
19 prescribed for a specified medical condition, medically appropriate for a  
20 particular patient and covered as a pharmacy or medical benefit by a health  
21 insurance plan, including self-administered and physician-administered  
22 drugs, are authorized to be covered by a health insurance plan.

23 (b) Every provider of a health insurance plan that is delivered, issued  
24 for delivery, amended or renewed on or after January 1, 2018, that utilizes  
25 a step therapy protocol shall establish guidelines governing the use of the  
26 step therapy protocol using clinical review criteria based on clinical  
27 practice guidelines subject to the following requirements:

28 (1) Such guidelines shall recommend that the prescription drugs be  
29 taken in the specific sequence required by the provider pursuant to the  
30 provider's step therapy protocol.

31 (2) The guidelines shall be developed and endorsed by a  
32 multidisciplinary panel of medical experts that manages conflicts of  
33 interest among the members of the panel by:

34 (A) Requiring members to disclose any potential conflict of interest  
35 with any relevant entity, including providers of health insurance plans and  
36 pharmaceutical manufacturers, and to abstain from voting on any issue for  
37 which the member has a conflict of interest;

38 (B) using a methodologist to work with the panel to provide  
39 objectivity in data analysis, rank evidence and facilitate consensus; and

40 (C) offering opportunity for public review and comment.

41 (3) The guidelines shall be based on high quality studies, research  
42 and medical practice.

43 (4) The guidelines shall be created by an explicit and transparent

1 process that minimizes bias and conflict of interest, explains the  
2 relationship between treatment options and outcomes, rates the quality of  
3 evidence supporting the panel's recommendations and considers relevant  
4 patient subgroups and preferences, including atypical patient populations  
5 and diagnoses.

6 (5) The guidelines shall be continually updated through review of  
7 new evidence, research and newly developed treatments.

8 (6) In the absence of clinical practice guidelines that satisfy the  
9 requirements of this subsection, the provider of the health insurance plan  
10 may use peer-reviewed publications to develop the step therapy protocol.

11 (c) (1) When a health insurance plan restricts coverage of a  
12 prescription drug for the treatment of any medical condition pursuant to a  
13 step therapy protocol, the plan provider shall provide to the prescribing  
14 healthcare provider access to a clear, convenient and readily accessible  
15 process to request an override of the step therapy protocol. A health  
16 insurance plan may use an existing medical exceptions process to satisfy  
17 the requirements of this subsection. A provider of a health insurance plan  
18 that utilizes a step therapy protocol shall make the process for override  
19 accessible on the provider's website.

20 (2) When a health insurance plan restricts coverage of a prescription  
21 drug for the treatment of any medical condition pursuant to a step therapy  
22 protocol, the plan provider shall expeditiously grant an override to such  
23 restriction if:

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

26 (B) the required prescription drug is expected to be ineffective based  
27 on the known clinical characteristics of the patient and the known  
28 characteristics of the prescription drug regimen;

29 (C) the patient has tried the required prescription drug while under  
30 their current or a previous health insurance plan, or another prescription  
31 drug in the same pharmacologic class or with the same mechanism of  
32 action, and such prescription drug was discontinued due to lack of efficacy  
33 or effectiveness, diminished effect, or an adverse event;

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

36 (E) the patient is stable on a prescription drug selected by their  
37 healthcare provider for the medical condition under consideration while on  
38 a current or previous health insurance plan.

39 (3) Upon granting an override of a step therapy protocol pursuant to  
40 this subsection, the health insurance plan shall authorize coverage for the  
41 prescription drug prescribed by the patient's healthcare provider.

42 (4) A provider of a health insurance plan shall respond to a request to  
43 override a step therapy protocol within 72 hours of receiving the request or

1 appeal. In cases where the healthcare provider has indicated that exigent  
2 circumstances exist, the provider shall respond within 24 hours of  
3 receiving the request or appeal. A provider shall permit a healthcare  
4 provider to appeal the provider's decision regarding a request to override a  
5 step therapy protocol subject to the same time limits as a request to  
6 override. If a provider fails to respond to a request or appeal within the  
7 prescribed time limits, the requested exception shall be deemed to be  
8 granted.

9 (d) This section shall not be construed to require a provider of a  
10 health insurance plan to establish a new entity to develop clinical review  
11 criteria to be used for a step therapy protocol.

12 (e) The department of insurance shall adopt rules and regulations as  
13 may be necessary to administer and implement this section prior to  
14 January 1, 2018.

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