

HOUSE BILL No. 2157

By Committee on Health and Human Services

1-27

1 AN ACT concerning health and healthcare; relating to health insurance
2 plans; establishing restrictions on the use of step therapy protocols for
3 prescription medication.
4

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

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

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

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

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

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

28 (5) "Prescriber" means the same as that term is defined in K.S.A. 65-
29 4101, and amendments thereto.

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

34 (7) "Step therapy protocol" means a protocol or program that
35 establishes the specific sequence in which prescription drugs for a
36 specified medical condition, including self-administered and physician-

1 administered drugs, are medically appropriate for a particular patient and
2 are covered under a health insurance plan.

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

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

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

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

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

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

1 based on the known characteristics of the specific patient and the known
2 characteristics of the required prescription drug.

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

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

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

17 (5) A health insurance plan shall respond to a request for a step
18 therapy exception, or any appeal therefor, within 72 hours of receipt of the
19 request or appeal. If a patient's prescriber indicates that exigent
20 circumstances exist, the health insurance plan shall respond to such a
21 request or appeal within 24 hours of receipt of the request or appeal. If the
22 health insurance plan fails to respond within the required time, the step
23 therapy exception or appeal shall be deemed granted. Upon granting a step
24 therapy exception, the health insurance plan shall authorize coverage for
25 and dispensation of the prescription drug prescribed by the patient's
26 prescriber.

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

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

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

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

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

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

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

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

1 (g) This section shall take effect on and after January 1, 2022.

2 Sec. 2. The insurance department shall adopt such rules and
3 regulations as may be necessary to implement and administer the
4 provisions of section 1, and amendments thereto, prior to January 1,
5 2022.

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