

HOUSE BILL No. 2120

By Representatives Mason, E. Smith, Bergquist, Bishop, Carlin, Concannon, Dierks, Dove, Eplee, Erickson, Esau, Finney, Hibbard, Highland, Hineman, Hoffman, Hoheisel, Humphries, Jennings, Johnson, Moore, Ousley, Owens, Rahjes, Resman, Samsel, Schreiber, Thimesch, Victors, Ward, Warfield, Wasinger and Wheeler

1-31

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

3
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 healthcare providers and patients in making decisions
8 about appropriate healthcare services for specific clinical circumstances
9 and conditions developed independently of a health insurance plan,
10 pharmaceutical manufacturer or any entity with a conflict of interest.

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

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

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

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

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

33 (7) "Step therapy protocol" means a protocol or program that

1 establishes the specific sequence in which prescription drugs for a
2 specified medical condition, including self-administered and physician-
3 administered drugs, are medically appropriate for a particular patient and
4 are covered under a health insurance plan.

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

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

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

23 (i) Cause an adverse reaction to the patient;

24 (ii) decrease the ability of the patient to achieve or maintain
25 reasonable functional ability in performing daily activities; or

26 (iii) cause physical or mental harm to the patient;

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

39 (C) the patient is currently receiving a positive therapeutic outcome
40 on a prescription drug for the medical condition under consideration if,
41 while on the patient's current health insurance plan or the immediately
42 preceding health plan, the patient received coverage for the prescription
43 drug and the patient's prescriber provides documentation to the health

1 insurance plan that the change in prescription drug required by the step
2 therapy protocol is expected to be ineffective or cause harm to the patient
3 based on the known characteristics of the specific patient and the known
4 characteristics of the required prescription drug.

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

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

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

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

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

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

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

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

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

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

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

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

3 (g) This section shall take effect on and after January 1, 2020.

4 Sec. 2. The insurance department shall adopt such rules and
5 regulations as may be necessary to implement and administer the
6 provisions of section 1, and amendments thereto, prior to January 1,
7 2020.

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