LEGISLATURE OF NEBRASKA

ONE HUNDRED SEVENTH LEGISLATURE

FIRST SESSION

LEGISLATIVE BILL 337

FINAL READING

Introduced by Kolterman, 24.

Read first time January 13, 2021

Committee: Banking, Commerce and Insurance

- 1 A BILL FOR AN ACT relating to prescription drug coverage; to adopt the
- 2 Step-Therapy Reform Act; and to provide a duty for the Revisor of
- 3 Statutes.
- 4 Be it enacted by the people of the State of Nebraska,

LB337 2021

1 Section 1. Sections 1 to 7 of this act shall be known and may be

- 2 <u>cited as the Step-Therapy Reform Act.</u>
- 3 Sec. 2. <u>For purposes of the Step-Therapy Reform Act:</u>
- 4 (1) Clinical practice quidelines means a systematically developed
- 5 <u>statement to assist decisionmaking by health care providers and decisions</u>
- 6 by covered persons about appropriate health care for specific clinical
- 7 circumstances and conditions;
- 8 (2) Clinical review criteria means the written screening procedures,
- 9 decision abstracts, clinical protocols, and clinical practice guidelines
- 10 <u>used by a health carrier or utilization review organization to determine</u>
- 11 the medical necessity and appropriateness of health care services;
- 12 (3) Health carrier means an entity subject to the insurance laws and
- 13 regulations of this state, or subject to the jurisdiction of the Director
- 14 of Insurance, that contracts or offers to contract to provide, deliver,
- 15 <u>arrange for, pay for, or reimburse any of the costs of health care</u>
- 16 <u>services</u>, <u>including a sickness and accident insurance company</u>, <u>a health</u>
- 17 maintenance organization, a nonprofit hospital and health service
- 18 corporation, or any other entity providing a plan of health insurance,
- 19 <u>health benefits, or health care services. Health carrier does not include</u>
- 20 <u>a managed care organization;</u>
- 21 (4) Pharmaceutical sample means a unit of a prescription drug that
- 22 is not intended to be sold and is intended to promote the sale of the
- 23 drug;
- 24 (5) Step-therapy override exception means that a step-therapy
- 25 protocol should be overridden in favor of coverage of the prescription
- 26 drug selected by a health care provider within the applicable timeframes,
- 27 based on a review of the request of the health care provider or covered
- 28 person for an override, along with supporting rationale and
- 29 <u>documentation;</u>
- 30 (6) Step-therapy protocol means a protocol, policy, or program that
- 31 establishes the specific sequence in which prescription drugs for a

LB337 2021

- 1 specified medical condition and medically appropriate for a particular
- 2 covered person are covered under a pharmacy or medical benefit by a
- 3 health carrier or a utilization review organization, including self-
- 4 administered drugs and drugs administered by a health care provider; and
- 5 (7) Utilization review organization means an entity that conducts a
- 6 utilization review other than a health carrier performing a review for
- 7 its own health benefit plans.
- 8 Sec. 3. A health carrier or utilization review organization shall
- 9 consider available recognized evidence-based and peer-reviewed clinical
- 10 practice guidelines when establishing a step-therapy protocol. Upon
- 11 <u>written request of a covered person, a health carrier or utilization</u>
- 12 <u>review organization shall provide any clinical review criteria applicable</u>
- 13 to a specific prescription drug covered by the health carrier or
- 14 <u>utilization review organization.</u>
- 15 Sec. 4. When coverage of a prescription drug for the treatment of
- 16 any medical condition is restricted for use by a health carrier or
- 17 utilization review organization through the use of a step-therapy
- 18 protocol, the prescribing health care provider and the covered person
- 19 <u>shall have access to a clear, readily accessible, and convenient process</u>
- 20 to request a step-therapy override exception. A health carrier or
- 21 <u>utilization review organization may use its existing medical exceptions</u>
- 22 process to satisfy this requirement. The process used shall be easily
- 23 <u>accessible on the Internet site of the health carrier or utilization</u>
- 24 review organization.
- 25 Sec. 5. (1) A step-therapy override exception shall be approved by
- 26 <u>a health carrier or utilization review organization if any of the</u>
- 27 following circumstances apply:
- 28 (a) The prescription drug required under the step-therapy protocol
- 29 is contraindicated pursuant to the drug manufacturer's prescribing
- 30 information for the drug or, due to a documented adverse event with a
- 31 previous use or a documented medical condition, including a comorbid

LB337 2021

- 1 condition, is likely to do any of the following:
- 2 (i) Cause an adverse reaction to the covered individual;
- 3 (ii) Decrease the ability of the covered individual to achieve or
- 4 maintain reasonable functional ability in performing daily activities; or
- 5 (iii) Cause physical or mental harm to the covered individual;
- (b) The prescription drug required under the step-therapy protocol 6
- 7 is expected to be ineffective based on the known clinical characteristics
- of the covered person, such as the covered person's adherence to or 8
- 9 compliance with the covered person's individual plan of care, and any of
- 10 the following:
- (i) The known characteristics of the prescription drug regimen as 11
- described in peer-reviewed literature or in the manufacturer's 12
- prescribing information for the drug; 13
- (ii) The health care provider's medical judgment based on clinical 14
- 15 practice guidelines or peer-reviewed journals; or
- (iii) The covered person's documented experience with the 16
- 17 prescription drug regimen;
- (c) The covered person has had a trial of a therapeutically 18
- 19 equivalent dose of the prescription drug under the step-therapy protocol
- while under the covered person's current or previous health benefit plan 20
- 21 for a period of time to allow for a positive treatment outcome, and such
- 22 prescription drug was discontinued by the covered person's health care
- provider due to lack of effectiveness; or 23
- 24 (d) The covered person is currently receiving a positive therapeutic
- 25 outcome on a prescription drug selected by the covered person's health
- care provider for the medical condition under consideration while under 26
- 27 the covered person's current or previous health benefit plan. Nothing in
- 28 the Step-Therapy Reform Act shall prohibit the distribution of a
- pharmaceutical sample, except that the pharmaceutical sample may not be 29
- 30 used to meet the requirements of this subdivision.
- (2) Upon the approval of a step-therapy override exception, the 31

20

21

1 health carrier or utilization review organization shall authorize

- 2 <u>coverage for the prescription drug selected by the covered person's</u>
- 3 prescribing health care provider if the prescription drug is a covered
- 4 prescription drug under the covered person's health benefit plan.
- 5 (3) Except in the case of an urgent care request, a health carrier or utilization review organization shall make a determination to approve 6 7 or deny a request for a step-therapy override exception within five calendar days after receipt of complete, clinically relevant written 8 9 documentation supporting a step-therapy override exception under 10 subsection (1) of this section. In the case of an urgent care request, a health carrier or utilization review organization shall approve or deny a 11 request for a step-therapy override exception within seventy-two hours 12 13 after receipt of such documentation. If a request for a step-therapy override exception is incomplete or additional clinically relevant 14 information is required, the health carrier or utilization review 15 16 organization may request such information within the applicable time 17 period provided in this section. Once the information is submitted, the applicable time period for approval or denial shall begin again. If a 18 19 health carrier or utilization review organization fails to respond to the
- 22 (4) If a request for a step-therapy override exception is denied, the health carrier or utilization review organization shall provide the 23 24 covered person or the covered person's authorized representative and the 25 covered person's prescribing health care provider with the reason for the denial and information regarding the procedure to request external review 26 27 of the denial pursuant to the Health Carrier External Review Act. Any 28 denial of a request for a step-therapy override exception that is upheld on an internal appeal shall be considered a final adverse determination 29 for purposes of the Health Carrier External Review Act and is eligible 30 for a request for external review by a covered person or the covered 31

request for a step-therapy override exception within the applicable time,

the step-therapy override exception shall be deemed granted.

1 person's authorized representative pursuant to the Health Carrier

- 2 <u>External Review Act.</u>
- 3 <u>(5) This section shall not be construed to prevent:</u>
- 4 (a) A health carrier or utilization review organization from
- 5 requiring a pharmacist to effect substitutions of prescription drugs
- 6 consistent with section 28-414.01, 38-28,111, or 71-2478;
- 7 <u>(b) A health care provider from prescribing a prescription drug that</u>
- 8 <u>is determined to be medically appropriate; or</u>
- 9 <u>(c) A health carrier or utilization review organization from</u>
- 10 requiring a covered person to try a prescription drug with the same
- 11 generic name and demonstrated bioavailability or a biological product
- 12 <u>that is an interchangeable biological product pursuant to the Nebraska</u>
- 13 <u>Drug Product Selection Act prior to providing coverage for the equivalent</u>
- 14 <u>branded prescription drug.</u>
- 15 Sec. 6. The Director of Insurance may adopt and promulgate rules
- 16 and regulations necessary to enforce the Step-Therapy Reform Act.
- 17 Sec. 7. (1) The Step-Therapy Reform Act applies to all individual
- 18 and group health insurance policies, contracts, and certificates issued
- 19 by health carriers, self-funded nonfederal governmental plans, and state
- 20 <u>employee health plans offered by the State of Nebraska.</u>
- 21 (2) The Step-Therapy Reform Act applies to any health insurance or
- 22 health benefit plans delivered, issued for delivery, or renewed on or
- 23 after January 1, 2022.
- 24 Sec. 8. The Revisor of Statutes shall assign sections 1 to 7 of
- 25 this act to Chapter 44.