LEGISLATURE OF NEBRASKA ONE HUNDRED SEVENTH LEGISLATURE

FIRST SESSION

LEGISLATIVE BILL 337

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,

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

- 2 cited as the Step-Therapy Reform Act.
- 3 Sec. 2. For purposes of the Step-Therapy Reform Act:
- 4 (1) Clinical practice quidelines means a systematically developed
- 5 statement to assist decisionmaking by health care providers and decisions
- 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 <u>decision abstracts, clinical protocols, and clinical practice guidelines</u>
- 10 used by a health carrier or utilization review organization to determine
- 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 arrange for, pay for, or reimburse any of the costs of health care
- 16 <u>services, including a sickness and accident insurance company, a health</u>
- 17 <u>maintenance organization, a nonprofit hospital and health service</u>
- 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) Step-therapy override exception means that a step-therapy
- 22 protocol should be overridden in favor of coverage of the prescription
- 23 drug selected by a health care provider within the applicable timeframes,
- 24 based on a review of the request of the health care provider or covered
- 25 person for an override, along with supporting rationale and
- 26 documentation;
- 27 (5) Step-therapy protocol means a protocol, policy, or program that
- 28 establishes the specific sequence in which prescription drugs for a
- 29 specified medical condition and medically appropriate for a particular
- 30 covered person are covered under a pharmacy or medical benefit by a
- 31 health carrier or a utilization review organization, including self-

1 administered drugs and drugs administered by a health care provider; and

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

1 maintain reasonable functional ability in performing daily activities; or

- 2 (iii) Cause physical or mental harm to the covered individual;
- 3 (b) The prescription drug required under the step-therapy protocol
- 4 is expected to be ineffective based on the known clinical characteristics
- 5 of the covered person, such as the covered person's adherence to or
- 6 compliance with the covered person's individual plan of care, and any of
- 7 the following:
- 8 <u>(i) The known characteristics of the prescription drug regimen as</u>
- 9 <u>described</u> in <u>peer-reviewed</u> literature or in the manufacturer's
- 10 prescribing information for the drug;
- 11 (ii) The health care provider's medical judgment based on clinical
- 12 practice guidelines or peer-reviewed journals; or
- 13 (iii) The covered person's documented experience with the
- 14 prescription drug regimen;
- 15 (c) The covered person has had a trial of a therapeutically
- 16 equivalent dose of the prescription drug under the step-therapy protocol
- 17 while under the covered person's current or previous health benefit plan
- 18 for a period of time to allow for a positive treatment outcome, and such
- 19 prescription drug was discontinued by the covered person's health care
- 20 provider due to lack of effectiveness; or
- 21 (d) The covered person is currently receiving a positive therapeutic
- 22 outcome on a prescription drug selected by the covered person's health
- 23 care provider for the medical condition under consideration while under
- 24 the covered person's current or previous health benefit plan.
- 25 (2) Upon the approval of a step-therapy override exception, the
- 26 health carrier or utilization review organization shall authorize
- 27 <u>coverage for the prescription drug selected by the covered person's</u>
- 28 prescribing health care provider if the prescription drug is a covered
- 29 prescription drug under the covered person's health benefit plan.
- 30 (3) Except in the case of an urgent care request, a health carrier
- 31 or utilization review organization shall make a determination to approve

- or deny a request for a step-therapy override exception within five calendar days after receipt of complete, clinically relevant written
- 3 <u>documentation</u> supporting a step-therapy override exception under
- 4 <u>subsection (1) of this section. In the case of an urgent care request, a</u>
- 5 <u>health carrier or utilization review organization shall approve or deny a</u>
- 6 request for a step-therapy override exception within seventy-two hours
- 7 <u>after receipt of such documentation</u>. If a request for a step-therapy
- 8 <u>override exception is incomplete or additional clinically relevant</u>
- 9 information is required, the health carrier or utilization review
- 10 <u>organization may request such information within the applicable time</u>
- 11 period provided in this section. Once the information is submitted, the
- 12 applicable time period for approval or denial shall begin again. If a
- 13 <u>health carrier or utilization review organization fails to respond to the</u>
- 14 request for a step-therapy override exception within the applicable time,
- 15 the step-therapy override exception shall be deemed granted.
- 16 (4) If a request for a step-therapy override exception is denied,
- 17 the health carrier or utilization review organization shall provide the
- 18 covered person or the covered person's authorized representative and the
- 19 covered person's prescribing health care provider with the reason for the
- 20 denial and information regarding the procedure to request external review
- 21 of the denial pursuant to the Health Carrier External Review Act. Any
- 22 denial of a request for a step-therapy override exception that is upheld
- 23 on an internal appeal shall be considered a final adverse determination
- 24 <u>for purposes of the Health Carrier External Review Act and is</u> eligible
- 25 for a request for external review by a covered person or the covered
- 26 person's authorized representative pursuant to the Health Carrier
- 27 External Review Act.
- 28 (5) This section shall not be construed to prevent:
- 29 <u>(a) A health carrier or utilization review organization from</u>
- 30 requiring a pharmacist to effect substitutions of prescription drugs
- 31 <u>consistent with section 28-414.01, 38-28,111, or 71-2478;</u>

1 (b) A health care provider from prescribing a prescription drug that

- 2 is determined to be medically appropriate; or
- 3 (c) A health carrier or utilization review organization from
- 4 requiring a covered person to try a prescription drug with the same
- 5 generic name and demonstrated bioavailability or a biological product
- 6 that is an interchangeable biological product pursuant to the Nebraska
- 7 <u>Drug Product Selection Act prior to providing coverage for the equivalent</u>
- 8 <u>branded prescription drug.</u>
- 9 Sec. 6. The Director of Insurance may adopt and promulgate rules
- 10 <u>and regulations necessary to enforce the Step-Therapy Reform Act.</u>
- 11 Sec. 7. (1) The Step-Therapy Reform Act applies to all individual
- 12 and group health insurance policies, contracts, and certificates issued
- 13 by health carriers, self-funded nonfederal governmental plans, and state
- 14 employee health plans offered by the State of Nebraska.
- 15 (2) The Step-Therapy Reform Act applies to any health insurance or
- 16 <u>health benefit plans delivered, issued for delivery, or renewed on or</u>
- 17 after January 1, 2022.
- 18 Sec. 8. The Revisor of Statutes shall assign sections 1 to 7 of
- 19 this act to Chapter 44.