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2021

LEGISLATIVE BILL 337

Approved by the Governor March 31, 2021

Introduced by Kolterman, 24.

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

Section 1. Sections 1 to 7 of this act shall be known and may be cited as the Step-Therapy Reform Act.

Sec. 2. For purposes of the Step-Therapy Reform Act:

(1) Clinical practice guidelines means a systematically developed statement to assist decisionmaking by health care providers and decisions by covered persons about appropriate health care for specific clinical circumstances and conditions;

(2) Clinical review criteria means the written screening procedures, decision abstracts, clinical protocols, and clinical practice guidelines used by a health carrier or utilization review organization to determine the medical necessity and appropriateness of health care services;

(3) Health carrier means an entity subject to the insurance laws and regulations of this state, or subject to the jurisdiction of the Director of Insurance, that contracts or offers to contract to provide, deliver, arrange for, pay for, or reimburse any of the costs of health care services, including a sickness and accident insurance company, a health maintenance organization, a nonprofit hospital and health service corporation, or any other entity providing a plan of health insurance, health benefits, or health care services. Health carrier does not include a managed care organization;

(4) Pharmaceutical sample means a unit of a prescription drug that is not intended to be sold and is intended to promote the sale of the drug;

(5) Step-therapy override exception means that a step-therapy protocol should be overridden in favor of coverage of the prescription drug selected by a health care provider within the applicable timeframes, based on a review of the request of the health care provider or covered person for an override, along with supporting rationale and documentation;

(6) Step-therapy protocol means a protocol, policy, or program that establishes the specific sequence in which prescription drugs for a specified medical condition and medically appropriate for a particular covered person are covered under a pharmacy or medical benefit by a health carrier or a utilization review organization, including self-administered drugs and drugs administered by a health care provider; and

(7) Utilization review organization means an entity that conducts a utilization review other than a health carrier performing a review for its own health benefit plans.

Sec. 3. A health carrier or utilization review organization shall consider available recognized evidence-based and peer-reviewed clinical practice guidelines when establishing a step-therapy protocol. Upon written request of a covered person, a health carrier or utilization review organization shall provide any clinical review criteria applicable to a specific prescription drug covered by the health carrier or utilization review organization.

Sec. 4. When coverage of a prescription drug for the treatment of any medical condition is restricted for use by a health carrier or utilization review organization through the use of a step-therapy protocol, the prescribing health care provider and the covered person shall have access to a clear, readily accessible, and convenient process to request a step-therapy override exception. A health carrier or utilization review organization may use its existing medical exceptions process to satisfy this requirement. The process used shall be easily accessible on the Internet site of the health carrier or utilization review organization.

Sec. 5. (1) A step-therapy override exception shall be approved by a health carrier or utilization review organization if any of the following circumstances apply:

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

(i) Cause an adverse reaction to the covered individual;

(ii) Decrease the ability of the covered individual to achieve or maintain reasonable functional ability in performing daily activities; or

(iii) Cause physical or mental harm to the covered individual;

(b) The prescription drug required under the step-therapy protocol is expected to be ineffective based on the known clinical characteristics of the covered person, such as the covered person's adherence to or compliance with the covered person's individual plan of care, and any of the following:

(i) The known characteristics of the prescription drug regimen as described in peer-reviewed literature or in the manufacturer's prescribing

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information for the drug;

(ii) The health care provider's medical judgment based on clinical practice guidelines or peer-reviewed journals; or

(iii) The covered person's documented experience with the prescription drug regimen;

(c) The covered person has had a trial of a therapeutically equivalent dose of the prescription drug under the step-therapy protocol while under the covered person's current or previous health benefit plan for a period of time to allow for a positive treatment outcome, and such prescription drug was discontinued by the covered person's health care provider due to lack of effectiveness; or

(d) The covered person is currently receiving a positive therapeutic outcome on a prescription drug selected by the covered person's health care provider for the medical condition under consideration while under the covered person's current or previous health benefit plan. Nothing in the Step-Therapy Reform Act shall prohibit the distribution of a pharmaceutical sample, except that the pharmaceutical sample may not be used to meet the requirements of this subdivision.

(2) Upon the approval of a step-therapy override exception, the health carrier or utilization review organization shall authorize coverage for the prescription drug selected by the covered person's prescribing health care provider if the prescription drug is a covered prescription drug under the covered person's health benefit plan.

(3) Except in the case of an urgent care request, a health carrier 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 documentation supporting a step-therapy override exception under 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 request for a step-therapy override exception within seventy-two hours after receipt of such documentation. If a request for a step-therapy override exception is incomplete or additional clinically relevant information is required, the health carrier or utilization review organization may request such information within the applicable time period provided in this section. Once the information is submitted, the applicable time period for approval or denial shall begin again. If a health carrier or utilization review organization fails to respond to the request for a step-therapy override exception within the applicable time, the step-therapy override exception shall be deemed granted.

(4) If a request for a step-therapy override exception is denied, the health carrier or utilization review organization shall provide the covered person or the covered person's authorized representative and the covered person's prescribing health care provider with the reason for the denial and information regarding the procedure to request external review of the denial pursuant to the Health Carrier External Review Act. Any denial of a request for a step-therapy override exception that is upheld on an internal appeal shall be considered a final adverse determination for purposes of the Health Carrier External Review Act and is eligible for a request for external review by a covered person or the covered person's authorized representative pursuant to the Health Carrier External Review Act.

(5) This section shall not be construed to prevent:

(a) A health carrier or utilization review organization from requiring a pharmacist to effect substitutions of prescription drugs consistent with section 28-414.01, 38-28,111, or 71-2478;

(b) A health care provider from prescribing a prescription drug that is determined to be medically appropriate; or

(c) A health carrier or utilization review organization from requiring a covered person to try a prescription drug with the same generic name and demonstrated bioavailability or a biological product that is an interchangeable biological product pursuant to the Nebraska Drug Product Selection Act prior to providing coverage for the equivalent branded prescription drug.

Sec. 6. The Director of Insurance may adopt and promulgate rules and regulations necessary to enforce the Step-Therapy Reform Act.

Sec. 7. (1) The Step-Therapy Reform Act applies to all individual and group health insurance policies, contracts, and certificates issued by health carriers, self-funded nonfederal governmental plans, and state employee health plans offered by the State of Nebraska.

(2) The Step-Therapy Reform Act applies to any health insurance or health benefit plans delivered, issued for delivery, or renewed on or after January 1, 2022.

Sec. 8. The Revisor of Statutes shall assign sections 1 to 7 of this act to Chapter 44.