VIRGINIA ACTS OF ASSEMBLY -- 2019 SESSION

CHAPTER 337

An Act to amend the Code of Virginia by adding a section numbered 38.2-3407.9:05, relating to accident and sickness insurance; step therapy protocols.

[H 2126]

Approved March 12, 2019

Be it enacted by the General Assembly of Virginia:

1. That the Code of Virginia is amended by adding a section numbered 38.2-3407.9:05 as follows:

§ 38.2-3407.9:05. Step therapy protocols.

A. As used in this section:

"Carrier" means any (i) insurer issuing individual or group accident and sickness insurance policies providing hospital, medical and surgical, or major medical coverage on an expense-incurred basis; (ii) corporation providing individual or group accident and sickness subscription contracts; or (iii) health maintenance organization providing a health care plan for health care services. "Carrier" includes any entity administering a policy or plan providing health insurance coverage to state employees pursuant to § 2.2-2818 but does not include any entity administering a policy or plan providing coverage pursuant to Title XVIII of the Social Security Act, 42 U.S.C. § 1395 et seq. (Medicare); Title XIX of the Social Security Act, 42 U.S.C. § 1396 et seq. (Medicaid); or Title XXI of the Social Security Act, 42 U.S.C. § 1397aa et seq. (CHIP).

"Clinical practice guideline" means a systematically developed statement to assist decision making by providers about appropriate health care for a specific clinical circumstance or condition.

"Clinical review criteria" means the written screening procedures, decision abstracts, clinical protocols, and practice guidelines used by a carrier, utilization review organization, or independent review organization to determine the medical necessity and appropriateness of a health care service.

"Health benefit plan" means a policy, contract, certificate, or agreement offered by a carrier to provide, deliver, arrange for, pay for, or reimburse any of the costs of services for the diagnosis, prevention, treatment, cure, or relief of a health condition, illness, injury, or disease and that provides coverage for prescription drugs. "Health benefit plan" includes any policy or plan providing health insurance coverage to state employees pursuant to § 2.2-2818.

"Patient" means a policyholder, subscriber, participant, or other individual covered by a health benefit plan.

"Provider" means a hospital, physician, or any type of provider licensed, certified, or authorized by statute to provide a covered service under the health benefit plan.

"Step therapy exception" means overriding a step therapy protocol in favor of immediate coverage of the provider's selected prescription drug provided that such drug is covered under the health benefit plan, which determination is based on a review of the patient's or prescribing provider's request for an override, along with supporting rationale and documentation.

"Step therapy protocol" means a protocol setting the sequence in which prescription drugs for a specified medical condition and medically appropriate for a particular patient are covered under a health benefit plan.

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

B. Carriers or utilization review organizations that develop step therapy protocols for a health benefit plan shall ensure that those step therapy protocols:

1. Are developed and endorsed by a multidisciplinary panel of experts that manages conflicts of interest among the members of the writing and review groups by requiring members to disclose to the carrier any potential conflict of interest, including carriers and pharmaceutical manufacturers, and recuse themselves of voting if they have a conflict of interest;

2. Are based on peer-reviewed research and medical practice, and may also consider published clinical practice guidelines established for relevant patient subgroups in addition to or in the absence of peer-reviewed research; and

3. Are continually updated based on a review of new evidence, research, and newly developed treatments.

C. When establishing a step therapy protocol, a utilization review agent may also take into account the needs of atypical patient populations and diagnoses when establishing clinical review criteria.

D. This section shall not be construed to require carriers to set up a new entity to develop clinical review criteria used for step therapy protocols.

E. When coverage of a prescription drug for the treatment of any medical condition is restricted for use by a carrier or utilization review organization through the use of a step therapy protocol, the

patient and prescribing provider shall have access to a clear, readily accessible, and convenient process to request a step therapy exception. A carrier or utilization review organization may use its existing medical exceptions process to satisfy this requirement. The process shall be made easily accessible on the carrier's or utilization review organization's website.

F. A step therapy exception request shall be granted if the prescribing provider's submitted justification and supporting clinical documentation, if needed, are determined to support the prescribing provider's statement that:

1. The required prescription drug is contraindicated;

2. The required drug would be ineffective based on the known clinical characteristics of the patient and the known characteristics of the prescription drug regimen;

3. The patient has tried the step therapy-required prescription drug while under their current or a previous health benefit plan, and such prescription drug was discontinued due to lack of efficacy or effectiveness, diminished effect, or an adverse event; or

4. The patient is currently receiving a positive therapeutic outcome on a prescription drug recommended by his provider for the medical condition under consideration while on a current or the immediately preceding health benefit plan.

G. Upon the granting of a step therapy exception, the carrier or utilization review organization shall authorize coverage for the prescription drug prescribed by the patient's treating provider, provided that the prescription drug is covered under the current health benefit plan.

H. The carrier or utilization review organization shall respond to a step therapy exception request within 72 hours of receipt, including hours on weekends, that the request is approved, denied, or requires supplementation. In cases where exigent circumstances exist, a carrier or utilization review organization shall respond within 24 hours of receipt, including hours on weekends, that the request is approved, denied, or requires supplementation.

I. A patient may appeal any step therapy exception request denial made pursuant to this section under the health benefit plan's existing appeal procedures.

J. Drug samples shall not be considered trial and failure of a preferred drug.

K. This section shall not be construed to prevent a carrier or utilization review organization from requiring an enrollee to try an AB-rated generic equivalent or interchangeable biological product prior to providing coverage, or substitute a generic for a branded drug.

L. Pursuant to the authority granted by § 38.2-223, the Commission may promulgate such rules and regulations as it may deem necessary to implement this section.

M. This section shall apply to any health benefit plan delivered, issued for delivery, or renewed on or after January 1, 2020.