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HOUSE BILL NO. 386

Offered January 10, 2018
Prefiled January 5, 2018

A BILL to amend the Code of Virginia by adding a section numbered 38.2-3407.9:04, relating to accident and sickness insurance; step therapy protocols.

Patrons—Davis, Peace, Adams, D.M., Fowler, Garrett, McGuire, Stolle and Webert

Referred to Committee on Commerce and Labor

Be it enacted by the General Assembly of Virginia:

1. That the Code of Virginia is amended by adding a section numbered 38.2-3407.9:04 as follows:

§ 38.2-3407.9:04. 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.

"Clinical practice guideline" means a systematically developed statement to assist decision making by a provider and patient decisions 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 override exception determination" means a determination as to whether a step therapy should apply in a particular situation, or whether the step therapy protocol should be overridden in favor of immediate coverage of the provider's selected prescription drug. This 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 or program that establishes the specific 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. Clinical review criteria used to establish step therapy protocols shall be based on clinical practice guidelines that:

1. Recommend that the prescription drugs be taken in the specific sequence required by the step therapy protocol;

2. 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:

a. Requiring members to disclose any potential conflict of interest with entities, including carriers and pharmaceutical manufacturers, and recuse themselves of voting if they have a conflict of interest;

b. Using a methodologist to work with writing groups to provide objectivity in data analysis and ranking of evidence through the preparation of evidence tables and facilitating consensus; and

c. Offering opportunities for public review and comments;

3. Are based on high quality studies, research, and medical practice;

4. Are created by an explicit and transparent process that:

a. Minimizes biases and conflicts of interest;

b. Explains the relationship between treatment options and outcomes; and

c. Rates the quality of the evidence supporting recommendations;

5. Considers relevant patient subgroups and preferences; and

6. Are continually updated through a review of new evidence, research, and newly developed treatments.

C. In the absence of clinical guidelines that meet the requirements of subsection B, peer-reviewed publications may be substituted.

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

E. 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.

F. 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 override exception determination. 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.

G. A step therapy override exception determination request shall be expeditiously granted if:

1. The required prescription drug is contraindicated or will likely cause physical or mental harm to the patient or an adverse reaction;

2. The required drug is expected to 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, or another prescription drug in the same pharmacologic class or with the same mechanism of action, and such prescription drugs were discontinued due to lack of efficacy or effectiveness, diminished effect, or an adverse event;

4. The step therapy-required prescription drug is not in the best interest of the patient, based on medical necessity; or

5. The patient is stable on a prescription drug recommended by his provider for the medical condition under consideration while on a current or previous health benefit plan.

H. Upon the granting of a step therapy override exception determination, the carrier or utilization review organization shall authorize coverage for the prescription drug prescribed by the patient's treating provider.

I. The carrier or utilization review organization shall respond to a step therapy override exception determination request or an appeal within 72 hours of receipt. In cases where exigent circumstances exist, a carrier or utilization review organization shall respond within 24 hours of receipt. If a response by a carrier or utilization review organization is not received within these time periods, the exception or appeal shall be deemed granted.

J. A patient may appeal any step therapy override exception determination made pursuant to this section.

K. This section shall not be construed to prevent:

1. A carrier or utilization review organization from requiring an enrollee try an AB-rated generic equivalent prior to providing reimbursement for an equivalent branded drug; or

2. A provider from prescribing a prescription drug he determines is medically appropriate.

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, 2019.