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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;*

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- 59 *b. Explains the relationship between treatment options and outcomes; and*
60 *c. Rates the quality of the evidence supporting recommendations;*
61 *5. Considers relevant patient subgroups and preferences; and*
62 *6. Are continually updated through a review of new evidence, research, and newly developed*
63 *treatments.*
64 *C. In the absence of clinical guidelines that meet the requirements of subsection B, peer-reviewed*
65 *publications may be substituted.*
66 *D. When establishing a step therapy protocol, a utilization review agent shall also take into account*
67 *the needs of atypical patient populations and diagnoses when establishing clinical review criteria.*
68 *E. This section shall not be construed to require carriers to set up a new entity to develop clinical*
69 *review criteria used for step therapy protocols.*
70 *F. When coverage of a prescription drug for the treatment of any medical condition is restricted for*
71 *use by a carrier or utilization review organization through the use of a step therapy protocol, the*
72 *patient and prescribing provider shall have access to a clear, readily accessible, and convenient process*
73 *to request a step therapy override exception determination. A carrier or utilization review organization*
74 *may use its existing medical exceptions process to satisfy this requirement. The process shall be made*
75 *easily accessible on the carrier's or utilization review organization's website.*
76 *G. A step therapy override exception determination request shall be expeditiously granted if:*
77 *1. The required prescription drug is contraindicated or will likely cause physical or mental harm to*
78 *the patient or an adverse reaction;*
79 *2. The required drug is expected to be ineffective based on the known clinical characteristics of the*
80 *patient and the known characteristics of the prescription drug regimen;*
81 *3. The patient has tried the step therapy-required prescription drug while under their current or a*
82 *previous health benefit plan, or another prescription drug in the same pharmacologic class or with the*
83 *same mechanism of action, and such prescription drugs were discontinued due to lack of efficacy or*
84 *effectiveness, diminished effect, or an adverse event;*
85 *4. The step therapy-required prescription drug is not in the best interest of the patient, based on*
86 *medical necessity; or*
87 *5. The patient is stable on a prescription drug recommended by his provider for the medical*
88 *condition under consideration while on a current or previous health benefit plan.*
89 *H. Upon the granting of a step therapy override exception determination, the carrier or utilization*
90 *review organization shall authorize coverage for the prescription drug prescribed by the patient's*
91 *treating provider.*
92 *I. The carrier or utilization review organization shall respond to a step therapy override exception*
93 *determination request or an appeal within 72 hours of receipt. In cases where exigent circumstances*
94 *exist, a carrier or utilization review organization shall respond within 24 hours of receipt. If a response*
95 *by a carrier or utilization review organization is not received within these time periods, the exception or*
96 *appeal shall be deemed granted.*
97 *J. A patient may appeal any step therapy override exception determination made pursuant to this*
98 *section.*
99 *K. This section shall not be construed to prevent:*
100 *1. A carrier or utilization review organization from requiring an enrollee try an AB-rated generic*
101 *equivalent prior to providing reimbursement for an equivalent branded drug; or*
102 *2. A provider from prescribing a prescription drug he determines is medically appropriate.*
103 *L. Pursuant to the authority granted by § 38.2-223, the Commission may promulgate such rules and*
104 *regulations as it may deem necessary to implement this section.*
105 *M. This section shall apply to any health benefit plan delivered, issued for delivery, or renewed on*
106 *or after January 1, 2019.*