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SENATE BILL NO. 1408

AMENDMENT IN THE NATURE OF A SUBSTITUTE
(Proposed by the Senate Committee on Commerce and Labor
on January 23, 2017)

(Patron Prior to Substitute—Senator DeSteph)

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; disclosure of information.*

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; disclosures.

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 coverage to state employees pursuant to § 2.2-2818.

"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 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 protocol" means a protocol or program that (i) establishes the specific sequence in which prescription drugs for a specified medical condition are medically appropriate for a particular patient and are covered under a pharmacy or medical benefit by a carrier, including self-administered and physician-administered drugs, or (ii) in any way conditions coverage of a prescription medication on a patient first trying an alternative medication without success.

"Step therapy protocol override" means a determination, based on a review of a prescribing provider's request for an override along with supporting rationale and documentation, as to whether a step therapy protocol should apply in a particular situation or whether the step therapy protocol should be overridden in favor of immediate coverage of the prescribing provider's selected prescription drug.

B. Any carrier that offers a health benefit plan that uses a step therapy protocol shall have in place a clear, convenient, and expeditious process for a prescribing provider to request an override of the restrictions of the step therapy protocol for a patient, such that if the request is granted by the carrier, the step therapy protocol shall not apply to the prescription drug for that patient. The process shall be made easily accessible on the carrier's website.

C. A step therapy protocol override shall be expeditiously granted if any of the following apply:

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

2. The required prescription drug is expected to be ineffective based on the known relevant physical or mental characteristics of the patient and the known characteristics of the prescription drug regimen;

3. The patient has tried the required prescription drug while under his 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 drug was discontinued due to lack of efficacy or effectiveness, diminished effect, or an adverse event;

4. A medical opinion is given by a second provider, not affiliated with the prescribing provider, reconfirming that the prescribed therapy is in the best interest of the patient based upon their personal examination of the patient and medical test results;

5. The required prescription drug is expected to be ineffective based on the known clinical characteristics of the patient and the known characteristics of the prescription drug regimen; or

6. Based on clinical appropriateness, a preceding prescription drug is not in the best interest of the covered individual because the covered individual's use of the preceding prescription drug is expected to:

a. Be a significant barrier to the covered individual's adherence to or compliance with the covered individual's plan of care;

- 60 *b. Worsen a comorbid condition of the covered individual; or*
61 *c. Decrease the covered individual's ability to achieve or maintain reasonable functional ability in*
62 *performing daily activities.*
- 63 *D. A carrier shall not require a step therapy protocol for any prescription drug prescribed for a*
64 *patient who previously has satisfied a step therapy protocol with respect to that prescription drug or for*
65 *whom there has been a step therapy protocol override with respect to that prescription drug, provided*
66 *that the patient or the prescribing provider submits documentation demonstrating to the carrier that the*
67 *step therapy protocol has been overridden.*
- 68 *E. Any carrier that offers a health benefit plan that uses a step therapy protocol shall provide to the*
69 *prescribing provider and patient, upon making a determination that the protocol requires denial of*
70 *coverage of a provider's selected prescription drug and approval of coverage for another prescription*
71 *drug or alternative medication in the protocol's sequence, written notice of the determination and an*
72 *explanation of the basis for such determination, together with notice of the procedures for submitting a*
73 *request for an override of the restrictions of the step therapy protocol.*
- 74 *F. The carrier or utilization review organization shall respond to a step therapy override exception*
75 *request or an appeal within 72 hours of receipt; however, in cases where exigent circumstances exist a*
76 *carrier or utilization review organization shall respond within 24 hours of receipt. If the carrier or*
77 *utilization review organization does not respond within the applicable period following receipt, the*
78 *exception or appeal shall be deemed granted.*