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HOUSE BILL NO. 362

Offered January 13, 2016

Prefiled January 5, 2016

A *BILL to amend the Code of Virginia by adding a section numbered 38.2-3407.13:3, relating to accident and sickness insurance; step therapy protocols; disclosure of information.*

Patron—Davis

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 38.2-3407.13:3 as follows:

§ 38.2-3407.13:3. 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.

"Clinical practice guidelines" means a systematically developed statement to assist providers and patients with decisions about appropriate health care for specific clinical circumstances and conditions.

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

"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.

"Patient" means a policyholder, subscriber, patient, 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 determination" means a determination, based on a review of the patient's or prescriber'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 provider's selected prescription drug.

"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 by a health benefit plan or (ii) in any way conditions coverage of a prescription medication on a patient first trying an alternative medication without success.

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 insurer, 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 determination request 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; or

4. The required prescription drug is not in the best interest of the patient, based on medical appropriateness.

D. A carrier shall not require a step therapy protocol for any prescription drug prescribed for a patient who previously has satisfied a step therapy protocol with respect to that prescription drug, or for whom there has been a step therapy override determination with respect to that prescription drug,

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59 *provided that the patient or the prescribing provider submits documentation demonstrating to the insurer*
60 *that the step therapy protocol has been overridden.*

61 *E. Any carrier that offers a health benefit plan that uses a step therapy protocol shall provide to the*
62 *prescribing provider and patient, upon making a determination that the protocol requires denial of*
63 *coverage of a provider's selected prescription drug and approval of coverage for another prescription*
64 *drug or alternative medication in the protocol's sequence, written notice of the determination and an*
65 *explanation of the basis for such determination, together with notice of the procedures for submitting a*
66 *request for an override of the restrictions of the step therapy protocol.*