

****REVISED****

**State Corporation Commission
2016 Fiscal Impact Statement**

1. Bill Number: HB362

House of Origin Introduced Substitute Engrossed

Second House In Committee Substitute Enrolled

2. Patron: Davis

3. Committee: Commerce and Labor

4. Title: Step therapy protocols; disclosures.

5. Summary: Step therapy protocols; disclosures. Requires health insurers that limit coverage for prescription drugs through the use of a step therapy protocol to have in place a process for a prescribing provider to request an override of the protocol for a patient. A step therapy protocol is a protocol or program that 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 that conditions coverage of a prescription medication on a patient first trying an alternative medication without success. The measure requires the granting of a step therapy protocol override in certain circumstances. Finally, the measure requires an insurer that offers a health benefit plan that uses a step therapy protocol to provide (i) written notice of a determination that the protocol requires denial of coverage of a provider's selected prescription drug, (ii) an explanation of the basis for such determination, and (iii) notice of the procedures for submitting a request for an override of the restrictions of the step therapy protocol.

6. Budget amendment necessary: No

7. Fiscal Impact Estimates: No Fiscal Impact on the State Corporation Commission. For the Department of Human Resource Management (DHRM), the fiscal impact estimate is unknown. See Line 8.

8. Fiscal implications: None on the State Corporation Commission. According to the Department of Human Resource Management, it is difficult to quantify how many prescribers would utilize the ability to bypass step therapy. DHRM noted as an example that if 10% of prescribers were to bypass step therapy, it could potentially have a \$120,000 impact.

9. Specific agency or political subdivisions affected: State Corporation Commission Bureau of Insurance; Department of Human Resource Management

10. Technical amendment necessary: The State Corporation Commission Bureau of Insurance offered the patron of House Bill 362 the following technical suggestions:

- Rather than adding a new section § 38.2-3407.13:3, the Bureau suggested creation of a new § 38.2-3407.9:04 to the Code of Virginia. The sections immediately preceding the suggested section are §§ 38.2-3407.9:01, 38.2-3407.9:02 and 38.2-3407.9:03, which relate to prescription drug formularies, prescription drug coverage requirements, and payments to pharmacy benefit administrators, respectively.

- The terms “Clinical practice guidelines” and “Clinical review criteria” are not used elsewhere in this section, and therefore, need not be defined on lines 18-22. The Bureau of Insurance suggested deleting these defined terms.
- The definition of “patient” on lines 27-28 includes the term “patient.” The term should be removed from the definition.
- The term “carrier” is defined on lines 14-17; however, lines 41 and 59 refer to the term “insurer.” The Bureau suggested using the defined term “carrier.”
- There is an inconsistency between lines 31 and 40 regarding who may make a request for a step therapy protocol override. Line 31 indicates that a step therapy override determination is a review of either the patient’s or the prescriber’s request. Line 40 indicates that the step therapy protocol is a process for a prescribing provider to request an override for a patient. The Bureau suggested clarification of this inconsistency.
- The term “step therapy override determination” is defined as a determination that the step therapy protocol is either upheld or overridden. Based on this definition, it is unclear in lines 44-55 whether it is required that the override request be expeditiously *approved* by the carrier, or that a *determination* to uphold or override the step therapy be made expeditiously by the carrier. The Bureau suggested to the patron that if it was the intent of the bill that an override be granted under any of the four conditions listed in Section C of proposed § 38.2-3407.13:3, the words “determination request” should be deleted from line 44.

11. Other comments: Senate Bill 332 is similar to House Bill 362. Senate Bill 331 also relates to step therapy protocols but for psychiatric medications only.

House Bill 362 has been assigned to subcommittee #2.

Date: 01/26/16/V. Tompkins

cc: Secretary of Health and Human Resources