HOUSE BILL 821:
Proper Administration of Step Therapy

2015-2016 General Assembly

Committee:	House Insurance	**Date:**	April 29, 2015
Introduced by:	Reps. Lewis, Wray	**Prepared by:**	Amy Jo Johnson
Analysis of:	Second Edition		Committee Counsel

SUMMARY: House Bill 821 would require insurers offering health benefit plans to establish a step therapy protocol based upon clinical review criteria. When coverage of a prescription drug is restriction for use by health benefit plan or utilization review organization through the use of a step therapy protocol, House Bill 821 would require the availability of a step therapy override determination process.

BACKGROUND:

Step therapy is a type of prior authorization requirement used in health benefit plans. Step therapy requires the insured to try one or more prerequisite drugs that are generally less costly before more costly medication will be covered.

BILL ANALYSIS:

House Bill 821 adds a new Part 8 to Article 50 of Chapter 58 of the General Statues that addresses the administration of step therapy protocols. A step therapy protocol is defined as "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 an insurer or health plan." An insurer would be required to use written screening procedures, decision abstracts, clinical protocols, and practice guideless to establish a step therapy protocol. These clinical review criteria must be based on clinical practice guidelines that meet the following requirements:

- Recommend the drugs be taken in the specific sequence required by the step therapy protocol.
- Are developed and endorsed by an independent, multidisciplinary panel of experts not affiliated with a health benefit plan or utilization review organization.
- Are based on high quality studies, research, and medical practice.
- Are created by an explicit and transparent process that:
    - Minimizes biases and conflicts of interest;
    - Explains the relationship between treatment options and outcomes;
    - Rates the quality of the evidence supporting recommendations; and
    - Considers relevant patient subgroups and preferences.
- Are continually updated through a review of new evidence and research.

House Bill 821 would also require that the patient and prescribing practitioner have access to a step therapy override determination process. A health benefit plan or utilization review organization may use its existing medical exceptions process for this purpose. A step therapy override determination request must be granted of any of the following apply:

- The required prescription drug is contraindicated or will likely cause an adverse reaction or physical or mental harm to the patient.
- 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.
- The patient has tried the required prescription drug while under their current or a previous health insurance or 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.
- The required prescription drug is not in the best interest of the patient, based on medical appropriateness.
- The patient is stable on a prescription drug selected by their health care provider for the medical condition under consideration.

House Bill 821 indicates that nothing will be construed to prevent a health benefit plan or utilization review organization from requiring a patient to try an AB rated generic equivalent prior to providing coverage for the equivalent branded prescription drug or a health care provider from prescribing a prescription drug that is determined to be medically appropriate. House Bill 821 also indicates that nothing will be construed to impact an insurer's ability to substitute a generic drug for a name brand drug.

EFFECTIVE DATE: This act becomes effective January 1, 2016, and applies to health benefit contracts issued, renewed, or amended on or after that date.