A BILL TO BE ENTITLED
AN ACT TO ENSURE THE PROPER ADMINISTRATION OF STEP THERAPY PROTOCOLS FOR PRESCRIPTION DRUGS.

Whereas, health benefit plans are increasingly making use of step therapy protocols under which patients are required to try one or more prescription drugs before coverage is provided for a drug selected by the patient's health care provider; and

Whereas, when step therapy protocols are based on well-developed scientific standards and administered in a flexible manner that takes into account the individual needs of patients, the protocols can play an important role in controlling health care costs; and

Whereas, in some cases, requiring a patient to follow a step therapy protocol may have adverse and even dangerous consequences for the patient who may either not realize a benefit from taking a prescription drug or may suffer harm from taking an inappropriate drug; and

Whereas, without uniform policies in the State for step therapy protocols, patients may not receive the best and most appropriate treatment; and

Whereas, it is imperative that step therapy protocols preserve the health care provider's right to make treatment decisions in the best interest of the patient; and

Whereas, the General Assembly declares it a matter of public interest that it require health benefit plans base step therapy protocols on appropriate clinical practice guidelines developed by independent experts with knowledge of the condition or conditions under consideration; that patients be exempt from step therapy protocols when inappropriate or otherwise not in the best interest of the patients; and that patients have access to a fair, transparent, and independent process for requesting an exception to a step therapy protocol when appropriate; Now, therefore,

The General Assembly of North Carolina enacts:

SECTION 1. Article 50 of Chapter 58 of the General Statutes is amended by adding a new Part to read:


§ 58-50-301. Definitions.
As used in this Article, unless the context clearly requires otherwise:

(1) Clinical practice guidelines. – A systematically developed statement to assist health care provider and patient decisions about appropriate health care for specific clinical circumstances and conditions.

(2) Clinical review criteria. – The written screening procedures, decision abstracts, clinical protocols, and practice guidelines used by an insurer,
health plan, or utilization review organization to determine the medical
necessity and appropriateness of health care services.

(3) **Step therapy override determination.** – A determination 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
health care provider's selected prescription drug. This determination is based
on a review of the patient's or prescriber's request for an override along with
supporting rationale and documentation.

(4) **Step therapy protocol.** – 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.

(5) **Utilization review organization.** – As defined in G.S. 59-50-61(a)(18).

"§ 58-50-305. Clinical review criteria.

Clinical review criteria used to establish a step therapy protocol shall be based on clinical
practice guidelines that meet all the following requirements:

(1) Recommend that the prescription drugs be taken in the specific sequence
required by the step therapy protocol.

(2) Are developed and endorsed by an independent, multidisciplinary panel of
experts not affiliated with a health benefit plan or utilization review
organization.

(3) Are based on high-quality studies, research, and medical practice.

(4) Are created by an explicit and transparent process that includes all of the
following:
   a. Minimizes biases and conflicts of interest.
   b. Explains the relationship between treatment options and outcomes.
   c. Rates the quality of the evidence supporting recommendations.
   d. Considers relevant patient subgroups and preferences.

(5) Are continually updated through a review of new evidence and research.


(a) **Exceptions Process.** – When coverage of a prescription drug for the treatment of any
medical condition is restricted for use by a health benefit plan or utilization review organization
through the use of a step therapy protocol, the patient and prescribing practitioner shall have
access to a clear and convenient process to request a step therapy override determination. A
health benefit plan or utilization review organization may use its existing medical exceptions
process to satisfy this requirement. The process shall be made easily accessible on the health
benefit plan's or utilization review organization's Web site.

(b) **Exceptions.** – A step therapy 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 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.

(4) 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.

(c) Effect of Exception. – Upon the granting of a step therapy override determination, the health benefit plan or utilization review organization shall authorize coverage for the prescription drug prescribed by the patient's treating health care provider, provided such prescription drug is a covered prescription drug under such policy or contract.

(d) Limitations. – This section shall not be construed to prevent any of the following:

(1) 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.

(2) A health care provider from prescribing a prescription drug that is determined to be medically appropriate.

(a) The Commissioner shall adopt rules to implement this Article.
(b) Nothing in this Part shall be construed to impact an insurers' ability to substitute a generic drug for a name brand drug."

SECTION 2. This act becomes effective January 1, 2016, and applies to health benefit contracts issued, renewed, or amended on or after that date.