

GENERAL ASSEMBLY OF NORTH CAROLINA
SESSION 2015

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HOUSE BILL 821
PROPOSED COMMITTEE SUBSTITUTE H821-PCS30374-TK-48

Short Title: Proper Administration of Step Therapy.

(Public)

Sponsors:

Referred to:

April 15, 2015

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

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

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

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

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

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

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

25 The General Assembly of North Carolina enacts:

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

28 "Part 8. Administration of Step Therapy Protocols.

29 "§ 58-50-301. Definitions.

30 As used in this Article, unless the context clearly requires otherwise:

- 31 (1) Clinical practice guidelines. – A systematically developed statement to assist
32 health care provider and patient decisions about appropriate health care for
33 specific clinical circumstances and conditions.
34 (2) Clinical review criteria. – The written screening procedures, decision
35 abstracts, clinical protocols, and practice guidelines used by an insurer.



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1 health plan, or utilization review organization to determine the medical
2 necessity and appropriateness of health care services.

3 (3) Step therapy override determination. – A determination as to whether a step
4 therapy protocol should apply in a particular situation or whether the step
5 therapy protocol should be overridden in favor of immediate coverage of the
6 health care provider's selected prescription drug. This determination is based
7 on a review of the patient's or prescriber's request for an override along with
8 supporting rationale and documentation.

9 (4) Step therapy protocol. – A protocol or program that establishes the specific
10 sequence in which prescription drugs for a specified medical condition are
11 medically appropriate for a particular patient and are covered by an insurer
12 or health plan.

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

14 **"§ 58-50-305. Clinical review criteria.**

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

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

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

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

23 (4) Are created by an explicit and transparent process that includes all of the
24 following:

25 a. Minimizes biases and conflicts of interest.

26 b. Explains the relationship between treatment options and outcomes.

27 c. Rates the quality of the evidence supporting recommendations.

28 d. Considers relevant patient subgroups and preferences.

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

30 **"§ 58-50-310. Exceptions process transparency.**

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

38 (b) Exceptions. – A step therapy override determination request shall be expeditiously
39 granted if any of the following apply:

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

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

45 (3) The patient has tried the required prescription drug while under their current
46 or a previous health insurance or health benefit plan or another prescription
47 drug in the same pharmacologic class or with the same mechanism of action
48 and such prescription drug was discontinued due to lack of efficacy or
49 effectiveness, diminished effect, or an adverse event.

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

1 (5) The patient is stable on a prescription drug selected by their health care
2 provider for the medical condition under consideration.

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

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

8 (1) A health benefit plan or utilization review organization from requiring a
9 patient to try an AB-rated generic equivalent prior to providing coverage for
10 the equivalent branded prescription drug.

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

13 **"§ 58-50-315. Rules and limitation of Part.**

14 (a) The Commissioner shall adopt rules to implement this Article.

15 (b) Nothing in this Part shall be construed to impact an insurers' ability to substitute a
16 generic drug for a name brand drug."

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