

GENERAL ASSEMBLY OF NORTH CAROLINA  
SESSION 2015

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HOUSE PRINCIPAL CLERK

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HOUSE DRH20262-MM-52 (03/04)

Short Title: Proper Administration of Step Therapy. (Public)

Sponsors: Representatives Lewis and Wray (Primary Sponsors).

Referred to:

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 **"§ 58-50-300. Definitions.**

30 Unless the context clearly indicates otherwise, the following words or phrases, as used in  
31 this Article, have the following meanings:

- 32 (1) "Clinical practice guidelines" means a systematically developed statement to  
33 assist health care provider and patient decisions about appropriate health  
34 care for specific clinical circumstances and conditions.



- 1           (2)    "Clinical review criteria" means the written screening procedures, decision  
2           abstracts, clinical protocols, and practice guidelines used by an insurer,  
3           health plan, or utilization review organization to determine the medical  
4           necessity and appropriateness of health care services.
- 5           (3)    "Step therapy override determination" means a determination as to whether a  
6           step therapy protocol should apply in a particular situation, or whether the  
7           step therapy protocol should be overridden in favor of immediate coverage  
8           of the health care provider's selected prescription drug. This determination is  
9           based on a review of the patient's or prescriber's request for an override,  
10           along with supporting rationale and documentation.
- 11          (4)    "Step therapy protocol" means a protocol or program that establishes the  
12           specific sequence in which prescription drugs for a specified medical  
13           condition are medically appropriate for a particular patient and are covered  
14           by an insurer or health plan.
- 15          (5)    "Utilization review organization" as defined in G.S. 59-50-61(a)(18).

16    **"§ 58-50-305. Clinical review criteria.**

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

- 19          (1)    Recommend that the prescription drugs be taken in the specific sequence  
20           required by the step therapy protocol.
- 21          (2)    Are developed and endorsed by an independent, multidisciplinary panel of  
22           experts not affiliated with a health benefit plan or utilization review  
23           organization.
- 24          (3)    Are based on high quality studies, research, and medical practice.
- 25          (4)    Are created by an explicit and transparent process that:  
26            a.    Minimizes biases and conflicts of interest;  
27            b.    Explains the relationship between treatment options and outcomes;  
28            c.    Rates the quality of the evidence supporting recommendations; and  
29            d.    Considers relevant patient subgroups and preferences.
- 30          (5)    Are continually updated through a review of new evidence and research.

31    **"§ 58-50-310. Exceptions process transparency.**

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

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

- 41          (1)    The required prescription drug is contraindicated or will likely cause an  
42           adverse reaction or physical or mental harm to the patient.
- 43          (2)    The required prescription drug is expected to be ineffective based on the  
44           known relevant physical or mental characteristics of the patient and the  
45           known characteristics of the prescription drug regimen.
- 46          (3)    The patient has tried the required prescription drug while under their current  
47           or a previous health insurance or health benefit plan or another prescription  
48           drug in the same pharmacologic class or with the same mechanism of action  
49           and such prescription drug was discontinued due to lack of efficacy or  
50           effectiveness, diminished effect, or an adverse event.

- 1           (4)    The required prescription drug is not in the best interest of the patient, based
- 2                    on medical appropriateness.
- 3           (5)    The patient is stable on a prescription drug selected by their health care
- 4                    provider for the medical condition under consideration.
- 5       (c)    Effect of Exception. – Upon the granting of a step therapy override determination,
- 6   the health benefit plan or utilization review organization shall authorize coverage for the
- 7   prescription drug prescribed by the patient's treating health care provider, provided such
- 8   prescription drug is a covered prescription drug under such policy or contract.
- 9       (d)    Limitations. – This section shall not be construed to prevent:
- 10       (1)    A health benefit plan or utilization review organization from requiring a
- 11                    patient to try an AB-rated generic equivalent prior to providing coverage for
- 12                    the equivalent branded prescription drug; or
- 13       (2)    A health care provider from prescribing a prescription drug that is
- 14                    determined to be medically appropriate.
- 15   "**§ 58-50-315. Rules.**
- 16       The Commissioner shall adopt rules to implement this Article."
- 17       **SECTION 2.** This act becomes effective October 1, 2015, and applies to health
- 18   benefit contracts issued, renewed, or amended on or after that date.