

**GENERAL ASSEMBLY OF NORTH CAROLINA
SESSION 2015**

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HOUSE BILL 1048

Short Title: Reduce Barriers to Improve NC Health & Safety. (Public)

Sponsors: Representatives Lewis, Jackson, Murphy, and Dobson (Primary Sponsors).
For a complete list of sponsors, refer to the North Carolina General Assembly web site.

Referred to: Insurance

May 9, 2016

A BILL TO BE ENTITLED

1 AN ACT TO INCREASE ACCESS TO ABUSE-DETERRENT OPIOID ANALGESICS AND
2 TO ENSURE THE PROPER ADMINISTRATION OF STEP THERAPY PROTOCOLS FOR
3 PRESCRIPTION DRUGS, AS RECOMMENDED BY THE HOUSE SELECT COMMITTEE
4 ON STEP THERAPY.
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6 Whereas, opioid-related deaths have doubled in North Carolina between 1999 and
7 2013; and

8 Whereas, a 2013 National Survey on Drug Use and Health found that over 63% of all
9 people who abuse prescription drugs obtained the drugs from family and friends; and

10 Whereas, opioid abuse in North Carolina is a serious and severe problem that affects
11 the health, social, and economic welfare of this State; and

12 Whereas, abuse-deterrent opioid analgesics have been labelled a top priority by the
13 United States Food and Drug Administration; and

14 Whereas, patient access to abuse-deterrent opioid analgesics is an important step in
15 addressing the opioid abuse epidemic; and

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

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

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

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

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

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

35 Now, therefore,



1 The General Assembly of North Carolina enacts:

2 **SECTION 1.** Article 3 of Chapter 58 of the General Statutes is amended by adding a
3 new section to read:

4 **"§ 58-3-295. Coverage for abuse-deterrent opioid analgesics.**

5 (a) The following definitions apply in this section:

6 (1) Abuse-deterrent opioid analgesic drug product. – A brand or generic opioid
7 analgesic drug product approved by the United States Food and Drug
8 Administration with an abuse-deterrence labeling claim that indicates that the
9 drug product is expected to deter abuse.

10 (2) Health benefit plan. – As defined in G.S. 58-3-167.

11 (3) Opioid analgesic drug product. – A drug product in the opioid analgesic drug
12 class prescribed to treat moderate to severe pain or other conditions in
13 immediate-release, extended-release, or long-acting form, regardless of whether
14 or not combined with other drug substances to form a single drug product or
15 dosage form.

16 (b) Any health benefit plan that provides coverage for abuse-deterrent opioid analgesic
17 drug products may impose a prior authorization requirement for an abuse-deterrent opioid
18 analgesic drug product only if the health benefit plan imposes the same prior authorization
19 requirement for each opioid analgesic drug product without an abuse-deterrence labeling claim.

20 (c) No health benefit plan that provides coverage for abuse-deterrent opioid analgesic drug
21 products may require the use of an opioid analgesic drug product without an abuse-deterrence
22 labeling claim before authorizing the use of an abuse-deterrent opioid analgesic drug product."

23 **SECTION 2.** Article 50 of Chapter 58 of the General Statutes is amended by adding a
24 new Part to read:

25 "Part 8. Administration of Step Therapy Protocols.

26 **"§ 58-50-301. Definitions.**

27 As used in this Article, unless the context clearly requires otherwise, the following definitions
28 apply:

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

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

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

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

46 (5) Utilization review organization. – As defined in G.S. 58-50-61(a)(18).

47 **"§ 58-50-305. Clinical review criteria.**

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

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

- 1 (2) Are developed and endorsed by an independent, multidisciplinary panel of
2 experts not affiliated with a health benefit plan or utilization review
3 organization.
- 4 (3) Are based on high-quality studies, research, and medical practice.
- 5 (4) Are created by an explicit and transparent process that includes all of the
6 following:
- 7 a. Minimizes biases and conflicts of interest.
- 8 b. Explains the relationship between treatment options and outcomes.
- 9 c. Rates the quality of the evidence supporting recommendations.
- 10 d. Considers relevant patient subgroups and preferences.
- 11 (5) Are continually updated through a review of new evidence and research.

12 **"§ 58-50-310. Exceptions process transparency.**

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

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

- 22 (1) The required prescription drug is contraindicated or will likely cause an adverse
23 reaction or physical or mental harm to the patient.
- 24 (2) The required prescription drug is expected to be ineffective based on the known
25 relevant physical or mental characteristics of the patient and the known
26 characteristics of the prescription drug regimen.
- 27 (3) The patient has tried the required prescription drug while under their current or
28 a previous health insurance or health benefit plan or another prescription drug
29 in the same pharmacologic class or with the same mechanism of action and
30 such prescription drug was discontinued due to lack of efficacy or effectiveness,
31 diminished effect, or an adverse event.
- 32 (4) The required prescription drug is not in the best interest of the patient, based on
33 medical appropriateness.
- 34 (5) The patient is stable on a prescription drug selected by their health care
35 provider for the medical condition under consideration.

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

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

- 41 (1) A health benefit plan or utilization review organization from requiring a patient
42 to try an AB-rated generic equivalent prior to providing coverage for the
43 equivalent branded prescription drug.
- 44 (2) A health care provider from prescribing a prescription drug that is determined
45 to be medically appropriate.

46 **"§ 58-50-315. Rules and limitation of Part.**

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

48 (b) Nothing in this Part shall be construed to impact an insurer's ability to substitute a
49 generic drug for a name brand drug."

50 **SECTION 3.** This act becomes effective October 1, 2016, and applies to insurance
51 contracts issued, renewed, or amended on or after that date.