GENERAL ASSEMBLY OF NORTH CAROLINA
SESSION 2015

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HOUSE BILL DRH20420-MRz-16D (03/31)

Short Title:	Reduce Barriers to Improve NC Health & Safety.	(Public)
Sponsors:	Representatives Lewis, Jackson, Murphy, Dobson (Primary Sponsors); and Wray.	
Referred to:		

A BILL TO BE ENTITLED

AN ACT TO INCREASE ACCESS TO ABUSE-DETERRENT OPIOID ANALGESICS AND TO ENSURE THE PROPER ADMINISTRATION OF STEP THERAPY PROTOCOLS FOR PRESCRIPTION DRUGS, AS RECOMMENDED BY THE HOUSE SELECT COMMITTEE ON STEP THERAPY.

Whereas, opioid-related deaths have doubled in North Carolina between 1999 and 2013; and

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

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

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

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

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 3 of Chapter 58 of the General Statutes is amended by adding a new section to read:

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

(a) The following definitions apply in this section:

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

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

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

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

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

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

"Part 8. Administration of Step Therapy Protocols.

"**§ 58-50-301. Definitions.**

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

(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. 58-50-61(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.

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

(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.
(5) 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.

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

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

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

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