HOUSE BILL 450:
Reduce Barriers to Improve NC Health & Safety.

2019-2020 General Assembly

Committee:	House Health. If favorable, re-refer to Rules, Calendar, and Operations of the House	**Date:**	April 4, 2019
Introduced by:	Reps. Potts, Dobson, Lewis, Sasser	**Prepared by:**	Jason Moran-Bates
Analysis of:	First Edition		Committee Staff

OVERVIEW: House Bill 450 would require insurers to pre-authorize abuse-deterrent opioids on the same terms as they pre-authorize opioids with higher abuse potential. It would also prohibit insurers from authorizing opioids with higher abuse potential unless they first authorized abuse-deterrent opioids. Finally, it would create regulations, including an override process, to step therapy protocols.

CURRENT LAW: Currently, insurers are not required to authorize abuse-deterrent opioids before authorizing opioids with higher abuse potential. There are no provisions in the General Statutes specifically governing step therapy protocols.

BILL ANALYSIS:

Section 1 would create definitions for "abuse-deterrent opioid analgesic drug product" (Deterrent) and "opioid analgesic drug product" (Opioid). It would prohibit insurers from requiring pre-authorization for Deterrents if they did not also require pre-authorization for all covered Opioids. It would also prohibit insurers that provide coverage for Deterrents from authorizing the use of Opioids unless they first authorized the use of a Deterrent.

Section 2 would add a new part to Article 50 of Chapter 58 regulating step therapy protocols.

- 58-50-305 would create definitions for "clinical practice guidelines," "clinical review criteria," "step therapy override determination," "step therapy protocol," and "utilization review organization."
- 58-50-310 would require that any clinical review criteria used to establish a step therapy protocol:
    - Recommend that prescription drugs be taken in a specific sequence.
    - Are developed by an independent panel of experts not affiliated with a health benefit plan of utilization review organization.
    - Are based on high-quality research.
    - Minimize bias and conflict of interest.
    - Explain the relationship between treatment and outcome.
    - Rate the quality of supporting evidence.
    - Consider relevant patient subgroups.
    - Are continually updated.

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- 58-50-315 would require insurers to create a process for overriding an established step therapy protocol. This process must be easily accessible on the insurer's website. It would require insurers to override the protocol if any of the following apply:
    - The required drug is contraindicated.
    - The required drug is expected to be ineffective, based on characteristics of the patient or drug.
    - The patient has already tried the required drug and found it to be ineffective.
    - Then required drug is not in the best interest of the patient.
    - The patient is already stable on a different drug.

  Once an exception is granted, the insurer must authorize the prescribed drug, so long as it is covered under the policy. Insurers must respond to an exception request within 72 hours, or 24 hours in exigent circumstances. Nothing in this section will prevent an insurer from requiring patients to try generic drugs or providers from prescribing medically-appropriate drugs.
- 58-50-320 would require the Commissioner of Insurance the power to adopt rules implementing the act.

EFFECTIVE DATE: The act would be effective October 1, 2019, and apply to insurance contracts issued, renewed, or amended on or after that date.

BACKGROUND:

Abuse Deterrent Opioids

The Food and Drug Administration will allow opioids to be labelled as an "abuse-deterrent formulation" (ADF) if the drug is formulated in a way that makes it resistant to known or expected routes of abuse, such as crushing in order to snort or dissolving in order to inject. FDA guidance recognizes physical/chemical barriers, agonist/antagonist combinations, aversion effects, changes in the delivery system, and new molecular entities as formulations that may be used to combat abuse. Currently, OxyContin, Targiniq ER, Embeda, Hysingla ER, MorphaBond ER, Xtampza ER, Arymo ER, and RoxyBond have been approved by the FDA to be labelled as ADFs.

Step Therapy Protocol

Step Therapy is the process of initially using less expensive drugs to treat a condition. If the less expensive drugs are not effective, the patient can "step up" to more expensive drugs. Currently 18 states have some regulations for step therapy, and an additional 10 states were considering step therapy legislation in 2018.