



STEP THERAPY PROTOCOLS

SB140 | 2022 LEGISLATIVE SESSION

Kentucky was a pioneer in patient protections when it enacted step therapy reforms a decade ago. Now, more than half of the states have stronger laws in place. In 2022, in the wake of evolving clinical practices and insurance policies, Sen. Max Wise introduced Senate Bill 140 to update and clarify existing statutes that address step therapy protocols mandated by insurers and pharmacy benefit managers. The legislation was unanimously approved by both chambers and signed by the governor, taking effect on Jan 1., 2023.

The new law requires step therapy protocols to be based on widely accepted medical and clinical guidelines and will update the clinically justified circumstances for a patient and health care provider to override a step therapy protocol.

HIGHLIGHTS



Establishes requirements for clinical review criteria and clinical practice guidelines used to establish step therapy protocols.



Requires certain notices and disclosures relating to step therapy protocols; establish requirements for exception requests, internal appeals, and external reviews of step therapy protocols.



Requires Medicaid, the Kentucky Children's Health Insurance Program, self-insured employer group health plans provided by the governing board of a state postsecondary education institution, and the state employee health plan to comply with the step therapy protocol requirements.

EXCEPTIONS

Pursuant to §304.17 A-163 Kentucky Revised Statutes, the patient qualifies for an exception to the step therapy protocol because any one of the following conditions has been met: (Determinations required within 48 hours.)

- The required drug is contraindicated.
- The required drug is likely to cause an adverse reaction or physical or mental harm.
- The required drug is expected to be ineffective based on the known clinical characteristics of the patient and the drug regimen.
- The required drug is not in the best interest of the patient because it is expected to cause a significant barrier to adherence or compliance with a plan of care, worsen a comorbid condition, or decrease ability to achieve reasonable functional ability performing daily activities.
- The patient tried the required drug, or another drug in the same pharmacologic class or with the same mechanism of action, and it was discontinued due to lack of efficacy, effectiveness, diminished effect, or an adverse event.
- The patient is stable on a prescription drug other than the required drug.

SB140 is one of many KMA priorities that have been signed into law, thanks to the advocacy of KMA members. For more information on this and other legislative successes, visit kyma.org/advocacy.

