

Support H.R. 2630/S. 652 - The Safe Step Act

Issue: Reform step therapy protocols to improve patient care and reduce administrative burden by lifting barriers that prevent patients from accessing appropriate, evidence-based treatments.

Why Action is Needed: Step therapy is a price management practice used by Pharmacy Benefit Managers (PBMs) and group health insurers that requires patients try and fail on lower-priced drugs selected by their insurer before the drug prescribed by their physician will be covered. This approach not only leads to unnecessary administrative burden for physicians, but it delays effective treatment, deemed most appropriate by patients' physicians, which can exacerbate symptoms and lead to negative health outcomes. Currently, there is high [variation in the use of step therapy](#) across the country with health plans using step therapy protocols differently for different disease conditions. [Research](#) shows that these inconsistencies have the potential to negatively affect patients when they switch health plans. This could lead to "a loss of eligibility for the drug under the new plan and could require completion of the new plan's step therapy protocol to regain access."

ACP believes that there should be a transparent exceptions process for step therapy, to provide physicians and patients with clarity for treatment options and prevent delays in care. Patients and their physicians would benefit greatly from insurers being required to have a clear and transparent process for when either party requests an exception to a step therapy protocol. The Safe Step Act provides five exceptions to fail first protocols and requires that a group health plan grant an exemption if an application clearly demonstrates any of the following situations:

- The patient already tried and failed on the required drug.
- The delayed treatment will cause irreversible consequences and negatively affect the patient's medication.
- The prescription drug to which the health plan is requiring the patient to "fail first" on will cause harm to the patient.
- The required drug will prevent a patient from working or fulfilling activities of daily living.
- The patient is stable on their current medication.

ACP's Position

We call on Congress to improve physicians' ability to provide seamless evidence-based care for their patients without unnecessary administrative delays. ACP released a [position paper](#), that details recommendations for reforming the practice of step therapy and medication switching:

- All step therapy and medication switching policies should aim to minimize care disruption, harm, side effects, and risks to the patient.
- All step therapy and nonmedical drug switching policies should be designed with patients at the center, taking into account unique needs and preferences.
- All step therapy and nonmedical drug switching protocols should be designed with input from physicians and pharmacists; feature transparent, minimally burdensome processes that consider the expertise of a patient's physician; and include a timely appeals process.

Call to Action

Co-sponsor and pass H.R.2630/S. 652, the Safe Step Act, which would require group health plans to provide a transparent exception process for any medication step therapy protocol. This bipartisan and bicameral bill would ensure patients' access to appropriate treatments based on clinical decision-making and medical necessity rather than arbitrary step therapy protocols.