



April 3, 2023

The Honorable Lisa Murkowski
U.S. Senate
Washington, DC 20510

The Honorable Maggie Hassan
U.S. Senate
Washington, DC 20510

The Honorable Roger Marshall
U.S. Senate
Washington, DC 20510

The Honorable Jack Rosen
U.S. Senate
Washington, DC 20510

Dear Senators Murkowski, Hassan, Marshall and Rosen et al:

On behalf of the American College of Physicians (ACP), thank you for introducing S. 652, the *Safe Step Act of 2023*. ACP supports S. 652, amending the Employee Retirement Income Security Act (ERISA) to require group health plans to provide an exception process for the administering of prescription drugs in their step therapy protocols. While the legislation does not ban step therapy protocols, it does place reasonable limits on their use and creates a clear process for patients and doctors to seek exceptions to the step therapy requirements and accelerates approval, when necessary, for needed medications.

The College is the largest medical specialty organization and the second-largest physician membership society in the United States. ACP members include 160,000 internal medicine physicians, related subspecialists, and medical students. Internal medicine physicians are specialists who apply scientific knowledge, clinical expertise, and compassion to the preventive, diagnostic, and therapeutic care of adults across the spectrum from health to complex illness.

The Safe Step Act of 2023

Patients and their physicians would benefit greatly from the requirement in the bill that insurers implement a clear and transparent process for when either party requests an exception to a step therapy protocol. The bill lays out 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.

In addition, the legislation would require health plans to provide a timely response to the exemption requests including 72 hours in all circumstances and 24 hours if the patient's life is at risk.

Step Therapy Protocols

This legislation is necessary because Pharmacy Benefit Managers (PBMs) and group health insurers have developed a series of price management tools to curb the rising cost of prescription drugs that can delay and potentially hinder patient care. Among these, step therapy policies, commonly called “[fail-first](#)” policies, require patients to be initiated on [lower-priced medications](#) before being approved for originally prescribed medications. Carriers can also change coverage in an attempt to force patients off their current therapies for cost reasons, a practice known as [nonmedical drug switching](#).

Evidence concerning the effectiveness of these protocols is mixed. Some [studies](#) have found they can successfully drive cost savings without negatively impacting patient care. [Others](#) have shown that overall health spending actually increased due to an uptick in hospitalizations and other services resulting from new symptoms or complications. Meanwhile, these policies have drawn scrutiny for restricting patient access to effective treatments, putting patient health and safety in jeopardy by subjecting patients to potential adverse effects, interfering with the patient—physician relationship, and absorbing practice resources with burdensome approvals and documentation requirements.

In 2020, ACP released a [position paper](#), that details our policies concerning “Mitigating the Negative Impact of Step Therapy Practices and Non-Medical Switching of Prescription Drugs.” In that paper, we provide the following recommendations to 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.

Conclusion

ACP appreciates your leadership on S. 652. We urge the Senate to pass the *Safe Step Act*, which would ensure patient access to appropriate treatments based on clinical decision-making and medical necessity, not arbitrary step therapy protocols. This legislation would require insurers to implement a clear and transparent process to request an exception to group health plans' step therapy policies. Should you have any questions, or if we can be of further assistance, please contact George Lyons at glyons@acponline.org.

Sincerely,

A handwritten signature in black ink, appearing to read 'R. Mire', enclosed within a large, loopy oval flourish.

Ryan D. Mire, MD, MACP
President