

**STEP THERAPY**  
**S. 652/H.R. 2630, *Safe Step Act***

**REQUEST**

The Alliance of Specialty Medicine (the “Alliance”) urges members of Congress to **cosponsor and advance the bipartisan *Safe Step Act* (S. 652/H.R. 2630)** introduced in the Senate by Sens. **Lisa Murkowski** (R-AK), **Maggie Hassan** (D-NH), **Roger Marshall**, MD (R-KS), and **Jacky Rosen** (D-NV), and in the House by Reps. **Raul Ruiz**, MD (D-CA), **Brad Wenstrup**, DPM (R-OH), **Lucy McBath** (D-GA), and **Mariannette Miller-Meeks**, MD (R-IA). The Alliance thanks the Senate Health, Education, Labor and Pensions (HELP) Committee for adopting a bipartisan amendment offered by Sens. Murkowski, Hassan, and Marshall to include the *Safe Step Act* in S. 1339, the *Pharmacy Benefit Manager Reform Act*, which was favorably reported to the full Senate on May 11, 2023.<sup>1</sup>

**BACKGROUND**

A medication step-therapy protocol establishes a specific sequence in which a group health plan or a health insurance issuer covers prescription drugs. Step-therapy protocols may require patients to try and fail an insurer-preferred medication before being covered by the physician-prescribed medication. Many insurers have instituted this practice to help control the costs of expensive medications. However, while this practice may initially reduce insurer costs, it can have devastating health consequences for patients and ultimately lead to more expensive health care costs in the long run. Patients who are denied first coverage of medications recommended by their physicians can end up with poor health outcomes due to adverse health events, which can lead to costly hospitalizations. In the era of personalized medicine, patients with chronic diseases such as inflammatory bowel disease, rheumatoid arthritis, cancer, psoriasis, or age-related macular degeneration may respond differently to various medications used to treat these diseases.

**BILL SUMMARY**

The *Safe Step Act* amends the Employee Retirement Income Security Act of 1974 (ERISA) to require a group health plan to establish an exception process to medication step-therapy protocol:

- When the treatment is contraindicated;
- Expected to be ineffective;
- Likely to cause an adverse reaction;
- Expected to decrease the individual’s ability to perform daily activities or occupational responsibilities; or
- The individual is stable based on the prescription drugs already selected.

The legislation would require that requests be granted in a timely manner — within three days after receipt of the request or 24 hours when the protocol jeopardizes the life or health of the individual.

**CONTACTS**

To cosponsor **S. 652**, please contact Cassidy\_Hobbs@murkowski.senate.gov (Sen. Murkowski) or Jasmine\_Masand@hassan.senate.gov (Sen. Hassan).

To cosponsor **H.R. 2630**, please contact Erin.Doty@mail.house.gov (Rep. Ruiz) or Kelsi.Wilson@mail.house.gov (Rep. Wenstrup).

<sup>1</sup> <https://www.murkowski.senate.gov/press/release/icymi-murkowski-led-bill-to-provide-transparent-and-safe-access-to-treatment-passes-help-committee->