

March 15, 2024

The Honorable Virginia Foxx  
Chairwoman  
Education and Workforce Committee  
U.S. House of Representatives  
Washington, DC 20515

The Honorable Bobby Scott  
Ranking Member  
Education and Workforce Committee  
U.S. House of Representatives  
Washington, DC 20515

Dear Chairwoman Foxx, Ranking Member Scott, and Members of the Education and Workforce Committee,

The Safe Step Act Ad Hoc Coalition represents patient and provider organizations who believe patients should have access to high quality, affordable healthcare. The 101 undersigned organizations appreciate the opportunity to respond to the Committee's request for information on ways to strengthen the Employee Retirement Income Security Act (ERISA). We urge the Committee take action to reform step therapy, which negatively impacts patient care, and to mark up H.R. 2630, the Safe Step Act.

Insurance-mandated step therapy is a complex prior authorization protocol in which plans require patients to try and fail insurer-preferred treatments before the plan will cover the treatment initially selected by the patient and their provider. Plans require beneficiaries to prove failure for 2-3 months which, if the treatment is medically inappropriate, causes a serious delay in care that can lead to severe or irreversible health outcomes for the patient.

The Safe Step Act (S. 652/H.R. 2630) is endorsed by over 200 patient and provider organizations from across the nation.<sup>1</sup> Based on laws that have passed in 36 states,<sup>2</sup> including North Carolina and Virginia, the Safe Step Act would ensure that employer plans offer a clear, medically reasonable, and expedient step therapy exceptions process. The bill outlines a timeline in which plans should respond to an exception request – within 24 to 72 hours – which would modernize employer health plan policies in line with Medicare and most states.

Step therapy is prevalent in employer-sponsored health insurance. While step therapy is applied to all prescription drugs, a study using the Tufts Specialty Drug Evidence and Coverage (SPEC) database found that the largest commercial plans including employer-sponsored plans

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<sup>1</sup> [www.steptherapy.com/safe-step-act-flyer](http://www.steptherapy.com/safe-step-act-flyer)

<sup>2</sup> <https://steptherapy.com/step-therapy-legislation-by-state/>

applied step therapy to 38.9% of specialty drug coverage decisions.<sup>3</sup> The study also found that plans required patients to fail on more than one treatment, and in some cases, as many as 8.

Step therapy often steers patients to medications that are medically inappropriate. The Tufts study reviewed step therapy protocols for ten diseases and found that the step therapy protocols were more stringent than clinical guidelines 55% of the time with wide variation across disease states. For example, step therapy was more stringent than clinical guidelines 99% of the time for psoriasis, 88% of the time for multiple sclerosis, and 68% of the time for rheumatoid arthritis.

As currently utilized, step therapy is dangerous for patients because of the combination of long wait times and medically inappropriate failure requirements. For many patients, ‘proving failure’ often means permanently losing body function or even death. Step therapy has also been shown to reduce medication adherence and diminish patient trust in their provider. Many studies across disease states demonstrate the negative medical impact of step therapy on patients, or illustrate the consequences of delayed care. Below are a few examples:

- In depression, step therapy reduced medication adherence and increased adverse events by 20% in employer plans.<sup>4</sup>
- “Breast cancer patients with a treatment delay of three months or more had a 12 percent lower five-year survival rate compared with breast cancer patients with only a zero to three month delay.”<sup>5</sup> Quoted from “Does A ‘One Size Fits All’ Formulary Policy Make Sense?” ([Chung, Health Affairs, 2016](#)).
- In pediatric inflammatory bowel disease, any prior authorization including step therapy was associated with a 12.9% increased likelihood of serious adverse events.<sup>6</sup>

While insurers claim step therapy saves money, there is mounting evidence that step therapy savings to the prescription drug benefit are eclipsed by spending in the medical benefit even *within the plan year*. This is because medically inappropriate step therapy increases patient healthcare utilization. Below are examples:

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<sup>3</sup> Lenahan, K. et al, “Variation In Use And Content Of Prescription Drug Step Therapy Protocols, Within And Across Health Plans” *Health Affairs*, 2021 <https://doi.org/10.1377/hlthaff.2021.00822>

<sup>4</sup> Mark, T. et al, “The effects of antidepressant step therapy protocols on pharmaceutical and medical utilization and expenditures.” *The American journal of psychiatry* vol. 167,10 (2010): 1202-9.  
doi:10.1176/appi.ajp.2010.09060877

<sup>5</sup> Richards, MA. et al, “Influence of delay on survival in patients with breast cancer: a systematic review,” *The Lancet*, 1999, [https://doi.org/10.1016/S0140-6736\(99\)02143-1](https://doi.org/10.1016/S0140-6736(99)02143-1)

<sup>6</sup> Constant, B. et al, “Delays Related to Prior Authorization in Inflammatory Bowel Disease.” *Pediatrics*, March 2022, <https://doi.org/10.1542/peds.2021-052501>

- Step therapy prior authorization for antipsychotics in Georgia was associated with an increase in medical benefit spending that outweighed the prescription drug savings for individuals with schizophrenia.<sup>7</sup>
- A model of step therapy applied to antidepressants found that the protocol increased total costs by \$0.06 per member per month.<sup>8</sup>
- A retrospective analysis of prescriptions filled for cardiovascular patients found that preferred drug lists (enforced by step therapy) resulted in estimated Medicaid reimbursement costs increasing.<sup>9</sup>

The pharmacy benefit managers (PBMs) that design prescription drug formularies are not exposed to the medical consequences of refusing treatment for a beneficiary. This is why the Senate Health, Education, Labor and Pensions Committee voted nearly unanimously to include the Safe Step Act in S. 1339, the PBM Reform Act.

Despite the harm and cost, patients and their providers are unable to successfully seek timely exceptions to medically inappropriate step therapy protocols in employer-sponsored plans. The timeframes in which employers must respond to a pre-service claim range from 72 hours to 15 days. Employers can wait to respond to an appeal for 30 days. These timeframes are too long to prevent permanent disease progression for many people with chronic illnesses whose health can deteriorate within a few days absent treatment. Furthermore, electronic health records and the internet make it possible for plans to respond faster. In Medicare as well as in most states, plans must respond to step therapy exception requests within 24-72 hours. The Safe Step Act would apply this 24-72 hour timeframe to step therapy exceptions in employer-sponsored plans.

In addition, self-insured employer plans that contract with health insurers for administrative-services-only pose even greater hurdles for patients and providers to seek an exception to a medically inappropriate step therapy protocol. Patients and providers hit a dead end when they contact the insurer, and they are not redirected to the beneficiary's human resources (HR) department. Because of this, some providers call these plans 'no appeals plans.' If a beneficiary eventually realizes they must contact their HR, they speak with colleagues that have no medical background and often initially refuse further action. Each barrier erected in the process exponentially increases the chances that a patient may give up seeking appropriate care. The

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<sup>7</sup> Farley, J., et al. "Retrospective assessment of Medicaid step-therapy prior authorization policy for atypical antipsychotic medications." *Clinical therapeutics* vol. 30,8 (2008) doi:10.1016/j.clinthera.2008.08.009

<sup>8</sup> Panzer, P., et al. "Implications of an SSRI Generic Step Therapy Pharmacy Benefit Design: An Economic Model in Anxiety Disorders." *AJMC*, October 2005

<sup>9</sup> Murawski, M., et al. "Exploration of the Impact of Preferred Drug Lists on Hospital and Physician Visits and the Costs to Medicaid" *AJMC*, January 2005

Safe Step Act would ensure that employers offer a clear and accessible process for seeking a step therapy exception.

Step therapy reduces employee engagement which reduces taxable employer revenues. While we appreciate the Committee's recognition that employers may hesitate to cover needed care because they are uncertain that they will see the benefits, we pose that helping employees and their families stay healthy has immediate benefits for the employer. Gallup's Q<sup>12</sup> Employee Engagement Assessment found that companies with higher employee engagement experienced 23% higher profitability than those with lower employee engagement.<sup>10</sup> The American Medical Association's 2022 Prior Authorization Physician Survey found that 56% of physician respondents observed that prior authorization including step therapy impacted patient job performance.<sup>11</sup> The Safe Step Act's streamlined exceptions process will deter adverse health outcomes and ensure quick resolutions, enabling employees to remain productive.

We urge the Committee to mark up and pass H.R. 2630, the Safe Step Act. By creating a reasonable and timely step therapy exceptions process accessible to patients and their providers, the Safe Step Act enables employers to avoid wasting money on treatments that won't work, and on the increased spending associated with preventable surgeries and hospitalizations. The bill would also improve patient outcomes, which affect employee engagement and ultimately profits.

Thank you for your consideration of our views. For additional information, please contact Sarah Buchanan, National Psoriasis Foundation, at [sbuchanan@psoriasis.org](mailto:sbuchanan@psoriasis.org).

Sincerely,

ADAP Advocacy  
AiArthritis  
Allergy & Asthma Network  
Alliance for Aging Research  
Alliance for Headache Disorders Advocacy  
Alliance for Patient Access  
Alpha-1 Foundation  
American Academy of Neurology  
American Cancer Society Cancer Action Network

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<sup>10</sup> "The Benefits of Employee Engagement" *Gallup*, updated January 2023.

<https://www.gallup.com/workplace/236927/employee-engagement-drives-growth.aspx>

<sup>11</sup> <https://www.ama-assn.org/system/files/prior-authorization-survey.pdf>

American College of Gastroenterology  
American College of Osteopathic Internists  
American College of Rheumatology  
American Gastroenterological Association  
American Headache Society  
American Partnership for Eosinophilic Disorders  
American Society for Gastrointestinal Endoscopy  
American Society for Parenteral and Enteral Nutrition  
Arizona Prostate Cancer Coalition, Inc.  
Arthritis Foundation  
Association of Women in Rheumatology (AWIR)  
Asthma and Allergy Foundation of America  
Autoimmune Association  
Beyond Celiac  
Biomarker Collaborative  
Bleeding Disorders Foundation of North Carolina  
Cancer Support Community  
Caregiver Action Network  
Chronic Care Coalition  
Chronic Disease Coalition  
Chronic Migraine Awareness  
Coalition for Headache and Migraine Patients  
Coalition of Hematology and Oncology Practices  
Coalition of Wisconsin Aging and Health Groups  
Community Oncology Alliance (COA)  
Crohn's & Colitis Foundation  
CURED Nfp (Campaign Urging Research for Eosinophilic Disease)  
Depression and Bipolar Support Alliance (DBSA)  
Derma Care Access Network  
Epilepsy Alliance America  
Epilepsy Foundation  
EveryLife Foundation for Rare Diseases  
Exon 20 Group  
Fabry Support & Information Group  
Facial Pain Association  
Fair Health NC  
Families for Depression Awareness  
Foundation for Sarcoidosis Research (FSR)

Gaucher Community Alliance  
Global Healthy Living Foundation  
Headache Cooperative of the Pacific  
HealthyWomen  
Hemophilia Federation of America  
HIV+Hepatitis Policy Institute  
ICAN, International Cancer Advocacy Network  
Infusion Access Foundation  
Infusion Providers Alliance (IPA)  
International Myeloma Foundation  
International Pain Foundation  
Large Urology Group Practice Association (LUGPA)  
LUNgevity Foundation  
Lupus and Allied Diseases Association, Inc.  
Mental Health America  
MET Crusaders  
Miles for Migraine  
Multiple Sclerosis Foundation  
National Alliance on Mental Illness  
National Arthritis Foundation  
National Ataxia Foundation  
National Bleeding Disorders Foundation  
National Eczema Association  
National Health Council  
National Infusion Center Association (NICA)  
National Kidney Foundation  
National Multiple Sclerosis Society  
National Organization for Rare Disorders  
National Organization of Rheumatology Management  
Nevada Chronic Care Collaborative  
North American Society for Pediatric Gastroenterology, Hepatology and Nutrition  
North Carolina Academy of Physician Assistants  
Oklahoma Chapter - American College of Physicians  
Oklahoma Society of Clinical Oncology, Inc.  
PD-L1 Amplifieds  
Pennsylvania Society of Oncology and Hematology  
PlusInc  
Pontchartrain Cancer Center

Pulmonary Hypertension Association  
Rheumatology Nurses Society  
Sarasota Arthritis Centers  
South Carolina Advocates For Epilepsy  
Spinal CSF Leak Foundation  
Spondylitis Association of America  
Susan G. Komen  
The California Chronic Care Coalition  
The Headache and Migraine Policy Forum  
The Michael J. Fox Foundation for Parkinson's Research  
The Tourette Association of America  
Theranica  
Tristate Arthritis & Rheumatology  
TSC Alliance  
U.S. Pain Foundation  
United Ostomy Associations of America, Inc.