

October 15, 2024

The Honorable Chuck Schumer  
Majority Leader  
United States Senate  
322 Hart Senate Office Building  
Washington, DC 20510

The Honorable Mike Johnson  
Speaker  
U.S. House of Representatives  
568 Cannon House Office Building  
Washington, DC 20515

The Honorable Mitch McConnell  
Minority Leader  
United States Senate  
317 Russell Senate Office Building  
Washington, DC 20510

The Honorable Hakeem Jeffries  
Minority Leader  
U.S. House of Representatives  
2433 Rayburn House Office Building  
Washington, DC 20515

Dear Majority Leader Schumer, Speaker Johnson, Minority Leader McConnell, and Minority Leader Jeffries:

Thank you for your leadership to craft pharmacy benefit manager (PBM) reform legislation this Congress. On behalf of the below patient and provider organizations, **we write to urge you to include the Safe Step Act as marked up in S. 1339, the PBM Reform Act, in any final PBM or end-of-year package.** The Safe Step Act is a key patient-driven provision of PBM reform that would directly improve patient access to needed care.

The Safe Step Act ensures that employer health plans, including their contracted PBMs, offer an expedient and medically reasonable step therapy exceptions process. Step therapy is a utilization management protocol in which a plan or PBM requires patients to try insurer-preferred medications and demonstrate that they do not work before the payer will cover the treatment initially selected by the patient and their provider. When medically inappropriate, step therapy delays access to needed care and can lead to severe or irreversible health outcomes for patients.

The Safe Step Act is endorsed by over 215 patient and provider organizations<sup>1</sup> and is modeled after legislation that has passed in 38 states.<sup>2</sup> However, self-insured employer health plans are exempt from state law. Most Americans get their insurance through their employer, and it is important to establish a meaningful step therapy exception process for this segment. Payer-mandated step therapy protocols are included in employer plans and multiple studies have shown that they often conflict with clinical guidelines,<sup>3</sup> delay access to needed care,<sup>4</sup> and even increase overall healthcare spending.<sup>5</sup>

Thank you for your consideration to include the Safe Step Act in an end-of-year or final PBM reform package. We applaud your desire to improve the prescription drug market and we urge you to ensure

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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/>

<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> Zimmerman, R. "Need A New Drug? You May Be Asked To 'Fail' An Old Drug First" *Washington Post*, 2023 <https://www.washingtonpost.com/wellness/2023/02/06/prior-authorization-fail-first-step-therapy/>

<sup>5</sup> Howell, S. et al, "Quantifying The Economic Burden Of Drug Utilization Management On Payers, Manufacturers, Physicians, And Patients" *Health Affairs*, 2021 <https://doi.org/10.1377/hlthaff.2021.00036>

that your efforts directly support patient access to care by passing the Safe Step Act this year. For further discussion or additional information, please contact Charles Husser with the Arthritis Foundation at [chusser@arthritis.org](mailto:chusser@arthritis.org).

Sincerely,

Accessia Health  
ADAP Advocacy  
AiArthritis  
Aimed Alliance  
Alabama Society for the Rheumatic Diseases  
Alaska Rheumatology Alliance  
Allergy & Asthma Network  
Alliance for Aging Research  
Alliance for Gout Awareness  
Alliance for Headache Disorders Advocacy  
Alliance for Patient Access  
Alliance for Transparent and Affordable Prescriptions (ATAP)  
Alliance of Specialty Medicine  
Alpha-1 Foundation  
ALS Association  
American Academy of Allergy, Asthma & Immunology  
American Academy of Ophthalmology  
American Cancer Society Cancer Action Network  
American College of Gastroenterology  
American College of Mohs Surgery  
American College of Osteopathic Internists  
American College of Physicians  
American College of Physicians - Oklahoma Chapter  
American College of Rheumatology  
American Foundation for Women's Health/StopAfib.org  
American Gastroenterological Association  
American Headache Society  
American Liver Foundation  
American Lung Association  
American Medical Women's Association  
American Partnership for Eosinophilic Disorders  
American Podiatric Medical Association  
American Society for Gastrointestinal Endoscopy  
American Society for Parenteral and Enteral Nutrition (ASPEN)  
American Society of Plastic Surgeons  
American Urological Association  
Arizona Prostate Cancer Coalition, Inc.  
Arizona United Rheumatology Alliance  
Arthritis Foundation  
Association of Black Cardiologists  
Association of Women in Rheumatology  
Asthma and Allergy Foundation of America

Autoimmune Association  
Beyond Celiac  
Biomarker Collaborative  
Bleeding Disorders Foundation of North Carolina  
BLKHLTH  
Bone Health and Osteoporosis Foundation  
Cancer Support Community  
Caregiver Action Network  
Caring Ambassadors Program  
Carolinas Society of Endocrinologists  
Celiac Disease Foundation  
Chicago Rheumatism Society  
Child Neurology Foundation  
Chronic Disease Coalition  
Chronic Migraine Awareness, Inc.  
Coalition of Hematology and Oncology Practices  
Coalition of Skin Diseases  
Coalition of State Rheumatology Organizations  
Coalition of Wisconsin Aging and Health Groups  
Color of Gastrointestinal Illnesses (COGI)  
Colorectal Cancer Alliance  
Community Liver Alliance  
Crohn's & Colitis Foundation  
Cure SMA  
CURED Nfp (Campaign Urging Research for Eosinophilic Disease)  
Cushing's Support & Research Foundation  
Debbie's Dream Foundation: Curing Stomach Cancer  
Depression and Bipolar Support Alliance (DBSA)  
Derma Care Access Network  
Digestive Disease National Coalition  
Digestive Health Physicians Association  
Dup15q Alliance  
Eosinophilic & Rare Disease Cooperative  
Epilepsy Advocacy Network  
Epilepsy Alliance America  
Epilepsy Alliance Louisiana  
Epilepsy Foundation of America  
Epilepsy Information Service of Wake Forest School of Medicine  
Epilepsy Services Foundation, Inc.  
EveryLife Foundation for Rare Diseases  
Exon 20 Group  
Fabry Support & Information Group  
Facial Pain Association  
Fair Health North Carolina  
Florida Society of Rheumatology (FSR)  
Foundation for Sarcoidosis Research  
Gaucher Community Alliance  
GBS|CIDP Foundation International

Georgia Prostate Cancer Coalition, Inc.  
Georgia Society of Rheumatology  
Global Healthy Living Foundation  
Good Days  
Gout Support Group of America  
Headache and Migraine Policy Forum  
HEAL Board of Directors  
HealthyWomen  
Heart Rhythm Society  
Hemophilia Council of California  
Hemophilia Federation of America  
Hereditary Angioedema Association  
HIV+Hepatitis Policy Institute  
Hope Charities  
IBDMoms  
ICAN, International Cancer Advocacy Network  
Infusion Access Foundation  
Infusion Providers Alliance  
International Foundation for Autoimmune & Autoinflammatory Arthritis  
International Foundation for Gastrointestinal Disorders  
International Myeloma Foundation  
International Pain Foundation  
International Pemphigus & Pemphigoid Foundation  
IWWMF  
JoshProvides Epilepsy Assistance Foundation, Inc.  
Kentuckiana Rheumatology Alliance  
Large Urology Group Practice Association (LUGPA)  
Lennox-Gastaut Syndrome (LGS) Foundation  
Little Hercules Foundation  
Liver Coalition of San Diego  
Louisiana Hemophilia Foundation  
Louisiana Oncology Society  
Louisianan Hemophilia Foundation  
LUNGeivity Foundation  
Lupus and Allied Diseases Association, Inc.  
Lupus Foundation of America  
MANA, A National Latina Organization  
Maryland Society for the Rheumatic Diseases  
Massachusetts, Maine and New Hampshire Rheumatology Association  
Medical Society of Virginia  
Melanoma Research Foundation  
MET Crusaders  
Metro Maryland Ostomy Association  
Michigan Rheumatism Society  
Midwest Rheumatology Association  
Miles for Migraine  
Mississippi Arthritis and Rheumatism Society  
Movement Disorder Policy Coalition

Multiple Sclerosis Association of America  
Multiple Sclerosis Foundation  
Myasthenia Gravis Foundation of America (MGFA)  
National Alliance of State Prostate Cancer Coalitions  
National Association For Continence  
National Ataxia Foundation  
National Bleeding Disorders Foundation  
National Coalition for Infant Health  
National Eczema Association  
National Grange  
National Headache Foundation  
National Headache Foundation  
National Health Council  
National Infusion Center Association (NICA)  
National Kidney Foundation  
National Menopause Foundation  
National Organization for Rare Disorders  
National Organization of Rheumatology Management  
National Pancreas Foundation  
National Psoriasis Foundation  
Nebraska Oncology Society  
Nebraska Pharmacists Association  
Nebraska Rheumatology Society  
Nevada Chronic Care Collaborative  
New York State Rheumatology Society  
North American Society for Pediatric Gastroenterology, Hepatology and Nutrition  
North Carolina Chapter, American College of Physicians  
North Carolina Dermatology Association  
North Carolina Medical Society  
North Carolina Rheumatology Association  
North Carolina Society of Eye Physicians and Surgeons  
Nutritional Therapy for IBD  
Oklahoma Society of Clinical Oncology, Inc.  
Oley Foundation  
Oncology Nursing Society  
Pacific Northwest Bleeding Disorders  
PAN Foundation  
Partnership to Advance Cardiovascular Health  
Patients Rising  
PD-L1 Amplifieds  
Pennsylvania Society of Oncology & Hematology  
PlusInc  
Prevent Blindness  
Project Alive  
Pulmonary Hypertension Association  
Rheumatology Alliance of Louisiana  
Rheumatology Nurses Society  
Rheumatology Society of New Mexico

Richmond Academy of Medicine  
Society of Dermatology Physician Associates (SDPA)  
South Asian IBD Alliance (SAIA)  
South Carolina Advocates For Epilepsy  
Southern California Rheumatology Society  
Southern Headache Society  
Spondylitis Association of America  
State of Oklahoma Association of Rheumatology  
State of Texas Association of Rheumatologists (STAR)  
State of West Virginia Rheumatology Society  
Susan G. Komen  
TED Community Organization  
Tennessee Rheumatology Society  
Texas Society of Clinical Oncology  
The Headache Cooperative of the Pacific  
The Hepatitis C Mentor and Support Group-HCMMSG  
The Mended Hearts, Inc.  
The Michael J. Fox Foundation for Parkinson's Research  
The Rheumatism Society of the District of Columbia  
The Sturge-Weber Foundation  
The Sumaira Foundation  
Tourette Association of America  
Transplant Recipients International Organization (TRIO)  
TSC Alliance  
U.S. Pain Foundation  
United Ostomy Associations of America, Inc.  
Valley Children's Healthcare  
Vermont Medical Society  
Virginia Society of Rheumatology  
Vision Health Advocacy Coalition  
VWD Connect Foundation  
Washington Rheumatology Alliance  
West Virginia Oncology Society  
West Virginia Parkinson's Support Network  
West Virginia State Medical Society  
Wisconsin Rheumatology Association  
ZERO Prostate Cancer