

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 organizations¹ and is modeled after legislation that has passed in 38 states.² 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,³ delay access to needed care,⁴ and even increase overall healthcare spending.⁵

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

¹ www.steptherapy.com/safe-step-act-flyer

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

³ 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>

⁴ 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/>

⁵ 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.

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
IWMF
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
LUNgevity 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-HCMSG
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