H.R. 5509/ S. 2903, SAFE STEP ACT

Representative Allen (R-GA-12), Representative McBath (D-GA-6), Representative Miller-Meeks (R-IA-2), Representative Ruiz (D-CA-36), Representative Onder (R-MO-3), Senator Murkowski (R-AK), Senator Hassan (D-NH), Senator Marshall (R-KS), Senator Rosen (D-NV)

Purpose: Improve step therapy protocols and ensure patients are able to safely and efficiently access the best treatment for them.

Background: Step therapy is a tool used by health plans to control spending on patient's medications. While step therapy can be an important tool to contain the costs of prescription drugs, in some circumstances, it has negative impacts on patients, including delayed access to the most effective treatment, severe side effects, and irreversible disease progression. Currently, when a physician prescribes a particular drug treatment for a patient, the patient's insurance company may require them to try different medications and treatments before they can access the drug originally prescribed by their physician. This protocol is known as "step therapy" or "fail first." Step therapy protocols may ignore a patient's unique circumstances and medical history. That means patients may have to use medications that previously failed to address their medical issue, or – due to their unique medical conditions – could have dangerous side effects.

The Safe Step Act: The Safe Step Act amends the Employee Retirement Income Security Act (ERISA) to require a group health plan provide an exception process for any medication step therapy protocol. The bill:

- **Establishes a clear exemption process:** The Safe Step Act requires insurers implement a clear and transparent process for a patient or physician to request an exception to a step therapy protocol.
- **Outlines 5 exceptions to fail first protocols.** Requires that a group health plan grant an exemption if an application clearly demonstrates any of the following situations:
    1. Patient already tried and failed on the required drug. A patient has already tried the medicine and failed before.
    2. Delayed treatment will cause irreversible consequences. The drug is reasonably expected to be ineffective, and a delay of effective treatment would leave to severe or irreversible consequences.
    3. Required drug will cause harm to the patient. The treatment is contraindicated or has caused/is likely to cause an adverse reaction.
    4. Required drug will prevent a patient from working or fulfilling Activities of Daily Living The treatment has or will prevent a participant from fulfilling their occupational responsibilities at work or performing Activities of Daily Living. Activities of daily living (ADLs) mean basic personal everyday activities such as eating, toileting, grooming, dressing, bathing, and transferring (42 CFR § 441.505).
    5. Patient is stable on their current medication. The patient is already stable on the prescription drug selected by his or her provider, and that drug has been covered by their previous or current insurance plan.
- **Requires a group health plan respond to an exemption request within 72 hours in all circumstances, and 24 hours if the patient's life is at risk.**

Safe Step Act
Exception Examples

1. Patient already tried and failed on the required drug. Michael was eight years old when his parents noticed his foot turning in when he walked, prompting a series of doctor's appointments. Following numerous misdiagnoses, Michael was finally diagnosed with Psoriatic Arthritis at the age of 12. The search to find an effective treatment for Michael's disease proved to be a long, frustrating process. In Michael's case, the first two drugs failed, and the "fail first" process he endured took nearly ten months during which he received no treatment. The first drug he tried did nothing to abate his pain; the second caused him to develop lupus-like symptoms, resulting in more appointments and tests. The insurance company then wanted Michael to *try another remedy that was the same type he had already failed twice before covering his physician's recommended medication*. Finally, Michael's doctor was able get coverage approved for the medication he had initially prescribed. Despite the eventual success, this period of over a year without treatment caused Michael's disease to progress rapidly, resulting in Michael developing an additional chronic illness.

2. Delayed treatment will cause severe or irreversible consequences. Jake, from Alaska, was diagnosed with Crohn's disease as a young child. A year later, he experienced a severe flare and the doctors insisted he immediately be put on an anti-TNF biologic. Jake was a primary non-responder to the anti-TNF, which meant that he would not respond to any anti-TNF. His doctors then tried to put him on an alternative biologic, however, his insurance company required him to prove failure on an additional anti-TNF biologic even though it was against the clinical evidence and guidelines. This process delayed Jake's access to appropriate treatment for several weeks. By the time Jake was granted coverage for the new biologic, his disease had progressed so much that the treatment was not as effective as it would have been if prescribed earlier. As a result, Jake lost his colon. Jake turned 13 this year.

3. Required drug will cause harm to the patient. Jenn, from California, was diagnosed with psoriasis and psoriatic arthritis, her doctor prescribed a treatment that would ease her arthritis pain and slow down joint degeneration. Unfortunately, Jenn's doctor-prescribed treatment was denied by the insurance company and required her to take an alternate medication, which would have led to life-threatening side-effects on the patient's liver. After three months of back-and-forth between the provider, patient, and the insurance company, and explaining that the insurance preferred medication would result in a "death sentence" – Jenn was asked to try a third medication which exacerbated her condition. Finally after nearly a year, Jenn was approved for her original doctor-prescribed treatment and began seeing improvements within three weeks.

4. Required drug will prevent a patient from working. Elliot, nicknamed Duffy, from Alaska, is an epilepsy patient and works as a ski instructor and heavy machine operator. The first medication he tried controlled his seizures, however the side-effects made him feel like he was inebriated and dizzy, making it unsafe and even dangerous to perform the tasks necessary for his jobs. Despite his inability to work on the treatment, his insurer would not cover alternative treatments, and he was faced with the option of losing his job or paying out right for a different treatment, which would cost him $700 a month. Duffy opted to pay for the new treatment with no coverage. The new medication controlled his seizures with less side effects so that he could perform his occupational duties.

5. Patient is stable on their current medication. Katie, a psoriatic arthritis patient, has been stable on her treatment for years. Her treatment was covered by her employer's private insurance until, in the middle of the plan year, her insurer sent her a letter stating that her current treatment would no longer be covered until she went through step therapy protocols. Within four weeks, Katie, who had been an active adult, was back in a wheelchair. Her step therapy journey lasted for ten months, leading to 14 surgeries, countless doctors' visits, missed time from work, and ultimately health care costs that far exceeded the price of her treatment.

Safe Step Act
Endorsing Organizations

As of September 26, 2025 -- this bill has been endorsed by 224 organizations:

ADAP Advocacy Association
AIM at Melanoma
Aimed Alliance
Alamo Breast Cancer Foundation
Allergy & Asthma Network
Alliance for Balanced Pain Management
Alliance for Headache Disorders Advocacy
Alliance for Patient Access
Alpha-1 Foundation
American Academy of Allergy, Asthma & Immunology
American Academy of Dermatology Association
American Academy of Neurology
American Association of Clinical Urologists
American Cancer Society Cancer Action Network
American College of Gastroenterology
American College of Osteopathic Internists
American College of Rheumatology
American Diabetes Association
American Gastroenterological Association
American Heart Association
American Liver Foundation
American Muslim Senior Society
American Society for Parenteral and Enteral Nutrition (ASPEN)
American Partnership for Eosinophilic Disorders
American Psychiatric Association
American Society for Gastrointestinal Endoscopy
American Society of Hematology
American Society for Parenteral and Enteral Nutrition (ASPEN)
American Urological Association
Arizona Peer and Family Coalition
Arizona Prostate Cancer Coalition, Inc.
Arizona Psychiatric Society
Arizona United Rheumatology Alliance
Arkansas State Rheumatology Association
Arthritis Foundation
Association for Clinical Oncology
Association of Black Cardiologists
Association of Community Cancer Centers (ACCC)
Association of Diabetes Care & Education Specialists
Association of Gastrointestinal Motility Disorders (AGMD)
Association of Women in Rheumatology
Asthma and Allergy Foundation of America
Autoimmune Association
Beyond Celiac
Brain Injury Alliance of Nebraska
Cancer Advocacy Group of Louisiana
Cancer Support Community
Caregiver Action Network
Celiac Disease Foundation
Child Neurology Foundation
Chronic Disease Coalition
Clinical Association of California Endocrinologists
Coalition of Hematology Oncology Practices
Coalition of Skin Diseases
Coalition of State Rheumatology Organizations
Coalition of Wisconsin Aging and Health Groups
Color of Crohn's & Chronic Illness
Community Access National Network (CANN)
Community Liver Alliance
Connecting to Cure Crohn's and Colitis
Crazy Creole Mommy Life
Crohn's & Colitis Foundation
CURE Epilepsy
Cure SMA
CURED Nfp
Danny Did Foundation
Depression and Bipolar Support Alliance
Derma Care Access Network
Dia de la Mujer Latina, Inc.
Digestive Disease National Coalition
Dup15q Alliance
Dystonia Advocacy Network
Dystonia Medical Research Foundation
Epilepsy Alliance America
Epilepsy Foundation of America
Epilepsy Services of New Jersey
EveryLife Foundation for Rare Diseases
Fabry Support & Information Group
Foundation for Sarcoidosis Research
Gastroparesis: Fighting for Change
GBS|CIDP Foundation International
Georgia Academy of Family Physicians
Georgia AIDS Coalition
Geriatric Medicine PAs
Gilda's Club South Florida
Global Healthy Living Foundation
Global Liver Institute
GO2 Foundation for Lung Cancer
Gut It Out Foundation
Hawai'i Parkinson Association
Headache and Migraine Policy Forum
HealthyWomen
Heartland Endocrine Roundtable
Hemophilia Federation of America
HIV + Hepatitis Policy Institute
Hope Charities
IBDMoms
ICAN, International Cancer Advocacy Network
Illinois Association for Behavioral Health
Illinois Medical Oncology Society
Indiana Oncology Society
Infusion Access Foundation (IAF)
Infusion Providers Alliance
International Essential Tremor Foundation
International Foundation for Autoimmune &

Safe Step Act
Endorsing Organizations

Autoinflammatory Arthritis
International Foundation for Gastrointestinal Disorders (IFFGD)
International Myeloma Foundation
International Pain Foundation
International Topical Steroid Awareness Network
Iowa Oncology Society
Kentuckiana Rheumatology Alliance
Large Urology Group Practice Association (LUGPA)
Louisiana Dermatological Society
Louisiana Hemophilia Foundation
Louisiana Psychiatric Medical Association
Louisiana Urological Society
LUNGevity Foundation
Lupus and Allied Diseases Association, Inc.
Lupus Foundation of America
Mental Health America
METAvivor
Methodist Healthcare Ministries of South Texas, Inc.
Metro Maryland Ostomy Association
Mid-Atlantic Society of Endocrinology
Mississippi Arthritis and Rheumatism Society
Montana State Oncology Society
Movement Disorders Policy Coalition
Multiple Sclerosis Association of America
Multiple Sclerosis Foundation
NAMI Minnesota (National Alliance on Mental Illness)
NAMI Nevada
National Alliance of State Prostate Cancer Coalitions
National Alliance on Mental Illness
National Alopecia Areata Foundation
National Ataxia Foundation
National Celiac Association
National Council for Mental Wellbeing
National Eczema Association
National Headache Foundation
National Hemophilia Foundation
National Infusion Center Association (NICA)
National Multiple Sclerosis Society
National Organization for Rare Disorders
National Organization for Tardive Dyskinesia
National Organization of Rheumatology Management
National Pancreas Foundation
National Patient Advocate Foundation
National Psoriasis Foundation
Nebraska Academy of Eye Physicians and Surgeons
Nebraska Chapter - National Hemophilia Foundation
Nebraska Chapter of the American College of Cardiology
Nebraska Dermatology Society
Nebraska Neurological Society
Nebraska Nurse Practitioners
Nebraska Oncology Society
Nebraska Osteopathic Medical Society
Nebraska Pharmacists Association
Nebraska Rheumatology Society
Nevada Chronic Care Collaborative
Nevada Oncology Society
North American Society for Pediatric Gastroenterology, Hepatology and Nutrition
Ohio Association of Rheumatology
Oklahoma Chapter - American College of Physicians
Oklahoma Pharmacists Association
Oklahoma Society of Clinical Oncology
Pacific Northwest Bleeding Disorders
PACO Foundation
Parkinson's Foundation
Partnership to Advance Cardiovascular Health
PAN Foundation
Patient Services, Inc.
Patients Rising Now
Pennsylvania Society of Gastroenterology
Pennsylvania Society of Oncology & Hematology
Phaware Global Association
Pontchartrain Cancer Center
Prevent Blindness
Project Sleep
Prostate Conditions Education Council
Pulmonary Hypertension Association
Rheumatology Alliance of Louisiana
Rheumatology Association of Iowa
Rheumatology Association of Minnesota and the Dakotas
Rheumatology Nurses Society
Rheumatology Society of New Mexico
Scleroderma Foundation
Sick Cells
Society for the Study of Male Reproduction
Society for Women's Health Research
Society of Dermatology Physician Assistants
Society of Gastroenterology Nurses and Associates, Inc.
South Carolina Advocates For Epilepsy
Spondylitis Association of America
State of Texas Association of Rheumatologists
Susan G. Komen
Tennessee Rheumatology Society
Texas Endocrinology Association
The American Liver Foundation
The American Society for Parenteral and Enteral Nutrition
The American Society for Transplantation and Cellular Therapy
The Arc of Nebraska
The Arizona Clinical Oncology Society (TACOS)
The Leukemia & Lymphoma Society
The Life Raft Group
The Mended Hearts, Inc
The Michael J. Fox Foundation for Parkinson's Research
The Sturge-Weber Foundation
Tourette Association of America
Transplant Recipients International Organization (TRIO)

Safe Step Act
Endorsing Organizations

Transplant Support Organization (TSO)
TSC Alliance
U.S. Hereditary Angioedema Association
U.S. Pain Foundation
United for Charitable Assistance
United Ostomy Associations of America
Us TOO International
VHL Alliance
Virginia Association of Hematology & Oncology
Vivent Health
Western Endocrine Association
Wisconsin Association of Hematology & Oncology
Wound Ostomy Continence Nursing Certification Board
Wyoming State Oncology Society
ZERO - The End of Prostate Cancer