

# S. 464/H.R. 2163, SAFE STEP ACT OF 2021

*Senator Murkowski (R-AK), Senator Hassan (D-NH), Senator Cassidy (R-LA), Senator Rosen (D-NV)  
Representative Ruiz (D-CA-36), Representative Wenstrup (R-OH-2), Representative McBath (D-GA-6),  
Representative Miller-Meeke (R-LA-2)*

**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 of 2021:** 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.**

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### 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 to 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 of pocket 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.

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## **Endorsing Organizations**

This bill has been endorsed by 196 organizations:

ADAP Advocacy Association	CURE Epilepsy
AIM at Melanoma	Cure SMA
Aimed Alliance	CURED Nfp
Alamo Breast Cancer Foundation	Danny Did Foundation
Allergy & Asthma Network	Depression and Bipolar Support Alliance
Alliance for Balanced Pain Management	Derma Care Access Network
Alliance for Patient Access	Dia de la Mujer Latina, Inc.
American Academy of Dermatology Association	Digestive Disease National Coalition
American Academy of Neurology	Dup15q Alliance
American Association of Clinical Urologists	Dystonia Advocacy Network
American Autoimmune Related Diseases Association	Dystonia Medical Research Foundation
American Cancer Society Cancer Action Network	Epilepsy Alliance America
American College of Gastroenterology	Epilepsy Foundation
American College of Rheumatology	Epilepsy Services of New Jersey
American Diabetes Association	Fabry Support & Information Group
American Gastroenterological Association	Gastroparesis: Fighting for Change
American Heart Association	GBS CIDP Foundation International
American Liver Foundation	Georgia Academy of Family Physicians
American Partnership for Eosinophilic Disorders	Georgia AIDS Coalition
American Society for Gastrointestinal Endoscopy	Global Healthy Living Foundation
American Society of Hematology	Global Liver Institute
American Urological Association	GO2 Foundation for Lung Cancer
Arizona Peer and Family Coalition	Gut It Out Foundation
Arizona Prostate Cancer Coalition, Inc.	Hawai'i Parkinson Association
Arizona Psychiatric Society	HealthyWomen
Arizona United Rheumatology Alliance	Heartland Endocrine Roundtable
Arkansas State Rheumatology Association	Hemophilia Federation of America
Arthritis Foundation	HIV + Hepatitis Policy Institute
Association for Clinical Oncology	Hope Charities
Association of Black Cardiologists	IBDMoms
Association of Community Cancer Centers (ACCC)	ICAN, International Cancer Advocacy Network
Association of Diabetes Care & Education Specialists	Illinois Association for Behavioral Health
Association of Gastrointestinal Motility Disorders (AGMD)	Illinois Medical Oncology Society
Association of Women in Rheumatology	Indiana Oncology Society
Asthma and Allergy Foundation of America	Infusion Access Foundation (IAF)
Beyond Celiac	International Essential Tremor Foundation
Brain Injury Alliance of Nebraska	International Foundation for Gastrointestinal Disorders (IFFGD)
Cancer Advocacy Group of Louisiana	International Myeloma Foundation
Cancer Support Community	International Pain Foundation
Caregiver Action Network	Iowa Oncology Society
Celiac Disease Foundation	Kentuckiana Rheumatology Alliance
Child Neurology Foundation	Large Urology Group Practice Association (LUGPA)
Clinical Association of California Endocrinologists	Louisiana Dermatological Society
Coalition of Hematology Oncology Practices	Louisiana Hemophilia Foundation
Coalition of Skin Diseases	Louisiana Psychiatric Medical Association
Coalition of State Rheumatology Organizations	Louisiana Urological Society
Coalition of Wisconsin Aging and Health Groups	Lupus and Allied Diseases Association, Inc.
Color of Crohn's & Chronic Illness	Lupus Foundation of America
Community Access National Network (CANN)	Mental Health America
Community Liver Alliance	METAvivor
Connecting to Cure Crohn's and Colitis	Methodist Healthcare Ministries of South Texas, Inc.
Crazy Creole Mommy Life	Metro Maryland Ostomy Association
Crohn's & Colitis Foundation	Mid-Atlantic Society of Endocrinology

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## Endorsing Organizations

Mississippi Arthritis and Rheumatism Society	Phaware Global Association
Montana State Oncology Society	Pontchartrain Cancer Center
Movement Disorders Policy Coalition	Project Sleep
Multiple Sclerosis Association of America	Prostate Conditions Education Council
Multiple Sclerosis Foundation	Pulmonary Hypertension Association
NAMI Minnesota (National Alliance on Mental Illness)	Rheumatology Alliance of Louisiana
NAMI Nevada	Rheumatology Association of Minnesota and the Dakotas
National Alliance on Mental Illness	Rheumatology Association of Iowa
National Alopecia Areata Foundation	Rheumatology Nurses Society
National Ataxia Foundation	Rheumatology Society of New Mexico
National Celiac Association	Scleroderma Foundation
National Council for Behavioral Health	Society for the Study of Male Reproduction
National Eczema Association	Society of Dermatology Physician Assistants
National Hemophilia Foundation	Society of Gastroenterology Nurses and Associates, Inc.
National Infusion Center Association (NICA)	Spondylitis Association of America
National Multiple Sclerosis Society	State of Texas Association of Rheumatologists
National Organization for Rare Disorders	Susan G. Komen
National Organization for Tardive Dyskinesia	Tennessee Rheumatology Society
National Organization of Rheumatology Management	Texas Endocrinology Association
National Pancreas Foundation	The American Liver Foundation
National Patient Advocate Foundation	The American Society for Parenteral and Enteral Nutrition
National Psoriasis Foundation	The Arc of Nebraska
Nebraska Academy of Eye Physicians and Surgeons	The Arizona Clinical Oncology Society (TACOS)
Nebraska Chapter - National Hemophilia Foundation	The Leukemia & Lymphoma Society
Nebraska Chapter of the American College of Cardiology	The Life Raft Group
Nebraska Dermatology Society	The Mended Hearts, Inc
Nebraska Neurological Society	The Michael J. Fox Foundation for Parkinson's Research
Nebraska Nurse Practitioners	The Sturge-Weber Foundation
Nebraska Oncology Society	Tourette Association of America
Nebraska Osteopathic Medical Society	Tuberous Sclerosis Alliance
Nebraska Pharmacists Association	U.S. Hereditary Angioedema Association
Nebraska Rheumatology Society	U.S. Pain Foundation
Nevada Chronic Care Collaborative	United for Charitable Assistance
Nevada Oncology Society	United Ostomy Associations of America
North American Society for Pediatric Gastroenterology, Hepatology and Nutrition	Us TOO International
Ohio Association of Rheumatology	VHL Alliance
Oklahoma Chapter - American College of Physicians	Virginia Association of Hematology & Oncology
Oklahoma Pharmacists Association	Vivent Health
Oklahoma Society of Clinical Oncology	Western Endocrine Association
Pacific Northwest Bleeding Disorders	Wisconsin Association of Hematology & Oncology
PACO Foundation	Wound Ostomy Continence Nursing Certification Board
Parkinson's Foundation	Wyoming State Oncology Society
Partnership to Advance Cardiovascular Health	ZERO - The End of Prostate Cancer
Patient Services, Inc.	
Patients Rising Now	
Pennsylvania Society of Gastroenterology	
Pennsylvania Society of Oncology & Hematology	