

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

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Representative Ruiz (D-CA-36), Representative Wenstrup (R-OH-2), Representative McBath (D-GA-6),
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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 207 organizations:

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

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Endorsing Organizations

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