



**VIRTUAL  
IBD DAY  
ON THE HILL**



**Leave Behinds  
and Bill Texts  
2021**

# Quick Facts about IBD

## 1 IBD = Inflammatory Bowel Disease

- › Two major types
- › Crohn's disease (CD)
  - Inflammation anywhere in the gastrointestinal tract
- › Ulcerative colitis (UC)
  - Inflammation limited to colon and/or rectum
- › [www.crohnscolitisfoundation.org/ibdjourney](http://www.crohnscolitisfoundation.org/ibdjourney)

## 2 Statistics

- › An estimated 3.1 million Americans affected
- › 70,000 new IBD cases per year
- › Often diagnosed between ages 15–35

## 3 Disease Info

- › Common symptoms are diarrhea, weight loss, feeling tired, and abdominal cramps and pain
- › IBD can have an effect on areas outside of your digestive tract, such as eyes, skin, bones, and kidneys.
- › IBD can also have an impact on mental and emotional well-being. [www.crohnscolitisfoundation.org/mental-health](http://www.crohnscolitisfoundation.org/mental-health)

## 4 Use Our Tools and Resources

- › Download free brochures [online.crohnscolitisfoundation.org/brochures](http://online.crohnscolitisfoundation.org/brochures)

## 5 Treatment Options

- › Prescription medication (Rx)
- › Over-the-counter (OTC) medication
- › Surgery
- › Nutritional support therapy
- › Remember to take medication even when you don't feel like it or you feel okay.
- › [www.crohnscolitisfoundation.org/effective-partnering](http://www.crohnscolitisfoundation.org/effective-partnering)

## 6 Coping Options

- › Join a support group: [www.crohnscolitisfoundation.org/find-a-support-group](http://www.crohnscolitisfoundation.org/find-a-support-group)
- › Relax and de-stress with coping strategies, such as:
  - Yoga
  - Tai chi
  - Meditation
- › Find other ways to stay connected with the IBD community and support programs
- › Attend Camp Oasis: [www.crohnscolitisfoundation.org/get-involved/camp-oasis](http://www.crohnscolitisfoundation.org/get-involved/camp-oasis)

## 7 Things You Can Do

- › Regular exercise
  - At least 1 hour each day
- › Get enough sleep, 7–9 hours each night
- › Ask for school and workplace accommodations
- › Be informed and educated to stay healthy and make decisions with your doctor about managing your disease
- › Participate in research, and visit our Clinical Trials Community: [www.crohnscolitisfoundation.org/clinical-trials-community](http://www.crohnscolitisfoundation.org/clinical-trials-community)

## 8 Diet and Nutrition

- › Maintain a healthy diet: [www.MyPlate.gov](http://www.MyPlate.gov)
- › Keep a food journal
- › Stay hydrated
- › Get enough calcium
- › Consult with a dietician and your healthcare team to make sure you are getting all the nutrients your body needs.
- › [www.crohnscolitisfoundation.org/diet-and-nutrition](http://www.crohnscolitisfoundation.org/diet-and-nutrition)

### For More Information:

-  [www.crohnscolitisfoundation.org](http://www.crohnscolitisfoundation.org)
-  888.694.8872
-  [info@crohnscolitisfoundation.org](mailto:info@crohnscolitisfoundation.org)

# 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-Meeeks (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.**

## S. 464/H.R. 2163, Safe Step Act of 2021

### 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 exasperated 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.

# S. 464/H.R. 2163, Safe Step Act of 2021

## Endorsing Organizations

This bill has been endorsed by 85 organizations:

Aimed Alliance  
Allergy & Asthma Network  
Alliance for Patient Access  
American Academy of Dermatology Association  
American Academy of Neurology  
American Autoimmune Related Diseases Association  
American Cancer Society Cancer Action Network  
American College of Gastroenterology  
American College of Rheumatology  
American Gastroenterological Association  
American Heart Association  
American Liver Foundation  
American Partnership for Eosinophilic Disorders  
Arthritis Foundation  
Association for Clinical Oncology  
Association of Gastrointestinal Motility Disorders (AGMD)  
Asthma and Allergy Foundation of America  
Beyond Celiac  
Cancer Support Community  
Caregiver Action Network  
Celiac Disease Foundation  
Child Neurology Foundation  
Color of Crohn's & Chronic Illness  
Crazy Creole Mommy Life  
Crohn's & Colitis Foundation  
CURE Epilepsy  
CURED Nfp  
Danny Did Foundation  
Depression and Bipolar Support Alliance  
Digestive Disease National Coalition  
Dup15q Alliance  
Dystonia Advocacy Network  
Dystonia Medical Research Foundation  
Epilepsy Foundation  
Fabry Support & Information Group  
Gastroparesis: Fighting for Change  
GBS|CIDP Foundation International  
Global Healthy Living Foundation  
Global Liver Institute  
Hawai'i Parkinson Association  
Hemophilia Federation of America  
Hope Charities  
IBDMoms  
Infusion Access Foundation (IAF)  
International Essential Tremor Foundation  
International Foundation for Autoimmune & Autoinflammatory Arthritis (AiArthritis)  
International Foundation for Gastrointestinal Disorders (IFFGD)  
International Myeloma Foundation  
Lupus and Allied Diseases Association, Inc.  
Mental Health America  
METAvivor  
Metro Maryland Ostomy Association  
Movement Disorders Policy Coalition  
Multiple Sclerosis Association of America  
National Alliance on Mental Illness  
National Alopecia Areata Foundation  
National Ataxia Foundation  
National Eczema Association  
National Infusion Center Association (NICA)  
National Organization for Rare Disorders  
National Organization for Tardive Dyskinesia  
National Pancreas Foundation  
National Patient Advocate Foundation  
National Psoriasis Foundation  
Patient Services, Inc.  
Pennsylvania Society of Gastroenterology  
Project Sleep  
Pulmonary Hypertension Association  
Scleroderma Foundation  
Society of Gastroenterology Nurses and Associates, Inc.  
Spondylitis Association of America  
Susan G. Komen  
The American Liver Foundation  
The American Society for Parenteral and Enteral Nutrition  
The Life Raft Group  
The Michael J. Fox Foundation for Parkinson's Research  
The National Council for Behavioral Health  
The Sturge-Weber Foundation  
Tourette Association of America  
Tuberous Sclerosis Alliance  
U.S. Hereditary Angioedema Association  
U.S. Pain Foundation  
United for Charitable Assistance  
United Ostomy Associations of America  
VHL Alliance

# The Medical Nutrition Equity Act



## Co-Sponsor the Medical Nutrition Equity Act

The Crohn's & Colitis Foundation urges members of Congress to co-sponsor the Medical Nutrition Equity Act. This bill would ensure that public and private insurance covers medically necessary foods for inherited metabolic disorders and digestive diseases, including Crohn's disease and ulcerative colitis (inflammatory bowel disease or IBD).

### What are medically necessary foods?

The legislation defines medically necessary foods as:

- Recommended for use by a physician
- Specially formulated for partial or exclusive feeding of an individual
- Intended to meet medically determined nutrient requirements
- Intended for use under medical supervision

### How are medically necessary foods used to manage IBD?

Patients with IBD can turn to medically necessary foods to for nutritional support and to help them achieve remission.

#### For pediatric patients:

- The standard of care for inducing remission internationally in children with mild to moderate Crohn's disease is with orally or enterally administered formula.<sup>i</sup>
- Using enteral formula may reduce the frequency of use of higher cost medications.<sup>ii</sup>
- A diet consisting partially of formula may prolong remission without increasing the dosage of expensive therapies.
- Exclusive enteral nutrition (EEN) as a means to induce remission is safer, improves growth, and encourages healing in children over steroid therapy.<sup>iii, iv</sup>

### Parenteral and Enteral Nutrition

#### PARENTERAL NUTRITION

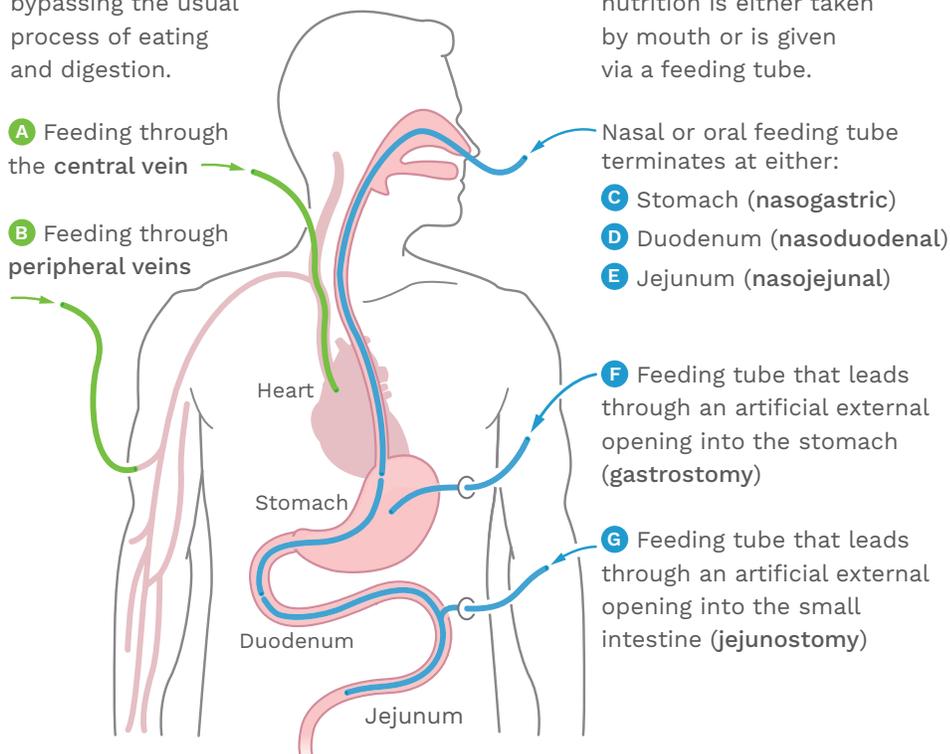
Feeding intravenously, bypassing the usual process of eating and digestion.

- A** Feeding through the central vein
- B** Feeding through peripheral veins

#### ENTERAL NUTRITION

Liquid supplemental nutrition is either taken by mouth or is given via a feeding tube.

- Nasal or oral feeding tube terminates at either:
  - C** Stomach (nasogastric)
  - D** Duodenum (nasoduodenal)
  - E** Jejunum (nasojejunal)



## What are the costs of medically necessary foods, and coverage landscape?

- Medically necessary foods can range from \$10–\$60 per day.
- Medically necessary foods are not typically covered by insurance unless they are delivered via a feeding tube—which is often unnecessary for IBD patients.
- Families that can't pay for medically necessary foods out of pocket may turn to more expensive medications that are covered by insurance but may have more side effects, such as steroids or biologics.

## Co-sponsor the Medical Nutrition Equity Act

This bill provides for coverage of medically necessary foods under Medicaid, CHIP, Medicare, FEHBP, and private insurance if prescribed by a patient's provider for patients with inherited metabolic disorders, as well as digestive diseases like Crohn's disease and ulcerative colitis.

<sup>i</sup> Ruemmele FM, Veres G, Kolho KL, Griffiths A, Levine A, Escher JC, et al. Consensus guidelines of ECCO/ESPGHAN on the medical management of pediatric Crohn's disease. *J Crohns Colitis*. 2014; 8(10):1179–207 doi:10.1016/j.crohns.2014.04.005.

<sup>ii</sup> Nguyen DL, Palmer LB, Nguyen ET, McClave SA, Martindale RG, Bechtold ML. Specialized enteral nutrition therapy in Crohn's disease patients on maintenance infliximab therapy: a meta-analysis. *Ther Adv Gastroenterol*. 2015;8(4):168-175. doi:10.1177/1756283X15578607.

<sup>iii</sup> Borrelli O, Cordischi L, Cirulli M, Paganelli M, Labalestra V, Uccini S, Russo PM, Cucchiara S Polymeric diet alone versus corticosteroids in the treatment of active pediatric Crohn's disease: A randomized controlled open-label trial. *Clin Gastroenterol Hepatol*. 2006;4:744–753.

<sup>iv</sup> Penagini F, Dilillo D, Borsani B, et al. Nutrition in pediatric inflammatory bowel disease: From etiology to treatment. A systematic review. *Nutrients*. 2016; 8(6):, 334. <http://doi.org/10.3390/nu8060334>

# Congressional Crohn's and Colitis Caucus



The Crohn's and Colitis Caucus is a bipartisan group of members of Congress dedicated to educating their colleagues and the American public on Crohn's disease and ulcerative colitis, collectively known as inflammatory bowel diseases (IBD). The Caucus works together to raise awareness, support IBD medical research, and protect patient access to care.

## Congressional Crohn's and Colitis Caucus Members

**Chairs: Representatives Carolyn Maloney (D-NY) and John Rutherford (R-FL)**

Donald Beyer (D-VA)	Zoe Lofgren (D-CA)
Sanford Bishop (D-GA)	Barry Loudermilk (R-GA)
Julia Brownley (D-CA)	Carolyn Maloney (D-NY)
Michael Burgess (R-TX)	Sean Patrick Maloney (D-NY)
Cheri Bustos (D-IL)	James McGovern (D-MA)
David Cicilline (D-RI)	Eleanor Holmes Norton (D-DC)
Emanuel Cleaver (D-MO)	Donald Payne (D-NJ)
Steve Cohen (D-TN)	Mark Pocan (D-WI)
Gerald Connolly (D-VA)	Bill Posey (R-FL)
Rodney Davis (R-IL)	David Price (D-NC)
Peter DeFazio (D-OR)	Jamie Raksin (D-MD)
Suzan Delbene (D-WA)	Lucille Roybal-Allard (D-CA)
Mario Diaz-Balart (R-FL)	C.A. "Dutch" Ruppertsberger (D-MD)
Mike Doyle (D-PA)	John Rutherford (R-FL)
Anna Eshoo (D-CA)	Tim Ryan (D-OH)
Ruben Gallego (D-AZ)	Janice Schakowsky (D-IL)
Garrett Graves (R-LA)	Adam Schiff (D-CA)
Alcee Hastings (D-FL)	Adam Smith (D-WA)
Hank Johnson (D-GA)	Lloyd Smucker (R-PA)
David Joyce (R-OH)	Jackie Speier (D-CA)
William Keating (D-MA)	Mike Thompson (D-CA)
Mike Kelly (R-PA)	Dana Titus (D-NY)
Derek Kilmer (D-WA)	Paul Tonko (D-NY)
Ann Kuster (D-NH)	Debbie Wasserman Schultz (D-FL)
Jim Langevin (D-RI)	Susan Wild (D-PA)
Andy Levin (D-MI)	Joe Wilson (R-SC)

To join the Caucus, or if you have any questions, please reach out to Lizzie Messer in Rep. Rutherford's office at [Lizzie.Messer@mail.house.gov](mailto:Lizzie.Messer@mail.house.gov) or Danielle Sumner in Rep. Maloney's office at [Danielle.Sumner@mail.house.gov](mailto:Danielle.Sumner@mail.house.gov)

117TH CONGRESS  
1ST SESSION

# S. 464

To amend the Employee Retirement Income Security Act of 1974 to require a group health plan or health insurance coverage offered in connection with such a plan to provide an exceptions process for any medication step therapy protocol, and for other purposes.

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## IN THE SENATE OF THE UNITED STATES

FEBRUARY 25, 2021

Ms. MURKOWSKI (for herself, Ms. HASSAN, Mr. CASSIDY, Ms. ROSEN, Mrs. HYDE-SMITH, Mrs. GILLIBRAND, Ms. SINEMA, Mrs. CAPITO, Ms. HIRONO, Mr. TILLIS, Mrs. SHAHEEN, Mr. CRAMER, Mr. MERKLEY, and Mr. BLUMENTHAL) introduced the following bill; which was read twice and referred to the Committee on Health, Education, Labor, and Pensions

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## A BILL

To amend the Employee Retirement Income Security Act of 1974 to require a group health plan or health insurance coverage offered in connection with such a plan to provide an exceptions process for any medication step therapy protocol, and for other purposes.

1 *Be it enacted by the Senate and House of Representa-*  
2 *tives of the United States of America in Congress assembled,*

3 **SECTION 1. SHORT TITLE.**

4 This Act may be cited as the “Safe Step Act”.

1 **SEC. 2. REQUIRED EXCEPTIONS PROCESS FOR MEDICA-**  
2 **TION STEP THERAPY PROTOCOLS.**

3 (a) IN GENERAL.—The Employee Retirement Income  
4 Security Act of 1974 is amended by inserting after section  
5 713 of such Act (29 U.S.C. 1185b) the following new sec-  
6 tion:

7 **“SEC. 713A. REQUIRED EXCEPTIONS PROCESS FOR MEDI-**  
8 **CATION STEP THERAPY PROTOCOLS.**

9 “(a) IN GENERAL.—In the case of a group health  
10 plan or health insurance coverage offered in connection  
11 with such a plan that provides coverage of a prescription  
12 drug pursuant to a medication step therapy protocol, the  
13 plan or coverage shall—

14 “(1) implement a clear and transparent process  
15 for a participant or beneficiary (or the prescribing  
16 health care provider on behalf of the participant or  
17 beneficiary) to request an exception to such medica-  
18 tion step therapy protocol, pursuant to subsection  
19 (b); and

20 “(2) where the participant or beneficiary or  
21 prescribing health care provider’s request for an ex-  
22 ception to the medication step therapy protocols sat-  
23 isfies the criteria and requirements of subsection (b),  
24 cover the requested drug in accordance with the  
25 terms established by the health plan or coverage for  
26 patient cost-sharing rates or amounts at the time of

1 the participant’s or beneficiary’s enrollment in the  
2 health plan or health insurance coverage.

3 “(b) CIRCUMSTANCES FOR EXCEPTION APPROVAL.—

4 The circumstances requiring an exception to a medication  
5 step therapy protocol, pursuant to a request under sub-  
6 section (a), are any of the following:

7 “(1) Any treatments otherwise required under  
8 the protocol, or treatments in the same pharma-  
9 cological class or having the same mechanism of ac-  
10 tion, have been ineffective in the treatment of the  
11 disease or condition of the participant or beneficiary,  
12 when prescribed consistent with clinical indications,  
13 clinical guidelines, or other peer-reviewed evidence.

14 “(2) Delay of effective treatment would lead to  
15 severe or irreversible consequences, and the treat-  
16 ment otherwise required under the protocol is rea-  
17 sonably expected to be ineffective based upon the  
18 documented physical or mental characteristics of the  
19 participant or beneficiary and the known character-  
20 istics of such treatment.

21 “(3) Any treatments otherwise required under  
22 the protocol are contraindicated for the participant  
23 or beneficiary or have caused, or are likely to cause,  
24 based on clinical, peer-reviewed evidence, an adverse

1 reaction or other physical harm to the participant or  
2 beneficiary.

3 “(4) Any treatment otherwise required under  
4 the protocol has prevented, will prevent, or is likely  
5 to prevent a participant or beneficiary from achiev-  
6 ing or maintaining reasonable and safe functional  
7 ability in performing occupational responsibilities or  
8 activities of daily living (as defined in section  
9 441.505 of title 42, Code of Federal Regulations (or  
10 successor regulations)).

11 “(5) The participant or beneficiary is stable for  
12 his or her disease or condition on the prescription  
13 drug or drugs selected by the prescribing health care  
14 provider and has previously received approval for  
15 coverage of the relevant drug or drugs for the dis-  
16 ease or condition by any group health plan or health  
17 insurance issuer.

18 “(6) Other circumstances, as determined by the  
19 Secretary.

20 “(c) REQUIREMENT OF A CLEAR PROCESS.—

21 “(1) IN GENERAL.—The process required by  
22 subsection (a)—

23 “(A) shall provide the prescribing health  
24 care provider or beneficiary or designated third-  
25 party advocate an opportunity to present such

1 provider’s clinical rationale and relevant med-  
2 ical information for the group health plan or  
3 health insurance issuer to evaluate such request  
4 for exception;

5 “(B) shall clearly set forth all required in-  
6 formation and the specific criteria that will be  
7 used to determine whether an exception is war-  
8 ranted, which may require disclosure of—

9 “(i) the medical history or other  
10 health records of the participant or bene-  
11 ficiary demonstrating that the participant  
12 or beneficiary seeking an exception—

13 “(I) has tried other drugs in-  
14 cluded in the drug therapy class with-  
15 out success; or

16 “(II) has taken the requested  
17 drug for a clinically appropriate  
18 amount of time to establish stability,  
19 in relation to the condition being  
20 treated and prescription guidelines  
21 given by the prescribing physician; or

22 “(ii) other clinical information that  
23 may be relevant to conducting the excep-  
24 tion review;

1           “(C) may not require the submission of  
2           any information or supporting documentation  
3           beyond what is strictly necessary to determine  
4           whether any of the circumstances listed in sub-  
5           section (b) exists; and

6           “(D) shall clearly outline conditions under  
7           which an exception request warrants expedited  
8           resolution from the group health plan or health  
9           insurance issuer, pursuant to subsection (d)(2).

10          “(2) AVAILABILITY OF PROCESS INFORMA-  
11          TION.—The group health plan or health insurance  
12          issuer shall make information regarding the process  
13          required under subsection (a) readily available on  
14          the internet website of the group health plan or  
15          health insurance issuer. Such information shall in-  
16          clude—

17                 “(A) the requirements for requesting an  
18                 exception to a medication step therapy protocol  
19                 pursuant to this section; and

20                 “(B) any forms, supporting information,  
21                 and contact information, as appropriate.

22          “(d) TIMING FOR DETERMINATION OF EXCEP-  
23          TION.—The process required under subsection (a)(1) shall  
24          provide for the disposition of requests received under such  
25          paragraph in accordance with the following:

1           “(1) Subject to paragraph (2), not later than  
2           72 hours after receiving an initial exception request,  
3           the plan or issuer shall respond to the requesting  
4           prescriber with either a determination of exception  
5           eligibility or a request for additional required infor-  
6           mation strictly necessary to make a determination of  
7           whether the conditions specified in subsection (b)  
8           are met. The plan or issuer shall respond to the re-  
9           questing provider with a determination of exception  
10          eligibility no later than 72 hours after receipt of the  
11          additional required information.

12           “(2) In the case of a request under cir-  
13          cumstances in which the applicable medication step  
14          therapy protocol may seriously jeopardize the life or  
15          health of the participant or beneficiary, the plan or  
16          issuer shall conduct a review of the request and re-  
17          spond to the requesting prescriber with either a de-  
18          termination of exception eligibility or a request for  
19          additional required information strictly necessary to  
20          make a determination of whether the conditions  
21          specified in subsection (b) are met, in accordance  
22          with the following:

23           “(A) If the plan or issuer can make a de-  
24          termination of exception eligibility without addi-  
25          tional information, such determination shall be

1           made on an expedited basis, and no later than  
2           24 hours after receipt of such request.

3           “(B) If the plan or issuer requires addi-  
4           tional information before making a determina-  
5           tion of exception eligibility, the plan or issuer  
6           shall respond to the requesting provider with a  
7           request for such information within 24 hours of  
8           the request for a determination, and shall re-  
9           spond with a determination of exception eligi-  
10          bility as quickly as the condition or disease re-  
11          quires, and no later than 24 hours after receipt  
12          of the additional required information.

13          “(e) MEDICATION STEP THERAPY PROTOCOL.—In  
14          this section, the term ‘medication step therapy protocol’  
15          means a drug therapy utilization management protocol or  
16          program under which a group health plan or health insur-  
17          ance issuer offering group health insurance coverage of  
18          prescription drugs requires a participant or beneficiary to  
19          try an alternative preferred, prescription drug or drugs be-  
20          fore the plan or health insurance issuer approves coverage  
21          for the non-preferred drug therapy prescribed.

22          “(f) CLARIFICATION.—This section shall apply with  
23          respect to any group health plan or health insurance cov-  
24          erage offered in connection with such a plan that provides  
25          coverage of a prescription drug pursuant to a policy that

1 meets the definition of the term ‘medication step therapy  
2 protocol’ in subsection (e), regardless of whether such pol-  
3 icy is described by such group health plan or health insur-  
4 ance coverage as a step therapy protocol.”.

5 (b) CLERICAL AMENDMENT.—The table of contents  
6 in section 1 of the Employee Retirement Income Security  
7 Act of 1974 (29 U.S.C. 1001 et seq.) is amended by in-  
8 serting after the item relating to section 713 the following  
9 new items:

“Sec. 713A. Required exceptions process for medication step therapy proto-  
cols.”.

10 (c) EFFECTIVE DATE.—

11 (1) IN GENERAL.—The amendment made by  
12 subsection (a) applies with respect to plan years be-  
13 ginning with the first plan year that begins at least  
14 6 months after the date of the enactment of this  
15 Act.

16 (2) REGULATIONS.—Not later than 6 months  
17 after the date of the enactment of this Act, the Sec-  
18 retary of Labor shall issue final regulations, through  
19 notice and comment rulemaking, to implement the  
20 provisions of section 713A of the Employee Retire-  
21 ment Income Security Act of 1974, as added by sub-  
22 section (a).

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