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

Sponsored by Reps. Raul Ruiz (D-CA-36), Brad Wenstrup, (R-OH-02), Lucy McBath (D-GA-06), Mariannette Miller-Meeks (R-IA-02), and Sens. Lisa Murkowski (R-AK), Maggie Hassan (D-NH), Bill Cassidy (R-LA), Jacky Rosen (D-NV)

Background: People with chronic illnesses often experience step therapy in their care journey. "Step therapy" – sometimes known as "fail first" – is a tool used by insurers that requires patients to try a drug, or drugs, that are preferred by the insurance company before the patient can access the therapy originally prescribed by their physician. Step therapy can be an important tool to contain the costs of prescription drugs; however, when inappropriately used, this practice can undermine the clinical judgment of healthcare providers and put patients' health at unnecessary risk. Step therapy protocols can cause unnecessary delays in care, or worse, require patients to try ineffective or potentially dangerous medications before finding the treatment most suited to their needs. The results for patients may include delayed access to the most effective treatment, severe side effects, and irreversible disease progression.

Legislation: The Safe Step Act aims to improve step therapy protocols and ensure patients are able to safely and efficiently access the best treatment for them. The legislation would require group health plans to provide an exception process for any medication step therapy protocol to help ensure patients are able to safely and efficiently access treatment. Specifically, the bill:

Establishes a clear exemption process. Insurers must implement a clear and transparent process for a patient or physician to request an exception to a step therapy protocol, and grant a request for exemption if:

- A patient already tried and failed on the required drug.
- The required drug is reasonably expected to be ineffective, and a delay of treatment would lead to severe or irreversible consequences; is contraindicated or will likely cause harm to the patient; or will prevent a patient from working or performing Activities of Daily Living.
- Patient is already stable on their current medication 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. If a patient's life is at risk, requires a response within 24 hours.

Request to Congress: Cosponsor H.R. 2163/S. 464, the Safe Step Act of 2021.

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H.R. 4472/S. 373: BENEFIT Act of 2021

Sponsored by Reps. Doris Matsui (D-CA-06) and Brad Wenstrup (R-OH-02), Sens. Amy Klobuchar (D-MN) and Roger Wicker (R-MS)

Background: Patients Rising NOW believes that the true measure of value in our healthcare system starts and ends with the concerns and goals of patients. Patients know best what makes a meaningful difference to them, and they have a key role to play alongside all other stakeholders in determining intended outcomes and priorities, acceptable uncertainty, as well as benefit/risk and value of a medicine. It is vital that the FDA provide patients and patient advocates the ability to play a larger role in the FDA's benefit/risk framework for drug approval and provide additional information to all stakeholders, particularly patients, and help further refine and develop such tools going forward.

Congress has worked to ensure that the patient perspective is considered by FDA reviewers who are evaluating candidate drugs and other medical products. In response to congressional direction in the Prescription Drug User Fee Act and the 21st Century Cures Act, the FDA has put in place policies to gather and assess patient perspectives as FDA reviewers evaluate the benefits and risks of potential therapies. **However, the FDA is not required include patient experience or patient-focused drug development (PFDD) data as a part of its benefit/risk framework**. This means that while the agency has to gather data from the patient perspective for evaluating risk-benefit, they don't have to actually use it.

Legislation: The bipartisan Better Empowerment Now to Enhance Framework and Improve Treatments (BENEFIT) Act would require that the patient experience, patient-focused drug development (PFDD) data, and related information be considered by the FDA as part of the benefit/risk assessment of a new drug. This would include information developed by a product sponsor or a third party, such as a patient advocacy organization or academic institution. Further, the bill will require that the FDA disclose ***whether and how*** patient experience and PFDD data was used in the benefit/risk assessment of a new drug.

This bill will not only enhance transparency and accountability at the FDA, it will also encourage and motivate stakeholders to develop more scientifically rigorous and meaningful tools to collect patient-focused data.

Request to Congress: Cosponsor H.R. 4472/S. 373, the BENEFIT Act of 2021.

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H.R. 3173: Improving Seniors' Timely Access to Care Act of 2021

Sponsored by Reps. Suzan DelBene (D-WA-01), Mike Kelly (R-PA-16), Ami Bera (D-CA-07), and Larry Bucshon (R-IN-08)

Background: "Prior authorization" is a practice that requires physicians to obtain pre-approval from Medicare Advantage (MA) plans for medical treatments or tests ***before*** rendering care to their patients. While prior authorization can play a role in ensuring people receive clinically appropriate treatments and helping control the cost of care, the process can result in cumbersome administrative burdens for providers, taking precious time away from patient care and delaying needed medical intervention.

In 2018, the U.S. Department of Health & Human Services' (HHS's) Office of the Inspector General raised concerns after an audit revealed that **MA plans ultimately approved 75% of requests that were originally denied**. The process for obtaining this approval is tedious, lengthy, and typically requires physicians or their staff to spend the equivalent of two or more days each week negotiating with insurance companies – time that would be better spent taking care of patients.

Legislation: H.R. 3173, the Improving Seniors' Timely Access to Care Act of 2021, would help protect patients from unnecessary delays in care by streamlining and standardizing the prior authorization in the MA program.

This bipartisan bill will bring needed transparency and oversight to the MA program by:

- Establishing an electronic prior authorization (ePA) program and requiring MA plans to adopt ePA capabilities
- Requiring the HHS Secretary to establish a list of items and services eligible for real-time decisions under an MA ePA program
- Standardizing and streamlining the prior authorization process for routinely approved items and services
- Ensuring prior authorization requests are reviewed by qualified medical personnel
- Increasing transparency around MA prior authorization and its use
- Protecting beneficiaries from any disruptions in care due to prior authorization requirements as they transition between MA plans

Request to Congress: Cosponsor H.R. 3173, the Improving Seniors' Timely Access to Care Act of 2021.

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FDA's Accelerated Approval Program

Background: The FDA's Accelerated Approval Program (AAP) is a targeted, robust, science-based pathway established by Congress and the FDA to speed the availability of new therapies to patients. Drugs approved through the AAP must meet the same rigorous statutory standards for safety and effectiveness as those granted traditional approval. Created to allow for a faster approval of drugs that are used to treat serious conditions, accelerated approval is reserved for severe diseases with no therapeutic options. By allowing scientists to take more immediate advantage of advances in research, the AAP has made more new, innovative therapies available to patients with rare and chronic conditions.

Drugs approved through the AAP are approved based on a surrogate endpoint or an intermediate clinical endpoint that is reasonably likely to predict a drug's clinical benefit. It can often take years to measure primary outcomes like survival, so surrogate or intermediate endpoints can serve as a proxy for clinical benefit when patients may not have years to wait.

Current Status: The Medicaid and CHIP Payment and Access Commission (MACPAC) has been examining how states can better manage the high cost of specialty drugs. In March 2021, MACPAC focused on drugs approved through the AAP, and considered two recommendations that would impose a new, differential rebate on those drugs. Such policy recommendations would undermine the intent of the accelerated approval pathway and serve to second-guess the FDA approval process, implying that winning approval through the accelerated pathway is somehow substandard or second rate.

Accelerated approval has been and continues to be used in select and appropriate circumstances where evaluating efficacy on clinical endpoints isn't practical, feasible, or ethical in a reasonable timeframe. It is an incredibly powerful tool for patients who would otherwise not have timely access to new and innovative treatments. MACPAC's policy recommendations could cause great harm to patients with rare and chronic conditions.

Request to Congress: Congress should work with interested stakeholders, including patients and patient advocates, to carefully consider whether any updates, revisions, or other improvements to the AAP are needed. Such decisions should be based on ensuring safe, effective treatments get to patients in need as quickly as possible.

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About Us: Patients Rising NOW advocates for patients with serious and chronic conditions to have access to life-improving and life-saving therapies and services. Access to such treatments and services is essential, and it spans affordability, insurance coverage and physical access. To support improved access, we are committed to engaging patients, caregivers, clinicians, media, health policy experts, payers, providers, and others to foster people-centered discussions about the entire U.S. healthcare system. Our goal is a balanced dialogue that illuminates the truth about healthcare innovations and advancements in a just and equitable way. Our programs that support that goal include:

- **Patients Rising University** empowers patients with information and helps them become more effective advocates, understand how insurance works, and expand their insights into other aspects of the U.S. healthcare system that can be complicated and confusing. Click here.

- **Patients Rising Concierge** helps patients and caregivers find solutions when they don't know how to find help when faced with access or affordability challenges by providing them with a team of patient navigators and a library of curated services. Click here.

- **Patients Rising Podcasts** are a weekly series of interviews and stories from patient voices, healthcare industry experts, and timely news commentary to educate listeners about the current healthcare policy landscape and solutions about different healthcare policy issues involving the challenges patients face in accessing needed medical care and potential pathways for reducing patient challenges. Click here.

- **Patients Rising Stories** is a platform for a grassroots movement and national network of patients dedicated to raising awareness and advocating for the rights of patients with chronic and life-threatening illnesses so they can have a measurable impact on awareness and advocacy activities nationwide. Click here.

- **Patient Access and Affordability Project** brings together policy and practical experts to help Patients Rising ensure that the patient is kept at the center of healthcare decisions, particularly as various frameworks (such as ICER's) are being used by public and private payers to assess new treatments. Click here.

To see a brochure with more details on our history and our programs, click here.

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