July 11, 2023

The Honorable Brad Wenstrup, DPM
United States House of Representatives
2335 Rayburn House Office Building
Washington, DC 20515

The Honorable Raul Ruiz, MD
United States House of Representatives
2342 Rayburn House Office Building
Washington, DC 20515

The Honorable Mariannette Miller-Meeks, MD
United States House of Representatives
1034 Longworth House Office Building
Washington, DC 20515

The Honorable Lucy McBath
United States House of Representatives
2246 Rayburn House Office Building
Washington, DC 20515

The Honorable Lori Chavez-DeRemer
United States House of Representatives
1722 Longworth House Office Building
Washington, DC 20515

The Honorable Earl Blumenauer
United States House of Representatives
1111 Longworth House Office Building
Washington, DC 20515

Dear Representatives Wenstrup, Ruiz, Miller-Meeks, McBath, Chavez-DeRemer and Blumenauer:

Thank you for your leadership of H.R. 2630, the *Safe Step Act*, legislation that would create guardrails for patients subjected to step therapy protocols. The 67 undersigned physician medical organizations write to share our endorsement of this timely legislation, communicate how this bill will benefit our patients and our practices, and to offer ourselves as a resource to advance the *Safe Step Act* expeditiously this Congress.

The *Safe Step Act* would ensure that employer health plans and pharmacy benefit managers (PBMs) provide an expedient and medically reasonable step therapy exceptions process. The bill is highly vetted and based on legislation that has passed in 36 states. However, most of our patients still have little recourse if subjected to a medically inappropriate step therapy protocol because employer plans, and the PBMs that contract with them, are exempt from state law.

Despite claims that utilization management, including step therapy, reduce costs, our experience is that when inappropriately applied, utilization management can result in increased spending on ineffective treatments and serious adverse health care outcomes. One study estimated that the costs associated with implementing and appealing utilization management, and patients paying out of pocket for restricted treatments, can be upwards of $90 billion annually.[1]

[1] Quantifying The Economic Burden Of Drug Utilization Management On Payers, Manufacturers, Physicians, And Patients. Scott Howell, Perry T. Yin, and James C. Robinson, Health Affairs 2021 40:8, 1206-1214

The exceptions process outlined in the *Safe Step Act* will bolster plan negotiations with drug manufacturers by reducing wasteful spending on drugs that will not work, reducing unintentional harm to patients, and easing the administrative burden on our practices.

While medically inappropriate step therapy may delay a patient in accessing appropriate care for months, providers are often ultimately successful in getting coverage for the treatment.[2] The extended delay worsens health outcomes, but it also means that plans are spending thousands of dollars on ineffective treatments in the meantime. For example, a scenario we often see for a patient requiring anti-inflammatory biologics to treat their immune-mediated disease involves failing for six months on the first- and second-preferred treatment, which based on the list price of common preferred treatments, equates to as much as $48,000 of wasted spending, no improvement, and a high likelihood of added surgical costs.

Unfortunately, the studies on the savings from step therapy typically focus on the prescription benefit only, and do not take into account adverse health outcomes such as surgeries, hospitalizations, and other events reflected in the medical benefit. Studies that have looked at the broader picture have found that spending in the medical benefit side can eclipse prescription savings within the plan year due to step therapy-related adverse events.[3] This means that step therapy actually *increases* total plan costs in some circumstances.

Lastly, step therapy increases the cost of managing medical practices, which is ultimately paid for by insurance reimbursement. The American Medical Association's 2022 Prior Authorization Physician Survey found that 35% of respondents have staff that work exclusively on prior authorizations (PA), 86% of respondents observed that PA increased healthcare utilization, and 58% of respondents felt that PA impacted their patient's job performance.[4]

Health care providers, not health insurers or PBMs, should prescribe treatments. Providers have the training and experience with the patient to know when a step therapy protocol will be inappropriate. Streamlining the step therapy exceptions process will reduce wasteful spending, ease the administrative burden on providers, and even improve job performance.

We look forward to working with your offices to pass the *Safe Step Act* expeditiously. Thank you for your consideration and leadership on this critical issue. For additional information, please contact Megan Tweed at Megan.Tweed@asco.org.

Sincerely,

Alabama Cancer Congress
Alaska Oncology and Hematology, LLC

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[2] Dickens, David S, and Brad H Pollock. "Medication prior authorization in pediatric hematology and oncology." Pediatric blood & cancer vol. 64,6 (2017): 10.1002/pbc.26339. doi:10.1002/pbc.26339

[3] Carlton. "Review of Outcomes Associated With Formulary Restrictions: Focus on Step Therapy." AJPB February 2010 Volume 2 Issue 1

[4] American Medical Association. "2022 Prior Authorization Physician Survey."

American Academy of Allergy, Asthma & Immunology
American Academy of Dermatology Association
American Academy of Neurology
American Academy of Otolaryngology - Head and Neck Surgery
American Association of Neurological Surgeons
American Association of Orthopaedic Surgeons
American College of Gastroenterology
American College of Mohs Surgery
American College of Osteopathic Internists
American College of Osteopathic Surgeons
American College of Rheumatology
American Gastroenterological Association
American Society for Gastrointestinal Endoscopy
American Society of Cataract and Refractive Surgery
American Society of Plastic Surgeons
American Society of Retina Specialists
American Urological Association
Association for Clinical Oncology
Association of Black Cardiologists
Association of Northern California Oncologists
Cancer Center of Kansas
Coalition of Hematology and Oncology Practices
Coalition of State Rheumatology Organizations
Congress of Neurological Surgeons
Connecticut Oncology Association
Delaware Society for Clinical Oncology
Florida Society of Clinical Oncology
Georgia Society of Clinical Oncology
Hawaii Society of Clinical Oncology
Illinois Medical Oncology Society
Indiana Oncology Society
Infusion Access Foundation
Iowa Oncology Society
Louisiana Oncology Society
Massachusetts Society of Clinical Oncologists
Medical Oncology Assoc. of Southern California
Michigan Society of Hematology and Oncology
Mississippi Oncology Society
Montana Oncology Society
National Association of Spine Specialists
National Infusion Center Association
National Oncology State Network
Nebraska Cancer Specialists and Nebraska Oncology Society
Nebraska Hematology Oncology

Nebraska Pharmacists Association
North American Society for Pediatric Gastroenterology, Hepatology and Nutrition
North Carolina Medical Society
Northern New England Clinical Oncology Society
Ohio Hematology Oncology Society
Oklahoma Society of Clinical Oncology, Inc.
Pennsylvania Society of Oncology & Hematology
Pontchartrain Cancer Center
Puerto Rico Hematology and Medical Oncology Association
Pulmonary Hypertension Association
Rheumatology Nurses Society
Rocky Mountain Oncology Society
Society of Gastroenterology Nurses and Associates
Society of Gynecologic Nurse Oncologists
Society of Interventional Radiology
State Of Texas Association of Rheumatologists
Texas Rheumatology Care
The Arizona Clinical Oncology Society
The Oncology Society of New Jersey
Wisconsin Association of Hematologists and Oncologists
Wyoming State Oncology Society

Cc: U.S. House of Representatives Committee on Education and the Workforce