June 11, 2021

The Honorable Lisa Murkowski  
U.S. Senate  
522 Hart Senate Office Building  
Washington, DC 20510

The Honorable Margaret Hassan  
U.S. Senate  
324 Hart Senate Office Building  
Washington, DC 20510

The Honorable Bill Cassidy  
U.S. Senate  
520 Hart Senate Office Building  
Washington, DC 20510

The Honorable Kyrsten Sinema  
U.S. Senate  
317 Hart Senate Office Building  
Washington, DC 20510

The Honorable Shelley Moore Capito  
U.S. Senate  
172 Russell Senate Office Building  
Washington, DC 20510

The Honorable Mazie K. Hirono  
U.S. Senate  
109 Hart Senate Office Building  
Washington, DC 20510

The Honorable Jeff Merkley  
U.S. Senate  
531 Hart Senate Office Building  
Washington, DC 20510

The Honorable Jacky Rosen  
U.S. Senate  
144 Russell Senate Office Building  
Washington, DC 20510

The Honorable Cindy Hyde-Smith  
U.S. Senate  
702 Hart Senate Office Building  
Washington, DC 20510

The Honorable Kirsten Gillibrand  
U.S. Senate  
478 Russell Senate Office Building  
Washington, DC 20510

The Honorable Thom Tillis  
U.S. Senate  
113 Dirksen Senate Office Building  
Washington, DC 20510

The Honorable Jeanne Shaheen  
U.S. Senate  
506 Hart Senate Office Building  
Washington, DC 20510

The Honorable Kevin Cramer  
U.S. Senate  
330 Hart Senate Office Building  
Washington, DC 20510

The Honorable Richard Blumenthal  
U.S. Senate  
706 Hart Senate Office Building  
Washington, DC 20510

Dear Senators Murkowski, Hassan, Cassidy, Sinema, Capito, Hirono, Merkley, Rosen, Hyde-Smith, Gillibrand, Tillis, Shaheen, Cramer, and Blumenthal:

On behalf of the American Medical Association (AMA) and our physician and student members, I write to offer our support for S. 464, the “Safe Step Act,” which allows for exceptions from medication step-therapy protocols.
Medication step-therapy protocols, and more broadly utilization management programs, can create significant barriers for patients by delaying the start or continuation of necessary medical treatment, which can negatively affect patient health outcomes. While a particular drug or therapy might generally be considered appropriate for a condition, the presence of comorbidities or patient intolerances may necessitate an alternative treatment. Furthermore, forcing patients to abandon already effective treatment and repeat a therapy that has been proven ineffective delays care and may result in negative health outcomes. Recognizing these negative impacts, the AMA and other organizations have created the Prior Authorization and Utilization Management Reform Principles (PA Principles), which promote commonsense concepts to improve prior authorization, step-therapy, and other utilization management programs.¹

S. 464 addresses concerns related to patient safety, negative clinical outcomes, and interruptions in care caused by utilization management programs by amending the Employee Retirement Income Security Act (ERISA) to require a group health plan to provide an exception process for any medication step-therapy protocol, which aligns with our PA Principles. Importantly, the bill requires that insurers implement a clear and transparent process for a patient or physician to request an exception to a step-therapy protocol. Additionally, the bill sets response deadlines for regular and urgent exemption requests. By creating this process, the Safe Step Act helps ensure that patients have timely access to treatment and reduces administrative costs to the health care system.

We applaud your leadership on this critical matter and look forward to working with you to enact S. 464, the Safe Step Act.

Sincerely,

[Signature]

James L. Madara, MD