

June 11, 2021

The Honorable Raul Ruiz  
U.S. House of Representatives  
2342 Rayburn House Office Building  
Washington, DC 20515

The Honorable Lucy McBath  
U.S. House of Representatives  
1513 Longworth House Office Building  
Washington, DC 20515

The Honorable Brad Wenstrup  
U.S. House of Representatives  
2419 Rayburn House Office Building  
Washington, DC 20515

The Honorable Mariannette Miller-Meeks  
U.S. House of Representatives  
1716 Longworth House Office Building  
Washington, DC 20515

Dear Representatives Ruiz, Wenstrup, McBath, and Miller-Meeks:

On behalf of the American Medical Association (AMA) and our physician and student members, I write to offer our support for H.R. 2163, 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.<sup>1</sup>

H.R. 2163 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.

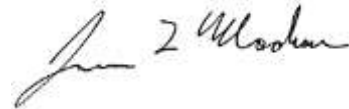
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<sup>1</sup> <https://www.ama-assn.org/system/files/2019-06/principles-with-signatory-page-for-slsc.pdf>

The Honorable Raul Ruiz  
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We applaud your leadership on this critical matter and look forward to working with you to enact H.R. 2163, the Safe Step Act.

Sincerely,

A handwritten signature in black ink, appearing to read "James L. Madara". The signature is written in a cursive style with a large, stylized initial "J".

James L. Madara, MD