AMERICAN PSYCHIATRIC ASSOCIATION

800 Maine Avenue, S.W.
Suite 900
Washington, D.C. 20024

July 9, 2019

The Honorable Raul Ruiz
2342 Rayburn House Office Building
Washington, D.C. 20515

Dear Representative Ruiz:

On behalf of the American Psychiatric Association (APA), the national medical specialty association representing over 38,500 psychiatric physicians, I want to thank you for your sponsorship of H.R. 2279, the Safe Step Act, which seeks to protect patients from unnecessary or harmful "step therapy" insurance policies.

APA has on many occasions stated its opposition to step therapy (otherwise known as "fail first") medication protocols, as applied to mental health and substance use disorder medications. Step therapy protocols are ill-advised, and potentially harmful, for patients requiring medication to treat a mental health and substance use disorders.

First, drugs for the treatment of mental health disorders are not clinically interchangeable, and no two medications have the same therapeutic effect or identical duration and intensity characteristics. Therefore, a physician's determination of which drug to use for a patient is based on a highly individualized determination of which type, dosage, and method of administration is most appropriate for that patient. Some medications used for the treatment of mental health disorders can exacerbate co-occurring physical conditions such as cardiovascular disease, obesity, and diabetes. Additionally, some patients may need daily oral medications, while others may require long-acting injectable medications. By reducing the pharmacological treatments available, step therapy protocols limit the ability of physicians to provide patient-centered care and follow clinical practice guidelines that identify a range of evidence-based medications based on the unique needs of patients.

Second, despite the stated goal of step therapy protocols to lower costs, applying step therapy protocols to mental health medications only serves to increase overall costs, particularly in light of the generally lower costs of these medications. In a study of Medicare Part D spending, antidepressants and anticonvulsants already tend to

have lower average per-prescription costs than other Part D drugs.[1] Most of these savings are attributable to the fact that many mental health medications have a higher rate of generic utilization, with only 8% of antipsychotic and 7% of anticonvulsant prescriptions for branded drugs with no generic alternatives. In clinical practice, step therapy protocols tend to serve only as a means of delaying access to clinically appropriate and evidence-based treatment, which can in turn lead to higher downstream costs for both the patient and the overall health care system.

Finally, and most importantly, step therapy has the potential to harm patients with mental health needs. Many mental illnesses are chronic, lifelong conditions that have both acute and stable phases, and are characterized by a broad array of symptoms, even among patients who have the same or similar diagnoses. If these mental illnesses go untreated, or are inappropriately treated, a patient's risk of inpatient hospitalization, persistent or significant disability, or death is heightened. This also burdens emergency room departments that are already struggling with referring patients to appropriate treatment. In a recent survey[2] of American College of Emergency Physicians (ACEP) members, 48% of respondents said that psychiatric patients are boarded at least once a day in their emergency department.

Your bill would reduce the unnecessary use of step therapy by requiring ERISA-covered plans to develop a publicly accessible procedure through which patients can override these protocols, subject to defined criteria and timeframes. We especially appreciate the creation of an expedited approval timeframe, as many patients experiencing a mental health crisis require immediate intervention to avoid harmful effects to themselves or others. Finally, by limiting the documentation required to demonstrate the need for overriding a step therapy protocol only to what is "strictly necessary," your legislation will help ensure that insurers will not simply replace one unnecessary bureaucratic hurdle with another.

Thank you for your leadership in introducing H.R. 2279. Please let us know how we can aid your efforts to advance this bill. If you have any questions, please contact Mike Troubh at mtroubh@psych.org / 202.559.3571.

Sincerely,

Saul Levin, MD, MPA, FRCP-E
CEO and Medical Director

cc: The Honorable Frank Pallone Jr., Chairman, House Energy & Commerce Committee
The Honorable Greg Walden, Ranking Member, House Energy & Commerce Committee

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[1] The Pew Charitable Trusts. Policy Proposal: Revising Medicare's Protected Classes Policy (March 2018), available at: https://www.pewtrusts.org/-/media/assets/2018/03/dsri_policy_proposal_revising_medicares_protected_classes_policy.pdf.

[2] American College of Emergency Physicians, "ACEP Physician Poll on Psychiatric Emergencies September 28 – October 6, 2016," available at: newsroom.acep.org/download/psychemergencypolloct2016.pdf.