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December 11, 2019

The Honorable Lisa Murkowski  
United States Senate  
522 Hart Senate Office Building  
Washington, D.C. 20510

The Honorable Doug Jones  
United States Senate  
330 Hart Senate Office Building  
Washington, DC 20510

Dear Senator Murkowski and Senator Jones:

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 S. 2546, the Safe Step Act, which seeks to protect patients from unnecessary or harmful "step therapy" insurance policies.

APA has consistently opposed step therapy (otherwise known as "fail first") medication protocols, specifically as applied to mental health and substance use disorder medications. Step therapy protocols are ill-advised, and potentially harmful, for patients requiring specific medication to treat mental health disorders.

Medications 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 medication to use for a patient is based on an 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 or complicating the pharmacological treatments available, step therapy protocols limit the ability of physicians to provide evidence-based patient-centered care.

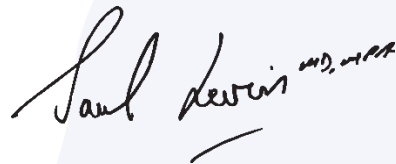
Given the individualized nature of psychiatric medication prescriptions, step therapy has the potential to harm patients with mental health illness. Many mental illnesses are chronic, lifelong conditions that have both acute and stable phases, and are characterized by a broad array of symptoms, even 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. Requiring a patient to first adhere to step therapy protocols, instead of starting or maintaining an appropriate medication the first time, raises the overall costs of care, delays patient stabilization, and risks patient safety.

As you know, the nation is currently in the midst of a suicide epidemic. Suicide is currently the 10<sup>th</sup> leading cause of death in the United States, and in 2017 alone, there were an estimated 1.4 million suicide attempts and over 47,000 reported deaths by suicide.<sup>1</sup> Clinical evidence from population-based studies clearly indicates that the risk of suicide attempts and completed suicide increases for patients with any psychiatric disorder, and this risk can increase exponentially for patients who suffer from disorders like depression and anxiety, who are unable to access the antidepressants that can control their symptoms. Especially in light of this crisis, now is the time to enable, not constrict, broader access to mental health services.

Your bill would reduce the unnecessary use of step therapy by requiring ERISA-covered plans to develop a transparent process through which these protocols can be overridden, subject to defined criteria and timeframes. We 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 S. 2546. 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](mailto:mtroubh@psych.org) / 202.559.3571.

Sincerely,

A handwritten signature in black ink that reads "Saul Levin" followed by "MD, MPA" in smaller, less legible handwriting.

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

cc: The Honorable Lamar Alexander, Chairman, Senate HELP Committee  
The Honorable Patty Murray, Ranking Member, Senate HELP Committee

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<sup>1</sup> American Foundation for Suicide Prevention, “Suicide Statistics”, available at: <https://afsp.org/about-suicide/suicide-statistics/>