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November 15, 2021

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

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On behalf of the American Psychiatric Association (APA), the national medical specialty society representing over 37,400 psychiatric physicians who treat mental health and substance use disorders, I write to express our support for the Safe Step Act (H.R. 2163), 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, in addition to the ongoing public health emergency, the nation is currently in the midst of a suicide epidemic. Suicide remains among the leading causes of death in

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the United States, and in 2019 alone, there were over 47,000 reported deaths by suicide.¹ 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. In light of this crisis, and accounting for ongoing stressors associated with the COVID-19 pandemic, now is the time to enable, not constrict, broader access to mental health services. To that end, your important legislation 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 H.R. 2163. 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 M. Levin, M.D., M.P.A., FRCP-E, FRCPSych
CEO and Medical Director
American Psychiatric Association

¹ Centers for Disease Control and Prevention, National Center for Health Statistics. Underlying Cause of Death 1999-2019 on CDC WONDER Online Database, released in 2020. Data are from the Multiple Cause of Death Files, 1999-2019, as compiled from data provided by the 57 vital statistics jurisdictions through the Vital Statistics Cooperative Program.