



# HOUSE BILL 727: Breakthrough Therapies Research/Advisory Act.

2023-2024 General Assembly

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<b>Committee:</b>	House Health. If favorable, re-refer to Appropriations. If favorable, re-refer to Rules, Calendar, and Operations of the House	<b>Date:</b>	May 16, 2023
<b>Introduced by:</b>	Reps. Sasser, Autry, Chesser, Goodwin	<b>Prepared by:</b>	Jason Moran-Bates
<b>Analysis of:</b>	First Edition		Committee Staff

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**OVERVIEW:** *House Bill 727 would establish a grant program for the study of MDMA and psilocybin to treat mental health disorders. It would also create a board in the Division of Mental Health, Developmental Disabilities, and Substance Abuse Services to administer the grant program. Finally, it would appropriate funds to the grant program and the board.*

**BILL ANALYSIS:** Part I of the bill would establish the Breakthrough Therapies Research (BTR) Grant Fund to award two competitive grants for research into using MDMA and psilocybin to treat mental health disorders. The MDMA grant recipient must concentrate on the treatment of PTSD in military veterans, first responders, frontline healthcare workers, or victims of domestic violence or sexual assault. The psilocybin grant recipient must concentrate on the treatment of anxiety or depression. Grant recipients must be federal medical or research entities or academic institutions. Both grant recipients must report to the BTR Advisory Board no later than January 15, 2028. The grants will be for \$2.5 million each, and will fund three years of research. DHHS is authorized to adopt the rules necessary to administer the grant program.

Part II of the bill would create the Breakthrough Therapies Advisory Board to administer the grant program. The Board will be in the Division of Mental Health, Developmental Disabilities, and Substance Abuse Services and will consist of:

- Four members appointed by the Governor.
- Three members appointed on the recommendation of the Speaker of the House of Representatives.
- Three members appointed on the recommendation of the President Pro Tempore of the Senate.
- One member of the Commission for Mental Health, Developmental Disabilities, and Substance Abuse Services.
- The Deputy Secretary for Health, or the deputy's designee.
- The Director of the Division of Mental Health, Developmental Disabilities, and Substance Abuse Services, or the director's designee

The Board will recommend the method and manner by which applicants can apply for the grants, recommend who should receive the grants, monitor research, and evaluate the research findings. The Board will disband on December 31, 2028.

Part III of the bill would appropriate \$5 million in nonrecurring funds for the 2023-25 fiscal biennium to fund the grants and \$400,000 for administrative costs of the program.

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**EFFECTIVE DATE:** The appropriation would be effective July 1, 2023. The remainder of the bill would be effective when it becomes law.

**BACKGROUND:**

The Food and Drug Administration Breakthrough Therapy Program is a process designed to expedite the development and review of drugs that are intended to treat a serious condition and preliminary clinical evidence indicates that the drug may demonstrate substantial improvement over available therapy.

MDMA (3,4-methylenedioxymethamphetamine) is the active ingredient in illegal Ecstasy. It has been shown to reduce clinical PTSD scores when used in a therapeutic manner by psychiatrists.

Psilocybin is the active ingredient in "magic mushrooms." Current research shows it has promise in treating a range of mental health disorders.