

**GENERAL ASSEMBLY OF NORTH CAROLINA**  
**SESSION 2023**

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**HOUSE BILL 727**

Short Title: Breakthrough Therapies Research/Advisory Act. (Public)

Sponsors: Representatives Sasser, Autry, Chesser, and Goodwin (Primary Sponsors).  
*For a complete list of sponsors, refer to the North Carolina General Assembly web site.*

Referred to: Health, if favorable, Appropriations, if favorable, Rules, Calendar, and Operations  
of the House

April 19, 2023

A BILL TO BE ENTITLED

AN ACT TO ESTABLISH THE BREAKTHROUGH THERAPIES RESEARCH GRANT  
PILOT PROGRAM AND THE BREAKTHROUGH THERAPIES RESEARCH  
ADVISORY BOARD.

The General Assembly of North Carolina enacts:

**SECTION 1.(a)** Establishment of Fund. – The Breakthrough Therapies Research (BTR) Grant Fund is established as a nonreverting special fund in the Department of Health and Human Services, Division of Mental Health, Developmental Disabilities, and Substance Abuse Services (Division). Funds shall be used to award two competitive BTR Grants to recipients for eligible research projects or studies, as outlined in this section. The funds shall be used by the recipient to pay for costs associated with an eligible research project or study, which is intended to last three years.

For the purposes of this act, the term "breakthrough therapies" shall mean any drug that has been designated as a Breakthrough Therapy for which an expedited approval pathway has been granted by the United States Food and Drug Administration (FDA).

**SECTION 1.(b)** Eligible Research Projects or Studies. – The Division shall accept applications in a timely fashion for the grant awards to be made no later than August 1, 2024. Applications are limited to federal medical or research entities and academic institutions located in this State with infrastructure and staff experience to support the research being funded under this act. All research must be conducted within this State and participants must be age 21 or older. To be eligible for a BTR Grant, the recipient must attest that the grant funds will be used to conduct research in this State on the use of one of two psychedelics, MDMA and psilocybin, and that the research will adhere to all FDA protocols and all applicable federal law. The research study involving MDMA shall be concentrated on the treatment of posttraumatic stress disorder, specifically targeted toward any of the following populations that are disproportionately impacted by trauma:

- (1) Military veterans.
- (2) Active or former first responders, specifically individuals with specialized training who are among the first to arrive, and aid or provide incident resolution, at the scene of an emergency. This population includes law enforcement officers, paramedics, emergency medical technicians, and firefighters.
- (3) Frontline healthcare personnel, specifically individuals with specialized training to provide direct healthcare services to members of the community.



1 These healthcare services include preventing, detecting, and treating diseases  
2 or other public health issues. Frontline healthcare personnel includes licensed  
3 doctors, physician assistants, nurses, pharmacists, and community health  
4 workers.

5 (4) Individuals who have experienced domestic violence or sexual assault.

6 The research study involving psilocybin shall be concentrated on the treatment of  
7 anxiety disorder, depressive disorder, or both. All research studies awarded a grant must measure  
8 participant baseline pain levels and any changes to the pain levels that may be related to the  
9 breakthrough therapies.

10 Each grant recipient shall be required to submit a report on the research findings and  
11 recommendations to the Division and the BTR Advisory Board, established under Section 2 of  
12 this act, no later than January 15, 2028. The grant amount is intended to fund three years' worth  
13 of research study.

14 **SECTION 1.(c) Grant Awards.** – Upon the recommendation of the BTR Advisory  
15 Board, established under Section 2 of this act, and no later than July 1, 2024, the Division shall  
16 award two competitive grants in the amount of two million five hundred thousand dollars  
17 (\$2,500,000) each to two separate recipients. No later than July 1, 2024, the Division shall  
18 announce the recipients of the competitive grant awards authorized under this section and report  
19 to the Joint Legislative Oversight Committee on Health and Human Services on the following  
20 information related to the research project or studies to be conducted by each eligible competitive  
21 grant recipient:

22 (1) The scope and purpose.

23 (2) The anticipated number of people participating and a description of the  
24 participating targeted population.

25 (3) The geographic area to be served.

26 (4) The anticipated time frame for completion.

27 **SECTION 1.(d) Rules.** – The Division may adopt any rules, emergency, temporary,  
28 or otherwise, for the purposes of this act. The Division shall determine the method and manner  
29 by which applicants may apply for the competitive grant, including what information the  
30 Division requires of the applicants.

31 **SECTION 2.(a) Establishment of Advisory Board.** – There is established within the  
32 Department of Health and Human Services, Division of Mental Health, Developmental  
33 Disabilities, and Substance Abuse Services (Division), the Breakthrough Therapies Research  
34 (BTR) Advisory Board. This advisory board shall consist of the following members:

35 (1) Four members appointed by the Governor.

36 (2) Three members appointed on the recommendation of the Speaker of the House  
37 of Representatives.

38 (3) Three members appointed on the recommendation of the President Pro  
39 Tempore of the Senate.

40 (4) One member of the Commission for Mental Health, Developmental  
41 Disabilities, and Substance Abuse Services.

42 (5) The Deputy Secretary for Health, or the deputy's designee.

43 (6) The Director of the Division of Mental Health, Developmental Disabilities,  
44 and Substance Abuse Services, or the director's designee.

45 Appointed members shall be individuals who (i) have experience in psychedelic  
46 research and who possess a PhD or MD; (ii) have a background in psychedelic medicine  
47 cultivation or synthesis; (iii) are mental health professionals with a minimum of five years  
48 licensure by the respective North Carolina professional licensing board with demonstrable proof  
49 of training or experience in the field of psychedelic medicine; (iv) possess a background in law  
50 enforcement or criminal justice; or (v) are disproportionately impacted by trauma, such as  
51 military veterans, first responders, frontline healthcare workers, or individuals who have

1 experienced domestic violence or sexual assault. It is intended that the makeup of appointed  
2 members shall provide statewide geographic representation that is balanced and diverse. The  
3 initial advisory board shall be appointed no later than December 1, 2023. On or after December  
4 1, 2023, any vacancies shall be filled in the manner appointed.

5 **SECTION 2.(b)** Duties of the Advisory Board. – The BTR Advisory Board shall  
6 have the following duties:

- 7 (1) Make recommendations to the Division regarding the method and manner by  
8 which applicants may apply for the competitive BTR Grant, including what  
9 information the Division requires of the applicants. Preference for grant  
10 applications focusing on implementation research shall be given.
- 11 (2) Review grant applications and make recommendations to the Division  
12 regarding research projects or studies to be funded.
- 13 (3) Monitor research projects or studies conducted by recipients of the BTR  
14 Grant.
- 15 (4) No later than December 1, 2024, and annually thereafter for three additional  
16 years, report to the Division regarding any updates based upon the monitoring  
17 of the BTR Grant research projects or studies, in accordance with subdivision  
18 (3) of this subsection.
- 19 (5) Evaluate the research findings and recommendations submitted by the BTR  
20 Grant recipients and include this evaluation in the report due to the Division  
21 no later than December 1, 2028, along with any recommendations for the  
22 continuation of the Breakthrough Therapies Research Grant Pilot Program  
23 and any recommended changes to the pilot program.

24 **SECTION 2.(c)** This section shall expire December 31, 2028.

25 **SECTION 3.** Effective July 1, 2023, there is appropriated from the General Fund to  
26 the Department of Health and Human Services, Division of Mental Health, Developmental  
27 Disabilities, and Substance Abuse Services, the sum of five million four hundred thousand dollars  
28 (\$5,400,000) in nonrecurring funds for the 2023-2025 fiscal biennium. Of those funds, five  
29 million dollars (\$5,000,000) in nonrecurring funds shall be deposited into the BTR Grant Fund,  
30 as established under Section 1(a) of this act. The remaining four hundred thousand dollars  
31 (\$400,000) in nonrecurring funds shall be used by the Division for administrative costs related  
32 to the BTR Grant Pilot Program established under Section 1 of this act, including costs of the  
33 BTR Advisory Board, established under Section 2 of this act.

34 **SECTION 4.** Except as otherwise provided, this act is effective when it becomes  
35 law.