

GENERAL ASSEMBLY OF NORTH CAROLINA
SESSION 2023

H.B. 727
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HOUSE PRINCIPAL CLERK

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HOUSE BILL DRH10345-MRa-21A

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

Sponsors: Representative Sasser.

Referred to:

1 A BILL TO BE ENTITLED
2 AN ACT TO ESTABLISH THE BREAKTHROUGH THERAPIES RESEARCH GRANT
3 PILOT PROGRAM AND THE BREAKTHROUGH THERAPIES RESEARCH
4 ADVISORY BOARD.

5 The General Assembly of North Carolina enacts:

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

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

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

- 27 (1) Military veterans.
28 (2) Active or former first responders, specifically individuals with specialized
29 training who are among the first to arrive, and aid or provide incident
30 resolution, at the scene of an emergency. This population includes law
31 enforcement officers, paramedics, emergency medical technicians, and
32 firefighters.
33 (3) Frontline healthcare personnel, specifically individuals with specialized
34 training to provide direct healthcare services to members of the community.
35 These healthcare services include preventing, detecting, and treating diseases
36 or other public health issues. Frontline healthcare personnel includes licensed



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1 doctors, physician assistants, nurses, pharmacists, and community health
2 workers.

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

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

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

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

20 (1) The scope and purpose.

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

23 (3) The geographic area to be served.

24 (4) The anticipated time frame for completion.

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

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

33 (1) Four members appointed by the Governor.

34 (2) Three members appointed on the recommendation of the Speaker of the House
35 of Representatives.

36 (3) Three members appointed on the recommendation of the President Pro
37 Tempore of the Senate.

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

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

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

43 Appointed members shall be individuals who (i) have experience in psychedelic
44 research and who possess a PhD or MD; (ii) have a background in psychedelic medicine
45 cultivation or synthesis; (iii) are mental health professionals with a minimum of five years
46 licensure by the respective North Carolina professional licensing board with demonstrable proof
47 of training or experience in the field of psychedelic medicine; (iv) possess a background in law
48 enforcement or criminal justice; or (v) are disproportionately impacted by trauma, such as
49 military veterans, first responders, frontline healthcare workers, or individuals who have
50 experienced domestic violence or sexual assault. It is intended that the makeup of appointed
51 members shall provide statewide geographic representation that is balanced and diverse. The

1 initial advisory board shall be appointed no later than December 1, 2023. On or after December
2 1, 2023, any vacancies shall be filled in the manner appointed.

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

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

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

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

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