HOUSE BILL 2075
By Terry

SENATE BILL 2149

By Walley

AN ACT to amend Tennessee Code Annotated, Title 9; Title 33; Title 53; Title 63 and Title 68, relative to clinical trials.

WHEREAS, ibogaine is a naturally occurring psychoactive compound that has demonstrated promise in treating a wide range of mental health and neurological conditions, including opioid use disorder, post-traumatic stress disorder (PTSD), traumatic brain injury, depression, anxiety, multiple sclerosis, and more; and

WHEREAS, ibogaine is classified as a Schedule I drug by the federal government, making research and access difficult, and forcing patients to seek unregulated treatment abroad; and

WHEREAS, multiple states have authorized and funded research into ibogaine, and Texas has launched a research consortium facilitating a multistate effort to conduct clinical trials on ibogaine as a medical treatment; and

WHEREAS, recent studies demonstrate ibogaine's ability to significantly reduce symptoms of substance use addiction, PTSD, depression, and anxiety after one treatment; and

WHEREAS, ibogaine treatment has been associated with marked improvements in patients with traumatic brain injury, with results that include significant improvements in concentration, information processing, memory, and impulse control; and

WHEREAS, Stanford University has studied the impact of treatment on veterans who have been supported by nonprofit organizations that facilitate veterans traveling to ibogaine retreats abroad with reported substantial improvements in depression scores, PTSD symptoms, anxiety, sleep, quality of life, substance abuse, and emotional well-being; and

WHEREAS, trusted institutions, including the federal Food and Drug Administration and Department of Veterans Affairs, are actively supporting and investing in research on psychedelic-assisted therapies for PTSD and related mental health conditions; and

WHEREAS, expediting research into the medical potential of ibogaine is an effective and safe way to ensure patients have access to a potentially groundbreaking treatment; now, therefore,

BE IT ENACTED BY THE GENERAL ASSEMBLY OF THE STATE OF TENNESSEE:

SECTION 1. Tennessee Code Annotated, Title 33, is amended by adding the following as a new chapter:

33-12-101. Short title.

This chapter is known and may be cited as the "Helping Open Pathways to Effective (HOPE) Treatment Act."

33-12-102. Chapter definitions.

As used in this chapter:

(1) "Commissioner" means the commissioner of mental health and substance abuse services;

(2) "Department" means the department of mental health and substance abuse services;

(3) "Drug developer" means a pharmaceutical company, biotechnology company, or contract development and manufacturing organization engaged in drug development and manufacturing;

(4) "Hospital" means any institution, place, building, or agency represented and held out to the general public as ready, willing, and able to furnish care, accommodations, facilities, and equipment for the use, in connection with the services of a physician or dentist, of one (1) or more

nonrelated persons who may be suffering from deformity, injury, or disease or from any other condition for which nursing, medical, or surgical services would be appropriate for care, diagnosis, or treatment;

(5) "Ibogaine" means ibogaine and ibogaine-based therapeutics, including ibogaine analogs; and

(6) "Institution of higher education" means any postsecondary institution operated by the board of trustees for the University of Tennessee system, the board of regents, or a state university board that offers courses of instruction leading to a certificate or degree.

33-12-103. Establishment of cohort.

(a) A cohort may be established under this section and apply for department selection under this chapter to conduct drug development clinical trials with ibogaine and secure the United States food and drug administration's approval of ibogaine as a medication for the treatment of:

(1) Opioid use disorder;

(2) Co-occurring substance use disorder; and

(3) Any other neurological or mental health condition for which ibogaine demonstrates efficacy.

(b) A cohort established under this section must include one (1) or more of each of the following entities:

(1) A drug developer;

(2) A research institution, which may be an institution of higher education; and

(3) A hospital.

33-12-104. Lead institution - Administration - Personnel.

(a) A cohort established under this chapter shall select a project lead from among the cohort's members to represent the cohort and perform administrative functions under this chapter, including contracting with and reporting to the department as required by this chapter. It is the intent of the general assembly that the research institution be selected as project lead.

(b) A project lead selected by the department under this chapter may employ personnel, including clinical, administrative, and data management personnel, necessary to support any cohort member's activities related to drug development clinical trials conducted under this chapter. Such activities may include participation in the Texas consortium for the purpose of clinical trial collaboration.

33-12-105. Cohort proposal.

(a) The cohort project lead shall submit to the department a proposal and request for funding on behalf of the cohort for purposes of conducting ibogaine drug development clinical trials in accordance with this chapter.

(b) A proposal submitted under subsection (a) must provide:

(1) The identity of all cohort members;

(2) A detailed description of the planned strategy for obtaining approval for the drug development clinical trials from the United States food and drug administration;

(3) A detailed drug development clinical trial design that includes:

(A) A description of the composition of the cohort's drug development clinical trial team and the expertise of the team members;

(B) A drug development clinical trial participant recruitment plan;

(C) Patient screening criteria and cardiac safety protocols;

(D) Administration protocols;

(E) An aftercare and post-acute treatment support plan; and

(F) A data integrity plan;

(4) A detailed plan to seek a breakthrough therapy designation for ibogaine from the United States food and drug administration under 21 U.S.C. § 356;

(5) A proposal to recognize this state's commercial interest in all intellectual property that may be generated over the course of the drug development clinical trials, including:

(A) The treatment that is the subject of the trials;

(B) Administration protocols;

(C) Treatment models or techniques; and

(D) Technology used in the trials;

(6) A plan to establish a corporate presence in this state and to promote and maintain ibogaine-related biomedical research, development, treatment, manufacturing, and distribution in this state;

(7) A plan to secure third-party payor approval for ibogaine treatment following approval by the United States food and drug administration through:

(A) Private insurers;

(B) Medicare;

(C) Medicaid; and

(D) The TRICARE program of the United States department of defense;

(8) A plan to ensure ibogaine treatment access to uninsured individuals following approval by the United States food and drug administration;

(9) A plan to train and credential medical providers to administer ibogaine treatment according to developed clinical standards; and

(10) Financial disclosures that verify the cohort's capacity to fully match state funding with funds received from non-state sources.

33-12-106. Department selection.

The department, in the department's sole discretion, shall select a cohort established in accordance with § 33-12-103 for the purpose of conducting ibogaine drug development clinical trials under this chapter.

33-12-107. Contract with lead institution.

(a) As soon as practicable after selecting a cohort to conduct ibogaine drug development clinical trials under § 33-12-106, the department shall enter into an interagency agreement with the project lead of the selected cohort to provide funding to implement the cohort's proposed ibogaine drug development clinical trials.

(b) The interagency contract described by subsection (a) must specify:

(1) The goals and objectives of the proposed ibogaine drug development clinical trials;

(2) The proposed budget;

(3) The timeline for completing the proposed objectives;

(4) The for-profit, nonprofit, or public benefit corporate entities collaborating with the cohort in the drug development clinical trials under this chapter or a clinical trial initiated in another state, including the clinical trial conducted by the Texas consortium;

(5) The percentage of the revenue arising from the drug development clinical trials to be paid to the state; and

(6) Any other information required by the department.

(c) As soon as practicable after entering into an interagency contract under subsection (a), the department shall report the existence of the contract to the general assembly by sending notice to the chief clerks of the senate and house of representatives.

(d) The department shall not disburse funds to or for a selected cohort under the interagency contract described by subsection (a) until the cohort receives and the department verifies the receipt of matching funds from sources other than the state.

33-12-108. Investigational new drug application.

On the department's notification that a cohort is selected to conduct the drug development clinical trials under this chapter, a drug developer or hospital member of the selected cohort or the project lead of the cohort, as specified by written agreement of the cohort members, shall, as soon as practicable:

(1) Submit an investigational new drug application to the United States food and drug administration in accordance with 21 CFR Part 312; and

(2) Seek a breakthrough therapy designation for ibogaine from the United States food and drug administration under 21 U.S.C. § 356.

33-12-109. Drug development clinical trial sites.

For purposes of conducting a drug development clinical trial under this chapter, only a research institution or a hospital shall serve as a trial site.

33-12-110. Funding - Disbursement by department.

(a) The department and cohort members may solicit and accept gifts, grants, and donations of any kind received from sources other than the state for purposes of funding drug development clinical trials under this chapter.

(b) Disbursements of funds by the department may be made incrementally based on the completion of clearly defined objectives as negotiated in the contract

described by § 33-12-107, including verifiable documentation demonstrating the efficient expenditure of both state and matching funds.

33-12-111. Reporting requirements.

(a) A cohort selected to conduct ibogaine drug development clinical trials shall prepare and submit to the department quarterly:

(1) A report on the progress of the drug development clinical trials conducted under this chapter; and

(2) A financial status report, including information to verify expenditures of state funds and required matching funds.

(b) The department shall submit a report to the general assembly on the progress of the drug development clinical trials conducted under this chapter no later than December 1 of each year. The report must be submitted to the chief clerk of the senate, the chief clerk of the house of representatives, and the legislative librarian, and may be submitted by electronic means.

33-12-112. Allocation of revenue attributable to intellectual property and other rights.

(a) The revenue attributable to all intellectual property rights and other commercial rights arising from drug development clinical trials conducted by a cohort under this chapter during the period for which the trials are funded and any following period of commercialization shall be allocated as follows:

(1) No less than five percent (5%) to the state as specified in the contract under § 33-12-107; and

(2) The remainder to the members of the cohort in the amounts specified by written agreement of the members.

(b) For purposes of this section, intellectual property rights and other commercial rights arising from the drug development clinical trials conducted under this chapter include any of the following as related to the trials:

(1) Intellectual property, technology, and inventions;

(2) Patents, trademarks, and licenses;

(3) Proprietary and confidential information;

(4) Trade secrets, data, and databases;

(5) Tools, methods, and processes;

(6) Treatment models or techniques;

(7) Administration protocols; and

(8) Works of authorship.

33-12-113. Use of state revenue.

(a) The state treasurer shall deposit the revenue received under § 33-12-112(a)(1) as follows:

(1) No less than fifty percent (50%) into the Tennessee mental health innovation fund, created by § 33-12-114; and

(2) The remainder into the general fund.

(b) The state treasurer shall develop accounting procedures for the purpose of implementing this section.

33-12-114. Creation of innovation fund - Purpose.

(a) There is created within the state general fund a special account to be known as the Tennessee mental health innovation fund.

(b) Unless otherwise specified in this part, moneys realized from intellectual property and other commercial rights pursuant to § 33-12-112(a)(1) and allocated pursuant to § 33-12-113(a)(1) must be deposited in the fund and used only to implement

and administer the purposes set forth in subsection (f). In addition to appropriations made to the fund, the commissioner may accept other funds, public or private, by way of gift or grant to the fund. Any such gift or grant must be deposited into the fund to be expended in accordance with this part.

(c) The state treasurer shall invest moneys in the fund for the benefit of the fund in accordance with § 9-4-603. Interest accruing on investments and deposits of the fund must be credited to and remain part of the fund.

(d) Any unencumbered moneys and any unexpended balance of the fund remaining at the end of a fiscal year do not revert to the general fund, but must be carried forward until expended in accordance with this part. No part of the fund shall be diverted to the general fund or any other public fund.

(e) The commissioner shall administer the fund, and moneys in the fund must be expended and obligated only in accordance with this part and in accordance with appropriations made by the general assembly. All expenditures from the fund are subject to review in the form of an annual report submitted by the commissioner to the general assembly.

(f) The purpose of the Tennessee mental health innovation fund is to fund proposals from behavioral health providers to train and support clinical and supportive care staff in best practices for supporting patients who have undergone ibogaine therapy.

33-12-115. Applicability of chapter.

This chapter applies only if ibogaine is approved by the United States food and drug administration to treat a medical condition.

33-12-116. Medical supervision.

A physician licensed under title 63, chapter 6 or 9, who has prescribed ibogaine for a patient shall supervise the administration of ibogaine at a hospital or other licensed healthcare facility to ensure the patient's safety while the patient is undergoing ibogaine treatment.

33-12-117. Administration under federal law.

This chapter does not preclude a physician from administering ibogaine in accordance with federal law.

33-12-118. Waiver authority - Deadline to begin accepting proposals.

(a) If the department, or another department of state government involved in the administration of this chapter, determines that a waiver or authorization from a federal agency is necessary to implement a provision of this chapter, then the department responsible for implementing such provision shall request the waiver or authorization and may delay implementing that provision until the waiver or authorization is granted.

(b) The department shall begin accepting proposals from cohorts under this chapter no later than September 1, 2026.

SECTION 2. The headings in this act are for reference purposes only and do not constitute a part of the law enacted by this act. However, the Tennessee Code Commission is requested to include the headings in any compilation or publication containing this act.

SECTION 3. This act takes effect July 1, 2026, the public welfare requiring it.

Senate Finance, Ways, and Means 1

Amendment No. 2 to SB2149

Watson
Signature of Sponsor

AMEND Senate Bill No. 2149 House Bill No. 2075*

by deleting all language after the caption and substituting:

WHEREAS, ibogaine is a naturally occurring psychoactive compound that has demonstrated promise in treating a wide range of mental health and neurological conditions, including opioid use disorder, post-traumatic stress disorder (PTSD), traumatic brain injury, depression, anxiety, multiple sclerosis, and more; and

WHEREAS, ibogaine is classified as a Schedule I drug by the federal government, making research and access difficult, and forcing patients to seek unregulated treatment abroad; and

WHEREAS, multiple states have authorized and funded research into ibogaine, and Texas has launched a research consortium facilitating a multistate effort to conduct clinical trials on ibogaine as a medical treatment; and

WHEREAS, recent studies demonstrate ibogaine's ability to significantly reduce symptoms of substance use addiction, PTSD, depression, and anxiety after one treatment; and

WHEREAS, ibogaine treatment has been associated with marked improvements in patients with traumatic brain injury, with results that include significant improvements in concentration, information processing, memory, and impulse control; and

WHEREAS, Stanford University has studied the impact of treatment on veterans who have been supported by nonprofit organizations that facilitate veterans traveling to ibogaine retreats abroad with reported substantial improvements in depression scores, PTSD symptoms, anxiety, sleep, quality of life, substance abuse, and emotional well-being; and

WHEREAS, trusted institutions, including the federal Food and Drug Administration and Department of Veterans Affairs, are actively supporting and investing in research on psychedelic-assisted therapies for PTSD and related mental health conditions; and

WHEREAS, Tennessee continues to experience devastating losses from the opioid epidemic, with thousands of Tennesseans dying each year from opioid overdoses, and existing treatment options leaving many patients without adequate relief; and

WHEREAS, Tennessee is home to a significant veteran population, many of whom suffer from treatment-resistant PTSD and have sought ibogaine treatment abroad due to the lack of authorized options in the United States, at great personal expense and at times without proper clinical safety protections; and

WHEREAS, expediting research into the medical potential of ibogaine is an effective and safe way to ensure patients have access to a potentially groundbreaking treatment; now, therefore,

BE IT ENACTED BY THE GENERAL ASSEMBLY OF THE STATE OF TENNESSEE:

SECTION 1. Tennessee Code Annotated, Title 33, is amended by adding the following as a new chapter:

33-12-101. Short title.

This chapter is known and may be cited as the "Helping Open Pathways to Effective (HOPE) Treatment Act."

33-12-102. Chapter definitions.

As used in this chapter:

(1) "Coordinating institution" means the participating institution designated by the council pursuant to § 33-12-105 to serve as the primary contracting and reporting entity for this state's participation in a multistate consortium;

(2) "Council" means the council on emerging behavioral health treatments, created by § 33-12-103;

(3) "Hospital" means any institution, place, building, or agency represented and held out to the general public as ready, willing, and able to furnish care, accommodations, facilities, and equipment for the use, in connection with the services of a physician or dentist, of one (1) or more nonrelated persons who may be suffering from deformity, injury, or disease or from any other condition for which nursing, medical, or surgical services would be appropriate for care, diagnosis, or treatment;

(4) "Ibogaine" means ibogaine and ibogaine-based therapeutics, including ibogaine analogs;

(5) "Institution of higher education" means a postsecondary institution operated by the board of trustees for the University of Tennessee system, the board of regents, or a state university board that offers courses of instruction leading to a certificate or degree;

(6) "Multistate consortium" means a multistate ibogaine drug development clinical trial consortium operating under the authorization of one (1) or more states for the purpose of conducting coordinated clinical trials on ibogaine as a medical treatment; and

(7) "Participating institution" means an academic medical center, university-affiliated research hospital, or accredited institution of higher education with an established clinical research program, located in this state, that has been authorized by the council to participate in a multistate consortium under this chapter.

33-12-103. Creation of council.

(a) There is created the council on emerging behavioral health treatments to administer this chapter and oversee this state's participation in emerging behavioral health treatment research.

(b) The council is composed of eleven (11) members as follows:

(1) The chair of the committee of the house of representatives having jurisdiction over health;

(2) The chair of the health and welfare committee of the senate;

(3) One (1) person appointed by the governor;

(4) One (1) person appointed by the speaker of the house of representatives;

(5) One (1) person appointed by the speaker of the senate;

(6) One (1) non-voting representative from the department of mental health and substance abuse services;

(7) One (1) non-voting representative from the department of health;

(8) Two (2) non-voting representatives of nonprofit advocacy-focused organizations, selected by majority vote of the voting members of the council pursuant to a published selection process; and

(9) Two (2) non-voting representatives of licensed mental health providers, selected by majority vote of the voting members of the council pursuant to a published selection process.

(c) The appointing authorities identified in subdivisions (b)(3)-(5) shall make their respective appointments not later than September 1, 2026. The council shall hold its organizational meeting no later than thirty (30) days after all five (5) voting members have been appointed. The voting members shall complete their selection of non-voting members no later than ninety (90) days after the organizational meeting.

(d) Three (3) voting members constitute a quorum. Official action of the council requires an affirmative vote of a majority of voting members present. Non-voting members may participate in council deliberations, but may not vote.

33-12-104. Participation in multistate ibogaine research consortium.

(a) The council may authorize one (1) or more qualified institutions in this state to participate as members in a multistate ibogaine drug development clinical trial consortium for the purpose of conducting coordinated ibogaine drug development clinical trials.

(b) Authorization under this section must not require the formation of a Tennessee-specific cohort or consortium. A qualified institution in this state may participate individually or jointly with other institutions in this state as a member of an existing multistate consortium.

(c) As a condition of authorization under this section, a participating institution must:

(1) Execute a participation agreement required by the multistate consortium and provide a copy to the council;

(2) Agree to report to the council on a quarterly basis consistent with the requirements of § 33-12-112; and

(3) Ensure that any clinical trial activity conducted in this state complies with applicable state and federal law, including the requirements of § 33-12-117.

(d) The council may provide funding to an institution in this state authorized under this section pursuant to the contracting and disbursement requirements of § 33-12-108.

33-12-105. Coordinating institution.

(a) When two (2) or more institutions in this state participate in a multistate consortium under § 33-12-104, the council shall designate one (1) institution as the coordinating institution for the purposes of contracting with and reporting to the council.

(b) It is the intent of the general assembly that a research institution, preferably an academic medical center with existing clinical trial infrastructure, serve as the coordinating institution where practicable.

(c) The coordinating institution may employ personnel necessary to support the activities of participating institutions in this state under this chapter.

33-12-106. Application for participation authorization.

(a) An institution in this state seeking authorization to participate in a multistate consortium under this chapter must submit an application to the council that includes:

(1) The identity of the institution and its proposed role within the multistate consortium;

(2) Evidence of the institution's eligibility for membership in the multistate consortium, including a letter of intent, invitation, or executed agreement from the consortium;

(3) A description of clinical trial activities proposed to be conducted in this state, including patient recruitment, trial sites, and safety protocols;

(4) Cardiac safety protocols and patient screening criteria consistent with current United States federal food and drug administration (FDA) guidance on ibogaine research;

(5) An aftercare and post-acute treatment support plan;

(6) Documentation of FDA investigational new drug authorization or evidence of a pending application;

(7) A plan to serve populations of this state disproportionately impacted by opioid use disorder, including veterans and rural residents; and

(8) Financial disclosures demonstrating the institution's capacity to manage state funds and fulfill any matching requirements imposed by the council.

(b) The council may waive or modify application requirements under this section upon a finding that the multistate consortium's existing documentation satisfies the relevant requirements.

33-12-107. Council selection.

The council has the sole discretion to authorize one (1) or more participating institutions to participate in a multistate consortium under this chapter and shall designate a coordinating institution pursuant to § 33-12-105. The council shall begin accepting applications pursuant to § 33-12-106 no later than September 1, 2026.

33-12-108. Contract with coordinating institution.

(a) As soon as practicable after authorizing a participating institution under § 33-12-107, the council shall enter into an interagency contract with the coordinating institution to provide funding to implement the authorized ibogaine drug development clinical trials.

(b) The interagency contract under subsection (a) must specify:

(1) The goals and objectives of the proposed ibogaine drug development clinical trials;

(2) The proposed budget;

(3) The timeline for completing the proposed objectives;

(4) The for-profit, nonprofit, or public benefit corporate entities collaborating with the participating institutions in this state in the drug development clinical trials under this chapter or a clinical trial initiated in another state, including any multistate consortiums that the participating institutions in this state are members;

(5) The state's financial interest or monetary return on any FDA-approved medication that is developed by the drug development clinical trials; and

(6) Any other information required by the council.

(c) As soon as practicable after entering into an interagency contract under subsection (a), the council shall report the existence of the contract to the general assembly by sending notice to the chief clerks of the senate and the house of representatives.

(d) The council shall not disburse funds to or for a participating institution under the interagency contract described in subsection (a) until the institution receives and the council verifies the receipt of matching funds from sources other than the state. The council may waive the matching funds requirement of this subsection (d) upon a finding, adopted by majority vote and entered into the council's minutes, that extraordinary circumstances make compliance impracticable.

33-12-109. Investigational new drug application.

A participating institution conducting clinical trial activities in this state under this chapter shall ensure that such activities are conducted pursuant to a valid investigational new drug (IND) application submitted to the United States food and drug administration (FDA) in accordance with 21 CFR Part 312. Where a participating institution joins a multistate consortium that holds or is pursuing a consortium-level IND, compliance with that IND satisfies the requirements of this section. A participating institution that conducts independent clinical trial activities in this state shall submit or ensure the submission of a separate IND application as soon as practicable following authorization under § 33-12-107.

33-12-110. Drug development clinical trial sites.

For purposes of conducting a drug development clinical trial under this chapter, only a participating institution that is a research institution, institution of higher education with clinical research capacity, or a hospital may serve as a trial site in this state.

33-12-111. Funding - Disbursement by council.

(a) The council and participating institutions may solicit and accept gifts, grants, and donations of any kind received from sources other than the state for purposes of funding drug development clinical trials under this chapter.

(b) The council may disburse funds incrementally, based on the completion of clearly defined objectives as negotiated in the contract described in § 33-12-108,

including verifiable documentation demonstrating the efficient expenditure of both state and matching funds.

33-12-112. Reporting requirements.

(a) Each participating institution authorized under this chapter shall prepare and submit to the council quarterly:

(1) A report on the progress of the drug development clinical trials conducted under this chapter; and

(2) A financial status report, including information to verify expenditures of state funds and required matching funds.

(b) The council shall submit a report to the general assembly on the progress of the drug development clinical trials conducted under this chapter no later than December 1 of each year. The report must be submitted to the chief clerk of the senate, the chief clerk of the house of representatives, and the legislative librarian, and may be submitted by electronic means.

33-12-113. Allocation of revenue attributable to the state's financial interest or monetary return.

From any revenue attributable to the state's financial interest or monetary return on any FDA-approved medication that is developed by the drug development clinical trials, there is allocated as follows:

(1) No less than two percent (2%) of the state's financial interest or monetary return to the state as specified in the contract pursuant to § 33-12-108; and

(2) The remainder to the members of the participating institutions in the amounts specified by written agreement of the members.

33-12-114. Use of state revenue.

(a) The state treasurer shall deposit the revenue received under § 33-12-113(1) as follows:

(1) No less than fifty percent (50%) of the revenue must be deposited into the emerging behavioral health treatment innovation fund, created by § 33-12-115; and

(2) The remainder of the revenue must be deposited into the state general fund.

(b) The state treasurer shall develop accounting procedures to implement this section.

(c) The council shall include in its annual report to the general assembly a projection of anticipated revenue attributable to the state's financial interest or monetary return for the succeeding fiscal year to assist the general assembly in appropriations planning.

33-12-115. Creation of innovation fund - Purpose.

(a) There is created within the state general fund a special account to be known as the emerging behavioral health treatment innovation fund.

(b) Unless otherwise specified in this part, moneys realized from the state's financial interest or monetary return on any FDA-approved medication that is developed by the drug development clinical trials pursuant to § 33-12-113(1) and allocated pursuant to § 33-12-114(a)(1) must be deposited in the fund and used only to implement and administer the purposes set forth in subsection (f). The council may accept, by gift or grant to the fund, public or private funds. Any such gift or grant must be deposited into the fund to be expended in accordance with this part.

(c) The state treasurer shall invest moneys in the fund for the benefit of the fund in accordance with § 9-4-603. Interest accruing on investments and deposits of the fund must be credited to and remain part of the fund.

(d) Any unencumbered moneys and any unexpended balance of the fund remaining at the end of a fiscal year do not revert to the general fund, but must be

carried forward until expended in accordance with this part. No part of the fund may be diverted to the general fund or any other public fund.

(e) The council shall administer the fund, and moneys in the fund must be expended and obligated only in accordance with this part and in accordance with appropriations made by the general assembly. All expenditures from the fund are subject to review in the form of an annual report submitted by the council to the general assembly.

(f) The purpose of the emerging behavioral health treatment innovation fund is to:

(1) Fund research by behavioral health providers and institutions into emerging and innovative behavioral health treatments, including ibogaine and other psychedelic-assisted therapies;

(2) Support training and credentialing of clinical and supportive care staff in evidence-based and emerging behavioral health treatment modalities;

(3) Fund grants to nonprofit organizations providing direct behavioral health services, patient navigation, and recovery support to residents of this state;

(4) Support public education and provider outreach regarding emerging behavioral health treatments authorized under this chapter; and

(5) Fund community education and public policy education efforts by nonprofit organizations working to expand access to emerging behavioral health treatments for citizens of this state.

33-12-116 Scope of authorized activity.

This chapter does not authorize the administration of ibogaine to human subjects in this state except in the context of a clinical trial conducted pursuant to a valid United States federal food and drug administration (FDA) investigational new drug authorization in accordance with § 33-12-109.

33-12-117. Medical supervision.

A physician licensed under title 63, chapter 6 or 9, who has prescribed ibogaine for a patient shall supervise the administration of ibogaine at a hospital or other licensed healthcare facility participating in a clinical trial authorized under this chapter to ensure the patient's safety while the patient is undergoing ibogaine treatment.

33-12-118. Administration under federal law.

This chapter does not preclude a physician from administering ibogaine in accordance with federal law.

33-12-119. Waiver authority - Deadline to begin accepting proposals.

If the council, or another entity of state government involved in the administration of this chapter, determines that a waiver or authorization from a federal agency is necessary to implement a provision of this chapter, then the state entity responsible for implementing such provision shall request the waiver or authorization and may delay implementing the provision until the waiver or authorization is granted.

33-12-120. Conflict of interest.

(a) A voting member of the council shall disclose any financial interest in an entity that has applied for or received authorization or funding under this chapter and shall recuse themselves from any deliberation or vote involving such entity.

(b) An entity in which a voting member holds a board position, employment relationship, or ownership interest is not eligible to receive authorization or funding under this chapter during that member's tenure on the council.

(c) Disclosures made under this section must be made in writing and must be included in the council's public meeting minutes.

33-12-121. Exemption from controlled substances liability.

Notwithstanding title 53, chapter 11, a physician, researcher, or institution participating in an ibogaine clinical trial authorized by the council under this chapter is not subject to criminal liability under this state's controlled substances laws solely on the

basis of the possession, administration, or use of ibogaine in furtherance of that participation as long as all activities are conducted in compliance with this chapter, the terms of the council's authorization, and applicable federal law.

SECTION 2. If any provision of this act or its application to any person or circumstance is held invalid, then the invalidity does not affect other provisions or applications of the act that can be given effect without the invalid provision or application, and to that end, the provisions of this act are severable.

SECTION 3. The headings in this act are for reference purposes only and do not constitute a part of the law enacted by this act. However, the Tennessee Code Commission is requested to include the headings in any compilation or publication containing this act.

SECTION 4. This act takes effect July 1, 2026, the public welfare requiring it.

House Finance, Ways, and Means 1

Amendment No. 3 to HB2075

Hicks G
Signature of Sponsor

AMEND Senate Bill No. 2149 House Bill No. 2075*

by deleting all language after the caption and substituting:

BE IT ENACTED BY THE GENERAL ASSEMBLY OF THE STATE OF TENNESSEE:

SECTION 1. Tennessee Code Annotated, Title 53, is amended by adding the following as a new chapter:

53-16-101. Short title.

This chapter is known and may be cited as the "HOPE Treatment Act."

53-16-102. Legislative intent.

It is the intent of the general assembly to encourage Tennessee-based research institutions to participate in federally authorized ibogaine clinical trials and multistate research collaborations addressing opioid use disorder, post-traumatic stress disorder, traumatic brain injury, and other serious conditions.

53-16-103. Chapter definitions.

As used in this chapter:

(1) "Healthcare provider" means an individual who is licensed, registered, certified, authorized, or permitted by the laws of this state to administer health care in the ordinary course of business or practice of a profession;

(2) "Ibogaine" means ibogaine and ibogaine-based therapeutics, including analogs;

(3) "Researcher" means an individual who conducts research or research-related activities as part of a federally authorized clinical trial; and

(4) "Research institution" means a hospital, academic medical center, or institution of higher education with clinical research capacity located in this state.

53-16-104. Authorization for research participation.

(a) Notwithstanding another law to the contrary, a research institution may participate in one (1) or more clinical trials involving ibogaine, whether alone or in participation with a multistate research consortium, as long as all clinical trial activity is conducted in compliance with applicable state and federal law.

(b) Participation in a clinical trial under this section must include compliance with a valid United States food and drug administration investigational new drug (IND) authorization, when such authorization is required by federal law.

(c) A research institution may receive and administer federal, private, or philanthropic funding for purposes of conducting research authorized under this section.

53-16-105. Scope of authorized activity.

This chapter does not authorize the administration of ibogaine except in the context of a clinical trial conducted pursuant to applicable state and federal law.

53-16-106. Medical direction and safety.

(a) Ibogaine may only be administered in this state:

(1) As part of a clinical trial conducted at a hospital or qualified research facility; and

(2) Under the medical direction of a physician licensed in this state.

(b) A research institution that is conducting or participating in a federally authorized clinical trial for ibogaine shall implement appropriate patient screening and safety protocols consistent with federal law, rule, and guidance.

53-16-107. Liability protection.

Notwithstanding chapter 11 of this title, the Tennessee Drug Control Act of 1989, compiled in title 39, chapter 17, part 4, or another law to the contrary, a healthcare provider, researcher, patient, or research institution participating in a clinical trial

involving ibogaine in compliance with this chapter and applicable federal law is not subject to criminal liability under the controlled substance laws of this state solely for conduct that occurs as part of such clinical trial, if such conduct is authorized by federal law.

SECTION 2. If any provision of this act or its application to any person or circumstance is held invalid, then the invalidity does not affect other provisions or applications of the act that can be given effect without the invalid provision or application, and to that end, the provisions of this act are severable.

SECTION 3. The headings in this act are for reference purposes only and do not constitute a part of the law enacted by this act. However, the Tennessee Code Commission is requested to include the headings in any compilation or publication containing this act.

SECTION 4. This act takes effect upon becoming a law, the public welfare requiring it.