PROPOSED AMENDMENT

SB 180 # 7

DIGEST

Neuroplastogen treatments. Adds provisions from SB 173 (as printed January 16, 2026) that would do the following: (1) Allow for certain practitioners to provide neuroplastogen treatment concerning qualified patients with life threatening conditions if certain requirements are met. (2) Allow for research to be conducted on neuroplastogen access. (3) Require reporting of adverse events and annual reporting of patient statistical information concerning the neuroplastogen treatment. (4) Provide for immunity when treating using neuroplastogens.

Page 1, between the enacting clause and line 1, begin a new paragraph and insert:

"SECTION 1. IC 16-18-2-247.5 IS ADDED TO THE INDIANA CODE AS A **NEW** SECTION TO READ AS FOLLOWS [EFFECTIVE JULY 1, 2026]: **Sec. 247.5. "Neuroplastogen", for purposes of IC 16-42-26.7, has the meaning set forth in IC 16-42-26.7-1.**

SECTION 2. IC 16-18-2-288, AS AMENDED BY P.L.96-2014, SECTION 4, IS AMENDED TO READ AS FOLLOWS [EFFECTIVE JULY 1, 2026]: Sec. 288. (a) "Practitioner", for purposes of IC 16-42-19, has the meaning set forth in IC 16-42-19-5.

(b) "Practitioner", for purposes of IC 16-41-14, has the meaning set forth in IC 16-41-14-4.

(c) "Practitioner", for purposes of IC 16-42-21, has the meaning set forth in IC 16-42-21-3.

(d) "Practitioner", for purposes of IC 16-42-22 and IC 16-42-25, has the meaning set forth in IC 16-42-22-4.5.

(e) "Practitioner", for purposes of IC 16-42-26.7, has the meaning set forth in IC 16-42-26.7-2.

SECTION 3. IC 16-18-2-317.4 IS ADDED TO THE INDIANA CODE AS A **NEW** SECTION TO READ AS FOLLOWS [EFFECTIVE JULY 1, 2026]: **Sec. 317.4. "Research institution", for purposes of IC 16-42-26.7, has the meaning set forth in IC 16-42-26.7-3.**".

Page 2, between lines 5 and 6, begin a new paragraph and insert:

"SECTION 6. IC 16-42-26.7 IS ADDED TO THE INDIANA CODE AS A **NEW** CHAPTER TO READ AS FOLLOWS [EFFECTIVE JULY 1, 2026]:

Chapter 26.7. Right to Try Investigational Neuroplastogens

Sec. 1. As used in this chapter, "neuroplastogen" means a drug or compound that:

(1) demonstrates rapid onset neuroplastic effects in humans; and

(2) has successfully completed Phase I of a federal Food and Drug Administration approved clinical trial.

The term includes psilocybin (as defined in IC 12-21-9-2).

Sec. 2. As used in this chapter, "practitioner" means a health professional who:

(1) is licensed and in good standing under IC 25;

(2) has prescriptive authority; and

(3) is acting within the health professional's scope of practice.

Sec. 3. As used in this chapter, "research institution" means an organization that meets all of the following:

(1) Has an academic institution that operates an institutional review board (IRB) that oversees research.

(2) Publishes the results of previous clinical trials in peer reviewed publications.

(3) Has access to a clinical research center and the center's resources, including research dedicated medical staff.

Sec. 4. An individual must meet the following requirements in order to qualify as an eligible patient under this chapter:

(1) Has been diagnosed with a life threatening condition as defined in 21 CFR 312.81 and meets the criteria set forth in 21 U.S.C. 360bbb-0a.

(2) Provides written informed consent to the practitioner for the treatment.

Sec. 5. (a) Notwithstanding IC 35-48, a practitioner may administer or supervise the psychotherapy supported administration of a neuroplastogen to a patient if the following conditions are met:

(1) The practitioner has evaluated the patient, reviewed the patient's medical history, and documented in the patient's medical charts the clinical rationale for the practitioner determining that the patient is qualified and could benefit

from the treatment.

(2) The practitioner has obtained and documented the patient's written informed consent as set forth in subsection (b) for the treatment.

(3) The patient meets the requirements set forth in section 4 of this chapter.

(4) The practitioner takes reasonable steps to ensure patient safety, including structured psychological monitoring and integration services, during the patient's neuroplastogen treatment and recovery.

(5) The neuroplastogen is obtained from a manufacturer or distributor that is registered with the federal Drug Enforcement Agency.

(6) The practitioner notifies the state department in the manner prescribed by the state department not later than thirty (30) days from the initial administration of the neuroplastogen to a patient.

(7) The practitioner submits the report required by section 7 of this chapter.

(b) Written informed consent under subsection (a)(2) must include the following:

(1) An explanation of the currently approved products and treatments for the individual's condition.

(2) An attestation by the individual of the individual's life threatening condition and that the individual concurs with the individual's physician that all currently approved treatments are unlikely to prolong the individual's life or improve the individual's life threatening condition.

(3) A clear identification of the investigational neuroplastogen treatment proposed to be used to treat the individual.

(4) A description of the best and worst outcomes, including the most likely outcome, resulting from use of the investigational treatment of the individual's life threatening condition. The description of outcomes must be based on the treating physician's knowledge of both the investigational neuroplastogen treatment and the individual's life threatening condition.

(5) A statement acknowledging that new, unanticipated, different, or worse symptoms or death may result from the proposed treatment.

(6) A statement that the individual's health insurance may not be obligated to pay for any care or treatment and that the patient may be liable for all expenses of the treatment unless specifically required to do so by contract or law.

(7) A statement that eligibility for hospice care may be withdrawn if the individual begins investigational neuroplastogen treatment and does not meet hospice care eligibility requirements.

(8) A statement that the individual or the individual's legal guardian consents to the investigational neuroplastogen treatment for the life threatening condition.

(c) The state department shall establish a notification procedure described in subsection (a)(6) to be used under this chapter.

Sec. 6. (a) A practitioner, research institution, or clinic may conduct neuroplastogen outcomes access research if the following conditions are met:

(1) Any data collected and maintained in a patient registry that complies with the federal Health Insurance Portability and Accountability Act (HIPAA) and only includes de-identified patient data.

(2) The practitioner or clinic follows any best practice guidelines and protocols that have been issued by the United States Department of Health and Human Services, including:

(A) safety monitoring;

(B) psychotherapy support; and

(C) outcome measures.

(b) The state department may do the following:

(1) Implement Institutional Review Board (IRB) oversight protocols, including protocols for streamlined reporting of data under this chapter.

(2) Collaborate with research institutions in the development of standards and protocols to be used for research conducted under this chapter.

(3) Establish a registry to maintain data collected under this chapter.

(4) Adopt rules under IC 4-22-2 to implement this chapter, including rules concerning the following:

(A) Safety standards.

(B) Standardized informed consent forms.

(C) Data elements for inclusion in a registry.

(D) Adverse event reporting.

(E) Staff qualifications for psychotherapy support.

(F) Standardized notification forms for section 4 of this chapter.

(G) Report formatting.

Sec. 7. (a) Before February 1 of each year, a practitioner who performs neuroplastogen treatment under this chapter shall report the following information concerning the previous calendar year to the state department:

(1) The number of patients for whom the practitioner has conducted neuroplastogen treatment.

(2) Each neuroplastogen used and the typical dosage range.

(3) Any adverse event (as defined in 21 CFR 312.32(a)).

The report may not include patient identifying information.

(b) Before May 1 of each year, the state department shall aggregate and publish on the state department's website de-identified statistics from the reports submitted under subsection (a).

Sec. 8. Nothing in this chapter may be construed to do any of the following:

(1) Allow nonmedical use of neuroplastogens.

(2) Supersede federal law or regulation.

(3) Reschedule a controlled substance.

(4) Create a fiscal burden on the state.

(5) Require a practitioner, clinic, research institution, or other person to participate in providing treatment under this chapter.

(6) Mandate insurance coverage for treatment under this chapter.

Sec. 9. A practitioner, eligible facility (as defined in IC 16-42-26.5-1), research institution, or other person participating in providing treatment that complies with the requirements of this chapter is immune from criminal or civil liability.".

Page 8, between lines 32 and 33, begin a new paragraph and insert:

"SECTION 17. IC 34-30-2.1-256.5 IS ADDED TO THE INDIANA CODE AS A **NEW** SECTION TO READ AS FOLLOWS [EFFECTIVE JULY 1, 2026]: **Sec. 256.5. IC 16-42-26.7-9 (Concerning practitioners, eligible facilities, research institutions, and other persons participating in providing neuroplastogen treatment).**".

Renumber all SECTIONS consecutively.

(Reference is to SB 180 as printed January 16, 2026.)