

SENATE BILL No. 237

DIGEST OF INTRODUCED BILL

Citations Affected: IC 16-18-2; IC 16-42-26.5.

Synopsis: Individualized investigational treatment. Allows: (1) a manufacturer to provide; and (2) a patient to receive; individualized investigational treatment if certain conditions are met. Sets forth disclosures.

Effective: July 1, 2025.

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January 9, 2025, read first time and referred to Committee on Health and Provider Services.



First Regular Session of the 124th General Assembly (2025)

PRINTING CODE. Amendments: Whenever an existing statute (or a section of the Indiana Constitution) is being amended, the text of the existing provision will appear in this style type, additions will appear in **this style type**, and deletions will appear in ~~this style type~~.

Additions: Whenever a new statutory provision is being enacted (or a new constitutional provision adopted), the text of the new provision will appear in **this style type**. Also, the word **NEW** will appear in that style type in the introductory clause of each SECTION that adds a new provision to the Indiana Code or the Indiana Constitution.

Conflict reconciliation: Text in a statute in *this style type* or ~~this style type~~ reconciles conflicts between statutes enacted by the 2024 Regular Session of the General Assembly.

SENATE BILL No. 237

A BILL FOR AN ACT to amend the Indiana Code concerning health.

Be it enacted by the General Assembly of the State of Indiana:

1 SECTION 1. IC 16-18-2-106.7 IS ADDED TO THE INDIANA
2 CODE AS A **NEW** SECTION TO READ AS FOLLOWS
3 [EFFECTIVE JULY 1, 2025]: **Sec. 106.7. "Eligible facility", for**
4 **purposes of IC 16-42-26.5, has the meaning set forth in**
5 **IC 16-42-26.5-1.**

6 SECTION 2. IC 16-18-2-188.6 IS ADDED TO THE INDIANA
7 CODE AS A **NEW** SECTION TO READ AS FOLLOWS
8 [EFFECTIVE JULY 1, 2025]: **Sec. 188.6. "Individualized**
9 **investigational treatment", for purposes of IC 16-42-26.5, has the**
10 **meaning set forth in IC 16-42-26.5-2.**

11 SECTION 3. IC 16-18-2-204.2 IS ADDED TO THE INDIANA
12 CODE AS A **NEW** SECTION TO READ AS FOLLOWS
13 [EFFECTIVE JULY 1, 2025]: **Sec. 204.2. "Life threatening or**
14 **severely debilitating disease", for purposes of IC 16-42-26.5, has**
15 **the meaning set forth in IC 16-42-26.5-3.**

16 SECTION 4. IC 16-42-26.5 IS ADDED TO THE INDIANA CODE
17 AS A **NEW** CHAPTER TO READ AS FOLLOWS [EFFECTIVE



1 JULY 1, 2025]:

2 **Chapter 26.5. Individualized Investigational Treatment**

3 **Sec. 1. As used in this chapter, "eligible facility" means an entity**
4 **that operates under the Federalwide Assurance for the Protection**
5 **of Human Subjects in accordance with 42 U.S.C. 289(a) and 45**
6 **CFR 46.**

7 **Sec. 2. As used in this chapter, "individualized investigational**
8 **treatment" means a drug, biological product, or device that is**
9 **unique to and produced exclusively for use by an individual**
10 **patient, based on the individual's own genetic profile. The term**
11 **includes individualized gene therapy, antisense oligonucleotides**
12 **(ASO), and individualized neoantigen vaccines.**

13 **Sec. 3. As used in this chapter, "life threatening or severely**
14 **debilitating disease" has the meaning described in 21 CFR 312.81.**

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

17 (1) **Has been diagnosed with a life threatening or severely**
18 **debilitating disease, as attested by the individual's physician.**

19 (2) **Has considered other treatment options currently**
20 **approved by the United States Food and Drug**
21 **Administration.**

22 (3) **Has received a recommendation from the individual's**
23 **physician for an individualized investigational treatment**
24 **based on analysis of the patient's genomic sequence, human**
25 **chromosomes, deoxyribonucleic acid, ribonucleic acid, genes,**
26 **gene products, or metabolites.**

27 (4) **Has given written informed consent as set forth in section**
28 **5 of this chapter for the use of the individualized**
29 **investigational treatment.**

30 (5) **Has documentation from the individual's physician that**
31 **the individual meets the requirements of this section.**

32 **Sec. 5. (a) Written informed consent as required under section**
33 **4(4) of this chapter must include the following:**

34 (1) **An explanation of the currently approved products and**
35 **treatments for the individual's disease or condition.**

36 (2) **An attestation by the individual that the individual**
37 **concurs with the individual's physician that all currently**
38 **approved treatments are unlikely to prolong the individual's**
39 **life.**

40 (3) **A clear identification of the specific individualized**
41 **investigational treatment proposed to be used to treat the**
42 **individual.**



- 1 **(4) A description of the best and worst outcomes, including**
 2 **the most likely outcome, resulting from use of the**
 3 **individualized investigational treatment of the individual's life**
 4 **threatening or severely debilitating illness.**
 5 **(5) A statement acknowledging that new, unanticipated,**
 6 **different, or worse symptoms or death may result from the**
 7 **proposed treatment.**
 8 **(6) A statement that the individual's health insurance is not**
 9 **obligated to pay for any care or treatment and that the patient**
 10 **is liable for all expenses of the treatment unless specifically**
 11 **required to do so by contract or law.**
 12 **(7) A statement that eligibility for hospice care may be**
 13 **withdrawn if the individual begins individualized**
 14 **investigational treatment and does not meet hospice care**
 15 **eligibility requirements.**
 16 **(8) A statement that the individual or the individual's legal**
 17 **guardian consents to the individualized investigational**
 18 **treatment for the life threatening or severely debilitating**
 19 **illness.**
 20 **(b) The description of outcomes described in subsection (a)(4)**
 21 **must be based on the treating physician's knowledge of both the**
 22 **individualized investigational treatment and the individual's life**
 23 **threatening or severely debilitating disease.**
 24 **Sec. 6. (a) A manufacturer operating within an eligible facility**
 25 **and in accordance with federal law may make available to an**
 26 **eligible patient the manufacturer's individualized investigational**
 27 **treatment from an eligible facility.**
 28 **(b) Nothing in this chapter may be construed to require a**
 29 **manufacturer of an individualized investigational treatment to**
 30 **make the individualized investigational treatment available to an**
 31 **eligible patient.**
 32 **(c) A manufacturer of an individualized investigational**
 33 **treatment may do any of the following:**
 34 **(1) Provide an individualized investigational treatment to an**
 35 **eligible patient without receiving compensation.**
 36 **(2) Require an eligible patient to pay the costs of or associated**
 37 **with the manufacture of the individualized investigational**
 38 **treatment.**
 39 **(d) This chapter does not create a cause of action against a**
 40 **manufacturer of an individualized investigational treatment for**
 41 **any harm to an eligible patient resulting from use of an**
 42 **individualized investigational treatment.**



1 **Sec. 7. If an eligible patient dies while being treated with an**
2 **individualized investigational treatment, the eligible patient's heirs**
3 **are not liable for any outstanding debt related to the individualized**
4 **investigational treatment.**

5 **Sec. 8. The medical licensing board of Indiana may not revoke,**
6 **suspend, fail to renew, or take any other disciplinary action against**
7 **a physician licensed under IC 25-22.5 based solely on the**
8 **physician's recommendations to an eligible patient concerning**
9 **access to or treatment with an individualized investigational**
10 **treatment.**

11 **Sec. 9. This chapter does not affect coverage for clinical trials**
12 **set forth in IC 5-10-8-15, IC 12-15-5-9.2, IC 27-8-25, or**
13 **IC 27-13-7-20.2.**

