

GENERAL ASSEMBLY OF NORTH CAROLINA
SESSION 2023

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HOUSE BILL 1029
PROPOSED COMMITTEE SUBSTITUTE H1029-PCS10575-SHa-53

Short Title: Right To Try Individualized Treatments.

(Public)

Sponsors:

Referred to:

May 7, 2024

1 A BILL TO BE ENTITLED
2 AN ACT TO PROVIDE ELIGIBLE PATIENTS THE RIGHT TO TRY INDIVIDUALIZED
3 INVESTIGATIONAL DRUGS, BIOLOGICAL PRODUCTS, AND DEVICES TO TREAT
4 LIFE-THREATENING OR SEVERELY DEBILITATING ILLNESSES AND TO
5 APPROPRIATE FUNDS TO THE DEPARTMENT OF HEALTH AND HUMAN
6 SERVICES.

7 The General Assembly of North Carolina enacts:

8 **SECTION 1.** Article 23A of Chapter 90 of the General Statutes is amended by
9 adding a new Part to read:

10 "Part 3. Individualized Treatments.

11 **"§ 90-325.30. Definitions.**

12 The following definitions apply in this Part, unless the context requires otherwise:

- 13 (1) Eligible facility. – Any institution operating under Federalwide Assurance for
14 the Protection of Human Subjects in accordance with 45 C.F.R. § 46 and 42
15 U.S.C. § 289(a).
- 16 (2) Eligible patient. – An individual who meets all of the following criteria:
- 17 a. Has a life-threatening or severely debilitating illness, attested to by a
18 treating physician.
- 19 b. Has, in consultation with a treating physician, considered all other
20 treatment options currently approved by the United States Food and
21 Drug Administration.
- 22 c. Has received a recommendation from the treating physician for use of
23 an individualized investigational drug, biological product, or device
24 for treatment of the life-threatening or severely debilitating illness.
- 25 d. Has given informed consent in writing to use of the individualized
26 investigational drug, biological product, or device for treatment of the
27 life-threatening or severely debilitating illness or, if the individual is a
28 minor or is otherwise incapable of providing informed consent, the
29 parent or legal guardian has given informed consent in writing to use
30 of the individualized investigational drug, biological product, or
31 device.
- 32 e. Has documentation from the treating physician that the individual
33 meets all of the criteria for this definition. This documentation shall
34 include an attestation from the treating physician that the treating
35 physician was consulted in the creation of the written, informed
36 consent required under this Part.



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- 1 (3) Individualized investigational drug, biological product, or device. – A drug,
2 biological product, or device that is unique and produced exclusively for use
3 for an individual patient, based on their own genetic profile, including
4 individualized gene therapy antisense oligonucleotides and individualized
5 neoantigen vaccines.
- 6 (4) Institution. – As defined in 45 C.F.R. § 46.102(f).
- 7 (5) Life-threatening illness. – Diseases or conditions where the likelihood of death
8 is high unless the course of the disease is interrupted; and diseases or
9 conditions with potentially fatal outcomes where the end point of clinical trial
10 analysis is survival.
- 11 (6) Severely debilitating illness. – Diseases or conditions that cause major
12 irreversible morbidity.
- 13 (7) Written, informed consent. – A written document that is signed by an eligible
14 patient; or if the patient is a minor, by a parent or legal guardian; or if the
15 patient is incapacitated, by a designated health care agent pursuant to a health
16 care power of attorney, that at a minimum includes all of the following:
- 17 a. An explanation of the currently approved products and treatments for
18 the eligible patient's life-threatening or severely debilitating illness.
- 19 b. An attestation that the eligible patient concurs with the treating
20 physician in believing that all currently approved treatments are
21 unlikely to prolong the eligible patient's life.
- 22 c. Clear identification of the specific individualized investigational drug,
23 biological product, or device proposed for treatment of the eligible
24 patient's terminal illness.
- 25 d. A description of the potentially best and worst outcomes resulting
26 from use of the individualized investigational drug, biological product,
27 or device to treat the eligible patient's life-threatening or severely
28 debilitating illness, along with a realistic description of the most likely
29 outcome. The description shall be based on the treating physician's
30 knowledge of the proposed treatment in conjunction with an
31 awareness of the eligible patient's life-threatening or severely
32 debilitating illness and shall include a statement acknowledging that
33 new, unanticipated, different, or worse symptoms might result from,
34 and that death could be hastened by, the proposed treatment.
- 35 e. A statement that eligibility for hospice care may be withdrawn if the
36 eligible patient begins treatment of the life-threatening or severely
37 debilitating illness with an individualized investigational drug,
38 biological product, or device and that hospice care may be reinstated
39 if such treatment ends and the eligible patient meets hospice eligibility
40 requirements.
- 41 f. A statement that the eligible patient's health benefit plan or third-party
42 administrator and provider are not obligated to pay for any care or
43 treatments consequent to the use of the individualized investigational
44 drug, biological product, or device, unless specifically required to do
45 so by law or contract.
- 46 g. A statement that the eligible patient understands that he or she is liable
47 for all expenses consequent to the use of the individualized
48 investigational drug, biological product, or device and that this
49 liability extends to the eligible patient's estate, unless a contract
50 between the patient and the manufacturer of the drug, biological
51 product, or device states otherwise.

1 h. A statement that the eligible patient or, for an eligible patient who is a
2 minor or lacks capacity to provide informed consent, that the parent or
3 legal guardian consents to the use of the individualized investigational
4 drug, biological product, or device for treatment of the life-threatening
5 or severely debilitating illness.

6 **"§ 90-325.31. Authorized access to and use of individualized investigational drugs,**
7 **biological products, or devices.**

8 (a) A manufacturer operating within an eligible facility and in accordance with all
9 applicable federal law may make available to an eligible patient, and an eligible patient may
10 request, the manufacturer's individualized investigational drug, biological product, or device
11 from an eligible facility or manufacturer operating within an eligible facility. However, nothing
12 in this Part shall be construed to require a manufacturer of an individualized investigational drug,
13 biological product, or device to make such individualized investigational drug, biological
14 product, or device available to an eligible patient.

15 (b) A manufacturer of an individualized investigational drug, biological product, or
16 device may provide the individualized investigational drug, biological product, or device to an
17 eligible patient without receiving compensation or may require the eligible patient to pay the
18 costs of, or the costs associated with, the manufacture of the individualized investigational drug,
19 biological product, or device.

20 **"§ 90-325.32. No liability to heirs for outstanding debt related to use of individualized**
21 **investigational drugs, biological products, or devices.**

22 If an eligible patient dies while being treated with an individualized investigational drug,
23 biological product, or device, the eligible patient's heirs are not liable for any outstanding debt
24 related to the treatment, including any costs attributed to lack of insurance coverage for the
25 treatment.

26 **"§ 90-325.33. Sanctions against health care providers prohibited.**

27 (a) A licensing board shall not revoke, fail to renew, suspend, or take any other
28 disciplinary action against a health care provider licensed under this Chapter, based solely on the
29 health care provider's recommendations to an eligible patient regarding access to or treatment
30 with an individualized investigational drug, biological product, or device.

31 (b) An entity responsible for Medicare certification shall not take action against a health
32 care provider's Medicare certification based solely on the health care provider's recommendation
33 that a patient have access to an individualized investigational drug, biological product, or device.

34 **"§ 90-325.34. Prohibited conduct by State officials.**

35 No official, employee, or agent of this State shall block or attempt to block an eligible
36 patient's access to an individualized investigational drug, biological product, or device.
37 Counseling, advice, or a recommendation consistent with medical standards of care from a
38 licensed health care provider, or denial of coverage by the Medicaid program authorized under
39 Part 6, Article 2, of Chapter 108A of the General Statutes, do not constitute a violation of this
40 section.

41 **"§ 90-325.35. No private right of action against manufacturers of individualized**
42 **investigational drugs, biological products, or devices.**

43 No private right of action may be brought against a manufacturer of an individualized
44 investigational drug, biological product, or device, or against any other person or entity involved
45 in the care of an eligible patient using an individualized investigational drug, biological product,
46 or device, for any harm caused to the eligible patient resulting from use of the individualized
47 investigational drug, biological product, or device as long as the manufacturer or other person or
48 entity has made a good-faith effort to comply with the provisions of this Part and has exercised
49 reasonable care in actions undertaken pursuant to this Part.

50 **"§ 90-325.36. Insurance coverage of clinical trials.**

1 Nothing in this Part shall be construed to affect a health benefit plan's obligation to provide
2 coverage for an insured's participation in a clinical trial pursuant to G.S. 58-3-255."

3 **SECTION 2.** There is appropriated from the General Fund to the Department of
4 Health and Human Services the nonrecurring sum of fifty thousand dollars (\$50,000) for the
5 2024-2025 fiscal year to implement the provisions of this act.

6 **SECTION 3.** Section 1 of this act becomes effective October 1, 2024. Section 2 of
7 this act becomes effective July 1, 2024. The remainder of this act is effective when it becomes
8 law.