GENERAL ASSEMBLY OF NORTH CAROLINA
SESSION 2023

SESSION LAW 2024-36
HOUSE BILL 98

AN ACT TO PROVIDE ELIGIBLE PATIENTS THE RIGHT TO TRY INDIVIDUALIZED INVESTIGATIONAL DRUGS, BIOLOGICAL PRODUCTS, AND DEVICES TO TREAT LIFE-THREATENING OR SEVERELY DEBILITATING ILLNESSES.

The General Assembly of North Carolina enacts:

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

"Part 3. Individualized Treatments.

"**§ 90-325.30. Definitions.**

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

(1) Eligible facility. – Any institution operating under Federalwide Assurance for the Protection of Human Subjects in accordance with 45 C.F.R. § 46 and 42 U.S.C. § 289(a).

(2) Eligible patient. – An individual who meets all of the following criteria:

a. Has a life-threatening or severely debilitating illness, attested to by a treating physician.

b. Has, in consultation with a treating physician, considered all other treatment options currently approved by the United States Food and Drug Administration.

c. Has received a recommendation from the treating physician for use of an individualized investigational drug, biological product, or device for treatment of the life-threatening or severely debilitating illness.

d. Has given informed consent in writing to use of the individualized investigational drug, biological product, or device for treatment of the life-threatening or severely debilitating illness or, if the individual is a minor or is otherwise incapable of providing informed consent, the parent or legal guardian has given informed consent in writing to use of the individualized investigational drug, biological product, or device.

e. Has documentation from the treating physician that the individual meets all of the criteria for this definition. This documentation shall include an attestation from the treating physician that the treating physician was consulted in the creation of the written, informed consent required under this Part.

(3) Individualized investigational drug, biological product, or device. – A drug, biological product, or device that is unique and produced exclusively for use for an individual patient, based on their own genetic profile, including individualized gene therapy antisense oligonucleotides and individualized neoantigen vaccines.

(4) Institution. – As defined in 45 C.F.R. § 46.102(f).

(5) Life-threatening or severely debilitating illness. – As those terms are defined in 21 C.F.R. § 312.81.

(6) Written, informed consent. – A written document that is signed by an eligible patient; or if the patient is a minor, by a parent or legal guardian; or if the patient is incapacitated, by a designated health care agent pursuant to a health care power of attorney, that at a minimum includes all of the following:

a. An explanation of the currently approved products and treatments for the eligible patient's life-threatening or severely debilitating illness.

b. An attestation that the eligible patient concurs with the treating physician in believing that all currently approved treatments are unlikely to prolong the eligible patient's life.

c. Clear identification of the specific individualized investigational drug, biological product, or device proposed for treatment of the eligible patient's terminal illness.

d. A description of the potentially best and worst outcomes resulting from use of the individualized investigational drug, biological product, or device to treat the eligible patient's life-threatening or severely debilitating illness, along with a realistic description of the most likely outcome. The description shall be based on the treating physician's knowledge of the proposed treatment in conjunction with an awareness of the eligible patient's life-threatening or severely debilitating illness and shall include a statement acknowledging that new, unanticipated, different, or worse symptoms might result from, and that death could be hastened by, the proposed treatment.

e. A statement that eligibility for hospice care may be withdrawn if the eligible patient begins treatment of the life-threatening or severely debilitating illness with an individualized investigational drug, biological product, or device and that hospice care may be reinstated if such treatment ends and the eligible patient meets hospice eligibility requirements.

f. A statement that the eligible patient's health benefit plan or third-party administrator and provider are not obligated to pay for any care or treatments consequent to the use of the individualized investigational drug, biological product, or device, unless specifically required to do so by law or contract.

g. A statement that the eligible patient understands that he or she is liable for all expenses consequent to the use of the individualized investigational drug, biological product, or device and that this liability extends to the eligible patient's estate, unless a contract between the patient and the manufacturer of the drug, biological product, or device states otherwise.

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

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

(a) A manufacturer operating within an eligible facility and in accordance with all applicable federal law may make available to an eligible patient, and an eligible patient may request, the manufacturer's individualized investigational drug, biological product, or device

from an eligible facility or manufacturer operating within an eligible facility. However, nothing in this Part shall be construed to require a manufacturer of an individualized investigational drug, biological product, or device to make such individualized investigational drug, biological product, or device available to an eligible patient.

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

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

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

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

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

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

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

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

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

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

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

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

SECTION 2. Section 1 of this act becomes effective October 1, 2024. The remainder of this act is effective when it becomes law.

In the General Assembly read three times and ratified this the 28th day of June, 2024.

s/ Phil Berger
President Pro Tempore of the Senate

s/ Tim Moore
Speaker of the House of Representatives

s/ Roy Cooper
Governor

Approved 4:51 p.m. this 8th day of July, 2024