This Bill Analysis reflects the contents of the bill as it was presented in committee.

HOUSE BILL 1029: Right To Try Individualized Treatments.

2023-2024 General Assembly

Committee:	House Health. If favorable, re-refer to Appropriations. If favorable, re-refer to Rules, Calendar, and Operations of the House	**Date:**	June 11, 2024
Introduced by:	Reps. Chesser, Blackwell, Potts, Reeder	**Prepared by:**	Theresa Matula Committee Staff
Analysis of:	PCS to First Edition H1029-CSSHa-53		

OVERVIEW: ***House Bill 1029 would allow eligible patients with life-threatening or severely debilitating illnesses the right to try individualized investigational drugs, biological products, and devices. This portion of the bill would become effective October 1, 2024.***

The bill also appropriates $50,000 to the Department of Health and Human Services for the 2024-2025 fiscal year for implementation. The appropriation section of the bill would become effective July 1, 2024.

The PCS adds definitions for "life-threatening illness" and "severely debilitating illness" which are consistent with the definitions currently found in 21 C.F.R §312.81; and provides that denial of coverage by the Medicaid program does not constitute prohibited conduct by State officials.

CURRENT LAW: S.L. 2015-137 (HB 652) created Article 23A (Right to Try Act), Chapter 90 of the General Statutes, which established a process for *terminally ill eligible patients* to obtain access to investigational drugs, biological products, and devices when various criteria are met. G.S. 90-325.1(2) provides the following definition of *Investigational drug, biological product, or device*. – A drug, biological product, or device that has successfully completed Phase I of a clinical trial but has not yet been approved for general use by the United States Food and Drug Administration and remains under investigation in a clinical trial approved by the United States Food and Drug Administration."

S.L. 2019-70 (HB 934) labeled the initial language from S.L. 2015-137 as "Part 1. Experimental Treatments" and created "Part 2. Investigational Adult Stem Cell Treatments" to authorize access to and use of investigational adult stem cell treatments for patients with certain severe chronic diseases.

BILL ANALYSIS: Section 1 of House Bill 1029 would create "Part 3. Individualized Treatments" under Article 23A of Chapter 90 of the General Statutes to allow an eligible patient access to an individualized investigational drug, biological product, or device.

The bill contains the elements outlined below.

- Creates a definitions section (G.S. 90-325.30) containing definitions for: "eligible facility;" "eligible patient;" "individualized investigational drug, biological product, or device;" "institution;" "life-threatening or severely debilitating illness;" and "written, informed consent." Information on select definitions is provided below.

- *Eligible facility* – An 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).
- *Eligible patient* – Must meet all of the following criteria: an individual with a physician-attested life-threatening or severely debilitating illness; has considered all FDA treatment options in consultation with a treating physician; received a recommendation from the treating physician for use of the individualized investigational drug, biological product, or device; has given informed consent in writing; and has documentation from the treating physician that the individual meets all of the criteria.
- *Individualized investigational drug, biological product, or device* - A drug, biological product, or device that is unique and produced exclusively for an individual patient based on their own genetic profile, including individualized gene therapy antisense oligonucleotides and individualized neoantigen vaccines.
- *Life-threatening or severely debilitation illness* – As the term is defined in 21 C.F.R. §312.81. Life-threatening means: "(1) Diseases or conditions where the likelihood of death is high unless the course of the disease is interrupted; and (2) Diseases or conditions with potentially fatal outcomes, where the end point of clinical trial analysis is survival." Severely debilitating means "diseases or conditions that cause major irreversible morbidity."

- Authorizes access to and use of individualized investigational drugs, biological products, or devices by providing that a manufacturer operating within an eligible facility and in accordance with federal law, may make, but is not required to make, the manufacturer's product available to an eligible patient with or without compensation. (G.S. 90-325.31)
- Prohibits liability for the eligible patient's heirs for outstanding debt related to the use of the individualized investigational drug, biological product, or device if the eligible patient dies while being treated. (G.S. 90-325.32)
- Prohibits sanctions (revocation, failure to renew, suspension, or other disciplinary action) against a health care provider based solely on the provider's recommendation to an eligible patient related to the individualized investigational drug, biological product, or device. (G.S. 90-325.33)
- Prohibits an official, employee, or agent of the State from blocking access to an individualized investigational drug, biological product, or device. However, counseling, advice, or recommendations consistent with medical standards of care from a licensed health care provider, or denial of coverage by the Medicaid program is not a violation of the section on prohibited conduct by State officials. (G.S. 90-325.34)
- Prohibits a private right of action against manufacturers of individualized investigational drugs, biological products, or devices resulting from use, if the manufacturer, person, or entity made a good-faith effort to comply with the provisions of this Part and exercised reasonable care. (G.S. 90-325.35)
- A health benefit plan is not required to cover an insured's participation in a clinical trial. (G.S. 90-325.26)

Section 2 of the bill appropriates $50,000 from the General Fund to the Department of Health and Human Services, for the 2024-2025 fiscal year to implement the act.

EFFECTIVE DATE: The right to try portion of the bill would become effective October 1, 2024, the appropriation section would become effective July 1, 2024, and the remainder would become effective when it becomes law.