



HOUSE BILL 934: Right to Try Adult Stem Cell Treatments.

2019-2020 General Assembly

Committee:		Date:	December 10, 2019
Introduced by:		Prepared by:	Jason Moran-Bates Staff Attorney
Analysis of:	S.L. 2019-70		

OVERVIEW: *Session Law 2019-70 allows patients with chronic or terminal diseases to receive adult stem cell treatment that is in clinical trials on humans, but has not yet been approved by the Food and Drug Administration. It also makes conforming changes to the existing Right to Try Act.*

This became effective December 1, 2019, and applies to acts committed on or after that date.

CURRENT LAW: Under current law, individuals with terminal illnesses may receive treatment that includes investigational drugs, biological products, and devices.

BILL ANALYSIS:

S.L. 2019-70 allows patients with certain severe chronic or terminal illnesses to use investigational adult stem cell treatments for those diseases.

- 90-325.11 creates definitions for "adult stem cell," "clinical trial," "investigational adult stem cell treatment," "eligible patient," "severe chronic disease," "terminal illness," and "written informed consent."
- 90-325.12 allows eligible patients with chronic or terminal illnesses to receive adult stem cell treatment that is in clinical trials on humans, but has not yet been approved by the Food and Drug Administration, provided that treatment meets all of the following criteria:
 - It is administered by a licensed physician.
 - It is overseen by an institutional review board.
 - It is provided an accredited medical school, a facility affiliated with an accredited medical school, or any facility approved by an institutional review board.
- 90-325.13 requires institutional review boards to (i) be affiliated with accredited medical schools or licensed hospitals, (ii) keep records of all patients who receive adult stem cell treatment, and (iii) submit an annual report to the North Carolina Medical Board. The Board has the power to adopt rules to regulate institutional review boards.
- 90-325.14 makes it a Class A1 misdemeanor to knowingly offer to buy, offer to sell, acquire, receive, sell, or otherwise transfer adult stem cells for valuable consideration. Reimbursement of expenses and usual medical fees and offering consideration for adult stem cells used in otherwise lawful research or research that is approved and overseen by an institutional review board is not be unlawful.

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- 90-325.15 prohibits the Board from sanctioning physicians based on their recommendation that a patient have access to adult stem cell treatment. Entities responsible for Medicare certification are also be prohibited from taking action against physicians based on their recommendation that a patient have access to adult stem cell treatment.
- 90-325.16 prohibits State officials from interfering with eligible patients' access to adult stem cell treatment.
- 90-325.17 clarifies that health insurance is not required to provide coverage for adult stem cell treatment.

The act makes conforming changes to the Right to try Act.

EFFECTIVE DATE: This became effective December 1, 2019, and applies to acts committed on or after that date.