



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

2019-2020 General Assembly

Committee: Senate Rules and Operations of the Senate	Date: June 17, 2019
Introduced by: Reps. Blackwell, Lambeth, Murphy, Reives	Prepared by: Jason Moran-Bates
Analysis of: Third Edition	Staff Attorney

OVERVIEW: *House Bill 934 would allow 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.*

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

BILL ANALYSIS:

The bill would allow patients with certain severe chronic or terminal illnesses to use investigational adult stem cell treatments for those diseases.

- 90-325.11 would create 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 would allow 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, and any facility approved by an institutional review board.
- 90-325.13 would require 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 would have the power to adopt rules to regulate institutional review boards.
- 90-325.14 would make 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 would not be unlawful.
- 90-325.15 would prohibit the Board from sanctioning physicians based on their recommendation that a patient have access to adult stem cell treatment. Entities responsible for Medicare certification would also be prohibited from taking action against physicians based on their recommendation that a patient have access to adult stem cell treatment.

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- 90-325.16 would prohibit State officials from interfering with eligible patients' access to adult stem cell treatment.
- 90-325.17 would clarify that health insurance is not required to provide coverage for adult stem cell treatment.

The bill would also make technical changes to G.S. 90-325 through 90-325.7.

EFFECTIVE DATE: This act would be effective December 1, 2019, and would apply to acts committed on or after that date.