

THE FLORIDA SENATE
2025 SUMMARY OF LEGISLATION PASSED
Committee on Health Policy

CS/CS/SB 1768 — Stem Cell Therapy

by Rules Committee; Health Policy Committee; and Senator Trumbull

The bill authorizes licensed physicians (medical doctors and doctors of osteopathic medicine) to perform stem cell therapies that have not been approved by the U.S. Food and Drug Administration (FDA), specifically for orthopedic conditions, wound care, or pain management. It sets forth standards for the retrieval, manufacture, storage, and use of stem cells, ensuring that stem cells used in these therapies are obtained from facilities that meet rigorous regulatory and accreditation requirements. The facilities must be registered with the FDA and certified or accredited by the National Marrow Donor Program, the World Marrow Donor Association, the Association for the Advancement of Blood and Biotherapies, or the American Association of Tissue Banks. These facilities are also required to provide physicians with a post-thaw viability analysis report before the stem cells are used in treatments.

Before administering any stem cell therapy, the bill requires physicians to obtain signed informed consent from patients. This consent must clearly inform the patient of the nature and purpose of the proposed treatment, as well as the fact that the stem cell therapy has not been approved by the FDA. The patient must also be made aware of the anticipated results of the therapy, the recognized risks, complications, and potential benefits associated with the treatment, and alternative options, including non-treatment. Physicians are also required to encourage patients to consult with their primary care provider before proceeding with any stem cell therapy.

In addition, the bill mandates that physicians must include a specific notice in any advertisement for stem cell therapies that are not FDA-approved. This notice must be clearly legible and in a type size no smaller than the largest font size used in the advertisement.

The bill establishes criminal penalties and disciplinary actions for violations. Any physician who willfully performs or participates in treatments using human cells or tissues derived from a fetus or an embryo after an abortion commits a felony of the third degree. Additionally, physicians who are involved in the sale, manufacture, or distribution of computer products created using human cells, tissues, or cellular or tissue-based products in violation of the bill commit a felony of the third degree. These felonies are punishable as provided in ss. 775.082, 775.083, or 775.084, F.S.

Beyond criminal penalties, any violation of the provisions of the bill may subject the physician to disciplinary action by the Board of Medicine or the Board of Osteopathic Medicine, as applicable. The bill authorizes the Boards to adopt rules necessary to implement its provisions.

If approved by the Governor, or allowed to become law without the Governor's signature, these provisions take effect July 1, 2025.

Vote: Senate 37-0; House 112-0