The Florida Senate

BILL ANALYSIS AND FISCAL IMPACT STATEMENT

(This document is based on the provisions contained in the legislation as of the latest date listed below.)

Prepared By: The Professional Staff of the Committee on Health Policy

BILL:	SB 1768
INTRODUCER:	Senator Trumbull
SUBJECT:	Stem Cell Therapy
DATE:	March 31, 2025
REVISED:	

	ANALYST	STAFF DIRECTOR	REFERENCE	ACTION
1.	Smith	Brown	HP	**Pre-meeting**
2.			AHS	
3.			RC	

I. Summary:

SB 1768 authorizes 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) when used for orthopedic conditions, wound care, or pain management. The bill establishes standards for the manufacturing and storage of stem cells and requires a physician to obtain a signed informed consent form from a patient before administering any such therapy.

The bill also requires that written notice be provided to a patient prior to the performance of stem cell therapy, disclosing that the therapy is not approved by the FDA. This disclosure must also be included in any advertisement for the therapy. The bill directs the Department of Health (DOH) to adopt rules to implement the bill.

The bill provides an effective date of July 1, 2025.

II. Present Situation:

Overview of Stem Cells and Stem Cell Therapy

Stem cells are undifferentiated cells with the unique ability to develop into specialized cell types and to divide indefinitely under certain conditions.[1] They are broadly classified as either embryonic or adult (somatic) stem cells. Embryonic stem cells, derived from early-stage embryos, are pluripotent and capable of differentiating into nearly all cell types in the human body. Adult stem cells are more limited in scope and typically generate only cell types consistent with their tissue of origin.

[1] Department of Health, Senate Bill 1617 *Legislative Analysis* (Mar. 19, 2025) (on file with the Senate Committee on Health Policy). Note that House Bill 1617 would be substantively identical to Senate Bill 1768 except for the House bill's exclusion of legislative intent and the inclusion of the use of afterbirth placental perinatal stem cells in the definition of "stem cell therapy."

In 2007, researchers developed induced pluripotent stem cells (iPSCs), a type of adult stem cell reprogrammed to exhibit pluripotency.[2] These iPSCs have opened new frontiers in regenerative medicine by offering a potential alternative to the use of embryonic stem cells.

Stem cell therapy involves administering stem cells or derivatives to repair, replace, or regenerate human tissues. While hematopoietic stem cell transplants for blood disorders are established treatments, many other stem cell therapies remain experimental and are not approved by the FDA for routine clinical use.[3]

Federal Regulation of Human Cells, Tissues, and Cellular and Tissue-Based Products

The FDA regulates stem cell products that meet the definition of human cells, tissues, or cellular and tissue-based products (HCT/Ps) through its Center for Biologics Evaluation and Research (CBER).[4] CBER's authority derives from the Public Health Service Act (42 U.S.C. § 264) and the Federal Food, Drug, and Cosmetic Act (21 U.S.C. §§ 301 et seq.). Applicable federal regulations are found primarily in 21 C.F.R., part 1271.

Products that meet all of the criteria under 21 C.F.R. § 1271.10 -- commonly referred to as "361 HCT/Ps" -- are subject to less stringent oversight. To qualify, the product must be:

- Minimally manipulated;
- Intended solely for homologous use;
- Not combined with another article (except for certain preservatives or water); and
- Either non-systemic and not dependent on the metabolic activity of living cells for its primary function, or used autologously or in a first- or second-degree blood relative.

Products that do not meet these criteria are classified as "351 HCT/Ps" and are regulated as biological drugs. These products require premarket approval through the FDA's Investigational New Drug (IND) and Biologics License Application (BLA) pathways, under 21 C.F.R., parts 312 and 600–680.

Enforcement and Oversight by FDA

The FDA requires establishments that manufacture or manipulate HCT/Ps to register with CBER and to comply with current Good Tissue Practices (cGTPs) under 21 C.F.R. part 1271, subpart D.[5] These practices are designed to prevent the introduction or transmission of communicable diseases. The FDA conducts inspections, issues warning letters, and may pursue

[2] *Id*.
[3] Harvard Stem Cell Institute, *Frequently Asked Questions: Stem Cell Therapies*, *available at*: https://www.hsci.harvard.edu/faq/stem-cell-therapies (last visited Mar. 28, 2025).
[4] U.S. Food & Drug Administration, *Center for Biologics Evaluation and Research (CBER)*, *available at*: https://www.fda.gov/about-fda/fda-organization/center-biologics-evaluation-and-research-cber (last visited Mar. 28, 2025).
[5] *See also* U.S. Department of Health & Human Services, *Current Good Tissue Practice (CGTP) and Additional Requirements for Manufacturers of Human Cells, Tissues, and Cellular and Tissue-Based Products (HCT/Ps)*, *available at*: https://www.hhs.gov/guidance/document/current-good-tissue-practice-cgtp-and-additional-requirements-manufacturers-human-cells (last visited Mar. 28, 2025).

civil or criminal enforcement actions against facilities or providers offering unapproved or noncompliant stem cell therapies.

The FDA has issued warnings about the widespread marketing of unapproved regenerative medicine products, noting that approval is granted only after rigorous evaluation in clinical trials to ensure safety and efficacy.[6] The FDA has received reports of serious adverse events associated with unapproved regenerative medicine therapies, including blindness, tumor formation, and infections.[7] Consumers are advised to exercise caution and are encouraged to report any adverse effects or file complaints related to these products directly to the FDA.

Oversight by the Florida Boards of Medicine and Osteopathic Medicine[8]

The Florida Board of Medicine (BOM), under the DOH, is responsible for licensing, regulating, and disciplining medical doctors, a.k.a. allopathic physicians, pursuant to ch. 458, F.S. The Board of Osteopathic Medicine (BOOM), pursuant to ch. 459, F.S., exercises the same authority for osteopathic physicians. The BOM has the authority to impose disciplinary sanctions, including license suspension or revocation, for violations of the standard of care, deceptive advertising, or failure to obtain proper informed consent, under s. 456.072, F.S., and related provisions of the Medical Practice Act. The BOOM has the authority to impose similar disciplinary sanctions under s. 459.015, F.S., which governs grounds for disciplinary action against osteopathic physicians.

In recent years, the BOM has reviewed complaints against providers advertising unproven stem cell treatments for conditions such as orthopedic pain and neurodegenerative disorders. Some of these providers have been subject to formal investigations, fines, and, in certain cases, license restrictions or revocations. In 2013, the BOM revoked the licenses of two physicians in administrative cases involving stem cells for failing to meet the standard of care. In 2015, the BOM warned physicians and consumers that they should be aware of the risks involved accessing stem cell therapies and regenerative medicine that was not approved by the FDA. The BOM further warned that a physician providing stem cell treatment should do so only with an investigational new drug application (IND) or a single patient IND for Compassionate or Emergency Use.

Ethical Considerations and Prohibited Stem Cell Sources

Federal law does not explicitly prohibit the use of fetal-derived stem cells obtained from elective abortions; however, such use is subject to ethical oversight, particularly in federally funded research. The National Institutes of Health requires review by an ethics advisory board for proposed research involving fetal tissue.[9]

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[6] U.S. Food & Drug Administration, *Important Patient and Consumer Information About Regenerative Medicine Therapies*, *available at*: https://www.fda.gov/vaccines-blood-biologics/consumers-biologics/important-patient-and-consumer-information-about-regenerative-medicine-therapies (last visited Mar. 28, 2025).
[7] *Id.*
[8] *Supra* note 1.
[9] National Institutes of Health, *Policies and Procedures for the Use of Human Fetal Tissue (HFT) in Non-Transplantation Research*, *available at*: https://oir.nih.gov/sourcebook/ethical-conduct/special-research-considerations/policies-procedures-use-human-fetal-tissue-hft-non-transplantation-research (last visited Mar. 28, 2025).

III. Effect of Proposed Changes:

Section 1 of the bill creates s. 456.63, F.S., to authorize allopathic and osteopathic physicians to perform stem cell therapies that are not approved by the FDA and to impose requirements relating to the manufacture, use, notice, consent, and oversight of such therapies.

Subsection (1) of this section provides legislative findings and intent, recognizing the potential of stem cell therapies to advance medical treatment and improve patient outcomes. This portion of the bill emphasizes the importance of using ethically sourced stem cells and expresses the intent to prohibit the use of stem cells derived from aborted fetuses. Instead, the bill encourages the use of adult stem cells, umbilical cord blood, and other ethically obtained human cells, tissues, or cellular or tissue-based products.

Subsection (2) defines key terms used throughout the section:

- "Health care provider" is defined as a physician licensed under ch. 458, F.S., or an osteopathic physician licensed under ch. 459, F.S., acting within the scope of their employment.
- "Human cells, tissues, or cellular or tissue-based products" includes specified articles consisting of human cells or tissues collected from cord blood donors who are residents of the United States and intended for implantation, transplantation, infusion, or transfer into a human recipient. The subsection also lists exclusions from that definition, including vascularized human organs, whole blood and blood derivatives, secreted or extracted products (except semen, which is a human cell, tissue, or cellular-based tissue product under the bill), certain minimally manipulated bone marrow products, ancillary products used in manufacturing, non-human-derived tissues, in vitro diagnostic products, blood vessels recovered with organs for transplantation, fetal-derived stem cells, and adipose-derived mesenchymal stem cells for transplantation.
- "Minimally manipulated" is defined in two parts: for structural tissue, it means processing that does not alter the original relevant characteristics of the tissue relating to reconstruction, repair, or replacement; for cells or nonstructural tissues, it means processing that does not alter the relevant biological characteristics of the cells or tissues.
- "Stem cell therapy" is defined as a treatment involving human cells, tissues, or cellular or tissue-based products, and explicitly excludes any treatment or research using cells or tissues derived from a fetus or embryo following an abortion.

Subsection (3) authorizes health care providers licensed under ch. 458 or ch. 459, F.S., to perform stem cell therapy not approved by the FDA, if the therapy is used for treatment or procedures within the scope of the provider's practice and is limited to the fields of orthopedics, wound care, or pain management.

Subsection (3) also establishes requirements relating to the origin and preparation of the stem cells used. The stem cells must be manufactured in a clean room certified by the FDA for the use of high-efficiency particulate air (HEPA) filtration or ultra-low penetration air filtration to minimize contamination. Additionally, the facility where the stem cells are retrieved, manufactured, and stored must be registered and regulated by the FDA and licensed or registered with one of four specified organizations: 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.

Subsection (4) requires health care providers to comply with applicable current good manufacturing practices for the collection, removal, processing, implantation, and transfer of stem cells or stem cell-containing products. These practices must be consistent with the requirements of the Federal Food, Drug, and Cosmetic Act and relevant regulations under 21 C.F.R., part 1271.

Subsection (5) requires a provider to deliver a specific written notice to the patient before performing a stem cell therapy. The notice must state that the provider performs one or more stem cell therapies that have not yet been approved by the FDA and must advise the patient to consult with their primary care provider before undergoing any such therapy.

Subsection (6) specifies the formatting and delivery requirements for the written notice. The notice must be printed on paper at least 8.5 inches by 11 inches in size and in no less than 40-point type. It must be prominently displayed at the entrance to the provider's office and in an area visible to patients within the office. In addition, the notice must be included in all advertisements for the stem cell therapy and must appear in a font size no smaller than the largest font size used in the advertisement.

Subsection (7) requires that providers obtain a signed consent form from the patient or, if the patient is not legally competent, from the patient's representative, before performing the therapy. The form must include, in language understandable to the patient or representative, a description of the nature and character of the treatment, a statement about the treatment's FDA approval status, the anticipated results, alternative treatment options, and the recognized serious possible risks, complications, and benefits of the proposed treatment and of any alternatives, including the possible consequences of not undergoing treatment.

Subsection (8) identifies two categories of providers to whom the requirements of the section do not apply. The first exemption applies to a health care provider who has obtained FDA approval for an investigational new drug or device for the use of human cells, tissues, or cellular or tissue-based products. The second exemption applies to a provider who performs stem cell therapy under an employment or other contract on behalf of an institution that is certified by one of the following organizations: the Foundation for the Accreditation of Cellular Therapy; the Blood and Marrow Transplant Clinical Trials Network; the Association for the Advancement of Blood and Biotherapies; or another entity with expertise in stem cell therapy as determined by the DOH.

Subsection (9) provides that a violation of any provision in the section may subject the provider to disciplinary action. The appropriate regulatory board, the DOH, or the Agency for Health Care Administration (AHCA), as applicable, has authority to enforce compliance and impose sanctions.

Subsection (10) requires the DOH to adopt rules to implement the section.

The bill authorizes health care providers to administer stem cell therapies that have not been approved by the FDA. This action may expose providers to federal regulatory enforcement. If a

provider or supplier administers or distributes stem cell products in violation of FDA requirements, the FDA may take a range of enforcement actions, including issuing warning letters, initiating civil or criminal proceedings in coordination with the U.S. Department of Justice, seeking injunctions to prevent continued noncompliance, and disqualifying parties from participating in clinical investigations. In addition, the FDA has authority to issue orders for the retention, recall, destruction, or cessation of manufacturing of human cells, tissues, or cellular- and tissue-based products (HCT/Ps) when it has reasonable grounds to believe the products were manufactured in violation of applicable regulations.

Section 2 of the bill provides an effective date of July 1, 2025.

IV. Constitutional Issues:

A. Municipality/County Mandates Restrictions:

None.

B. Public Records/Open Meetings Issues:

None.

C. Trust Funds Restrictions:

None.

D. State Tax or Fee Increases:

None.

E. Other Constitutional Issues:

None.

V. Fiscal Impact Statement:

A. Tax/Fee Issues:

None.

B. Private Sector Impact:

None.

C. Government Sector Impact:

The Department of Health through the Board of Medicine and Board of Osteopathic Medicine, would incur rulemaking and implementation costs, which may include staff time for developing criteria for exemption determinations, monitoring compliance, and investigating violations. These costs are likely absorbable within existing resources but could require additional resources depending on volume and enforcement.

The DOH notes that there would be an undeterminable impact on its Bureau of Enforcement (BOE), given that the provisions of the bill do not grant the department authority to inspect facilities to determine compliance with the bill's notice, informed consent, or physical plant requirements.[10] It is anticipated that BOE can absorb the impact with existing resources and budget authority.[11]

VI. Technical Deficiencies:

Florida does not specifically regulate clinics that perform treatments using stem cells and that remains unchanged under this bill. The AHCA should not be tasked with enforcing violations of the section created by the bill, as referenced at line 186, because the bill does not confer regulatory authority over stem cell therapies to AHCA. However, AHCA may take enforcement action against a provider pursuant to other applicable provisions of law.

At line 187, the bill provides rulemaking authority to the DOH. The DOH notes that rulemaking authority should instead be given to the Boards of Medicine and Osteopathic Medicine because the bill applies to two specific professions.[12]

On lines 43-45, the bill defines the term "health care provider" to mean a physician licensed under ch. 458, F.S., or an osteopathic physician licensed under ch. 459, F.S., acting within the course and scope of his or her employment. However, the terms "health care provider" and "health care practitioner" are used differently throughout the Florida Statutes. For example, ch. 456, F.S., defines "health care practitioner" broadly to include most individuals licensed by the DOH to practice a health care profession, while ch. 408, part-II, F.S., defines "provider" to refer to entities regulated by the AHCA. In contrast, this bill uses "health care provider" to refer only to licensed physicians. Although the definition in the bill is technically accurate, it may create confusion when read in the broader statutory context.

The bill creates s. 456.63, F.S., within ch. 456, F.S., which governs general health professions regulation. However, because the bill's provisions apply only to physicians licensed under chs. 458 and 459, F.S., it may be more appropriate to codify the language directly within those chapters.

VII. Related Issues:

None.

[10] *Supra* note 1.
[11] *Id.*
[12] *Id.*

VIII. Statutes Affected:

This bill creates section 456.63 of the Florida Statutes.

IX. Additional Information:

A. Committee Substitute – Statement of Changes:
(Summarizing differences between the Committee Substitute and the prior version of the bill.)

None.

B. Amendments:

None.