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 Rules

BILL:	CS/CS/SB 1768
INTRODUCER:	Rules Committee; Health Policy Committee and Senator Trumbull
SUBJECT:	Stem Cell Therapy
DATE:	April 17, 2025
REVISED:	

	ANALYST	STAFF DIRECTOR	REFERENCE	ACTION
1.	Smith	Brown	HP	**Fav/CS**
2.	Gerbrandt	McKnight	AHS	**Favorable**
3.	Smith	Yeatman	RC	**Fav/CS**

Please see Section IX. for Additional Information:

COMMITTEE SUBSTITUTE - Substantial Changes

I. Summary:

CS/CS/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 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 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 Board of Medicine and Board of Osteopathic Medicine to adopt rules to implement the bill.

The bill has an indeterminate, yet negative fiscal impact on state expenditures which likely can be absorbed within existing resources. **See Section V., Fiscal Impact Statement.**

The bill takes effect 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.

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 Food and Drug Administration (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

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[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."

[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).

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 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 Department of Health (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 physicians advertising unproven stem cell treatments for conditions such as orthopedic pain and neurodegenerative disorders. Some of these physicians 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

[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 a*t: https://www.hhs.gov/guidance/document/current-good-tissue-practice-cgtp-and-additional-requirements-manufacturers-human-cells (last visited Mar. 28, 2025).
[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] Department of Health, Senate Bill 1617 *Legislative Analysis* (Mar. 19, 2025) (on file with the Senate Committee on Health Policy).

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]

III. Effect of Proposed Changes:

Sections 1 and 2 create ss. 458.3245 and 459.0127, F.S., to authorize allopathic and osteopathic physicians, respectively, to perform stem cell therapies that are not approved by the Food and Drug Administration (FDA) and to impose requirements relating to the manufacture, use, notice, consent, and oversight of such therapies.

Subsection (1) of each 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) of each section defines key terms used throughout the section:

- "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.
- "Physician" 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 his or her employment.
- "Stem cell therapy" is defined as a treatment involving human cells, tissues, or cellular or tissue-based products which complies with the regulatory and reporting requirements

[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).

provided in this section, and explicitly excludes any treatment or research using cells or tissues derived from a fetus or embryo following an abortion.

Subsection (3) of each section authorizes physicians to perform stem cell therapy not approved by the FDA, if the therapy is used for treatment or procedures within the scope of the physician's practice and is limited to the fields of orthopedics, wound care, or pain management.

Subsection (3) of each section 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. 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. Additionally, the stem cells used in therapy must be included in a post-thaw viability analysis report for the product lot. The viability analysis must be sent to the health care provider before use with the provider's patient. Stem cells used in therapy must contain viable or live cells pursuant to the analysis.

Subsection (4) of each section requires physicians 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) of each section requires a physician to include a specific written notice in any form of advertisement. The notice must state that the physician performs one or more stem cell therapies that have not yet been approved by the FDA and encourages readers to consult with their primary care provider before undergoing any such therapy. The notice must be legible and in a type size no smaller than the largest type size used in the advertisement.

Subsection (6) of each section requires that physicians 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, the recognized serious possible risks, complications, and benefits of the proposed treatment and of any alternatives, including the possible consequences of not undergoing treatment, and a statement encouraging the patient to consult with his or her primary care provider before undergoing stem cell therapy.

Subsection (7) of each section identifies two categories of physicians to whom the requirements of the section do not apply. The first exemption applies to a physician 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 physician 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 Department of Health (DOH).

Subsection (8) of each section provides that a violation of any provision in the section may subject the physician to disciplinary action. The appropriate regulatory board or the DOH may enforce compliance and impose sanctions.

Subsection (9) of section 1 requires the Board of Medicine to adopt rules to implement the section in consultation with the Board of Osteopathic Medicine. Conversely, subsection (9) of section 2 requires the Board of Osteopathic Medicine to adopt rules to implement the section in consultation with the Board of Medicine.

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

The bill takes effect 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 bill has an indeterminate yet negative fiscal impact on state expenditures. The Department of Health (DOH) will incur nonrecurring costs associated with rulemaking and updating systems, and these costs can be absorbed within existing resources.

According to the DOH, there may be an indeterminate fiscal impact on its Bureau of Enforcement to develop criteria for exemption determinations, monitoring compliance, and investigate violations. These costs can likely be absorbed within existing resources.[10]

VI. Technical Deficiencies:

None.

VII. Related Issues:

None.

VIII. Statutes Affected:

This bill creates the following sections of the Florida Statutes: 458.3245 and 459.0127.

[10] Department of Health, Senate Bill 1617 *Legislative Analysis* (Mar. 19, 2025) (on file with the Senate Committee on Health Policy).

IX. Additional Information:

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

CS/CS by Rules on April 16, 2025:
The CS/CS requires that stem cells used in stem cell therapy be included in a post-thaw viability analysis report for the product lot. The viability analysis would be sent to the physician before use with the physician's patient. Stem cells used in therapy must contain viable or live cells, pursuant to the analysis.

The CS/CS revises the patient notice requirement, removing provisions regarding alternative treatments and adding a provision encouraging the patient to consult with his or her primary care provider before undergoing the therapy.

The CS/CS also adds to the definition of the term "stem cell therapy" to ensure that "stem cell therapy" complies with the section of law created by the bill.

CS by Health Policy on April 1, 2025:
The underlying bill defined "health care providers" as physicians licensed under chs. 458 and 459, F.S. The CS replaces the term "health care providers" with "physicians" and relocates the new section from ch. 456, F.S., which generally applies to all health care practitioners, to chs. 458 and 459, F.S., which apply specifically to allopathic and osteopathic physicians, respectively.

The CS establishes that the Board of Medicine and Board of Osteopathic Medicine must adopt rules to implement the new sections, rather than the Department of Health (DOH). The CS also clarifies that enforcement authority rests with the boards and the DOH, not the Agency for Health Care Administration.

B. Amendments:

None.