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 1092
INTRODUCER:	Appropriations Committee on Health and Human Services; Health Policy Committee; and Senator Massullo
SUBJECT:	Podiatric Medicine
DATE:	February 23, 2026 REVISED:

	ANALYST	STAFF DIRECTOR	REFERENCE	ACTION
1.	Smith	Brown	HP	**Fav/CS**
2.	Gerbrandt	McKnight	AHS	**Fav/CS**
3.	Smith	Kruse	RC	**Pre-meeting**

Please see Section IX. for Additional Information:

COMMITTEE SUBSTITUTE - Substantial Changes

I. Summary:

CS/CS/SB 1092 limits the existing controlled substance prescribing continuing education requirement for all podiatric physicians to only those podiatric physicians registered with the U.S. Drug Enforcement Administration and authorized to prescribe controlled substances, exempting podiatric physicians who do not prescribe controlled substances.

The bill authorizes podiatric physicians to perform procedures using cellular or tissue-based product that have not been approved by the U.S. Food and Drug Administration (FDA), provided they meet specified criteria. Podiatric physicians must provide written notice to patients, and include a disclaimer in all advertisements, disclosing that the treatment is not approved by the FDA. The Board of Podiatric Medicine is authorized to adopt rules to implement the bill.

The bill has a negative fiscal impact on the Department of Health which can be absorbed within existing resources. **See Section V., Fiscal Impact Statement.**

The bill takes effect July 1, 2026.

II. Present Situation:

Podiatric Physicians

Podiatric physicians are licensed to practice podiatric medicine. Section 461.003, F.S., defines the "practice of podiatric medicine" to mean the diagnosis or medical, surgical, palliative, and mechanical treatment of ailments of the human foot and leg. Surgical treatment is anatomically limited to the area below the anterior tibial tubercle. The definition specifies that the practice includes amputation of the toes or other parts of the foot but does not include amputation of the foot or leg in its entirety.

Podiatrists are regulated by the Board of Podiatric Medicine (Board) within the Department of Health (DOH) under ch. 461, F.S., which establishes minimum requirements for the safe practice of podiatric medicine. At the end of Fiscal Year 2024-2025, there were 1,589 in-state and 312 out-of-state podiatric physicians licensed by the state of Florida.[1]

Licensed podiatrists are subject to discipline under ch. 456, F.S., and the podiatrist-specific grounds in ch. 461, F.S. The DOH and the Board may take action for rule violations, fraud, and other enumerated misconduct. The Board's implementing rules are codified in Chapter 64B18, F.A.C., addressing matters such as licensure and renewal, continuing medical education, advertising, and disciplinary grounds.

Prescribing Authority

Current law authorizes a podiatric physician to prescribe drugs that relate specifically to their authorized scope of practice within the definition of "practice of podiatric medicine."[2] To become authorized to prescribe controlled substances to treat chronic nonmalignant pain, a podiatrist must designate himself or herself as a controlled substance prescribing practitioner on his or her practitioner profile and comply with all requirements specified in s. 456.44, F.S., and in rules established by the Board of Podiatric Medicine.[3] Federal law requires a podiatrist to register with the U.S. Drug Enforcement Administration (DEA) before he or she may lawfully dispense[4] a controlled substance.[5]

As a condition to receiving DEA registration, a podiatrist must complete at least eight hours of training on the treatment and management of patients with opioid or other substance use disorders, the safe pharmacological management of dental pain and screening, brief intervention,

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[1] Department of Health, Division of Medical Quality Assurance, *Annual Report and Long-Range Plan: Fiscal Year 2024-2025*, at 29 *available at*: https://www.floridahealth.gov/wp-content/uploads/2026/01/2025.10.31.FY24-25MQAAR-FINAL1-1.pdf (last visited Feb. 6, 2026).
[2] Section 461.003(5), F.S.
[3] Section 456.44(2), F.S.; rule 64B18-23.002(2)(g), F.A.C.
[4] Federal law relating to drug abuse prevention and control states that the term "dispense" means "to deliver a controlled substance to an ultimate user or research subject by, or pursuant to the lawful order of, a practitioner, including the prescribing and administering of a controlled substance and the packaging, labeling or compounding necessary to prepare the substance for such delivery. The term "dispenser" means a practitioner who so delivers a controlled substance to an ultimate user or research subject. 21 U.S.C. § 802(10).
[5] 21 U.S.C. § 822(a)(2); 21 C.F.R. § 1301.11(a).

and referral for appropriate treatment of patients with or at risk of developing opioid or other substance use disorders.[6]

Federal law makes it unlawful for a registrant to dispense a controlled substance not authorized by his or her DEA registration to another registrant or other authorized person.[7] A registrant who engages in such unlawful practice is subject to a civil penalty of not more than $25,000 and to criminal prosecution.[8]

Continuing Education Requirements

Current law requires podiatric physicians to complete 40 hours of continuing education (CE) as a part of the biennial licensure renewal process, and at least two of those hours must be on the safe and effective prescribing of controlled substances. All podiatrists, including those who are not authorized to prescribe controlled substances, are required to take the CE on safe and effective prescribing of controlled substances. The Board must approve the criteria for CE programs or courses.[9]

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.[10] 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.[11] 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.[12]

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[6] 21 U.S.C. § 823(m)(1).
[7] 21 U.S.C. § 842(a)(2).
[8] 21 U.S.C. § 842(c).
[9] Section 461.007(3), F.S., and Rule 64B18-17, F.A.C. By rule, the Board approves of all CE programs sponsored or approved by the American Podiatric Medical Association, the Council on Podiatric Medical Education, the American Medical Association, the American Osteopathic Association, and the American Hospital Association. Rule 64B18-17.002(1), F.A.C.
[10] Department of Health, *Senate Bill 1617 Legislative Analysis* (Mar. 19, 2025) (on file with the Senate Committee on Health Policy).
[11] *Id*.
[12] Harvard Stem Cell Institute, *Frequently Asked Questions: Stem Cell Therapies*, *available at*: https://www.hsci.harvard.edu/faq/stem-cell-therapies (last visited Feb. 4, 2026).

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).[13] 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.[14] 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.[15] The FDA has received reports of serious adverse events associated with unapproved regenerative medicine therapies, including blindness, tumor formation, and infections.[16] 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.

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[13] 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 Feb. 4, 2026).
[14] *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 Feb. 6, 2026).
[15] 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 Feb. 4, 2026).
[16] *Id.*

Regulation by the Florida Boards of Medicine and Osteopathic Medicine

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.

On July 1, 2025, a new law took effect authorizing allopathic and osteopathic physicians to perform stem cell therapies that have not been approved by the FDA when used for orthopedic conditions, wound care, or pain management.[17] Sections 458.3245 and 459.0127, F.S., establish standards for the manufacturing and storage of stem cells and procedures for allopathic physician and osteopathic physicians, respectively, to perform stem cell therapy.

Allopathic and osteopathic physicians are exempt from the requirements in those sections if they perform stem cell therapy on behalf of an institution accredited by:

- 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
- An entity with expertise in stem cell therapy as determined by the DOH.

The DOH reports that it does not have rulemaking authority or a panel of experts to determine additional entities with stem cell expertise.[18] The 2025 law delegates rulemaking authority to the BOM and BOOM.[19] The Boards have formed a workgroup to discuss if any additional entities with expertise should be identified. The workgroup will make a recommendation to the Boards for consideration of a proposed rule.

III. Effect of Proposed Changes:

Section 1 amends s. 461.007, F.S., to establish that only podiatric physicians who are registered with the United States Drug Enforcement Administration (DEA) and who are authorized to prescribe controlled substances pursuant to 21 U.S.C. s. 822, are required to complete a minimum of two hours of continuing education related to the safe and effective prescribing of controlled substances as a condition of biennial licensure renewal. The bill eliminates the requirement for podiatric physicians who do not prescribe controlled substances to complete such training within the 40 hours of continuing education otherwise required for license renewal.

Section 2 creates s. 461.011, F.S., to authorize podiatric physicians to perform procedures using cellular or tissue-based products that are not approved by the United State Food and Drug Administration (FDA) and to impose requirements relating to the manufacture, use, notice, consent, and oversight of such therapies.

Subsection (1) of that section provides legislative findings and intent, recognizing the potential of cellular and tissue-based products to advance medical treatment and improve patient

[17] Chapter 2025-185, Laws of Fla.
[18] Department of Health, *Senate Bill 1092 Legislative Bill Analysis* (Jan. 15, 2026) (on file with the Senate Committee on Health Policy).
[19] Sections 458.3245(10) and 459.0127(10), F.S.

outcomes. This subsection emphasizes the importance of using ethically sourced cellular and tissue-based products and expresses the intent to prohibit the use of cells derived from aborted fetuses. Instead, the bill encourages the use of cellular or tissue-based products.

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

- "Cellular or tissue-based products" articles containing or consisting of human cells or tissues which are 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, or harvesting or reimplantation of autologous tissue.
- "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 podiatric physician licensed under ch. 461, F.S., acting within the scope of his or her employment.
- "Procedure using cellular or tissue-based products" is defined as a treatment involving the use of human cells, tissues, or cellular or tissue-based products, which complies with the regulatory requirements 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 that section authorizes podiatric physicians to perform procedures using cellular or tissue-based products that are 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 connective tissue, ligament and tendon repair, wound care, or pain management.

Subsection (3) also establishes requirements relating to the source and handling of cellular and tissue-based products in such therapy. Any cellular and tissue-based products used by a physician must be obtained from a facility that is registered and regulated by the FDA and that is 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. In addition, the cells must be included in a post-thaw viability analysis report for the product lot, which must be provided to the physician before use with a patient, and the cells must contain viable or live cells as demonstrated by that analysis.

Subsection (4) of that section requires a podiatric physician to include a specific written notice in any form of advertisement. The notice must state that he or she performs procedures using cellular or tissue-based products that have not yet been approved by the FDA and encourages patients 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 (5) of that section requires a podiatric physician who performs procedures using cellular or tissue-based products pursuant to this section to obtain a signed consent form from the

patient before performing the therapy. The consent form must be signed by the patient or, if the patient is not legally competent, the patient's representative, and must state, in language the patient or representative may reasonably be expected to understand: the nature and character of the proposed treatment; that the proposed treatment has not yet been approved by the FDA; the anticipated results of the proposed treatment; the recognized serious possible risks, complications, and anticipated benefits involved in the treatment and in recognized possible alternative forms of treatment, including nontreatment; and that the patient is encouraged to consult with his or her primary care provider before undergoing any treatment.

Subsection (6) of that section exempts two categories of podiatric physicians from the requirements of this section. The first exemption applies to a podiatric 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 podiatric physician who performs procedures using cellular or tissue-based products 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; or the Association for the Advancement of Blood and Biotherapies.

Subsection (7) of that section provides that a violation of any provision in the section may subject the podiatric physician to disciplinary action by the Board of Podiatric Medicine.

Subsection (8) of that section provides that a podiatric physician who willfully performs or procures the performance of stem cell therapy using cells or tissues derived from an aborted fetus, or who willfully sells, manufactures, distributes, or transfers any computer product created using human cells, tissues, or cellular or tissue-based products, commits a third-degree felony. In addition to criminal penalties, such conduct constitutes grounds for disciplinary action under ch. 461, F.S., and s. 456.072, F.S.

Subsection (9) of that section requires the Board of Podiatric Medicine to adopt rules to implement this section.

The bill authorizes podiatric physicians to perform procedures that have not been approved by the FDA. This action may expose podiatric physicians to federal regulatory enforcement. If a physician or supplier administers or distributes 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 3 provides an effective date of July 1, 2026.

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 a negative workload impact on the Department of Health due to the bill's provisions that will require technology updates. According to the DOH these costs can be absorbed within existing resources.[20]

VI. Technical Deficiencies:

None.

VII. Related Issues:

None.

[20] Department of Health, *Senate Bill 1092 Legislative Bill Analysis* (Jan. 15, 2026) (on file with the Senate Committee on Health Policy).

VIII. Statutes Affected:

This bill substantially amends section 461.007 of the Florida Statutes.

This bill creates section 461.011 of the Florida Statutes.

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 Appropriations Committee on Health and Human Services on February 18, 2026:

The committee substitute:

- Deletes contractual requirements between a podiatric physician and the facility from which the physician obtains human cells, tissues, or other cellular or tissue-based product.
- Deletes the requirement that podiatric physicians use products only from facilities that follow current good manufacturing practices under the Federal Food, Drug, and Cosmetic Act and 21 C.F.R. part 1271.
- Deletes all references to stem cells and effectively replaces "human cells, tissues, or other cellular or tissue-based products" with "cellular or tissue-based products."
- Specifies that harvesting and reimplantation of autologous tissue is not authorized by the new section.

CS by Health Policy on February 11, 2026:

The CS:

- Narrows the scope of the bill to authorize podiatrists to perform stem cell therapies only if such therapies are limited to the use of "human cells, tissues, or cellular or tissue-based products," as that term is defined in the bill. In so doing, the CS removes the underlying bill's authorization for the use of afterbirth placental perinatal stem cells.
- Applies the practitioner title "podiatric physician" throughout the bill consistent with the use of that title throughout ch. 461, F.S.
- Deletes a provision in the underlying bill which would have authorized the Department of Health to recognize certain accredited entities.

B. Amendments:

None.