

FLORIDA HOUSE OF REPRESENTATIVES FINAL BILL ANALYSIS

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BILL #: [CS/HB 567](#)
TITLE: Podiatric Medicine
SPONSOR(S): Chaney

COMPANION BILL: None
LINKED BILLS: None
RELATED BILLS: [CS/CS/SB 1092](#) (Massullo)

FINAL HOUSE FLOOR ACTION: 112 Y's 0 N's **GOVERNOR'S ACTION:** Approved

SUMMARY

Effect of the Bill:

The bill authorizes podiatrists to perform connective tissue repair, ligament repair, tendon repair, wound care, or pain management procedures using cellular or tissue-based products which are not approved by the U.S. Food and Drug Administration (FDA). The bill requires these podiatrists to only use products sourced from facilities regulated and registered with the FDA and certified or accredited by specified organizations. They must also obtain informed consent from patients, including a notification that the products are not approved by the FDA, and include a similar notice in all advertisements.

The bill prohibits treatment or research using human cells or tissues derived from a fetus or an embryo after an abortion and the sale, manufacture, or distribution of computer products created using human cells, tissues, or cellular or tissue-based products. The bill makes it a third-degree felony and a licensure violation for a physician to willfully perform or actively participate in either prohibited act. The bill authorizes rulemaking and licensure discipline by the Board of Podiatric Medicine.

The bill makes the current requirement for podiatrists to have two hours of continuing education on safe and effective controlled substance prescribing applicable only to those registered with the U.S. Drug Enforcement Administration and authorized to prescribe controlled substances under the Federal Controlled Substances Act.

Fiscal or Economic Impact:

The bill has a negative, indeterminate fiscal impact on the Department of Health (DOH) for enforcement, which DOH can absorb within existing resources. To the extent podiatrists profit from providing certain procedures using cellular or tissue-based products, the bill has a positive, indeterminate economic impact on the private sector.

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ANALYSIS

EFFECT OF THE BILL:

CS/HB 567 passed as CS/CS/SB 1092. (Please note that bill section parentheticals do not contain hyperlinks to bill sections for Senate bills).

Podiatric Medicine

Use of Cellular or Tissue-Based Products

The bill authorizes [podiatrists](#) to perform connective tissue repair, ligament repair, tendon repair, wound care, or pain management procedures using cellular or tissue-based products which are not approved by the United States Food and Drug Administration ([FDA](#)). This applies to articles containing or consisting of human cells or tissues which are intended for implantation, transplantation, infusion, or transfer into a human recipient.

The bill expressly excludes nine classes of articles from “cellular or tissue-based products” authorized for use under the bill:

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- Vascularized human organs for transplantation;
- Whole blood, blood components, or blood derivative products;
- Secreted or extracted human products, such as milk, collagen, and cell factors. However, the bill includes semen as a state recognized class of “cellular or tissue-based products”;
- Minimally manipulated¹ bone marrow for homologous use and not combined with another article, except for with water, crystalloids, or a sterilizing, preserving, or storage agent, if the addition of the agent does not raise new clinical safety concerns with respect to the bone marrow;
- Ancillary products used in the manufacture of human cells, tissues, or cellular or tissue-based products;
- Cells, tissues, and organs derived from animals other than humans;
- In vitro diagnostic products;
- Blood vessels recovered with an organ which are intended for use in organ transplantation and labeled, “for use in organ transplantation only”; and
- Harvesting and reimplantation of autologous tissue. (Section 2).

Standards

The bill establishes standards for podiatrists who perform an authorized procedures using cellular or tissue-based products. Specifically, the bill requires these podiatrists to use only cellular or tissue-based products which are obtained from, manufactured in, and stored in facilities:

- Regulated by and registered with the FDA; and
- Certified or accredited by the National Marrow Donor Program, World Marrow Donor Association, Association for the Advancement of Blood and Biotherapies, or American Association of Tissue Banks.

The bill also requires such products to contain viable or live cells in the product lot and post-thaw viability analysis report sent by an authorized facility. (Section 2).

The bill’s provisions authorizing podiatrists to perform connective tissue repair, ligament repair, tendon repair, wound care, or pain management procedures using cellular or tissue-based products which are not approved by the FDA may subject a podiatrist who performs these procedures to regulatory action by the FDA. 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.²

Patient Disclosure Requirements

Written Notice

The bill requires a podiatrist who performs a procedure using cellular or tissue-based products and advertises such procedure must include the following statement in any form of advertisement:

“THIS NOTICE MUST BE PROVIDED TO YOU UNDER FLORIDA LAW. This podiatric physician performs procedures using cellular or tissue-based products that have not yet been approved by the United States Food and Drug Administration. You are encouraged to consult with your primary care provider before undergoing any procedure using these products.”

¹ The bill gives minimal manipulation two meanings. For structural tissue, minimal manipulation is a process that does not alter the original relevant characteristics of the tissue relating to the tissue’s utility for reconstruction, repair, or replacement. For cells or nonstructural tissues, minimal manipulation means a process that does not alter the relevant biological characteristics of cells or tissues.

² U.S. Food & Drug Administration, “Important Patient and Consumer Information About Regenerative Medicine Therapies,” *U.S. Department of Health and Human Services*, (Jun. 3, 2021), <https://www.fda.gov/vaccines-blood-biologics/consumers-biologics/important-patient-and-consumer-information-about-regenerative-medicine-therapies> (last visited Mar. 13, 2026).

The bill requires the notice to be clearly legible and in a type size no smaller than the largest type size used in the advertisement. (Section 2).

Informed Consent

The bill requires a podiatrist to obtain written informed consent, signed by the patient, prior to performing non-FDA approved procedures using cellular or tissue-based products which must include:

- The nature and character of the proposed treatment.
- That the proposed procedure uses cellular or tissue-based products that have 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 the recognized possible alternative forms of treatment, including the nontreatment option.
- The option for the patient to consult with his or her primary care provider before undergoing stem cell therapy. (Section 2).

Criminal Conduct

The bill criminalizes the treatment or research using human cells or tissues derived from a fetus or an embryo after an abortion. The bill also criminalizes the sale, manufacture, or distribution of computer products created using human cells, tissues, or cellular or tissue-based products. If a podiatrist willfully performs or actively participates in either prohibited act, the state may charge the physician with a third-degree felony.³ (Section 2).

Licensure Discipline

The bill states that violations of standards which authorize podiatric physicians to perform certain procedures with cellular or tissue-based products may subject them to disciplinary action by the [Board of Podiatric Medicine](#).

The bill also expressly makes it a licensure violation for a podiatrist to willfully perform or actively participate in treatment or research using human cells or tissues derived from a fetus or an embryo after an abortion, or the sale, manufacture, or distribution of computer products created using human cells, tissues, or cellular or tissue-based products. (Section 2).

Exemptions

The bill expressly exempts a podiatrist from the requirements from the bill's provisions relating to procedures using cellular or tissue-based products if:

- The FDA approved the physician's application for an investigational new drug or investigational new device for use of the human cells, tissues, or cellular or tissue-based products.
- The physician performs procedures using cellular or tissue-based products under an employment or other contract on behalf of an institution certified or accredited by 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. (Section 2).

³ A third-degree felony conviction, without any enhancements, carries a term of imprisonment not exceeding five years and, or, a fine not exceeding \$5,000. [S. 775.082\(3\)\(e\), F.S.](#), [s. 775.083\(1\)\(c\), F.S.](#)

Podiatric Licensure – Continuing Education

The bill makes the current requirement for podiatrists to have two hours of [continuing education](#) on safe and effective [controlled substances](#) prescribing applicable only to those registered with the United States Drug Enforcement Administration and [authorized to prescribe controlled substances](#) under the [Federal Controlled Substances Act](#). (Section 1).

The bill was approved by the Governor on June 11, 2026, ch. 2026-124, L.O.F., and became effective on that date, (Section 3).

RULEMAKING:

The bill authorizes the Board of Podiatric Medicine to adopt rules necessary to implement the bill's provision relating to certain procedures performed by podiatrists using cellular or tissue-based products. (Section 2).

Lawmaking is a legislative power; however, the Legislature may delegate a portion of such power to executive branch agencies to create rules that have the force of law. To exercise this delegated power, an agency must have a grant of rulemaking authority and a law to implement.

FISCAL OR ECONOMIC IMPACT:

STATE GOVERNMENT:

To the extent the enforcement workload of the Department of Health Consumer Services Unit and Prosecution Services Unit may increase to protect the public from unauthorized performance of certain procedures using cellular or tissue-based products, the bill has a negative fiscal impact on state government. However, enforcement costs can be absorbed within existing resources.

PRIVATE SECTOR:

To the extent podiatric physicians increase their revenues due to the performance of procedures using cellular or tissue-based products, the bill has a positive, indeterminate economic impact on the private sector.

RELEVANT INFORMATION

SUBJECT OVERVIEW:

Regenerative Medicine

Regenerative medicine refers to a general approach to restore, replace, or recreate cells, tissues, or organs to treat or mitigate disease.⁴ Regenerative medicine includes the practices of rejuvenation (i.e., boosting the body's natural ability to heal itself), replacement (i.e., organ transplants), and repair (i.e. delivering specific types of cells or cell products to diseased tissues or organs, where they will ultimately restore tissue and organ function).⁵ As a discipline, regenerative medicine combines principles of biology and engineering to develop therapies for diseases

⁴ U.S. Food & Drug Administration, "Focus Area: Regenerative Medicine," *U.S. Department of Health and Human Services*, (last updated Sept. 6, 2022) <https://www.fda.gov/science-research/focus-areas-regulatory-science-report/focus-area-regenerative-medicine> (last visited Mar. 16, 2026).

⁵ Center for Regenerative Medicine, "About Regenerative Medicine," *University of Florida* <https://regenerative.medicine.ufl.edu/about/about-regenerative-medicine/> (last visited Mar. 16, 2026).

characterized by cell depletion, lost tissue, or damaged organs. Organoids,⁶ 3D organ printing, and tissue engineering are examples of biopowered technologies used in regenerative medicine.⁷

Regenerative Medicine Regulation

The Food and Drug Administration

The Center for Biologics Evaluation and Research (CBER), within the United States Food and Drug Administration (FDA), regulates “human cells, tissue, and [cellular and tissue-based products](#)” (HCT/P), which are human cells or tissue intended for implantation, transplantation, infusion, or transfer into a human recipient.⁸ For example, CBER regulates stem cell products as HCT/Ps under the federal Public Health Service Act (PHSA) and potentially as biological products, drugs, or devices under the PHSA and the federal Food, Drug, and Cosmetic Act.⁹

An establishment that manufactures HCT/Ps must register with CBER, if:¹⁰

- The HCT/P is minimally manipulated;
- The HCT/P is intended for homologous use only;
- The manufacture of the HCT/P does not involve the combination of cells or tissues with another article, except for water, crystalloids, or a sterilizing, preserving, or storage agent, provided that the addition of water, crystalloids, or the sterilizing, preserving, or storage agent does not raise new clinical safety concerns with respect to the HCT/P; and, either
 - The HCT/P does not have a systemic effect and is not dependent upon the metabolic activity of living cells for its primary function; or
 - The HCT/P has a systemic effect or is dependent upon the metabolic activity of living cells for its primary function, and:
 - Is for autologous use;
 - Is for allogeneic use in a first-degree or second-degree blood relative; or
 - Is for reproductive use.

⁶ Organoids are small clusters of cells that mimic a particular organ. Scientists grow organoids from pluripotent stem cells by bathing the cells in various chemicals to induce their transformation into different cell types. Nina Bai, “Advance in creating organoids could aid research, lead to treatment,” *Stanford Medicine*, (Jun. 5, 2025) <https://med.stanford.edu/news/all-news/2025/06/heart-organoid.html> (last visited Mar. 19, 2026).

⁷ Institute for Stem Cell and Regenerative Medicine, “What is Regenerative Medicine?” *University of Washington*, <https://iscrm.uw.edu/what-is-regenerative-medicine/> (last visited Mar. 16, 2026).

⁸ Examples of HCT/Ps are bone, skin, corneas, ligaments, tendons, dura mater, heart valves, hematopoietic stem/progenitor cells derived from peripheral and cord blood, oocytes and semen. CBER does not regulate the transplantation of vascularized human organ transplants such as kidney, liver, heart, lung or pancreas. The Health Resources Services Administration (HRSA) oversees the transplantation of vascularized human organs. U.S. Food & Drug Administration, “Tissue & Tissue Products,” *U.S. Department of Health and Human Services*, (last updated Mar. 1, 2024) <https://www.fda.gov/vaccines-blood-biologics/tissue-tissue-products> (last visited Mar. 13, 2026). U.S. Food & Drug Administration, “Center for Biologics Evaluation and Research,” *U.S. Department of Health and Human Services*, (last updated Aug. 15, 2025) <https://www.fda.gov/about-fda/fda-organization/center-biologics-evaluation-and-research-cber> (last visited Mar. 13, 2026). 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.

⁹ United States Food and Drug Administration, “Cellular & Gene Therapy Products,” *U.S. Department of Health and Human Services*, (last updated Jan. 11, 2026) <https://www.fda.gov/vaccines-blood-biologics/cellular-gene-therapy-products> (last visited Mar. 13, 2026). United States Food and Drug Administration, “Letter regarding FDA’s regenerative medicine framework and enforcement discretion period for HCT/Ps,” *U.S. Department of Health and Human Services* (Dec. 20, 2018) <https://www.fda.gov/media/119936/download?attachment> (last visited Mar. 13, 2026). For example, in order to lawfully market an HCT/P that is also a biological product and a drug, the manufacturer must have a valid biologics license in effect. The FDA issues such licenses only after a showing of safety and efficacy for the product’s intended use. While in the development stage, such products intended for clinical use in humans, generally require an investigational new drug application.

¹⁰ Department of Health, Agency Bill Analysis for HB 1617 (2025), pp. 3 (Mar. 19, 2025) <http://abar.laspbs.state.fl.us/ABAR/Attachment.aspx?id=36554> (last visited Mar. 16, 2026). Note that CS/CS/HB 1617 (2025) passed as CS/CS/SB 1768 (2025) and is current law governing allopathic and osteopathic physicians’ use of stem cell therapies not approved by the FDA. CS/HB 567 (2026) which passed as CS/CS/SB 1092 (2026) applies essentially the same regenerative medicine law to podiatric physicians. This means the DOH bill analysis for HB 1617 (2025) is relevant for this final bill analysis.

An establishment is not required to comply with registration and reporting requirements if the establishment:¹¹

- Uses HCT/Ps solely for nonclinical scientific or educational purposes;
- Removes HCT/Ps from an individual and implants such HCT/Ps into the same individual during the same surgical procedure;
- Is a carrier who accepts, receives, carries, or delivers HCT/Ps in the usual course of business as a carrier;
- Does not recover, screen, test, process, label, package, or distribute, but only receives or stores HCT/Ps solely for implantation, transplantation, infusion, or transfer within their facility;
- Only recovers reproductive cells or tissue and immediately transfers them into a sexually intimate partner of the cell or tissue donor; or
- Is an individual under contract, agreement, or other arrangement with a registered establishment and engaged solely in recovering cells or tissues and sending the recovered cells or tissues to the registered establishment; however, it must comply with all other applicable requirements.

FDA Enforcement

In November 2017, the FDA published a comprehensive regenerative medicine policy framework and informed manufacturers, health care providers, and other interested parties about the FDA’s compliance and enforcement policy for HCT/Ps generally. The FDA concurrently announced its intent to exercise enforcement discretion for the first 36 months (i.e., November 2020) following issuance of the framework relating to safety concerns, FDA-approved investigational HCT/Ps for experimental therapies, and FDA-approved HCT/Ps for FDA-approved uses. After November 2020, the FDA’s enforcement discretion ended, which means manufacturers, health care providers, and other interested parties with non-FDA approved HCT/Ps are subject to FDA regulatory action.¹²

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

Since November 2020, the FDA has issued warning letters to nine Florida-based providers for deviating from federal HCT/Ps regulations or for using products not approved by the FDA.¹⁴

Date of Warning	Provider	City (Florida)	Warning Letter
09/24/2025	New Life Medical Services, LLC	Lutz	MARCS-CMS 711102
08/15/2025	Platinum Biologics	Orlando	MARCS-CMS 705090
01/17/2025	BioStem Life Sciences	Pompano Beach	MARCS-CMS 673788
08/20/2024	Mother Stem Institute, Corp.	Coral Gables	MARCS-CMS 680118
06/05/2024	Neobiosis, LLC	Gainesville	MARCS-CMS 662985

¹¹ *Id.*

¹² U.S. Food & Drug Administration, “Letter regarding FDA’s regenerative medicine framework and enforcement discretion period for HCT/Ps,” *U.S. Department of Health and Human Services* (Dec. 20, 2018) <https://www.fda.gov/media/119936/download?attachment> (last visited Mar. 13, 2026).

¹³ U.S. Food & Drug Administration, “Important Patient and Consumer Information About Regenerative Medicine Therapies,” *U.S. Department of Health and Human Services*, (Jun. 3, 2021), <https://www.fda.gov/vaccines-blood-biologics/consumers-biologics/important-patient-and-consumer-information-about-regenerative-medicine-therapies> (last visited May 8, 2025).

¹⁴ U.S. Food & Drug Administration, “Warning Letters,” *U.S. Department of Health and Human Services*, (current as of Mar. 16, 2026) <https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/compliance-actions-and-activities/warning-letters> (last visited Mar. 16, 2026).

06/21/2023	Regenerative Labs	Pensacola	MARCS-CMS 638823
11/17/2022	Palm Beach Fertility Center	Boca Raton	MARCS-CMS 643090
10/24/2022	Cryos International USA LLC	Orlando	MARCS-CMS 639696
03/31/2022	OsteoLife Biomedical, LLC	Miami	MARCS-CMS 626889

The FDA uses warning letters to serve as notice and cure opportunities for providers to address FDA concerns within a certain timeframe. To the extent provider disagrees with the FDA's concerns, the provider has the opportunity to supply FDA with its reasoning and supporting information.¹⁵

Podiatric Medicine

Practice of Podiatric Medicine

Under current law [s. 461.003, F.S.](#), the practice of podiatric medicine involves the diagnosis or medical, surgical, palliative, and mechanical treatment of ailments of the human foot and leg. The amputation of the toes or other parts of the foot is within the scope of practice of podiatric medicine; however, the amputation of the foot or leg in its entirety is beyond the scope of practice of podiatric medicine. For surgical treatments, podiatric physicians may only operate anatomically below the anterior tibial tubercle.¹⁶

Podiatric Licensure

[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 Florida-licensed podiatric physicians.¹⁷

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

Prescribing

Current law authorizes a podiatric physician to prescribe drugs that relate specifically to the scope of practice authorized in ch. 461, F.S.¹⁸ To become [authorized to prescribe controlled substances](#), federal law requires a podiatrist to register with the United States Drug Enforcement Administration (DEA) before he or she may lawfully prescribe¹⁹ controlled substances.²⁰ A podiatric physician who prescribes controlled substances without a DEA registration is subject to certain criminal and civil penalties.²¹

¹⁵ U.S. Food & Drug Administration, "About Warning and Close-Out Letters," *U.S. Department of Health and Human Services*, (last updated Mar. 20, 2024) <https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/about-warning-and-close-out-letters> (last visited Mar. 16, 2026).

¹⁶ The anterior tibial tubercle is a bony bump on the upper part of the shin where the patellar tendon attaches the quadriceps muscles (or quads) to the leg. Orthopedics & Sports Medicine Center, "Tibial Tubercle Fracture," *Boston Children's Hospital*, https://www.childrenshospital.org/sites/default/files/media_migration/ebf29668-86a6-4162-aa13-6ba0204ae38f.pdf (last visited Mar. 17, 2026).

¹⁷ Division of Medical Quality Assurance, "Annual Report and Long-Range Plan: Fiscal Year 2024-2025," *Department of Health*, pp. 29 <https://www.floridahealth.gov/wp-content/uploads/2026/01/2025.10.31.FY24-25MQAAR-FINAL1-1.pdf> (last visited January 28, 2026).

¹⁸ [S. 461.003\(5\), F.S.](#)

¹⁹ Federal law relating to drug abuse prevention and control equates the act of prescribing with the act of dispensing. Federal law 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).

To register with the DEA, a podiatrist must complete at least 8 hours of training on the treatment and management of patients with opioid or other substance use disorders provided by an accredited organization or an accredited school of podiatric medicine.²²

[Continuing Education](#)

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 address safe and effective controlled substance prescribing. The Board must approve the criteria for CE programs or courses. 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.²³

[Controlled Substances](#)

Florida Law

Chapter 893, F.S., the Florida Comprehensive Drug Abuse Prevention and Control Act, classifies controlled substances into five categories, called schedules. These schedules regulate the manufacture, distribution, preparation, and dispensing of the substances listed therein. The distinguishing factors between the different drug schedules are the “potential for abuse”²⁴ of the substance and whether there is a currently accepted medical use for the substance.²⁵

The controlled substance schedules are as follows.

- Schedule I substances have a high potential for abuse and currently have no accepted medical use in the United States, including substances such as cannabis, heroin, LSD, MDMA, and psilocybin and psilocin.²⁶
- Schedule II substances have a high potential for abuse and have a currently accepted but severely restricted medical use in the United States, including substances such as amphetamine, codeine, fentanyl, methamphetamine, morphine, raw opium, and oxycodone.²⁷
- Schedule III substances have a potential for abuse less than the substances contained in Schedules I and II and have a currently accepted medical use in the United States, including substances such as anabolic steroids and ketamine.²⁸
- Schedule IV substances have a low potential for abuse relative to substances in Schedule III and have a currently accepted medical use in the United States, including substances such as benzodiazepines and barbiturates.²⁹

²⁰ 21 U.S.C. §§ 822(a)(2), (b); 21 C.F.R. § 1301.11(a). Diversion Control Division, Drug Enforcement Administration, “Practitioner’s Manual: An Informational Outline of the Controlled Substances Act: Revised 2023,” *U.S. Department of Justice*, pp. 12, [https://deaddiversion.usdoj.gov/GDP/\(DEA-DC-071\)\(EO-DEA226\)_Practitioner's_Manual_\(final\).pdf](https://deaddiversion.usdoj.gov/GDP/(DEA-DC-071)(EO-DEA226)_Practitioner's_Manual_(final).pdf) (last visited Feb. 16, 2026).

²¹ 21 U.S.C. § 841. Federal law makes it unlawful for any person to knowingly or intentionally dispense (which includes the act of prescribing) or possess with intent to dispense a controlled substance except as authorized by the Federal Controlled Substances Act, which includes, but is not limited to, DEA registration for prescribing practitioners.

²² 21 U.S.C. § 823(m)(1).

²³ [S. 461.007\(3\), F.S.](#), and Rule 64B18-17.002, F.A.C. By rule, the Board automatically approves 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.

²⁴ [S. 893.02\(22\), F.S.](#), defines “potential for abuse” to mean that a substance has properties as a central nervous system stimulant or depressant or a hallucinogen that create a substantial likelihood of its being: 1) used in amounts that create a hazard to the user’s health or safety of the community; 2) diverted from legal channels and distributed through illegal channels; or 3) taken on the user’s own initiative rather than on the basis of professional medical advice.

²⁵ See [s. 893.03, F.S.](#)

²⁶ [S. 893.03\(1\), F.S.](#)

²⁷ [S. 893.03\(2\), F.S.](#)

²⁸ [S. 893.03\(3\), F.S.](#)

²⁹ [S. 893.03\(4\), F.S.](#)

- Schedule V substances have a low potential for abuse relative to the substances in Schedule IV and have a currently accepted medical use in the United States, including substances such as mixtures that contain small quantities of opiates, narcotics, or stimulants.³⁰

Federal Law

The [Federal Controlled Substances Act](#)³¹ also classifies controlled substances into schedules based on the potential for abuse and whether there is a currently accepted medical use for the substance. The Drug Enforcement Administration (DEA) is required to consider the following when determining where to schedule a substance:³²

- The substance's actual or relative potential for abuse;
- Scientific evidence of the substance's pharmacological effect, if known;
- The state of current scientific knowledge regarding the substance;
- The substance's history and current pattern of abuse;
- The scope, duration, and significance of abuse;
- What, if any, risk there is to public health;
- The substance's psychic or physiological dependence liability; and
- Whether the substance is an immediate precursor of a substance already controlled.

OTHER RESOURCES:

[Board of Podiatric Medicine](#)

[United States Drug Enforcement Administration Diversion Control Division](#)

³⁰ [S. 893.03\(5\), F.S.](#)

³¹ 21 U.S.C. § 812.

³² 21 U.S.C. § 811(c).