

Regenerative Medicine in Florida

A library document on what patients in Jupiter and Palm Beach County can legally be offered after July 1, 2025 — and what Florida law, FDA rules, and orthopedic trials still do not allow anyone to promise.

Focus: Fla. Stat. §§ 458.3245 & 459.0127

Effective July 1, 2025

Physician-led · Timothy Mackey, D.O.

Updated September 2026

How to use this book

Florida changed its *practice-of-medicine* rules for certain non-FDA-approved stem-cell therapies in 2025. That is not the same thing as the FDA approving those therapies, and it is not the same thing as proof they rebuild cartilage.

Read Chapters 4–7 if you only need the legal map. Read Chapters 2 and 8 if you need to tell PRP apart from an umbilical-cord allograft. Read Chapter 11 before a consult at NovaGenix.

This book is education, not legal advice and not a finding that any specific product is lawful in a given exam room. Statutes get rules; boards issue discipline; FDA still regulates products that are drugs or biologics.

About NovaGenix

[NovaGenix](#) in Jupiter offers physician-led regenerative *consultations* under Timothy Mackey, D.O. The clinic's July 2026 orthopedic explainer is the document this volume tracks: FDA has not approved a regenerative product for knee pain or tendinitis; Florida created a conditional pathway; PRP and allograft cellular products are not interchangeable; evaluation does not guarantee a procedure.

That same explainer states NovaGenix does not currently offer PRP; an older service page on PRP remains on the site for historical/educational comparison. Always confirm what is actually available at the visit.

- [Jupiter regenerative medicine](#)
- [Stem cell therapy for orthopedic conditions — what the research says](#)
- [PRP for orthopedics \(older page\)](#)

1. What “regenerative medicine” actually means

The phrase is a marketing umbrella covering very different things:

- Autologous PRP (your blood, centrifuged, injected)
- Autologous bone-marrow or adipose procedures, with widely different amounts of processing
- Allograft perinatal tissues (umbilical cord, Wharton’s jelly, placenta after live birth)
- FDA-approved hematopoietic progenitor-cell products for blood disorders — the only stem-cell products FDA has approved, and *not* for arthritis
- Investigational products under an IND

Calling all of them “stem cells” is how patients get sold a miracle. The useful questions are: whose tissue, how processed, homologous use or not, FDA classification, Florida statutory box, and what the trials measured — pain, function, or actual tissue repair.

2. PRP is not a stem-cell product

Platelet-rich plasma is made from a patient’s own blood. Platelets release growth factors. That is not an allograft, and it is not an MSC injection. AAOS describes a growing literature supporting PRP for some patients with mild-to-moderate knee osteoarthritis, more favorable evidence for some chronic tendon problems (especially tennis elbow), weaker evidence for Achilles and patellar tendinopathy, and little or no demonstrated benefit as an add-on in some rotator-cuff repairs.

Preparation method changes the product. “PRP” on two invoices can be two different doses of platelets and white cells. That is one reason trial results disagree.

3. The federal map patients actually need: 361, 351, same surgical procedure

Pathway	What it is	What it is not
Section 361 HCT/P 21 CFR 1271.10(a)	Minimally manipulated, homologous use, not combined with a drug/device (with narrow exceptions), no systemic effect except through the cells' metabolic activity if living cells are present. Registration and tissue rules; no premarket BLA.	Not a license to treat osteoarthritis as if it were a labeled indication.
Section 351 biologic / drug	More than minimally manipulated, or non-homologous use, or otherwise outside 1271.10. Needs IND + BLA in ordinary course.	Not legalized by a state practice statute.
Same surgical procedure exception 21 CFR 1271.15(b)	Remove an HCT/P from a person and implant <i>such HCT/P</i> into the same person in the same procedure, with only rinsing, sizing, shaping.	Does not cover enzymatic SVF isolation. 11th Circuit (U.S. Stem Cell Clinic, 2021) and 9th Circuit (California Stem Cell Treatment Center, 2024) both held processed SVF is not “such HCT/P.”

FDA's public position, which NovaGenix quotes: the only FDA-approved stem-cell products in the U.S. are certain blood-forming progenitor cells from cord blood, for disorders of blood production — not for COVID, not for orthopedic pain.

4. Florida's current law — CS/CS/SB 1768, Chapter 2025-185

The Florida Legislature passed CS/CS/SB 1768 (companion CS/CS/HB 1617 laid on the table). Governor approved June 25, 2025. Chapter 2025-185. Effective **July 1, 2025**.

The act created:

- **Fla. Stat. § 458.3245** — medical doctors (Board of Medicine)
- **Fla. Stat. § 459.0127** — osteopathic physicians (Board of Osteopathic Medicine)

Senate vote 37–0; House 112–0. This is not a fringe rider. It is the state’s current written policy.

Legislative intent, in the statute’s own voice: foster innovation using adult stem cells, umbilical cord blood, and other ethically obtained human cells; do *not* use cells derived from a fetus or embryo after an abortion.

Florida Department of Health summary: the bill authorizes Florida-licensed physicians to offer certain FDA-unapproved stem-cell therapies and sets sourcing, advertising, consent, and penalty rules. It is a **state practice framework**. NovaGenix’s orthopedic post says the sentence that belongs on every brochure: it is not proof the treatment works, not blanket legalization of every product, and not a replacement for FDA regulation.

Board of Medicine updated disciplinary guidelines after the bill and scheduled a Stem Cell Therapy Workgroup (January 8, 2026 on FMA’s 2025 recap) to adopt implementing rules. Check current Board rules before treating the 2025 session text as the last word on paperwork.

5. What Florida allows — and what it makes a felony

Who may perform the unapproved therapies

Only physicians licensed under Chapter 458 or 459 — M.D. or D.O. — acting in the course and scope of practice. Not every licensee in a wellness office. Not a nurse-only protocol dressed up as “regenerative.”

For which conditions

The unapproved therapies the statute addresses must be related to **orthopedics, wound care, or pain management**, and within that physician’s scope. The statute is not a permission slip for anti-aging infusions, COPD, autism, or “systemic optimization.”

What cells may be used

Afterbirth placental perinatal stem cells or other HCT/Ps that meet the statute’s manufacturing and sourcing rules. Retrieval, manufacture, and storage must occur in facilities that are FDA-registered and certified or accredited by named bodies, including:

- National Marrow Donor Program

- World Marrow Donor Association
- Association for the Advancement of Blood & Biotherapies (AABB)
- American Association of Tissue Banks (AATB)
- or another entity with stem-cell expertise determined by the department

Physicians must adhere to applicable current good manufacturing practices. Cells must meet viability-after-processing expectations described in the statute. Contracts with source facilities have required terms. A physician may not obtain cells from a facility that fails those tests.

What is criminal

Willfully performing or actively participating in treatment or research using human cells or tissues derived from a fetus or an embryo after an abortion is a **third-degree felony** and a licensure offense. The statute also criminalizes a separately defined manufacturing/sale offense involving computer products created using HCT/Ps (the session language is odd; do not ignore it — read the enrolled chapter if that clause could touch a business model).

Who is outside the new section

A physician who has FDA IND/device approval for the HCT/P use, or who performs the therapy on behalf of certain institutions named in the exemption, is not running under this section's extra state overlay in the same way. That does not mean FDA rules vanish.

6. The advertising notice and the consent Florida requires

Any form of advertisement for these therapies must include this notice, clearly legible, in a type size no smaller than the largest type in the ad:

THIS NOTICE MUST BE PROVIDED TO YOU UNDER FLORIDA LAW.

This physician performs one or more stem cell therapies 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 stem cell therapy.

Before the procedure, the physician must obtain a signed consent that, in language the patient can reasonably understand, states:

1. The nature and character of the proposed treatment.
2. That the proposed stem-cell therapy has not yet been approved by the FDA.
3. The anticipated results.
4. Recognized serious possible risks, complications, and anticipated benefits of the treatment and of recognized alternatives, including no treatment.
5. That the patient is encouraged to consult a primary care provider first.

NovaGenix reprints this architecture on its orthopedic explainer. If a Florida clinic's landing page never shows the statutory notice, that is a compliance fact, not a branding choice.

7. Federal law still applies — Florida did not repeal the FDA

State practice acts can tell physicians how they must practice inside Florida. They cannot rewrite the FDCA or the Public Health Service Act. A product that is a 351 biologic still needs an approved BLA or a lawful IND path. Enzymatically digested SVF marketed to treat disease has already lost in the Eleventh Circuit — the circuit that includes Florida.

United States v. U.S. Stem Cell Clinic, LLC, 11th Cir. 2021: same-surgical-procedure exception did not apply because the implanted SVF was not “such HCT/P” as the adipose tissue removed; 361 homologous-use criteria also failed.

The Ninth Circuit reached the same SVF conclusion in 2024; the Supreme Court declined review in 2025. Three-circuit alignment is the environment a Florida clinic now works in, even with SB 1768 on the books.

Practical translation for a patient: “Florida lets my D.O. talk to me about a non-approved orthopedic cellular product under statutory consent rules” is not the same sentence as “this vial is FDA-approved to grow my meniscus back.”

8. Orthopedic evidence without the brochure

Keep three questions separate: Did pain scores move? Did function move? Did imaging or histology show structural repair? A better WOMAC score is not cartilage regeneration.

PRP. Best-supported orthopedic uses in AAOS-facing summaries: selected mild-to-moderate knee OA and some chronic tendon problems (lateral epicondylitis more than Achilles/patellar). Heterogeneous

products, heterogeneous trials.

MSC / “stem cell” injections for knee OA. A 2024 systematic review and meta-analysis of 16 randomized trials (807 participants), cited on the NovaGenix explainer, concluded intra-articular MSC injections probably produced little to no improvement in pain or physical function, with low-certainty evidence of more post-injection pain and swelling. Other reviews are more optimistic. Difference in cell source, dose, viability, processing, and comparators makes a single slogan dishonest.

Hip OA evidence is thinner than knee. Disc, “anti-aging IV stem cells,” and neurologic claims are outside both the Florida statutory box and the evidence NovaGenix is willing to put on its current explainer.

9. Risks that are not theoretical

FDA warnings on unapproved regenerative products include infection, immune or inflammatory reactions, contamination, unwanted tissue growth, and other serious events. Contamination of clinic-processed or poorly banked products has produced documented outbreaks in the national record. Post-injection flare is common enough to show up in trial adverse-event tables.

Cost is a risk. These procedures are usually cash. Florida’s 72-hour advertising rule for free/discounted exam offers still applies to how the visit is sold.

10. How a Florida patient should use this field in 2026

1. Get an orthopedic diagnosis first — imaging, mechanical symptoms, alignment — not a stem-cell consult in a vacuum.
2. Ask whether the proposed product is PRP, autologous minimally manipulated tissue, or an allograft perinatal HCT/P.
3. Ask for the FDA-registration number and accreditation of the source facility (AABB, AATB, NMDP, WMDA, or department-recognized equivalent).
4. Read the statutory advertising notice and the consent out loud. If those documents are missing, leave.
5. Ask what outcome will be measured at 3 and 6 months, and what happens if nothing changes.
6. Keep physical therapy, weight, and — when indicated — conventional injections or surgery on the table. Regenerative care is not a moral substitute for a knee replacement a patient actually

needs.

11. How NovaGenix frames the evaluation

From the clinic's own regenerative pages: listen, diagnose, review imaging and prior treatment, discuss conventional options, then decide whether a regenerative path is even worth considering. No procedure is described as guaranteed tissue regeneration or a guaranteed way to avoid surgery.

Home-page language still lists stem-cell therapy among services. The July 2026 explainer is more precise and should govern how the library talks. Confirm live offerings — including whether PRP is on the menu — at the visit.

NovaGenix pages and posts

Regenerative cluster

[Jupiter regenerative medicine](#)

[Orthopedic stem cells — research and Florida law](#)

[PRP for orthopedics \(older page\)](#)

[BPC-157 \(peptide, not a cell product\)](#)

[Contact](#)

Adjacent education

[Peptide guide \(Volume 5 topic\)](#)

[PRP for hair \(historical post\)](#)

[Dr. Mackey](#)

Regenerative pages at NovaGenix

[Regenerative medicine, Jupiter](#)

[PRP injections](#)

[Stem cell therapy](#)

[IV stem cell therapy](#)

Reading on the evidence

[Stem cells for orthopedic conditions](#)

[PRP: how your own blood is used](#)

[PRP for athletes and sports injuries](#)

[PRP for skin](#)

Related repair peptides

[Peptide therapy — overview](#)

[BPC-157](#)

[TB-500](#)

[The “Wolverine stack”](#)

[Dr. Timothy Mackey, D.O.](#)

Statutes, FDA documents, cases, and research

Florida

- CS/CS/SB 1768 (2025), Chapter 2025-185, effective July 1, 2025. Senate summary: [flsenate.gov bill summary](#)
- Fla. Stat. § 459.0127 (osteopathic parallel): [Justia text](#)
- Fla. Stat. § 458.3245 (allopathic twin section)
- Laws of Florida chapter page: [laws.flrules.org/2025/185](#)
- Florida DOH 2025 legislation recap: [floridahealth.gov MQA legislative updates](#)
- Florida Medical Association 2025 regulatory recap (Board disciplinary guidelines + workgroup): [flmedical.org](#)

Federal

- 21 CFR 1271.10(a) — 361 HCT/P criteria; 21 CFR 1271.15(b) — same surgical procedure exception
- FDA HCT/P and same-surgical-procedure guidances
- FDA consumer communications: unapproved stem-cell products; no orthopedic indication
- *United States v. U.S. Stem Cell Clinic, LLC*, 11th Cir. 2021: [Justia](#)
- *California Stem Cell Treatment Center v. FDA*, 9th Cir. 2024 (SVF / SSP exception)

Evidence

- 2024 systematic review/meta-analysis of intra-articular MSC injections for knee OA (16 RCTs, n=807) — little to no clinically important average improvement; cited on the NovaGenix explainer
- AAOS appropriate-use and evidence summaries for PRP in knee OA and tendinopathy
- ISSCR patient handbook on unproven stem-cell interventions

Institutes and public-education destinations

Scientific and regulatory

[FDA consumer alert: regenerative products](#)

[International Society for Stem Cell Research](#)

[AABB](#)

[American Association of Tissue Banks](#)

[American Academy of Orthopaedic Surgeons](#)

Explainers

[Mayo Clinic: transplant \(approved use case\).](#)

[A Closer Look at Stem Cells \(ISSCR public site\).](#)

[MedlinePlus: stem cells](#)

Other Florida and national clinics — comparison, not endorsement

Florida’s statute will attract medical-tourism marketing. Compare source-facility accreditation, whether the statutory notice is actually on the ad, whether an M.D. or D.O. is accountable, and whether the pitch stays inside orthopedics / wound / pain. Academic orthopedic departments remain the right second opinion for surgical-level joint disease.

Frequently asked questions

▼ Did Florida legalize stem-cell therapy for knees?

Florida authorized licensed M.D.s and D.O.s to perform certain non-FDA-approved stem-cell therapies for orthopedics, wound care, or pain management if sourcing, advertising, and consent rules are met. It did not FDA-approve those products and it did not prove they work.

▼ Can a med spa in Miami inject cord-tissue “stem cells” for anti-aging under this law?

The statutory box is orthopedics, wound care, or pain management, by an M.D. or D.O., with named facility standards. Anti-aging IVs are not what the legislature wrote.

▼ If it is legal in Florida, why does the ad have to say it is not FDA-approved?

Because those are two different legal systems. The statute requires that sentence in every advertisement.

▼ Is PRP covered by SB 1768?

PRP is autologous blood, not the perinatal/HCT/P pathway the stem-cell statute is built around. It has its own evidence and practice questions.

▼ Does NovaGenix offer PRP?

The July 2026 explainer says no; an older PRP service page still exists. Confirm at the consult.

Glossary

- **HCT/P** — human cell, tissue, or cellular or tissue-based product.
- **351 / 361** — Public Health Service Act sections that sort “needs a BLA” from “tissue rules only.”
- **Homologous use** — the HCT/P does in the recipient the same basic job it did in the donor.

- **Minimal manipulation** — processing that does not alter the original relevant characteristics of the tissue.
- **SVF** — stromal vascular fraction from adipose tissue; courts have treated enzymatic SVF as a drug.
- **SB 1768 / Ch. 2025-185** — Florida’s 2025 stem-cell practice statute.

Medical and legal disclaimer

Educational compilation only. Not medical advice, not a legal opinion, not a representation that any product is approved or effective. Statutes and Board rules change; verify current text. Emergencies: 911.

novagenix.org/medical-disclaimer

Florida advertising notice: The patient and any other person responsible for payment has a right to refuse to pay, cancel payment, or be reimbursed for payment for any other service, examination, or treatment that is performed as a result of and within 72 hours of responding to the advertisement for the free, discounted fee, or reduced fee service, examination, or treatment.

NovaGenix Patient Education Series · Volume 4: Regenerative Medicine in Florida · Jupiter · 561-277-8260 · novagenix.org

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