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/CS/SB 512
INTRODUCER:	Rules Committee; Appropriations Committee; Health Policy Committee; and Senator Hutson
SUBJECT:	Nonembryonic Stem Cell Banks
DATE:	February 27, 2020 REVISED:

	ANALYST	STAFF DIRECTOR	REFERENCE	ACTION
1.	Rossitto-Van Winkle	Brown	HP	**Fav/CS**
2.	McKnight	Kynoch	AP	**Fav/CS**
3.	Rossitto-Van Winkle	Phelps	RC	**Fav/CS**

Please see Section IX. for Additional Information:

COMMITTEE SUBSTITUTE - Substantial Changes

I. Summary:

CS/CS/CS/SB 512 creates section 381.4017, Florida Statutes, in order to authorize the administration of adult human nonembryonic stem cells and HCT/Ps and the use of such cells in health care products. The bill:

- Defines multiple terms relating to the receiving, manufacturing, storing, making, dispensing, delivering, and administering of adult human nonembryonic stem cells and HCT/Ps.
- Requires the Agency for Health Care Administration (AHCA) to license establishments meeting the definition of adult human nonembryonic stem cell banks (NSCBs) as health care clinics.
- Authorizes the AHCA to adopt rules consistent with federal regulations that include criteria for advertising, procedures and protocols, incident reporting, informed consent, and recordkeeping.
- Requires NSCBs to apply for a health care clinic license and meet current licensure requirements and additional requirements to be provided by the AHCA in rule.
- Provides licensure exemption for hospitals, ambulatory surgical centers, and clinical facilities affiliated with an accredited medical school that provides training to medical students, residents, or fellows.
- Requires that NSCBs comply with specified requirements, including commercial and professional liability coverage, appointment of a Medical Director that meets specific

qualification and notification requirements, and adherence to manufacturing processes for the collection, removal, manufacturing, processing, compounding, and implantation of nonembryonic stem cells.

The AHCA estimates that the bill will have a significant negative fiscal impact on its expenditures that will be offset by the positive fiscal impact to the AHCA's revenues from the licensure, registration and inspection fees collected from NSCBs under SB 7066, which is linked to the bill.[1] **See Section V.**

The bill takes effect on July 1, 2020, contingent on SB 7066 or similar legislation taking effect on that same date, if such legislation is adopted in the same legislative session or an extension thereof and becomes a law.

II. Present Situation:

Stem Cells

Stem cells are unspecialized cells that have the ability to divide for indefinite periods of time in culture medium and to give rise to specialized cells.[2] Stem cells have the potential to develop into many different types of cells during early life and growth. In addition, in many human tissues, stem cells serve as an internal repair system, dividing essentially without limit, to replenish other cells as long as a person is still alive. When a stem cell divides, each new cell has the potential to either remain an undifferentiated stem cell or become a cell with a specialized function such as a muscle, red blood, or brain cell.[3]

Federal Regulation of Stem Cells

Certain stem cells are labeled as a drug and subject to the U.S. Food and Drug Administration (FDA) regulation if the stem cell has been derived from structural tissue or non-structural tissue in a manufacturing process involving more than minimal manipulation.[4]

The FDA regulates articles containing or consisting of human cells or tissues that are intended for implantation, transplantation, infusion or transfer into a human recipient as human cells, tissues, or cellular or tissue-based products (HCT/Ps) which are known as stem cells.[5]

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[1] Agency for Health Care Administration, *CS/SB 512 Analysis* (Feb. 14, 2020) (on file with the Senate Committee on Appropriations).
[2] National Institutes of Health, Stem Cell Information, Glossary, *Stem Cells* https://stemcells.nih.gov/glossary.htm#stemcells (last visited Jan. 27, 2020).
[3] National Institutes of Health, Stem Cell Information, *Stem Cell Basics I.*, https://stemcells.nih.gov/info/basics/1.htm (last visited Jan. 27, 2020).
[4] U.S. Food and Drug Administration, Center for Evaluation and Research, Center for Devices and Radiological Health, Office of Combination Products, *Regulatory Considerations for Human Cells, Tissues, and Cellular and Tissue-Based Products: Minimal Manipulation and Homologous Use, Guidance for Industry and Food and Drug Administration Staff* (Nov. 2017, corrected Dec. 2017), *available at* https://www.fda.gov/downloads/biologicsbloodvaccines/guidancecomplianceregulatoryinformation/guidances/cellularandgenetherapy/ucm585403.pdf (last visited Jan. 27, 2020).
[5] 21 C.F.R. 1271.3(d).

The U.S. Center for Biologics Evaluation and Research (CBER) regulates HCT/Ps.[6] The CBER does not regulate the transplantation of vascularized human organ transplants such as the kidney, liver, heart, lung, or pancreas. The Health Resources and Services Administration (HRSA) of the U.S. Department of Health and Human Services oversees the transplantation of vascularized human organs.[7]

Minimally manipulated bone marrow is also used in stem cell treatments but is not considered by the FDA to be an HCT/Ps,[8] and thus is not regulated by the FDA.[9] The HRSA regulates minimally manipulated bone marrow stem cells used for transplant.[10]

Due to the unique nature of HCT/Ps, the FDA uses a tiered, risk-based approach to the regulation of HCT/Ps, rather than the federal Food, Drug and Cosmetic Act (federal FDCA), for products that meet the definition of a drug, biologic, or device. The tiered, risk-based approach includes recommendations on how the transmission of communicable diseases can be prevented; the process controls necessary to prevent contamination and preserve the integrity and function of the products; and how clinical safety and effectiveness can be assured.[11]

An HCT/P is exempt from registration and regulation under the Public Health Service Act (PHSA)[12] and 21 C.F.R. 1271, if the establishment:[13]

- Uses the 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/P's in the usual course of business;
- Does not recover, screen, test, process, label, package, or distribute, but only receives or stores HCT/P's, solely for implantation, transplantation, infusion, or transfer within its facility; or
- Only recovers reproductive cells or tissue and immediately transfers them into a sexually intimate partner of the cell or tissue donor.

If an individual is under contract with a registered establishment, and engaged solely in recovering cells or tissues and sending the recovered cells or tissues to the registered

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[6] See 21 C.F.R., 1270 and 1271. The CBER is a part of the U.S. Food and Drug Administration.
[7] U.S. Food and Drug Administration, *Tissue and Tissue Products* (as of July 11, 2019), *available at* https://www.fda.gov/BiologicsBloodVaccines/TissueTissueProducts/default.htm (last visited Jan. 27, 2020).
[8] *See* 21 C.F.R. 1271.3(d)(4).
[9] U.S. Food and Drug Administration, *FDA Warms About Stem Cell Therapies*, *available at* https://www.fda.gov/ForConsumers/ConsumerUpdates/ucm286155.htm (last visited Jan. 27, 2020).
[10] U.S. Department of Health and Human Services, Health Resources and Services Administration, *Healthcare Systems*, *available at* https://www.hrsa.gov/sites/default/files/ourstories/organdonation/factsheet.pdf (last visited Jan. 27, 2020).
[11] *Supra* note 4.
[12] 42 U.S.C. s. 262.
[13] Establishment means a place of business under one management, at one general physical location, that engages in the manufacture of human cells, tissues, and cellular and tissue-based products. Establishment includes: (1) Any individual, partnership, corporation, association, or other legal entity engaged in the manufacture of human cells, tissues, and cellular and tissue-based products; and (2) Facilities that engage in contract manufacturing services for a manufacturer of human cells, tissues, and cellular and tissue-based products. 21 C.F.R. 1271.3(b).

establishment, he or she is not required to register or list the establishment's HCT/Ps independently, but he or she must comply with all other applicable requirements.[14]

If an HCT/P does not meet the above criteria, and the manufacturer of the HCT/P does not qualify for an exception,[15] the HCT/P will be regulated as a drug, device, and/or biological product under the federal FDCA, the PHSA,[16] and applicable regulations;[17] and premarket review will be required.[18]

According to the FDA, if a manufacturer or establishment isolates cells from structural tissue to produce a cellular therapy product, the definition of minimal manipulation applies regardless of the method used to isolate the cells. The definition applies because the assessment of whether the HCT/P is a structural tissue or cellular/nonstructural tissue is based on the characteristics of the HCT/P as it exists in the donor, prior to recovery, and prior to any processing that takes place.[19]

Federal law requires tissue establishments[20] that do not meet an exemption to:
- Screen and test donors;
- Prepare and follow written procedures for prevention of the spread of communicable disease; and
- Maintain records.[21]

The FDA has published rules to broaden the scope of products subject to regulation and to include more comprehensive requirements to prevent the introduction, transmission, and spread of communicable disease. The requirements are intended to improve protection of the public health while minimizing regulatory burden.[22]

The only HCT/Ps that are FDA-approved for use in the United States consist of blood-forming stem cells, referred to as hematopoietic progenitor cells, derived from cord blood. These products are approved for limited use in patients with disorders that affect the hematopoietic system – the body system that is involved in the production of blood. The FDA-approved stem cell products are listed on the FDA website.[23]

[14] 21 C.F.R. 1271.15.
[15] 21 C.F.R., 1271.10, 1271.15 and 1271.155.
[16] *Supra* note 12.
[17] 21 C.F.R. 1271.
[18] *Supra* note 4.
[19] *Id.*
[20] *Supra* note 13.
[21] *See* 21 C.F.R 1270 and 1271.2121.
[22] *Supra* note 7.
[23] U.S. Food and Drug Administration, *FDA Regulation of Human Cells, Tissues, and Cellular and Tissue-Based Products (HCT/P's) Product List* (page updated Feb. 2, 2018), *available at* https://www.fda.gov/vaccines-blood-biologics/tissue-tissue-products/fda-regulation-human-cells-tissues-and-cellular-and-tissue-based-products-hctps-product-list (last visited Jan. 31, 2020).

Florida Regulation of Stem Cells

Stem Cell Preparation/Manufacturing

The registration of stem cell banks does not exist under current Florida law. The Department of Business and Professional Regulation (DBPR) administers and enforces the Florida Drug and Cosmetic Act to prevent fraud, adulteration, misbranding, or false advertising in the preparation, manufacture, repackaging, or distribution of drugs, devices, and cosmetics.[24] In Florida, "a person may not sell, offer for sale, hold for sale, manufacture, repackage, distribute, or give away any new drug unless an approved application has become effective under the federal act or unless otherwise permitted by the Secretary of the United States Department of Health and Human Services for shipment in interstate commerce."[25]

The Florida Drug and Cosmetic Act defines a "drug" as an article that is:

- Recognized in the current edition of the United States Pharmacopoeia and National Formulary (USP-NF),[26] official Homeopathic Pharmacopoeia of the United States (HPUS),[27] or any supplement to any of those publications;
- Intended for use in the diagnosis, cure, mitigation, treatment, therapy, or prevention of disease in humans or other animals;
- Intended to affect the structure or any function of the body of humans or other animals; or
- Intended for use as a component of any article:
  - Listed in the USP-FM, or HPUS;
  - Used in the diagnosis, cure, mitigation, treatment, therapy, or prevention of disease in humans or other animals;
  - Used to affect the structure or any function of the body of humans or other animals; and
  - That includes active pharmaceutical ingredients.[28]

The Florida Drug and Cosmetic Act defines the manufacturing of a drug to mean the preparation, deriving, compounding, propagation, processing, producing, or fabrication of a substance into a drug.[29]

Stem cells recovered, processed, and implanted in Florida that meet the above definition are "unapproved new drugs" under both federal and state regulation and require a manufacturing permit issued by the DBPR to ensure the drugs are manufactured in accordance with good manufacturing practices.[30]

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[24] *See* part I of ch. 499, F.S.
[25] Section 499.023, F.S.
[26] The USP-NF is a combination of two compendia, the United States Pharmacopeia (USP) and the National Formulary (NF). It contains standards for medicines, dosage forms, drug substances, excipients, biologics, compounded preparations, medical devices, dietary supplements, and other therapeutics. *See* 21 U.S.C. s. 301(g)(1).
[27] The HPUS is declared a legal source of information on drug products (along with the USP/NF) in the Federal Food Drug and Cosmetic Act, 21 U.S.C. § 301. Section 201(g)(1) of the Act. 21 U.S.C. s. 321 defines the term "drug" as articles recognized in the official United States Pharmacopoeia, official Homeopathic Pharmacopeia of the United States, or official National Formulary or any supplement to any of them.
[28] Section 499.003(17), F.S.
[29] Section 499.003(28), F.S.
[30] Department of Business and Professional Regulation, Division of Drugs, Devices and Cosmetics, *Does my company need a permit?, available at* http://www.myfloridalicense.com/DBPR/drugs-devices-and-cosmetics/do-i-need-a-license/#1508505246226-7153ba5b-b4c4 (last visited Jan. 31, 2020). See also s. 499.003(28), F.S.

The Florida Drug and Cosmetic Act defines the "distribution" of a drug to include the selling, purchasing, trading, delivering, handling, storing, or receiving of a drug; but does not include the administration or dispensing of a drug.[31]

Stem Cell Implantation or Transplantation

Stem cells may be collected, processed, and implanted or transplanted in a physician's office, health care clinic, ambulatory surgical center, or hospital.[32] In order to ship, mail, or deliver, in any manner, a medicinal drug into Florida, a nonresident pharmacy must be registered under s. 465.0156, F.S. In order to ship, mail, deliver, or dispense, in any manner, a compounded sterile product into Florida, a nonresident pharmacy, or an outsourcing facility, must hold a nonresident sterile compounding permit issued by the Board of Pharmacy (BOP).[33]

Physician's Office

The Department of Health (DOH) Office of Surgery Registration and Inspection Program was established to register and set standards for allopathic and osteopathic physicians performing surgery in an office setting. The DOH requires all physicians who perform the following to register their office with the DOH:

- Liposuction procedures where more than 1,000 cubic centimeters of supernatant fat is removed;
- Level II procedures; and
- All Level III surgical procedures.[34]

Each registered physician's office must establish financial responsibility[35] and designate a physician who is responsible for the office's compliance with the office health and safety requirements. The designated physician must have a full, active, and unencumbered license and must practice at the office for which he or she is responsible. Within ten days after the termination of the designated physician, the office must notify the DOH of the designation of another physician to serve as the designated physician. If the office fails to comply with these requirements the DOH may suspend the registration.[36]

The DOH will inspect registered physicians' offices that are not nationally accredited, to ensure the safety of the people of Florida.[37]

[31] Section 499.003(16), F.S.
[32] See ss. 395.002, 458.328, 459.0138, and 400.9935, F.S.; Rules 64B8-9.009 and 64B15-14.007, F.A.C..
[33] Section 465.0158, F.S.
[34] Sections 458.328 and 459.0138, F.S.; Rules 64B8-9.009 and 64B15-14.007, F.A.C..
[35] Section 458.328(1)(c), F.S.
[36] Section 458.328(1)(b), F.S.
[37] Department of Health, Licensing and Regulation, *Office Surgery Registration, available at* http://www.floridahealth.gov/licensing-and-regulation/office-surgery-registration/index.html (last visited Jan. 31, 2020).

Health Care Clinics

The Health Care Clinic Act[38] provides the AHCA with licensing and regulatory authority to provide standards and oversite for health care clinics.[39] A clinic is defined as an entity where health care services are provided and which tenders charges for reimbursement for such services. Numerous exceptions to licensure exist.[40] The AHCA interprets the scope of its regulatory powers to solely include entities that bill third parties, such as Medicare, Medicaid, and insurance companies. Entities that provide health care services and accept "cash only" for services are excluded from the definition of "clinic" and are not subject to licensure or regulation by the AHCA.[41]

Hospitals and Ambulatory Surgical Centers

The AHCA is responsible for licensing, registering, and regulating hospitals and ambulatory surgical centers (ASCs) pursuant to ch. 395, F.S. An ASC is a facility, the primary purpose of which is to provide elective surgical care, in which the patient is admitted to and discharged from such facility within 24 hours, and which is not part of a hospital.[42]

Regulation of Physicians in Florida

The Board of Medicine (BOM) and the Board of Osteopathic Medicine (BOOM) (the Boards) within the DOH have the authority to adopt rules to regulate the practice of medicine and osteopathic medicine, respectively. The boards have authority to establish, by rule, standards of practice and standards of care for particular settings.[43] Such standards may include education and training, medications including anesthetics, assistance of and delegation to other personnel, sterilization, performance of complex or multiple procedures, records, informed consent, and policy and procedures manuals.[44]

Currently, the BOM is warning physicians and consumers that they should be aware of the risks involved in stem cell therapies and regenerative medicine that have not been FDA-approved.[45] Although certain stem-cell therapies offer hope and hold great potential in treating devastating conditions, the FDA has approved few treatments involving stem cells. The BOM warns physicians providing stem cell treatment that he or she should have an investigational new drug application (IND) or a single patient IND for Compassionate or Emergency Use.[46] Florida does not specifically regulate clinics that perform treatments using stem cells, but the Boards have authority to investigate and discipline physicians who fail to meet the standard of care for providing any medical services.

[38] Part X of ch. 400, F.S.
[39] Section 400.990, F.S.
[40] Section 400.9905(4). F.S.
[41] *Id*.
[42] Section 395.002(3), F.S.
[43] Sections 458.331(v) and 459.015(z), F.S.
[44] *Id*.
[45] The Department of Health, Board of Medicine, *Information on Stem Cell Clinics Offering Unapproved Therapies*, *available at* http://flboardofmedicine.gov/latest-news/october-2015-newsletter/ (last visited Jan. 31 2020).
[46] *Id*.

III. Effect of Proposed Changes:

The bill creates s. 381.06017, F.S., relating to nonembryonic stem cell banks (NSCBs). The bill defines "adult human nonembryonic stem cells" as cells derived from adult human nonembryonic HCT/Ps through enzymatic digestion, mechanical disruption, or similar processing. The term includes only drugs, devices, or biological products that are approved by the United States Food and Drug Administration.

The bill defines "HCT/Ps" as human cells, tissues, or cellular or tissue-based products that are intended for implantation, transplantation, infusion, or transfer into a human recipient and specifically excludes from the meaning of HCT/Ps the following:

- Vascularized human organs for transplantation;
- Whole blood, blood components, blood derivative products, or platelet-rich plasma;
- Human secretions, including milk, collagen, and cell factors, but not semen;
- Minimally manipulated bone marrow that is for homologous use only and that is not combined with any other article except water, crystalloids, or sterilizing, preserving, or storage agents;
- Ancillary products used in the manufacture of nonembryonic adult human allogenic or autologous HCT/Ps;
- Cells, tissue, or organs derived from animals;
- In vitro diagnostic products; and
- Blood vessels recovered with an organ for transplantation.

The bill also defines the following specific terms relating to the dispensing, making, storing, and administration of nonembryonic stem cells:

"Dispense" has the same meaning as in s. 465.003(6), F.S.[47]

"Establishment" means a place of business which is at one general physical location and may extend to one or more contiguous suites, units, floors, or buildings operated and controlled exclusively by entities under common operation and control. The term includes multiple buildings with an intervening thoroughfare if the buildings are under common exclusive ownership, operation, and control. For purposes of permitting, each suite, unit, floor, or building must be identified in the most recent permit application.

"FD&C Act" means the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. ss. 301 et seq.; 52 Stat. 1040 et seq.

"Minimally manipulated" means:

[47] Under s. 465.003(6), F.S., "dispense" means the transfer of possession of one or more doses of a medicinal drug by a pharmacist to the ultimate consumer or her or his agent. As an element of dispensing, the pharmacist shall, prior to the actual physical transfer, interpret and assess the prescription order for potential adverse reactions, interactions, and dosage regimen she or he deems appropriate in the exercise of her or his professional judgment, and the pharmacist shall certify that the medicinal drug called for by the prescription is ready for transfer. The pharmacist shall also provide counseling on proper drug usage, either orally or in writing, if in the exercise of her or his professional judgment counseling is necessary. The actual sales transaction and delivery of such drug shall not be considered dispensing. The administration shall not be considered dispensing.

- For structural tissues, processing that does not alter the original characteristics of the tissue which relate to the tissue's utility for reconstruction, repair, or replacement; or
- For cells or nonstructural tissues, processing that does not alter the relevant biological characteristics of the cell or tissue; and
- For both structural and nonstructural tissues, the washing, rinsing, cleaning, sizing, shaping, or concentrating of adult human nonembryonic HCT/Ps which does not alter the relevant characteristics or basic functions of the tissue or cell.

"Nonembryonic stem cell bank" is a publicly or privately owned establishment that:

- Operates its own laboratories;
- Retains control over all aspects of processing and storage;
- Is managed by a single entity; and
- Performs any of the following activities in the course of its business:
  - Engages in the manufacture, use, implantation, transplantation, infusion, dispensing, transfer, or storage of adult human allogenic and autologous nonembryonic stem cells.
  - Accepts, receives, carries, or delivers human allogenic and autologous nonembryonic stem cells, drugs, or products that are approved by the United States Food and Drug Administration and regulated as drugs, devices, or biological products.
  - Recovers, collects, screens, and tests, in the facility, adult human autologous nonembryonic HCT/Ps from a specific patient for implantation, transplantation, infusion, or transfer back into the same patient during a single surgery within the facility.
  - Provides patient-specific health care services using adult human autologous nonembryonic HCT/Ps in the facility during a single procedure.
  - Advertises adult human nonembryonic stem cell services or adult human autologous nonembryonic HCT/P services, including, but not limited to the collection, manufacture implantation, transplantation, infusion, transfer, storage, dispensing, use, or purported use, of United States Food and Drug Administration-approved adult human autologous nonembryonic stem cells or adult human autologous nonembryonic HCT/Ps that are intended to diagnose, cure, mitigate, treat, provide therapy for, or prevent an injury or a disease.
  - Performs any procedure that is intended to collect or store adult human autologous nonembryonic HCT/Ps for autonomous homologous use or diagnoses, cures, mitigates, treats, provides therapy for, or prevents an injury or a disease through the use, or purported use, of adult human autologous nonembryonic HCT/Ps.
  - Compounds patient-specific adult human autologous nonembryonic HCT/Ps into a drug product by combining or mixing the patient-specific adult human nonembryonic HCT/Ps, at the prescriptive direction of a licensed physician authorized within the scope of his or her license to prescribe and administer adult human autologous nonembryonic HCT/Ps with one or more drugs or products to create a patient-specific drug or product.
  - Dispenses adult human autologous nonembryonic stem cells or HCT/Ps to any of the following for a specific patient pursuant to a valid order from a licensed physician authorized within the scope of his or her license to prescribe and administer adult human autologous nonembryonic HCT/Ps: the specific patient's physician with privileges to practice at the nonembryonic stem cell bank; or, for office use, the specific patient's physician's office or a health care facility or treatment setting where the physician has privileges to administer adult human autologous nonembryonic HCT/Ps.

"Office use" includes the provision and administration of any United States Food and Drug Administration-approved adult human nonembryonic stem cell drug, compounded drug, or compounded product regulated as a drug, device, or any biological product under the FD&C Act, the PHS Act, 42 U.S.C. 262, s. 351, or part I of chapter 499, to a patient's physician in the physician's office or in a health care facility or treatment setting, including a hospital, an ambulatory surgical center, or a health care clinic licensed under ch. 395 or ch. 400, F.S. The term also includes the patient-specific dispensing, provision, or administration of the patient's adult human autologous nonembryonic HCT/Ps.

"PHS Act" means the Public Health and Safety Act, 42 U.S.C. ss. 262 et seq., and applicable regulations, including 21 C.F.R. part 1271.

"Physician" means a person who is licensed to practice medicine under ch. 458, F.S., or osteopathic medicine under ch. 459, F.S.

The bill requires NSCBs that manufacture adult human nonembryonic HCT/Ps to register with and submit a list of all HCT/Ps manufactured to the Food and Drug Administration and obtain a permit from the DBPR, if the HCT/P manufactured is:

- Minimally manipulated;
- Intended only for homologous use;
- Manufactured through a process that does not involve the combination of the cells or tissue with another article, except water, crystalloids, or a sterilizing, preserving, or storing agent; and
- For an adult human nonembryonic HCT/P, either:
  - Does not have a systemic effect and is not dependent upon the metabolic activity of living cells for their primary function; or
  - Has a systemic effect or is dependent upon the metabolic activity of living cells for its primary function and is for autologous use or for allogenic use in a first-degree or second-degree blood relative.

The bill provides that:

- NSCBs that manufacture adult human nonembryonic HCT/Ps that do not meet the above criteria are exempt from the registration and listing requirements of s. 361 of the PHS Act but must obtain a permit from and submit a list of all HCT/Ps manufactured to the DBPR if the establishment:
  - Uses the adult human nonembryonic HCT/Ps for nonmedicinal scientific purposes; or
  - Removes human adult nonembryonic HCT/Ps from a patient and implants the same HCT/Ps into the same patient during the same surgical procedure with only minimal manipulation of the HCT/Ps which does not alter the original relevant biological characteristics of the cells or tissues.
- NSCBs that manufacture adult human nonembryonic HCT/Ps are prohibited from manipulating, more than minimally, through enzymatic digestion, mechanical disruption, or similar processing, any adult human nonembryonic stem cell or HCT/P to alter the HCT/P's original structural characteristics or relevant biological characteristics or to isolate differentiated cells from undifferentiated cells that have lost their original structural function, so that the undifferentiated cells can be differentiated into a specialized cell type, unless the

nonembryonic stem cell bank has first registered the HCT/P with the United States Food and Drug Administration and the Department of Business and Professional Regulation as a drug, device, or biological product manufacturer and complies with all applicable regulations under the FD&C Act, the PHS Act, 21 C.F.R. parts 1-1299, and part I of chapter 499.

- An NSCB that advertises, collects, stores, manufactures, dispenses, compounds, uses, or purports to use adult human nonembryonic stem cells or adult human autologous nonembryonic HCT/Ps, is deemed a clinic and must comply with all of the following requirements:
  - Adhere to the current good manufacturing practices for the collection, removal, manufacturing, processing, using, compounding, and implantation of nonembryonic stem cells, or products containing them, under Florida and federal law.
  - Obtain a health care clinic license and register each establishment separately, unless the clinic is a facility licensed under ch. 395, F.S., or the clinic is affiliated with an accredited medical school that provides training to medical students, residents, or fellows.
  - Have a physician medical director, with a full, active, and unencumbered license, who actively practices at the NSCB, and who is responsible for the NSCB's compliance with all licensure, operations and good manufacturing practices requirements.
  - Notify the AHCA, in writing, on a form approved by the AHCA within 10 days after termination of a physician medical director; and notify the AHCA within 10 days after such termination of the identity of the new physician medical director who has assumed the responsibilities for the NSCB. Failure to have a physician medical director practicing at the location of the NSCB must be the basis for a summary suspension of the NSCB's license pursuant to s. 400.607 or s. 120.60(6), F.S.
  - Maintain commercial and professional liability insurance in an amount not less than $250,000 per claim.
  - Operate each establishment using the same name as the one used to obtain the health care clinic license; and requiring all invoices, packing slips, and other business records to list the same name.
  - Obtain a pharmacy permit for each person and establishment before dispensing, offering office use for the compounding of human nonembryonic stem cells, or dispensing a compounded product for office use.

The bill prohibits the sale or dispensing of human nonembryonic stem cells, a compounded drug containing human nonembryonic stem cells; or products containing human nonembryonic stem cells by any person or establishment, other than the NSCB or pharmacist at the NSCB that manufactured the human nonembryonic stem cells, the compounded drug, or product containing human nonembryonic stem cells, except that:

- A health care practitioner who requests the dispensing of the human nonembryonic stem cells, compounded drug, or compounded product from the manufacturing NSCB may sell or dispense such items to his or her patient if the health care practitioner is authorized within the scope of his or her license to prescribe and administer human nonembryonic stem cells; or
- A pharmacist, pharmacy, or establishment that requests the dispensing of the human nonembryonic stem cells, compounded drug, or compounded product from the manufacturing NSCB may sell or dispense such items to a health care practitioner who is authorized within the scope of his or her license to prescribe and administer human nonembryonic stem cells to patients.

The bill prohibits a physician, advanced practice registered nurse, or a physician assistant from practicing in a NSCB that is not licensed with the AHCA. The license of a health care practitioner who violates this paragraph is subject to disciplinary action by the appropriate regulatory board.

The bill requires health care practitioners to adhere to the applicable current good manufacturing practices for the collection, removal, manufacturing, processing, compounding, and implantation of stem cells or products containing stem cells pursuant to federal regulations.

The bill requires the AHCA to adopt rules necessary to administer the licensure and regulation of NSCBs, including, but not limited to, rules regarding all of the following, which must be consistent with the best practices specified in federal regulations:

- Advertising;
- NSCB procedures and protocols for the collection, manufacturing, storing, dispensing, and use of nonembryonic stem cells, drugs containing nonembryonic stem cells, and products containing nonembryonic stem cells in accordance with the applicable current best practices;
- Adverse incident reportings;
- Informed consent; and
- Recordkeeping, record retention, and availability of records for inspection.

The bill takes effect on July 1, 2020, contingent on SB 7066[48] or similar legislation taking effect on that same date, if such legislation is adopted in the same legislative session or an extension thereof and becomes a law.

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.

[48] SB 7066 is a stand-alone bill providing that establishments meeting criteria for permitting, registration, or licensure as required under CS/CS/CS/SB 512 must pay any fees associated with such permitting, registration, or licensure.

V. Fiscal Impact Statement:

A. Tax/Fee Issues:

None.

B. Private Sector Impact:

CS/CS/CS/SB 512 requires the AHCA to license establishments meeting the definition of a nonembryonic stem cell bank (NSCB) as a health care clinic. NSCBs are required to maintain commercial and professional liability insurance in an amount not less than $250,000 per claim.

C. Government Sector Impact:

The AHCA estimates a recurring increase in workload and costs associated with the registration of NSCBs as health care clinics. Specifically, the AHCA estimates the need for three full-time equivalent positions and $285,007 in State Fiscal Year 2020-2021 and a recurring $300,250 thereafter to implement the bill's requirements.[49]

The anticipated increase in expenditures by the AHCA will be offset by the revenues collected under SB 7066, which is linked to the bill, from the facilities that the AHCA estimates may require a health care clinic license under the bill.

VI. Technical Deficiencies:

None.

VII. Related Issues:

None.

VIII. Statutes Affected:

This bill creates section 381.06017 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/CS by Rules on February 26, 2020:
The CS:

- Defines additional terms, clarifies definitions, removes definition of compounding to align the bill with Federal law;
- Limits who can operate a NSCB to an establishment:
  - That operates their own laboratories;

[49] *Id*.

- Retains control over all aspects of processing and storage; and
- Is managed by a single entity.

- Limits practitioners to Florida licensed physicians authorized within the scope of their license to prescribe and administer adult human nonembryonic cells or tissue with one or more drugs or products to create a patient-specific drug or product;
- Required NSCBs to registered with the FDA if they are actually manufacturing more than minimally manipulated cells that have lost their structural characteristics.

CS/CS by Appropriations on February 20, 2020:
The CS:

- Removes the requirement for nonembryonic stem cell banks licensed as health care clinics to pay all fees associated with licensure, registration, and inspection.
- Provides a contingent effective date based on SB 7066 or similar legislation taking effect on the same date, if such legislation is adopted in the same legislative session or an extension thereof and becomes a law.

CS by Health Policy on February 4, 2020:
The CS:

- Creates s. 381.06017, F.S., rather than s. 381.4017, F.S., which authorizes NSCB's to operate in Florida;
- Requires NSCBs to register with the AHCA as a health care clinic, rather than the DOH;
- Defines an NSCB broadly, not just a facility that stores nonembryonic stem cells, but as any establishment that:
  - Manufactures, collects, or stores human embryonic stem cells;
  - Provides patient-specific health care services using human nonembryonic stem cells;
  - Advertises human nonembryonic stem cell services;
  - Preforms procedures that:
    1) Collects or stores human embryonic stem cells; or
    2) Use non-FDA approved human nonembryonic stem cells, alone, or as a compounded drug or product, to diagnose, cure, treat, provide therapy for, or to prevent injury or disease; or
  - Compounds human nonembryonic stem cells into a compounded drug or product.
- Authorizes the administration of nonembryonic stem cells only by health care practitioners that the scope of the practitioner's license permits the prescribing and administering of human nonembryonic stem cells; and does not authorize:
  - The self-administration of nonembryonic stem cells; or
  - The administration of nonembryonic stem cells by just any person licensed or authorized to administer, or assist in the administration of, medications or health care;
- Does not authorize every pharmacy, owned or operated in Florida, to compound health care products using nonembryonic stem cells either alone or with other sterile ingredients.
- Does not authorize a person to import any sterile compound, drug, or other treatment containing nonembryonic stem cells if such compound, drug, or other treatment:

  - Was obtained legally from the jurisdiction from which it came; and
  - Is for personal use.
- Requires the NSCB to carry both commercial and liability insurance in an amount not less than $250,000 per claim, where the original bill did not specify limits; and
- Authorizes the AHCA to adopt rules necessary to administer the licensure and regulation of NSCBs.

B. Amendments:

None.