HOUSE OF REPRESENTATIVES STAFF ANALYSIS

BILL #: CS/HB 313 Voluntary Registration of Stem Cell Providers
SPONSOR(S): Health Quality Subcommittee, Donalds
TIED BILLS: **IDEN./SIM. BILLS:**

REFERENCE	ACTION	ANALYST	STAFF DIRECTOR or BUDGET/POLICY CHIEF
1) Health Quality Subcommittee	12 Y, 0 N, As CS	Guzzo	McElroy
2) Health Care Appropriations Subcommittee	10 Y, 0 N	Mielke	Clark
3) Health & Human Services Committee			

SUMMARY ANALYSIS

A stem cell is a cell that has the ability to develop into a specialized cell in the body. Stem cell therapy, also called regenerative medicine, is the use of stem cells to treat or prevent a disease or condition. The use of stem cells have shown potential in regenerative and reconstructive medicine. These practices are regulated by the United States Food and Drug Administration.

CS/HB 313 creates a voluntary registration program within the Department of Health (DOH) for stem cell providers. Physicians licensed under chapter 458 or chapter 459 who provide stem cell services may register with the program. Any physician who registers agrees to adhere to current good manufacturing practices established pursuant to the Federal Food, Drug, and Cosmetic Act. A manufacturer or distributor of stem cell products may also register with the program.

The bill requires DOH to establish and maintain an online registry on its website of all physicians, manufacturers, and distributors participating in the voluntary registration program. DOH is required to update this registry monthly.

The bill has an insignificant, negative fiscal impact on the DOH that can be absorbed with existing resources. The bill has no fiscal impact on local governments.

The bill has an effective date of July 1, 2020.

FULL ANALYSIS

I. SUBSTANTIVE ANALYSIS

A. EFFECT OF PROPOSED CHANGES:

Present Situation

Stem Cells

Stem cells are cells that have the ability to divide for indefinite periods in culture and to give rise to specialized cells.[1] Under certain physiologic or experimental conditions, stem cells can be induced to become tissue- or organ-specific cells with special functions.[2] Stem cells are referred to as "undifferentiated" because they have not yet committed to a developmental path for a specific tissue or organ.[3] Differentiation is the process of changing into a specific type of cell.[4] Stem cells have the potential to repair, restore, replace, and regenerate cells, and could possibly be used to treat a number of medical conditions.[5]

Scientists primarily work with two categories of stem cells: embryonic and adult.[6] Embryonic stem cells are derived from embryos, usually created by in vitro fertilization and donated for research with the informed consent of donors.[7] Embryonic stem cells may be used to generate every cell type found in the body because they are pluripotent.[8]

Adult stem cells (nonembryonic) are more specialized than embryonic stem cells and typically generate different cell types for the specific tissue or organ in which they live.[9] Adult stem cells have been found in organs that need to continuously replenish themselves, such as the blood, skin, and gut, but also are in other less generative organs such as the brain.[10]

In 2007, scientists identified conditions that would allow some specialized adult stem cells to be genetically reprogrammed or engineered to become pluripotent, i.e. behave like embryonic cells.[11] These reprogrammed cells are called induced pluripotent stem cells. It is not known if the induced pluripotent stem cells differ from embryonic stem cells in a clinically significant way.[12] However, induced pluripotent stem cells could replace the use of embryonic stem cells in research and clinics.[13]

Stem cell therapy is the treatment of a condition or illness with stem cells or cells that come from stem cells to replace or repair a patient's damaged cells or tissues.[14] Currently, the range of diseases for which there are proven treatments based on stem cell therapy is small.[15] However, treatments for disorders of the blood and immune systems and acquired loss of bone marrow, can in some cases be

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[1] National Institutes of Health, *Stem Cell Information: Glossary*, available at https://stemcells.nih.gov/glossary.htm (last visited January 31, 2020).
[2] National Institutes of Health, *Stem Cell Information: Stem Cell Basics I.*, available at https://stemcells.nih.gov/info/basics/1.htm (last visited January 31, 2020).
[3] National Institutes of Health, *Stem Cell Information: Stem cell Basics II.*, available at https://stemcells.nih.gov/info/basics/2.htm (last visited February 1, 2020).
[4] Id.
[5] U.S. Food and Drug Administration, *FDA Warns about Stem Cell Therapies*, (Nov. 16, 2017), available at https://www.fda.gov/ForConsumers/ConsumerUpdates/ucm286155.htm (last visited February 2, 2020).
[6] *Supra* note 2.
[7] National Institutes of Health, *Stem Cell Information: Stem Cell Basics III.*, available at https://stemcells.nih.gov/info/basics/3.htm (last visited February 1, 2020).
[8] Id. Pluripotent is the state of a single cell that is capable of differentiating into all tissues of an organism, but not alone capable of sustaining full organismal development (*supra* note 1).
[9] International Society for Stem Cell Research, *Stem Cell Facts*, available at https://www.closerlookatstemcells.org/wp-content/uploads/2018/10/stem-cell-facts.pdf (last visited February 1, 2020).
[10] Id.
[11] *Supra* note 9.
[12] National Institutes of Health, *Stem Cell Information: Stem Cell Basics VI.*, available at https://stemcells.nih.gov/info/basics/6.htm (last visited February 1, 2020).
[13] Vimal Singh, et al, *Induced Pluripotent Stem Cells: Applications in Regenerative Medicine, Disease Modeling, and Drug Discovery*,
[14] *Supra* note 9.
[15]

treated effectively with blood stem cells.[16] Tissue- and organ-specific treatments, such as those for skin and corneas, have proven successful.[17] However, other stem cell therapies are experimental, and may not yet be shown to be safe or effective.[18]

Stem Cell Regulation

The Center for Biologics Evaluation and Research (CBER), within the United States Food and Drug Administration (FDA), regulates biological products for human use, including gene therapy.[19] An establishment that manufactures human cells, tissues, and cellular and tissue-based products (HCT/Ps), must register with CBER, if the:[20]

- 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; 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.

An establishment is not required to comply with registration and reporting requirements if the establishment:[21]

- Uses HCT/P's solely for nonclinical scientific or educational purposes;
- Removes HCT/P's from an individual and implants such HCT/P's 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 as a carrier;
- 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 your 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.

The HCT/P is regulated as a drug, device, or biologic product under the Public Health Service Act and/or the Food, Drug, and Cosmetics Act, if it does not meet the above-referenced requirements or qualify for an exemption.[22]

In August 2017, the FDA announced plans to increase its regulation of clinics that use therapies involving biologic products that have not been approved by the FDA.[23] In November 2017, the FDA

[16] Id.
[17] Id.
[18] Id.
[19] U.S. Food and Drug Administration, *About the Center for Biologics Evaluation and Research*, available at https://www.fda.gov/AboutFDA/CentersOffices/OfficeofMedicalProductsandTobacco/CBER/default.htm (last visited February 1, 2020).
[20] 21 C.F.R. s. 1271.10.
[21] 21 C.F.R. s. 1271.15.
[22] 21 C.F.R. s. 1270.20.

published its comprehensive regenerative medicine policy framework.[24] The only stem cell-based therapies that have been approved by the FDA for use in the United States consist of blood-forming stem cells derived from cord blood.[25]

Regulation of Physicians in Florida

The Board of Medicine and the Board of Osteopathic Medicine (collectively, Boards), within the Department of Health (DOH), have the authority to adopt rules to regulate the practice of medicine and osteopathic medicine, respectively. The Boards have the authority to establish, by rule, standards of practice and standards of care for particular settings.[26] 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.[27]

In 2015, the Florida Board of Medicine warned physicians and consumers that they should be aware of the risks involved accessing stem cell therapies and regenerative medicine that has not approved by the FDA.[28] The Board of Medicine further warned that a physician providing stem cell treatment should have investigational new drug application (IND) or a single patient IND for Compassionate or Emergency Use.[29] Florida does not specifically regulate clinics that perform treatments using stem cells; however, the Board of Medicine and the Board of Osteopathic Medicine, have the authority to investigate and discipline physicians who fail to meet the standard of care for providing medical services. In 2013, the Board of Medicine revoked the licenses of two physicians in administrative cases involving stem cells for failing to meet the standard of care.[30]

Effect of Proposed Changes

CS/HB 313 creates a voluntary registration program within the Department of Health (DOH) for stem cell providers. Physicians licensed under chapter 458 or chapter 459 who provide stem cell services may register with the program. Any physician who registers agrees to adhere to current good manufacturing practices established pursuant to the Federal Food, Drug, and Cosmetic Act. A manufacturer or distributor of stem cell products may also register with the program.

The bill requires DOH to establish and maintain an online registry on its website of all physicians, manufacturers, and distributors participating in the voluntary registration program. DOH is required to update this registry monthly.

The bill has an effective date of July 1, 2020.

B. SECTION DIRECTORY:

Section 1: Creates s. 381.4017, F.S., voluntary registration of stem cell providers.
Section 2: Provides an effective date of July 1, 2020.

II. FISCAL ANALYSIS & ECONOMIC IMPACT STATEMENT

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[23] *Statement from FDA Commissioner Scott Gottlieb, M.D. on the FDA's New Policy Steps and Enforcement Efforts to Ensure Proper Oversight of Stem Cell Therapies and Regenerative Medicine,* August 28, 2017, available at https://www.fda.gov/news-events/press-announcements/statement-fda-commissioner-scott-gottlieb-md-fdas-new-policy-steps-and-enforcement-efforts-ensure (last visited February 1, 2020).
[24] *FDA Announces Comprehensive Regenerative Medicine Policy Framework*, November 15, 2017, available at https://www.fda.gov/news-events/press-announcements/fda-announces-comprehensive-regenerative-medicine-policy-framework (last visited February 1, 2020).
[25] *Supra* note 5.
[26] Sections 458.331(v) and 459.015(z), F.S.
[27] Id.
[28] Florida Board of Medicine, *Information on Stem Cell Clinics Offering Unapproved Therapies*, available at http://flboardofmedicine.gov/latest-news/october-2015-newsletter/ (last visited February 1, 2020).
[29] Id.
[30] Department of Health, *2018 Agency Analysis for House Bill 1185*, (Jan. 12, 2018), on file with the Health Quality Subcommittee.

A. FISCAL IMPACT ON STATE GOVERNMENT:

1. Revenues:

None.

2. Expenditures:

The DOH will incur costs to adopt rules for the voluntary registration of physicians, manufacturers, and distributors who provide stem cell services or products. This can be absorbed within existing resources.

The DOH may experience additional workload relating to the voluntary registration and maintenance of the online registry. It is unknown how many registrants there will be but it is estimated these costs can be handled with existing resources.

B. FISCAL IMPACT ON LOCAL GOVERNMENTS:

1. Revenues:

None.

2. Expenditures:

None.

C. DIRECT ECONOMIC IMPACT ON PRIVATE SECTOR:

None.

D. FISCAL COMMENTS:

None.

III. COMMENTS

A. CONSTITUTIONAL ISSUES:

1. Applicability of Municipality/County Mandates Provision:

Not Applicable. This bill does not appear to affect county or municipal governments.

2. Other:

None.

B. RULE-MAKING AUTHORITY:

The bill provides DOH sufficient rulemaking authority.

C. DRAFTING ISSUES OR OTHER COMMENTS:

None.

IV. AMENDMENTS/ COMMITTEE SUBSTITUTE CHANGES