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/SB 7066
INTRODUCER:	Rules Committee and Appropriations Committee
SUBJECT:	Fees
DATE:	March 3, 2020
REVISED:	

	ANALYST	STAFF DIRECTOR	REFERENCE	ACTION
	McKnight	Kynoch		**AP Submitted as Comm. Bill/Fav**
1.	McKnight	Phelps	RC	**Fav/CS**

Please see Section IX. for Additional Information:

COMMITTEE SUBSTITUTE - Substantial Changes

I. Summary:

CS/SB 7066, which is linked to CS/CS/CS/SB 512, provides 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.

This bill authorizes new state fees, requiring a two-thirds vote of the membership of the Senate. See Section IV.

The bill will have a significant negative fiscal impact on the Agency for Health Care Administration's (AHCA) and the Department of Business and Professional Regulation's (DBPR) expenditures that will be offset by the significant positive fiscal impact to the AHCA's and DBPR's revenues from the permitting, registration, and licensure fees collected from nonembryonic stem cell banks (NSCBs) under the bill. See Section V.

The bill takes effect on the same date that CS/CS/CS/SB 512 or similar legislation takes effect, if such legislation is adopted in the same legislative session or an extension thereof and becomes a law.

II. Present Situation:

The Florida Constitution

The Florida Constitution provides that no state tax or fee may be imposed, authorized, or raised by the Legislature except through legislation approved by two-thirds of the membership of each

house of the Legislature.[1] For purposes of this requirement, a "fee" is any charge or payment required by law, including any fee or charge for services and fees or costs for licenses and to "raise" a fee or tax means to:[2]

- Increase or authorize an increase in the rate of a state tax or fee imposed on a percentage or per mill basis;
- Increase or authorize an increase in the amount of a state tax or fee imposed on a flat or fixed amount basis; or
- Decrease or eliminate a state tax or fee exemption or credit.

A bill that imposes, authorizes, or raises any state fee or tax may only contain the fee or tax provision(s) and may not contain any other subject.[3]

The constitutional provision does not authorize any state tax or fee to be imposed if it is otherwise prohibited by the constitution and does not apply to any tax or fee authorized or imposed by a county, municipality, school board, or special district.[4]

Health Care Clinics

The Health Care Clinic Act[5] provides the Agency for Health Care Administration (AHCA) with licensing and regulatory authority to provide standards and oversite for health care clinics.[6] 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.[7] 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.

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.[8] 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."[9]

[1] Fla. Const. art. VII, s. 19(a)-(b). The amendment appeared on the 2018 ballot as Amendment 5.
[2] Fla. Const. art. VII, s. 19(d).
[3] Fla. Const. art. VII, s. 19(e).
[4] Fla. Const. art. VII s. 19(c).
[5] Part X of ch. 400, F.S.
[6] Section 400.990, F.S.
[7] Section 400.9905(4). F.S.
[8] *See* part I of ch. 499, F.S.
[9] Section 499.023, F.S.

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.[10]

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.[11]

Nonembryonic Stem Cell Banks

CS/CS/CS/SB 512 requires the AHCA to license establishments meeting the definition of nonembryonic stem cell banks (NSCBs) as health care clinics. Hospitals, ambulatory surgical centers, and clinical facilities affiliated with an accredited medical school that provides training to medical students, residents, or fellows, are exempt from licensure under CS/CS/CS/SB 512.

The bill also requires NSCBs that manufacture adult human nonembryonic human cells, tissues, or cellular or tissue-based products (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 meetings specific criteria established under CS/CS/CS/SB 512.

CS/CS/CS/SB 512 defines a NSCB as 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.
- 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

[10] Section 499.003(28), F.S.
[11] 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).

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.

III. Effect of Proposed Changes:

The bill, which is linked to CS/CS/CS/SB 512, provides 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.

The bill takes effect on the same date that CS/CS/CS/SB 512 or similar legislation takes effect, 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:

Article VII, s. 19 of the State Constitution requires that a new state tax or fee, as well as an increased state tax or fee, be approved by two-thirds of the membership of each house of the Legislature and be contained in a separate bill that contains no other subject.

Article VII, s. 19(d)(1) of the State Constitution defines "fee" to mean "any charge or payment required by law, including any fee for service, fee or cost for licenses, and charge for service."

The bill provides 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.

For the AHCA, these fees include a licensure fee not to exceed $2,000 authorized in s. 400.9925, F.S., and a biennial assessment of $300 pursuant to s. 408.033, F.S. The DBPR's permitting fee is $1,500 for a two-year permit, plus a one-time inspection fee of $150, pursuant to s. 499.041, F.S.

These fees are existing statutory fees that are not being increased; however, the bill requires NSCBs to pay all fees associated with permitting, registration, or licensure.

It is unclear if Article VII, s. 19 applies to these provisions of the bill. As such, the State Constitution may require that the fees be passed in a separate bill by a two-thirds vote of the membership of each house of the Legislature.

E. Other Constitutional Issues:

None.

V. Fiscal Impact Statement:

A. Tax/Fee Issues:

CS/SB 7066 provides 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. For the AHCA, these fees include a licensure fee not to exceed $2,000 authorized in s. 400.9925, F.S., and a biennial assessment of $300 pursuant to s. 408.033, F.S. The DBPR's permitting fee is $1,500 for a two-year permit, plus a one-time inspection fee of $150, pursuant to s. 499.041, F.S.

The bill's requirements also impose the costs associated with a level 2 background screening for applicants and personnel as required in s. 408.809(1)(e) pursuant to ch. 435 and s. 408.809, F.S., if they are not already required to be screened under a separate professional licensee. The cost for a level 2 background screening with five years of Care Provider Background Screening Clearinghouse (Clearinghouse) retention is $61.25 ($13.25 for the national criminal record check; $24 for the state criminal record check; and $24 paid up front for five years of state fingerprint Clearinghouse retention).

B. Private Sector Impact:

The Agency for Health Care Administration (AHCA) estimates that 500 facilities may require a health care clinic license under CS/CS/CS/SB 512.[12] Licensure fees would be collected every two years from applicants. Estimating 500 additional health care clinics would result in the collection of $500,000 in annual licensure fees, based on spreading initial applicants over a two year period (250 per year). Additionally, the facilities will pay a biennial assessment of $300 that would result in the collection of $150,000 biennially.

Based on the AHCA's estimate, 500 facilities would require a permit and an inspection by the DBPR that would result in the collection of $375,000 in annual permitting fees, based on spreading initial applicants over a two year period (250 per year). Each facility will also pay a one-time inspection fee of $150 that would result in the collection of $75,000.

The cost for a level 2 background screening with five years of Clearinghouse retention is $61.25. The number of individuals impacted by this requirement is indeterminate.

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 Fiscal Year 2020-2021, and a recurring $300,250 thereafter, to implement the bill's requirements.[13]

Due to permitting and inspection requirements under CS/CS/CS/SB 512, the DBPR will likely experience a recurring increase in workload and costs associated with the permitting and inspection of NSCBs. As of this writing, a fiscal impact for this bill or CS/CS/CS/SB 512 has not been provided by the DBPR.

The anticipated increase in expenditures by the AHCA and the DBPR will be offset by the revenues collected from the 500 facilities that the AHCA estimates may require a health care clinic license and a prescription drug manufacturer permit under CS/CS/CS/SB 512.

VI. Technical Deficiencies:

None.

VII. Related Issues:

None.

[12] Agency for Health Care Administration, CS/SB 512 Bill Analysis (Feb. 14, 2020) (on file with the Senate Committee on Appropriations).
[13] *Id*.

VIII. Statutes Affected:

This bill substantially amends section 381.06017 of the Florida Statutes.

IX. Additional Information:

A. Committee Substitute – Statement of Changes:
(Summarizing differences between the Committee Substitute and the prior version of the bill.)

CS by Rules on March 2, 2020:
The committee substitute conforms to amendments made to CS/CS/CS/SB 512 and provides 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.

B. Amendments:

None.