

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 Appropriations

BILL: SPB 7066

INTRODUCER: For consideration by the Appropriations Committee

SUBJECT: Licensure Fees

DATE: February 19, 2020

REVISED: _____

ANALYST	STAFF DIRECTOR	REFERENCE	ACTION
1. McKnight	Kynoch		Pre-meeting

I. Summary:

SPB 7066, which is linked to CS/SB 512, requires nonembryonic stem cell banks (NSCBs) licensed as health care clinics to pay all fees associated with licensure, registration and inspection under part X of chapter 400 and part II of chapter 408, Florida Statutes.

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) expenditures that will be offset by the significant positive fiscal impact to the AHCA's revenues from the licensure, registration, and inspection fees collected from NSCBs under the bill See Section V.

The bill takes effect on the same date that 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;

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).

- 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 Act⁵ provides the Agency for Health Care Administration (AHCA) with licensing and regulatory authority to provide standards and oversight 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.

Nonembryonic Stem Cell Banks

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/SB 512.

CS/SB 512 defines a NSCB as a publicly or privately owned establishment that does any of the following:

- Collects and stores human nonembryonic stem cells for use in a product or patient-specific medical administration.
- Provides patient-specific health care services using human nonembryonic stem cells.
- Advertises human nonembryonic stem cell services, including, but not limited to, collection, manufacturing, storage, dispensing, use, or purported use of human nonembryonic stem cells or products containing human nonembryonic stem cells, which:
 - Have not been approved by the U.S. Food and Drug Administration (FDA); or
 - Are not the subject of clinical trials approved by the FDA; and
 - Are intended to diagnose, cure, mitigate, treat, provide therapy for, or prevent an injury or a disease.
- Performs any procedure that is intended to:

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.

- Collect or store human nonembryonic stem cells for any purpose; or
- Diagnose, cure, mitigate, treat, provide therapy for, or prevent an injury or a disease with the use or purported use of human nonembryonic stem cells or any product containing human nonembryonic stem cells which has not been approved by the FDA or is not the subject of a clinical trial approved by the FDA.
- Compounds human nonembryonic stem cells from human nonembryonic cells or tissue into products by combining, mixing, or altering the ingredients of one or more drugs or products to create another drug or product.
- Manufactures, through recovery, processing, manipulation, enzymatic digestion, mechanical disruption, or a similar process, human nonembryonic stem cells from human nonembryonic cells or tissue into undifferentiated human nonembryonic stem cells, causing the cells to lose their original structural function so that the nonembryonic stem cells may be differentiated into specialized cell types.
- Dispenses human nonembryonic stem cells and products containing nonembryonic stem cells to any of the following, for a specific patient pursuant to a valid prescription from a licensed health care practitioner authorized within the scope of his or her license to prescribe and administer human nonembryonic stem cells:
 - A pharmacy permitted under ch. 465, F.S.;
 - A health care practitioner with privileges to practice at nonembryonic stem cell banks; or
 - A health care practitioner's office, a health care facility, or a treatment setting where the health care practitioner has privileges to practice, for office use.

III. Effect of Proposed Changes:

The bill, which is linked to CS/SB 512, requires nonembryonic stem cell banks licensed as health care clinics to pay all fees associated with licensure, registration and inspection under part X of ch. 400 and part II of ch. 408, F.S.

The bill takes effect on the same date that 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 requires nonembryonic stem cell banks (NSCBs) licensed as health care clinics to pay all fees associated with licensure, registration, and inspection under part X of ch. 400 and part II of ch. 408, F.S. 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. These fees are existing statutory fees that are not being increased; however, the bill requires NSCBs to pay all fees associated with licensure, registration, and inspection.

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:**

SPB 7066 requires nonembryonic stem cell banks (NSCBs) licensed as health care clinics to pay all fees associated with licensure, registration and inspection under part X of ch. 400 and part II of ch. 408, F.S. 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 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/SB 512.⁸ 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.

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.⁹

The anticipated increase in expenditures by the AHCA will be offset by the revenues collected from the 500 facilities that the AHCA estimates may require a health care clinic license under CS/SB 512. The AHCA estimates 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), and \$150,000 in biennial assessment fees.¹⁰

VI. Technical Deficiencies:

None.

VII. Related Issues:

None.

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.)

None.

⁸ Agency for Health Care Administration, CS/SB 512 Bill Analysis (Feb. 14, 2020) (on file with the Senate Committee on Appropriations).

⁹ *Id.*

¹⁰ *Id.*

B. Amendments:

None.

This Senate Bill Analysis does not reflect the intent or official position of the bill's introducer or the Florida Senate.
