

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 Health Policy

BILL: SB 798

INTRODUCER: Senator Rouson

SUBJECT: Procurement of Human Organs and Tissue

DATE: January 27, 2020

REVISED: _____

	ANALYST	STAFF DIRECTOR	REFERENCE	ACTION
1.	<u>Williams</u>	<u>Brown</u>	<u>HP</u>	<u>Pre-meeting</u>
2.	_____	_____	<u>CJ</u>	_____
3.	_____	_____	<u>RC</u>	_____

I. Summary:

SB 798 prohibits for-profit entities from obtaining certification as eye banks and from collecting any eye, cornea, eye tissue, or corneal tissue. The bill provides exceptions for specified entities.

The bill will result in the Agency for Health Care Administration (AHCA) collecting \$4,000 less in annual assessment fees for the currently operating for-profit eye banks in Florida. The fiscal impact of the bill on private stakeholders is unknown.¹

The effective date of the bill is July 1, 2020.

II. Present Situation:

Regulations and Standards for Tissue Processing

Tissue processing in the United States is governed by mandatory requirements enforced by federal and state regulatory authorities. The authorization of donated tissues is governed by the Uniform Anatomical Gift Act. Tissue banks in the United States are governed by the National Organ Transplantation Act (NOTA), which provides that tissue cannot be bought or sold. The law does allow for reimbursement of costs associated with the recovery, processing, and storing of tissue and the development of tissue processing technologies. Such activities can include research, screening and testing, sterilization processes, and precision-tooled shaping of allografts for transplantation.

Regardless of their status, all tissue banks must meet the same regulatory requirements and have the same goal of assisting in the process of making tissue safely available for transplants. Human tissue processed and distributed for transplantation by the American Association of Tissue Banks

¹ Agency for Health Care Administration, *Senate Bill 798 Analysis* (updated January 23, 2020) (on file with the Senate Committee on Health Policy).

(AATB)-accredited tissue banks is subject to federal Food and Drug Administration (FDA) regulation and AATB's standards.²

Statutory Provisions Specific to Eye Banks in Florida

Part V of ch. 765, F.S., contains provisions specific to the donation and procurement of human organs and tissues. Under this part, "procurement" is defined in s. 765.511(18), F.S., as "any retrieval, recovery, processing, storage, or distribution of human organs or tissues for transplantation, therapy, research, or education."

Section 765.542, F.S., provides requirements for the certification of procurement organizations in the state of Florida. Procurement organizations, as defined in subsection 765.511(19), F.S., include organ procurement organizations, eye banks, and tissue banks. Per s. 765.511(11), F.S., an eye bank is "an entity that is accredited by the Eye Bank Association of America or otherwise regulated under federal or state law to engage in the retrieval, screening, testing, processing, storage, or distribution of human eye tissue."

In accordance with s. 765.542(3), F.S., a person may not engage in the practice of eye procurement in the state of Florida without being appropriately certified as an eye bank by the AHCA. Funeral directors or direct disposers who retrieve eye tissue for a certified eye bank are exempt from being certified as eye banks.

All procurement organizations, including eye banks, are required to file an annual report and an annual assessment fee to the AHCA based on reported revenues from procurement and processing activities, as provided in s. 765.544, F.S. During State Fiscal Year 2018-2019, \$3,500 in annual assessment fees were received by the AHCA from for-profit eye banks.³

Chapter 873, F.S., governs the sale of anatomical matter by a person or a for-profit entity and includes provisions related to the purchase, sale, and transfer of human organs and tissues, including, but not limited to: the eye, cornea, kidney, liver, heart, lung, pancreas, bone, and skin.⁴

Section 873.01(2), F.S., prohibits for-profit entities, or any employee of a for-profit entity, from transferring human organs and tissues or arranging for the transfer of human organs and tissues for valuable consideration. "Valuable consideration" does not include the reasonable costs associated with the removal, storage, and transportation of a human organ or tissue.

Procurement Organizations Regulated by the Agency for Health Care Administration

According to the AHCA, there are currently 155 procurement organizations certified in the state of Florida. Of these, four are certified as organ procurement organizations, 24 are certified as eye banks, and 127 are certified as tissue banks. Of the 24 certified eye banks, three are physically located in Florida, and the remaining 21 eye banks certified in Florida are out-of-state

² American Association of Tissue Banks, Regulation and Standards, available at <https://www.aatb.org/regulatory> (last visited on Jan. 23, 2020).

³ *Supra* note 1.

⁴ Section 873.01(3)(a), F.S.

organizations. The three eye banks located in Florida are not-for-profit corporations. The profit status of Florida's certified eye banks is as follows:

- Sixteen not-for-profit entities, and
- Eight for-profit entities.⁵

Corporate Trends in the Eye-Tissue Banking Industry

In recent years, the market for corneal tissue procurement, transport, and surgeon partnerships has experienced somewhat of a shift from local, community-based eye banks to larger companies. Some of these larger companies are represented by not-for-profit corporations affiliated with for-profit "daughter" companies, which, in partnership with each other, play defined roles in the process, with the non-profit organization recovering the tissue while the for-profit organization processes, evaluates, and distributes the tissues to cornea surgeons.⁶

The for-profit status of any participant in the process has drawn criticism. However, defenders of such partnerships respond by noting that such for-profit companies operate under the NOTA, which states that it is illegal to buy or sell organs and tissues while it *is* legal to obtain reasonable payment associated with the removal, transportation, processing, preservation, quality control, and storage of corneas and eye tissue. Similarly, local eye banks routinely obtain payment related to these actions. Some argue that the for-profit connection fundamentally alters the relationship between physicians, eye banks, and donors by rendering the gift of the tissue as a commodity. The resulting ethical debate may be crucial to the future of eye banks.⁷

III. Effect of Proposed Changes:

Section 1 amends s. 765.542, F.S., relating to requirements to engage in organ, tissue, or eye procurement, to specify that a for-profit entity may not engage, directly or indirectly, in the procurement of any eye, cornea, eye tissue, or corneal tissue. The bill stipulates that this new provision does not apply to any hospital or ambulatory surgical center licensed under ch. 395, F.S., or to a district medical examiner appointed under ch. 406, F.S.

Section 2 amends s. 873.01, F.S., relating to the prohibition on the purchase or sale of human organs and tissues, to specify that a for-profit entity may not engage, directly or indirectly, in the procurement, as defined in s. 765.511, F.S., of any eye, cornea, eye tissue, or corneal tissue. The bill stipulates that this new provision does not apply to any hospital or ambulatory surgical center licensed under ch. 395, F.S., or to a district medical examiner appointed under ch. 406, F.S.

Section 3 provides an effective date of July 1, 2020.

⁵ *Supra* note 1.

⁶ Majid Moshirfar, Jackson L. Goldberg, et al., *A paradigm shift in eye banking: how new models are challenging the status quo*, U.S. National Library of Medicine, National Institutes of Health (Dec. 27, 2018), available at <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6311318/> (last visited Jan. 25, 2020)

⁷ *Id.*

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.

V. Fiscal Impact Statement:

A. Tax/Fee Issues:

None.

B. Private Sector Impact:

According to the AHCA, SB 798 will result in the delicensing of eight for-profit eye banks that are currently certified to do business in Florida and will prohibit any for-profit entities from applying for and obtaining certification as eye banks in the future.⁸

C. Government Sector Impact:

The AHCA will collect \$4,000 less in annual assessment fees for the currently operating for-profit eye banks doing business in Florida.⁹

VI. Technical Deficiencies:

None.

⁸ *Supra* note 1.

⁹ *Id.*

VII. Related Issues:

The statutory provisions proposed in the bill do not appear to conflict with applicable federal law relating to prohibition of organ purchases.¹⁰

VIII. Statutes Affected:

This bill substantially amends the following sections of the Florida Statutes: 765.542 and 873.01.

IX. Additional Information:**A. Committee Substitute – Statement of Changes:**

(Summarizing differences between the Committee Substitute and the prior version of the bill.)

None.

B. Amendments:

None.

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

¹⁰ See 42 U.S.C. 274e.