

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 516

INTRODUCER: Senator Rouson

SUBJECT: Procurement Activities of For-profit Eye Banks

DATE: December 1, 2021

REVISED: _____

	ANALYST	STAFF DIRECTOR	REFERENCE	ACTION
1.	Looke	Brown	HP	Pre-meeting
2.			CJ	
3.			RC	

I. Summary:

SB 516 amends ss. 765.542 and 873.01, F.S., to prohibit a for-profit eye bank from directly or indirectly engaging in the procurement of any eye, cornea, eye tissue, or corneal tissue for use in live-cell corneal transplantation.

The bill exempts hospitals, ambulatory surgical centers (ASC), and medical examiners from this prohibition.

The bill provides an effective date of July 1, 2022.

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.¹

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 American Association of Tissue Banks, Regulation and Standards, available at <https://www.aatb.org/regulatory> (last visited on Nov. 11, 2021).

(AATB)-accredited tissue banks is subject to federal Food and Drug Administration 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 s. 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 Agency for Health Care Administration (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.

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.³

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. A violation of this section constitutes a second-degree felony.⁴

Currently there are nine for-profit eye banks and 14 not-for-profit eye banks operating in Florida.⁵

² *Id.*

³ Section 873.01(3)(a), F.S.

⁴ Section 873.01(4), F.S. A second degree felony is punishable by up to 15 years in state prison and a fine of up to \$10,000. Sections 775.082 and 775.083, F.S. Section 775.084, F.S., provides enhanced penalties for qualifying repeat offenders.

⁵ Florida Health Finder (<https://www.floridahealthfinder.gov/>) report generated on Nov. 19, 2021, on file with Senate Health Policy Committee staff.

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:

SB 516 amends ss. 765.542 and 873.01, F.S., to prohibit a for-profit eye bank from directly or indirectly engaging in the procurement of any eye, cornea, eye tissue, or corneal tissue for use in live-cell corneal transplantation.

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IV. Constitutional Issues:

A. Municipality/County Mandates Restrictions:

None.

B. Public Records/Open Meetings Issues:

None.

C. Trust Funds Restrictions:

None.

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 Nov. 19, 2021).

⁷ *Id.*

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:

This bill may have an indeterminate negative fiscal impact on for-profit eye banks operating in Florida.

C. Government Sector Impact:

None.

VI. Technical Deficiencies:

None.

VII. Related Issues:

None.

VIII. Statutes Affected:

This bill substantially amends sections 765.542 and 873.01 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.

B. Amendments:

None.