

HOUSE OF REPRESENTATIVES STAFF ANALYSIS

BILL #: CS/HB 563 Procurement of Human Organs and Tissue

SPONSOR(S): Health & Human Services Committee, Daley

TIED BILLS: **IDEN./SIM. BILLS:** SB 798

| REFERENCE | ACTION | ANALYST | STAFF DIRECTOR or BUDGET/POLICY CHIEF |
|--|---------------------|---------|--|
| 1) Health Market Reform Subcommittee | 13 Y, 0 N | Morris | Calamas |
| 2) Justice Appropriations Subcommittee | 11 Y, 0 N | Jones | Gusky |
| 3) Health & Human Services Committee | 15 Y, 0 N, As CS | Morris | Calamas |

SUMMARY ANALYSIS

Organ and tissue donation is the process of surgically removing an organ or tissue from one person (the donor) and transplanting it into another person (the recipient). Transplantation in such cases is necessary because the recipient's organ has failed or has been damaged by disease or injury. Federal and state law prohibit the purchase and sale of human organs, including tissue, eyes, and corneas.

Eye banks are certified by the Agency for Health Care Administration (AHCA) and engage in screening, testing, retrieving, processing, distributing, or storing human eye tissue. AHCA currently certifies 24 eye banks; three located in Florida and 21 located in other states. All three Florida eye banks are non-profit entities.

CS/HB 563 prohibits eye banks/entities from obtaining certification as eye banks and from collecting any eye, cornea, eye tissue, or corneal tissue.

The bill has an insignificant, negative fiscal impact on AHCA. Additionally, the Criminal Justice Impact Conference considered the bill on February 10, 2020, and determined the bill will have a positive insignificant impact on prison beds (an increase of 10 or fewer beds) by expanding the elements of a second degree felony offense. See Fiscal Analysis and Impact Statement. The bill has no impact to local governments.

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

FULL ANALYSIS

I. SUBSTANTIVE ANALYSIS

A. EFFECT OF PROPOSED CHANGES:

Background

Organ and Tissue Donation

Organ and tissue donation is the process of surgically removing an organ or tissue from one person (the donor) and transplanting it into another person (the recipient). Transplantation in such cases is necessary because the recipient's organ has failed or has been damaged by disease or injury. Transplantable organs include the kidneys, liver, heart, lungs, pancreas and intestine.¹ Transplantable tissue include skin used as a temporary dressing for burns, serious abrasions and other exposed areas; heart valves used to replace defective valves; tendons used to repair torn ligaments on knees or other joints; veins used in cardiac by-pass surgery; corneas used to restore sight; and bone used in orthopedic surgery to facilitate healing of fractures or prevent amputation.²

A single person can save up to eight lives through organ donation, and dozens more lives may be improved through tissue donation.³ While most organ and tissue donations occur after the donor has died, some organs, including a kidney or part of a liver or lung, and tissues can be donated while the donor is alive.⁴ There are about as many living donors every year as there are deceased donors.⁵

Despite advances in medicine and technology, and increased awareness of organ donation and transplantation, more donors are needed to meet the demand for transplants.⁶ As of January 2020, there are more than 112,000 children and adults⁷, including over 5,000 Floridians, on the waiting list to receive an organ.⁸ Over 39,000 organ transplants were performed in 2019 with organs from more than 19,000 donors.⁹

The cornea is the clear dome-like covering on the front of the eye that allows light to pass through to the retina and enables sight.¹⁰ Corneal transplants help individuals who have experienced severe damage to their cornea, which cannot be repaired by other treatments, to restore sight.¹¹ Damaged corneas are replaced with healthy donor tissue either through a full or partial corneal transplant.¹²

Organ Donation Network

Established by the National Organ Transplant Act (NOTA) of 1984, the Organ Procurement and Transplantation Network (OPTN) is a public-private partnership that links all professionals involved in the nation's donation and transplant system.¹³ The United Network for Organ Sharing (UNOS), a private, non-profit organization based in Richmond, Virginia, serves as the OPTN under contract with the U.S. Department of Health and Human Resources.¹⁴ UNOS coordinates how donor organs are

¹ Donate Life Florida, *Frequently Asked Questions*, <https://www.donateliflorida.org/categories/donation/> (last visited Jan. 24, 2020).

² Id.

³ Id.

⁴ U.S. Government Information on Organ Donation and Transplantation, U.S. Department of Health & Human Services, *How Organ Donation Works*, <https://organdonor.gov/about/process.html> (last visited Jan. 24, 2020).

⁵ Id.

⁶ Organ Procurement and Transplantation Network, U.S. Department of Health & Human Services, <https://optn.transplant.hrsa.gov/> (last visited Jan. 24, 2020).

⁷ Id.

⁸ *Supra*, note 1.

⁹ Id.

¹⁰ Donate Life America, *Cornea Donation*, <https://www.donatelife.net/types-of-donation/cornea-donation/> (last visited Feb. 26, 2020).

¹¹ National Eye Institute, *Corneal Conditions*, <https://www.nei.nih.gov/learn-about-eye-health/eye-conditions-and-diseases/corneal-conditions> (last visited Feb. 26, 2020).

¹² Id.

¹³ U.S. Department of Health and Human Services, *Organ Procurement and Transplantation Network – About the OPTN*, <https://optn.transplant.hrsa.gov/governance/about-the-optn/> (last visited Jan. 24, 2020).

¹⁴ Id.

matched and allocated to patients on the waiting list.¹⁵ Non-profit, federally designated organ procurement organizations (OPOs) work closely with UNOS, hospitals, and transplant centers to facilitate the organ donation and transplantation process,¹⁶ including conducting a thorough medical and social history of the potential donor to help determine the suitability of his or her organs for transplantation.¹⁷ The NOTA prohibits human organs, including tissue, eyes, and corneas, from being bought or sold.¹⁸

State Regulation of Eye Banks

Procurement organizations are OPOs, eye banks, or tissue banks that are certified by the Agency for Health Care Administration (AHCA)¹⁹ which engage in the retrieval, recovery, processing, storage, or distribution of human organs or tissues for transplantation, therapy, research, or education.²⁰ Currently, 155 procurement organizations are certified by AHCA, 24 of which are eye banks 127 are tissue banks, and four are OPOs.²¹

Of the 24 eye banks certified by AHCA, three are physically located in Florida and the remaining 21 are located outside of the state.²² All three eye banks physically located in Florida are not-for-profit corporations.²³ Of the 21 out-of-state eye banks, 13 are not-for-profit and eight are for-profit.²⁴

Florida's three eye banks are located in Miami, Tampa, and Orlando. Lions Eye Bank and Lions Eye Institute are located in Miami and Tampa, respectively, while Keralink International is located in Orlando. The certified, out-of-state eye banks are located in Alabama, California, Illinois, Massachusetts, Maryland, Michigan, Missouri, North Carolina, New Jersey, New Mexico, Ohio, Oregon, Pennsylvania, Tennessee, Texas, Utah, and Washington.²⁵

Florida law prohibits the buying, selling, and transfer of human organs, tissue, and body parts, including eyes and corneas, by any person, violation of which is a second degree felony,²⁶ punishable by up to 30 years in prison and/or a fine up to \$10,000.²⁷ The interaction of these provisions with the OPO certification statute,²⁸ which does not ban for-profit entities from becoming certified, is unclear. Because organ procurement can involve distribution – or transfer – of organs, it appears this provision would prevent certification of for-profit procurement organizations if they receive valuable consideration for the distribution (transfer).

Trends in the Eye Banking Industry

Recently, the market for corneal tissue procurement, transport, and surgeon partnership has shifted from local, community-based eye banks to larger companies.²⁹ Some of these larger companies are represented by not-for-profit corporations affiliated with for-profit “daughter” companies. In partnership with each other, these organizations play defined roles in the eye and cornea procurement process,

¹⁵ U.S. Government Information on Organ Donation and Transplantation, U.S. Department of Health & Human Services, *The Organ Transplant Process*, <https://organdonor.gov/about/process/transplant-process.html> (last visited Jan. 24, 2020).

¹⁶ Donate Life Florida, *Organ Procurement Organizations and Transplant Centers*, <https://www.donateliflorida.org/local-resources/transplant-centers/> (last visited Jan. 24, 2020).

¹⁷ Organ Procurement and Transplantation Network, U.S. Department of Health & Human Services, *The Basic Path of Donation*, <https://optn.transplant.hrsa.gov/learn/about-donation/the-basic-path-of-donation/> (last visited Jan. 24, 2020).

¹⁸ 42 U.S.C. 274e.

¹⁹ Agency for Health Care Administration, Agency Analysis of 2020 SB 798, p. 2 (Jan. 21, 2020). See also s. 765.511, F.S.

²⁰ S 765.511(15), F.S.

²¹ *Supra*, note 19.

²² *Id.*

²³ *Id.*

²⁴ *Id.*

²⁵ Email from Lauren Keenan, Deputy Director of Legislative Affairs, Agency for Health Care Administration, RE: Bill Analysis, (Jan. 21, 2020) (On file with Health Market Reform Subcommittee staff).

²⁶ S. 873.01, F.S.

²⁷ Ss. 775.082, 775.083, and 775.084, F.S.

²⁸ S. 765.542, F.S.

²⁹ 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), <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6311318/> (last visited Jan. 31, 2020).

with the non-profit organization recovering the tissue while the for-profit organization processes, evaluates, and distributes the tissues to cornea surgeons.³⁰

Effect of Proposed Changes

The bill prohibits for-profit eye banks from procuring, directly or indirectly, any eye, cornea, eye tissue, or corneal tissue for use in live-cell corneal transplantation. As a result, eight AHCA-certified, for-profit, out-of-state eye banks will no longer be certified and collect any eye, cornea, eye tissue, or corneal tissue within this state. Non-profit eye banks, located within or outside of Florida, would still be able to be certified and perform such actions.

Because the buying, selling, and transfer of human organs, tissue, and body parts, including eyes and corneas, is a second degree felony under current law, any for-profit entity that engages in the procurement, directly or indirectly, of any eye, cornea, eye tissue, or corneal tissue for use in live-cell corneal transplantation would be committing a crime under the bill.

B. SECTION DIRECTORY:

- Section 1:** Amends s. 873.01, F.S., relating to purchase or sale of human organs and tissue prohibited.
- Section 2:** Amends s. 765.542, F.S., relating to requirements to engage in organ, tissue, or eye procurement.
- Section 3:** Provides an effective date of July 1, 2020.

II. FISCAL ANALYSIS & ECONOMIC IMPACT STATEMENT

A. FISCAL IMPACT ON STATE GOVERNMENT:

1. Revenues:

The bill has an insignificant, negative fiscal impact on AHCA. AHCA estimates a total loss of \$4,000 in annual assessment fees per year because the bill would cause eight for-profit, out-of-state certified eye banks to lose their certification.³¹ The current annual assessment fee for eye banks is \$500.³²

2. Expenditures:

The Criminal Justice Impact Conference considered the bill on February 10, 2020, and determined the bill will have a positive, insignificant impact on prison beds (an increase of 10 or fewer beds) by expanding the elements of a second degree felony offense.

B. FISCAL IMPACT ON LOCAL GOVERNMENTS:

1. Revenues:

None.

2. Expenditures:

None.

C. DIRECT ECONOMIC IMPACT ON PRIVATE SECTOR:

The bill has a negative impact on the eight out-of-state, for-profit eye banks that will no longer be licensed by AHCA and will not be able to conduct business in Florida.

³⁰ Id.

³¹ *Supra*, note 19, at 3.

³² Ch. 59A-1.004(3), F.A.C.

D. FISCAL COMMENTS:

None.

III. COMMENTS

A. CONSTITUTIONAL ISSUES:

1. Applicability of Municipality/County Mandates Provision:

Not applicable. The bill does not appear to affect county or municipal governments.

2. Other:

None.

B. RULE-MAKING AUTHORITY:

Current law provides sufficient rulemaking authority to implement the provisions of this bill.

C. DRAFTING ISSUES OR OTHER COMMENTS:

None.

IV. AMENDMENTS/ COMMITTEE SUBSTITUTE CHANGES

On February 26, 2020, the Health and Human Services Committee adopted an amendment and reported the bill favorable as a committee substitute. The amendment:

- Prohibits for-profit eye banks from obtaining certification as eye banks and from collecting any eye, cornea, eye tissue, or corneal tissue; and
- Removes the exemption in the bill for hospitals, ambulatory surgical centers, and district medical examiners to obtain certification as an eye bank.

The analysis is drafted to the committee substitute as passed by the Health and Human Services Committee.