

HOUSE OF REPRESENTATIVES STAFF ANALYSIS

BILL #: CS/HB 1187 Organ Donation
SPONSOR(S): Health Market Reform Subcommittee, Latvala
TIED BILLS: **IDEN./SIM. BILLS:**

REFERENCE	ACTION	ANALYST	STAFF DIRECTOR or BUDGET/POLICY CHIEF
1) Health Market Reform Subcommittee	13 Y, 0 N, As CS	Morris	Calamas
2) Health & Human Services Committee	15 Y, 0 N	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 and injury. CS/HB 1187 amends multiple sections of law related to organ donation.

The bill requires AHCA to include minimum volume standards for organ transplants and neonatal intensive care services in their rules for health care facilities. It also requires the Organ and Tissue Procurement and Transplantation Advisory Board to submit recommendations relating to the regulation of organ transplants to AHCA.

The bill prohibits a transplant facility from charging the donor, or his or her family, any fees for services related to the procurement or donation of his or her organs.

The bill adds a requirement to educate the public on state and federal law relating to the organ donation transplant process to the current public education program administered by AHCA.

The bill requires individuals who make requests to patients, living donors, or family members for a decedent's organs to explain the protocols of the hospital and federal and state regulations regarding organ donation.

The bill has no fiscal impact on AHCA.

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

FULL ANALYSIS

I. SUBSTANTIVE ANALYSIS

A. EFFECT OF PROPOSED CHANGES:

Background

Organ 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.⁸ Over 39,000 organ transplants were performed in 2019 with organs from more than 19,000 donors.⁹

Organ Donation and Transplant Process

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.¹⁰ 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 Services.¹¹ UNOS coordinates how donor organs are matched and allocated to patients on the waiting list.¹² Non-profit, federally designated organ procurement organizations (OPOs) work closely with UNOS, hospitals, and transplant centers to facilitate the organ donation and transplantation process,¹³ including conducting a thorough medical

¹ Donate Life Florida, *Frequently Asked Questions*, <https://www.donateliflorida.org/categories/donation/> (last visited Feb. 13, 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 Feb. 13, 2020).

⁵ Id.

⁶ Organ Procurement and Transplantation Network, U.S. Department of Health & Human Services, <https://optn.transplant.hrsa.gov/> (last visited Feb. 13, 2020).

⁷ Id.

⁸ Supra, note 1.

⁹ Id.

¹⁰ 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 Feb. 13, 2020).

¹¹ Id.

¹² 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 Feb. 13, 2020).

¹³ Donate Life Florida, *Organ Procurement Organizations and Transplant Centers*, <https://www.donateliflorida.org/local-resources/transplant-centers/> (last visited Feb. 13, 2020).

and social history of the potential donor to help determine the suitability of his or her organs for transplantation.¹⁴

The donation process begins when a person, or their family if the person was not already a registered donor before brain death, decides to become an organ donor. After brain death is declared, the donor's body is kept functioning by artificial means, such as a ventilator support.¹⁵ Specially-trained medical practitioners from the OPO evaluates the patient to determine if they are medically suitable to donate their organs.¹⁶ If the patient is suitable, their organs are surgically removed and sent to the transplant hospitals where transplant candidates are waiting.¹⁷ The deceased donor's blood type, height, weight, the hospital zip code, and other data are entered into UNOS' national computer system to begin the organ allocation process.¹⁸

Transplant candidates are patients on the transplant waiting list. A patient is usually referred to a transplant center by their physician for placement on the waiting list.¹⁹ The transplant center's transplant teams, composed of transplant physicians, surgeons and other practitioners, perform a medical evaluation of the patient.²⁰ Each transplant center sets its own criteria to help determine if a patient is a good or bad candidate.²¹ Typical criteria includes weight, age, and health history. If the patient is a bad candidate, the patient is not placed on the waiting list, but can try to get placed on the waiting list at another transplant center or be reconsidered by the same transplant center if their condition improves (for example, losing weight as directed).²² If a patient is determined to be a good candidate for an organ transplant, they are placed on the waiting list by the transplant center and wait for an organ to become available. Candidates are able to be placed on the waiting list at more than one transplant center.²³

When an organ becomes available, the OPO will query the OPTN database for a match based on a variety of factors, including relative location of the recipient to the organ, blood type, weight, and age.²⁴ If a match is found, the transplant surgeon will evaluate the potential recipient of the organ transplant and make a determination on whether the potential recipient is medically suitable.²⁵ The transplant team only has one hour to make this determination.²⁶ If suitable, the organ is transported to the transplant center where the recipient is waiting and the transplant surgery is performed, otherwise the potential recipient remains on the waiting list.

¹⁴ 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 Feb. 13, 2020).

¹⁵ Donate Life Florida, *Frequently Asked Questions - Donation*, <https://www.donateliflorida.org/categories/donation/> (last visited Feb. 13, 2020).

¹⁶ UNOS, *Deceased Donation*, <https://unos.org/transplant/deceased-donation/> (last visited Feb. 13, 2020).

¹⁷ *Id.*

¹⁸ *Id.*

¹⁹ Health Resources & Services Administration, *The Organ Transplant Process*, <https://www.organdonor.gov/about/process/transplant-process.html#list> (last visited Feb. 13, 2020).

²⁰ U.S. Department of Health and Human Services, *The Transplant Team*, <https://optn.transplant.hrsa.gov/learn/about-transplantation/the-transplant-team/> (last visited Feb. 13, 2020).

²¹ UNOS, *Frequently Asked Questions – What do I need to do to be considered for a transplant?*, <https://unos.org/transplant/frequently-asked-questions/> (last visited Feb. 13, 2020).

²² UNOS Transplant Living, *Frequently Asked Questions – Are there age limits or medical conditions that rule out organ transplantation?*, <https://transplantliving.org/before-the-transplant/frequently-asked-questions/> (last visited Feb. 13, 2020).

²³ UNOS, *What Every Patient Needs to Know* (2019), <https://unos.org/wp-content/uploads/unos/WEPNTK.pdf> (last visited Feb. 13, 2020).

²⁴ Health Resources & Services Administration, *Matching Donors and Recipients*, <https://www.organdonor.gov/about/process/matching.html#criteria> (last visited Feb. 13, 2020). See also Health Resources & Services Administration, *Find Your Local Organ Procurement Organization*, <https://www.organdonor.gov/awareness/organizations/local-opo.html> (last visited Feb. 13, 2020).

²⁵ UNOS Transplant Living, *Frequently Asked Questions – How does the matching process work?* <https://transplantliving.org/before-the-transplant/frequently-asked-questions/> (last visited Feb. 13, 2020).

²⁶ *Id.*

Regulation of Organ Donation and Transplantation in Florida

The Agency for Health Care Administration (AHCA) oversees the various organizations and facilities involved in the organ procurement and transplant process in this state. AHCA licenses transplant facilities, contracts with an organization to educate the public on organ donation, sets requirements for training individuals who engage with families whose deceased relatives may be a good candidate for organ donation, and oversees the Organ Transplant Advisory Council and the Organ and Tissue Procurement and Transplantation Advisory Board.

Donor Education

AHCA, in collaboration with the Department of Highway Safety and Motor Vehicles, contracts with Donate Life Florida (DFL) to operate a statewide donor registry, increase registry enrollment, and educate Floridians about organ donation.²⁷ Established in 1997, DFL is a non-profit organization dedicated to motivating Floridians to designate themselves as organ, tissue, and eye donors.²⁸ Florida law requires DFL to operate a continuing program to educate the public about state laws relating organ transplants and the need for organ donations.²⁹

When a patient dies in a hospital and is not a registered organ donor, but is determined to be a good candidate by the hospital's medical staff and the OPO, a representative of the OPO or a member of the hospital's staff may approach the patient's family about organ donation.³⁰ AHCA has developed rules for training and guidelines for the person making the request for organ donation.³¹ The requestor is trained in explaining the process of organ donation to the patient's family, including their right to allow or refuse donation and for what purpose the organs would be donated (transplantation, research, or education).³² The requestor is also specifically trained in the different types of approaches to deal with a family's grief and offering them the opportunity for organ donation.³³ The current rules require the requestor to explain the requirements needed to be met under Florida law in order for a donation to be allowed, but not federal regulations stating such requirements.

Organ Donation Fees

Generally, an organ donor and their family are not charged by a transplant facility for the medical care required to donate an organ.³⁴ Families pay for medical care and funeral costs, but costs related to living or deceased donation are paid by the recipient, usually through insurance, Medicare, or Medicaid.³⁵ Typically, any cost that falls outside of the transplant center's donor evaluation or actual surgery, such as travel, lodging, lost wages, and other non-medical expenses, is borne by the living donor or recipient.³⁶

²⁷ Agency for Health Care Administration, Agency Bill Analysis for 2020 HB 1187 (Jan. 31, 2020) (On file with Health Market Reform Subcommittee Staff). See also Donate Life Florida <https://www.donateliflorida.org> (last visited Feb. 13, 2020).

²⁸ Donate Life Florida, *About the Joshua Abbott Organ Donation and Tissue Donor Registry*, <https://www.donateliflorida.org/about/> (last visited Feb. 13, 2020).

²⁹ S. 765.5155, F.S.

³⁰ Health Resources and Services Administration, *The Deceased Donation Process*, <https://www.organdonor.gov/about/process/deceased-donation.html#authorize> (last visited Feb. 13, 2020). See also s. 765.522, F.S.

³¹ Ch. 59A-3.274, F.A.C.

³² Id.

³³ Id.

³⁴ Health Resources Services Administration, *Organ Donation Frequently Asked Questions*, <https://www.organdonor.gov/about/facts-terms/donation-faqs.html> (last visited Feb. 13, 2020).

³⁵ Id. See also UNOS, *Living Donation Costs*, <https://transplantliving.org/financing-a-transplant/living-donation-costs/> (last visited Feb. 13, 2020).

³⁶ UNOS, *Living Donation Costs*, <https://transplantliving.org/financing-a-transplant/living-donation-costs/> (last visited Feb. 13, 2020).

Organ and Tissue Procurement and Transplantation Advisory Board

Created by the Legislature in 1991, the Organ and Tissue Procurement and Transplantation Advisory Board (board) is housed at AHCA. Current law requires the board to assist AHCA in the development of professional qualifications of people involved in the organ donation and transplant process. The board is also tasked with helping AHCA monitor expenses associated with organ and tissue procurement, processing, and distribution for transplantation. Current law requires the board to provide assistance to the Florida Medical Examiners Commission in the development of appropriate procedures and protocols to ensure the continued improvement in the approval and release of potential donors by the district medical examiners and associate medical examiners.³⁷

Additionally, the board works with AHCA on necessary recommendations for procedures and protocols to assure that all Floridians have reasonable access to available organ and tissue transplants according to the severity of his or her medical condition and need. In collaboration with AHCA, the board also develops recommendations for any changes to state laws or administrative rules to ensure that the statewide organ and tissue procurement and transplantation system is able to function smoothly, effectively, and efficiently, in accordance with federal laws.³⁸

The board consists of 14 members who are appointed by the Secretary of AHCA, including:³⁹

- Two with expertise in vascular organ transplant surgery;
- Two with expertise in vascular organ procurement, preservation, and distribution;
- Two with expertise in musculoskeletal tissue transplant surgery;
- Two with expertise in musculoskeletal tissue procurement, processing, and distribution;
- One with expertise in eye and cornea transplant surgery;
- One with expertise in eye and cornea procurement, processing, and distribution;
- One with expertise in bone marrow procurement, processing, and transplantation;
- A representative from the Florida Pediatric Society;
- A representative from the Florida Society of Pathologists; and
- A representative from the Florida Medical Examiners Commission.

The board has not met since 2013.⁴⁰

Organ Transplantation Regulation

Federal law requires transplant hospitals to be a member of the OPTN and abide by OPTN bylaws in order to provide transplant services.⁴¹ The federal certification requirements include minimum volume standards for initial certification.⁴² To obtain initial certification, an organ-specific transplant program must generally perform 10 transplants over a 12-month period.⁴³

Current AHCA rule contains provisions relating to licensure of organ transplantation programs in the state, but does not include minimum volume standards for organ transplant services.⁴⁴ AHCA recently proposed a rule to require organ transplant licensees and applicants to seek and maintain federal certification from the federal Centers for Medicare and Medicaid Services.⁴⁵

³⁷ S. 765.543, F.S.

³⁸ *Id.*

³⁹ S. 765.543, F.S. See also Agency for Health Care Administration, *Organ and Tissue Procurement and Transplantation Advisory Board*, https://ahca.myflorida.com/MCHQ/Health_Facility_Regulation/Lab_HomeServ/OrganTissueBoard.shtml (last visited Feb. 13, 2020).

⁴⁰ *Supra*, note 27.

⁴¹ 42 C.F.R. §482.72.

⁴² 42 C.F.R. §482.80.

⁴³ *Id.*

⁴⁴ R. 59C-1.044, F.A.C.

⁴⁵ Proposed rule 59A-3.246, F.A.C. A public hearing is scheduled on February 27, 2020. A copy of the draft rule is available at https://ahca.myflorida.com/MCHQ/Health_Facility_Regulation/Hospital_Outpatient/Hospitals/docs/Text_DRAFT_59A-3.246_Licensed_Programs_H.pdf (last visited February 13, 2020).

A proposed AHCA rule requires a hospital providing adult heart, kidney, liver, or lung transplants to meet such requirement within one year from initial licensure of each transplant program and to maintain such requirement in order to keep their license.⁴⁶ OPTN bylaws require transplant programs to meet the following volume requirements to remain functionally active:⁴⁷

For This Transplant Program Type	Functional Inactivity Definition
Kidney, Liver, or Heart	Failure to perform at least 1 transplant in 3 consecutive months
Lung	Failure to perform at least 1 transplant in 6 consecutive months
Stand-alone pediatric	Failure to perform at least 1 transplant in 12 consecutive months
Pancreas	<p><i>Both of the following:</i></p> <ol style="list-style-type: none"> 1. Failure to perform at least 2 transplants in 12 consecutive months; and 2. <i>Either of the following in 12 consecutive months:</i> <ul style="list-style-type: none"> • A median waiting time of the program's kidney-pancreas and pancreas candidates that is above the 67th percentile of the national waiting time; or • The program had no kidney-pancreas or pancreas candidates registered at the program.
Islet, intestinal, and vascularized composite allograft	No functional inactivity definitions have been established.

Neonatal Intensive Care Units

A Neonatal Intensive Care Unit (NICU) is a specialized area in a hospital for newborn babies who need extra care with breathing, medicines, and life-saving procedures.⁴⁸ Current AHCA rule requires a hospital applying for a level II Neonatal Intensive Care Services license to meet minimum volume requirements, including a minimum service volume of 1,000 live births for the most recent 12-month period.⁴⁹ Current AHCA rule also requires a hospital applying for a level III Neonatal Intensive Care Service license to have a minimum volume of 1,500 live births for the most recent 12-month period.⁵⁰ AHCA recently developed a proposed rule that provides requirements for initial and continued licensure as a level II or III Neonatal Intensive Care Unit (NICU).⁵¹ The proposed rule also creates a level IV NICU and provides requirements for initial and continued licensure of such facilities.

The proposed rule does not include minimum volume standards for any NICU level.

⁴⁶ *Supra*, note 45.

⁴⁷ OPTN, *Bylaws*, (Jan. 13, 2020) https://optn.transplant.hrsa.gov/media/1201/optn_bylaws.pdf (last visited Feb. 13, 2020).

⁴⁸ UF Health, *Neonatal Unit (NICU) Guide*, <https://neonatology.pediatrics.med.ufl.edu/resources/neonatal-unit-nicu-guide/> (last visited Feb. 13, 2020).

⁴⁹ R. 59C-1.042(6), F.A.C.

⁵⁰ *Id.*

⁵¹ Proposed rule 59A-3.249, F.A.C. A public hearing is scheduled on February 27, 2020. A copy of the draft rule is available at https://ahca.myflorida.com/MCHQ/Health_Facility_Regulation/Hospital_Outpatient/Hospitals/docs/Text_DRAFT_59A-3.249_Neonatal_Intensive_Care_H.pdf (last visited February 13, 2020).

Effect of Proposed Changes

Regulation of Organ Donation and Transplantation in Florida

The bill substantially revises the duties of AHCA relating to organ donation, including the duties of the Organ and Tissue Procurement and Transplantation Advisory Board, rulemaking, and mandated reports.

Donor Education

The bill requires Donate Life to modify their education program to include federal laws relating to anatomical gifts and the organ donation and transplantation process. AHCA may need to amend their current contract with Donate Life to address the new requirements.

The bill amends AHCA's requirement to develop rules and guidelines associated with organ donor education to require that individuals designated by the hospital administrator or organ procurement organization who make a request for donor consent clearly explain hospital protocols and state and federal regulations pertaining to organ donation.

Organ Donation Fees

The bill prohibits an organ transplantation facility from charging a donor or his or her family member any fee for services related to the donation or procurement of his or her organs. The impact of this is unclear, since, generally, the recipient or his or her insurance carrier pay for the services.

The bill also requires the uniform donor registration card to include language declaring that neither the donor nor the donor's family is responsible for the payment of fees associated with procurement of the donor's organs. A uniform donor card is used to express the donor's wishes for the donation of his or her organs. This new requirement may not be appropriate for inclusion in the uniform donor card.

Organ and Tissue Procurement and Transplantation Advisory Board

The bill revises the duties of the Organ and Tissue Procurement and Transplantation Advisory Board by requiring the board to submit recommendations to AHCA by September 1, 2021, relating to the following:

- Frequency of communication between patients and transplant coordinators;
- Monitoring of transplant facilities and annual reporting of aggregate organ recipient data, including relevant information regarding the number of patients on the waiting list statewide and the number of patients who receive transplants;
- Establishment of a communication system between living donors and transplant facilities;
- Incentives necessary to increase organ donation;
- Creation of a more efficient organ donation process;
- Opportunities and incentives for organ transplantation research;
- Best practices for transplant hospitals and OPOs to promote the most effective and efficient patient outcomes; and
- Monitoring of OPOs.

Organ Transplantation Regulation

The bill requires AHCA to include minimum volume standards for organ transplants in their rule regulating minimum standards for health care facilities.

Current rules do not require minimum volume standards for the provision of organ transplant services. AHCA is currently in the rulemaking process to establish initial and continued licensure requirements for organ transplant programs. The current proposed rule draft includes minimum volume standards for

the provision of organ transplant services. If AHCA finalizes the rules prior to the bill becoming law, AHCA will not have to change the rules to include minimum volume standards.

Neonatal Intensive Care Units

The bill requires AHCA to include minimum volume standards for neonatal intensive care services in their rule regulating minimum standards for health care facilities.

Current rules require minimum volume standards for the provision of neonatal intensive care services. AHCA is currently in the rulemaking process to establish initial and continued licensure requirements for NICU programs. The current proposed rule drafts do not include minimum volume standards for the provision of neonatal intensive care services. If AHCA finalizes the rules prior to the bill becoming law, AHCA may have to change the rules to include minimum volume standards.

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

B. SECTION DIRECTORY:

- Section 1:** Amends s. 395.1055, F.S., relating to rules and enforcement.
- Section 2:** Amends s. 765.5155, F.S., relating to donor registry, education program.
- Section 3:** Amends s. 765.517, F.S., relating to rights and duties at death.
- Section 4:** Amends s. 765.522, F.S., relating to duty of hospital administrators; liability of hospital administrators and procurement organizations.
- Section 5:** Amends s. 765.543, F.S., relating to Organ and Tissue Procurement and Transplantation Advisory Board; duties.
- Section 6:** Provides an effective date of July 1, 2020.

II. FISCAL ANALYSIS & ECONOMIC IMPACT STATEMENT

A. FISCAL IMPACT ON STATE GOVERNMENT:

- 1. Revenues:
None.
- 2. Expenditures:
None.

B. FISCAL IMPACT ON LOCAL GOVERNMENTS:

- 1. Revenues:
None.
- 2. Expenditures:
None.

C. DIRECT ECONOMIC IMPACT ON PRIVATE SECTOR:

The bill prohibits transplant facilities from charging a donor or the donor's family for fees related to the donation or procurement of the donor's organs. Since such facilities generally do not charge such fees, this provision has no fiscal impact to transplant facilities.

D. FISCAL COMMENTS:

None.

III. COMMENTS

A. CONSTITUTIONAL ISSUES:

1. Applicability of Municipality/County Mandates Provision:

Not Applicable. This bill does not appear to affect county or municipal governments.

2. Other:

None.

B. RULE-MAKING AUTHORITY:

Current law and the bill provide sufficient rule-making authority for AHCA to implement the provisions of this bill.

C. DRAFTING ISSUES OR OTHER COMMENTS:

AHCA recommends repealing s. 765.53, F.S., relating to the Organ Transplant Advisory Council.⁵²

The duties of the council are also performed by the federal Centers for Medicare and Medicaid Services, the OPTN, Health Resources and Services Administration, UNOS, OPOs, and the Joint Commission.⁵³ According to AHCA, there has been no substantive reason for the council to meet in recent years.⁵⁴

IV. AMENDMENTS/ COMMITTEE SUBSTITUTE CHANGES

On February 4, 2020, the Health Market Reform Committee adopted an amendment and was reported favorably as a committee substitute. The amendment:

- Requires AHCA to include minimum volume standards for organ transplants and neonatal intensive care services in their rule regulating minimum standards for health care facilities;
- Adds a requirement to educate the public on state and federal law relating to the organ donation transplant process to the current AHCA public education program;
- Prohibits a transplant facility from charging the donor, or his or her family, any fees for services related to the procurement or donation of his or her organs;
- Requires individuals who make organ requests to living donors, or to patients, or family members for a decedent's organs, to explain the protocols of the hospital and federal and state regulations regarding organ donation; and
- Requires the Organ and Tissue Procurement and Transplantation Advisory Board to submit recommendations relating to organ transplants to AHCA.

The analysis is drafted to the committee substitute as passed by the Health Market Reform Subcommittee.

⁵² *Supra*, note 40.

⁵³ *Id.*

⁵⁴ *Id.*