

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 1318

INTRODUCER: Senator Harrell

SUBJECT: Organ Donation and Transplantation

DATE: March 30, 2021

REVISED: _____

	ANALYST	STAFF DIRECTOR	REFERENCE	ACTION
1.	Looke	Brown	HP	Pre-meeting
2.			AHS	
3.			AP	

I. Summary:

SB 1318 amends various sections of the Florida statutes related to organ donation and transplantation. The bill:

- Requires locations where hunting, fishing, or trapping licenses are sold to make educational materials regarding organ donation available to the public and includes such recreational licenses and permits in the current program designed to encourage persons to sign up as an organ donor when being issued a driver license or identification card. Additionally, the bill requires that each person who applies for such license or permit over the Internet must be provided with a link to the statewide donor registry.
- Requires the Agency for Health Care Administration (AHCA) to include minimum volume standards for organ transplantation and neonatal intensive care services in the AHCA's licensure rules for tertiary services.¹
- Allows the AHCA to pay, through Medicaid, for organ transplantation services, including pre-transplant, transplant, and post-discharge services, and treatment of complications after transplantation, for transplants deemed necessary and appropriate within the guidelines set by the Organ Transplant Advisory Council.
- Prohibits a preexisting condition provision in a health insurance policy from excluding coverage solely on the basis that the insured is a living organ donor.
- Expands the donor registry education program to include federal law, to require the contractor providing the education program to work with the AHCA and the State Board of Education to develop an instructional curriculum for students in grades 9 through 12 relating to organ donor registration, and to require public schools to teach organ donor registration to students in grades 9 through 12.
- Prohibits an organ transplantation facility from charging a donor or his or her family member any fee for services relating to the procurement or donation of his or her organs.

¹ Including organ transplantation, neonatal intensive care services, inpatient psychiatric services, inpatient substance abuse services, or comprehensive medical rehabilitation.

- Requires any individual who requests the consent for an anatomical gift from the health care surrogate or family of a person who is, or will be, recently deceased in a hospital to clearly explain to patients and living organ donors the protocols of the hospital and the federal and state laws regarding organ donation.
- Requires the Organ and Tissue Procurement and Transplantation Advisory Board (OTPTAB) to work with relevant public and private entities to develop the necessary professional qualifications, including continuing education, for licensed health care practitioners and other persons engaged in the various facets of organ and tissue procurement. The bill also requires the OTPTAB to submit specified recommendations to the AHCA by September 1, 2022.

The bill provides an effective date of July 1, 2021.

II. Present Situation:

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.² 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 bypass surgery; corneas used to restore sight; and bone used in orthopedic surgery to facilitate healing of fractures or prevent amputation.³

A single person can save up to eight lives through organ donation, and dozens more lives may be improved through tissue donation.⁴ While most organ and tissue donations occur after the donor has died, some organs and tissues can be donated while the donor is alive, such as a kidney or part of a liver or lung.⁵ There are approximately as many living donors every year as there are deceased donors.⁶

Organ Donation, Procurement, 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.⁷ 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.⁸ UNOS coordinates

² Donate Life Florida, *Frequently Asked Questions*, available at <https://www.donateliflorida.org/categories/donation/> (last visited Mar. 23, 2021).

³ *Id.*

⁴ *Id.*

⁵ U.S. Government Information on Organ Donation and Transplantation, U.S. Department of Health & Human Services, *How Organ Donation Works*, available at <https://organdonor.gov/about/process.html> (last visited Mar. 3, 2021).

⁶ *Id.*

⁷ U.S. Department of Health and Human Services, *Organ Procurement and Transplantation Network – About the OPTN*, available at <https://optn.transplant.hrsa.gov/governance/about-the-optn/> (last visited Mar. 23, 2021).

⁸ *Id.*

how donor organs are matched and allocated to patients on the waiting list.⁹ Non-profit, federally designated organ procurement organizations (OPOs) work closely with UNOS, hospitals, and transplant centers to facilitate the organ donation and transplantation process,¹⁰ including conducting a thorough medical and social history of the potential donor to help determine the suitability of his or her organs for transplantation.¹¹

Regulation of Organ Donation, Procurement, and Transplantation in Florida

The AHCA oversees the various organizations and facilities involved in the organ procurement and transplant process in this state. The 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 supports the Organ Transplant Advisory Council and the Organ and Tissue Procurement and Transplantation Advisory Board.

Organ Donor Registry

In 2008,¹² Florida's Legislature found that a shortage of organ and tissue donors existed in Florida. Findings included a need for:

- A statewide donor registry with online donor registration capability; and
- Enhanced donor education, to increase the number of organ and tissue donors.

The online registry would afford more persons who are awaiting organ or tissue transplants the opportunity for a full and productive life.¹³ As directed by the Legislature, the AHCA and the Department of Highway Safety and Motor Vehicles (DHSMV) jointly contracted for the operation of Florida's interactive web-based donor registry that allows for online donor registration and the recording of organ and tissue donation records submitted through the driver license identification program or through other sources. The AHCA and the DHSMV selected Donate Life Florida, which is a coalition of Florida's organ, tissue, and eye donor programs, to run the donor registry and maintain donor records.

Floridians aged 18 or older can join the donor registry either online, at the DHSMV (or their local driver license office), or by contacting Donate Life Florida for a paper application.¹⁴ Children aged 13 to 17 may join the registry, but the final decision on any organ donation of a minor rests with the parent or guardian. The registry collects personal information from each donor including, but not limited to, his or her name, address, date and place of birth, race, ethnicity, and driver's license number.

As of March 23, 2021, there were 11,496,288 people registered in the donor registry.¹⁵

⁹ U.S. Government Information on Organ Donation and Transplantation, U.S. Department of Health & Human Services, *The Organ Transplant Process*, available at <https://organdonor.gov/about/process/transplant-process.html> (last visited Mar. 23, 2021).

¹⁰ Donate Life Florida, *Organ Procurement Organizations and Transplant Centers*, available at <https://www.donatelifeflorida.org/local-resources/transplant-centers/> (last visited Mar. 23, 2021).

¹¹ Organ Procurement and Transplantation Network, U.S. Department of Health & Human Services, *The Basic Path of Donation*, available at <https://optn.transplant.hrsa.gov/learn/about-donation/the-basic-path-of-donation/> (last visited Mar. 23, 2021).

¹² Ch. 2008-223, Laws of Fla.

¹³ Section 765.5155(1), F.S.

¹⁴ Donate Life Florida, *Welcome to the Joshua Abbott Organ and Tissue Donor Registry*, available at <http://www.donatelifeflorida.org/> (last visited Mar. 23, 2021)

¹⁵ *Id.*

A person may make an anatomical gift of all or part of his or her body by:¹⁶

- Signing an organ and tissue donor card;
- Registering online with the donor registry;
- Signifying an intent to donate on his or her driver license or identification card issued by the DHSMV;¹⁷
- Expressing a wish to donate in a living will or other advance directive;
- Executing a will that includes a provision indicating that the testator wishes to make an anatomical gift;¹⁸ or
- Expressing a wish to donate in a document other than a will.¹⁹

Donor Education

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.²⁰ The AHCA has developed rules for training and guidelines for the person making the request for organ donation.²¹ 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).²² 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.²³ The current rules require the requestor to explain the requirements that need to be met under Florida law in order for a donation to be allowed but is silent regarding an explanation of federal regulations relating to organ donation.

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.²⁴ Families pay for medical care and funeral costs, but costs related to living or deceased donation are paid by the recipient, usually through insurance, including Medicare, or Medicaid.²⁵ 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.²⁶

¹⁶ Section 765.514(1), F.S.

¹⁷ Revocation, suspension, expiration, or cancellation of the driver license or identification card does not invalidate the gift.

¹⁸ The gift becomes effective upon the death of the testator without waiting for probate. If the will is not probated or if it is declared invalid for testamentary purposes, the gift is nevertheless valid to the extent that it has been acted upon in good faith.

¹⁹ The document must be signed by the donor in the presence of two witnesses who shall sign the document in the donor's presence. If the donor cannot sign, the document may be signed for him or her at the donor's direction and in his or her presence and the presence of two witnesses who must sign the document in the donor's presence. Delivery of the document of gift during the donor's lifetime is not necessary to make the gift valid.

²⁰ Health Resources and Services Administration, *The Deceased Donation Process*, available at

<https://www.organdonor.gov/about/process/deceased-donation.html#authorize> (last visited March 3, 2021). See also s. 765.522, F.S.

²¹ Fla. Admin. Code R. 59A-3.274 (2021).

²² *Id.*

²³ *Id.*

²⁴ Health Resources Services Administration, *Organ Donation Frequently Asked Questions*, available at

<https://www.organdonor.gov/about/facts-terms/donation-faqs.html> (last visited Mar. 23, 2021).

²⁵ *Id.* See also UNOS, *Living Donation Costs*, available at <https://transplantliving.org/financing-a-transplant/living-donation-costs/> (last visited Mar. 23, 2021).

²⁶ UNOS, *Living Donation Costs*, available at <https://transplantliving.org/financing-a-transplant/living-donation-costs/> (last visited Mar. 23, 2021).

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 the AHCA. Current law requires the board to assist the 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.²⁷

Additionally, the board works with the 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 the 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.²⁸

The board consists of 14 members who are appointed by the Secretary of the AHCA, including:²⁹

- 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 2013.³⁰

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.³¹ The federal certification requirements include

²⁷ Section 765.543, F.S.

²⁸ *Id.*

²⁹ Section 765.543, F.S. See also Agency for Health Care Administration, *Organ and Tissue Procurement and Transplantation Advisory Board*, available at https://ahca.myflorida.com/MCHO/Health_Facility_Regulation/Lab_HomeServ/OrganTissueBoard.shtml (last visited Mar. 23, 2021).

³⁰ Agency for Health Care Administration, *Organ and Tissue Procurement and Transplantation Advisory Board*, available at https://ahca.myflorida.com/MCHO/Health_Facility_Regulation/Lab_HomeServ/OrganTissueBoard.shtml (last visited Mar. 23, 2021).

³¹ 42 C.F.R. §482.72.

minimum volume standards for initial certification.³² To obtain initial certification, an organ-specific transplant program must generally perform 10 transplants over a 12-month period.³³

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.³⁴ The AHCA recently proposed a rule to require organ transplant licensees and applicants to seek and maintain federal certification from the federal Centers for Medicare & Medicaid Services.³⁵

The 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.³⁶ OPTN bylaws require transplant programs to meet the following volume requirements to remain functionally active:³⁷

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> <p>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.</p>
Islet, intestinal, and vascularized composite allograft	No functional inactivity definitions have been established.

Required Instruction in Schools

Florida law specifies required coursework and instruction for public school students. Specifically, each district school board must provide all courses required for middle grades promotion, high school graduation, and appropriate instruction designed to ensure that students meet State Board of Education (SBE) adopted standards in the following subject areas: reading and other language arts, mathematics, science, social studies, foreign languages, health and physical education, and the arts.³⁸

³² 42 C.F.R. §482.80.

³³ *Id.*

³⁴ Fla. Admin. Code R. 59C-1.044 (2021).

³⁵ Proposed rule 59A-3.246, F.A.C. A public hearing was 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 Mar. 23, 2021).

³⁶ *Id.*

³⁷ Organ Procurement and Transplantation Network, *Bylaws*, (Dec. 7, 2020) available at https://optn.transplant.hrsa.gov/media/1201/optn_bylaws.pdf (last visited March 23, 2021).

³⁸ Section 1003.42(1), F.S.

Instructional staff of public schools, subject to the rules of the SBE and the district school board, must provide instruction in:³⁹

- The history and content of the Declaration of Independence;
- The history, meaning, significance, and effect of the provisions of the Constitution of the United States;
- The arguments in support of adopting our republican form of government;
- Flag education, including proper flag display and flag salute;
- The elements of civil government;
- The history of the United States;
- The history of the Holocaust;
- The history of African Americans;
- The elementary principles of agriculture;
- The effects of alcoholic and intoxicating liquors and beverages and narcotics;
- Kindness to animals;
- The history of the state;
- Conservation of natural resources;
- Comprehensive health education;
- The study of Hispanic contributions to the United States;
- The study of women's contributions to the United States;
- The nature and importance of free enterprise to the United States economy;
- A character-development program in kindergarten through grade 12; and
- The sacrifices that veterans and Medal of Honor recipients have made serving the country.

III. Effect of Proposed Changes:

SB 1318 amends multiple sections of the Florida statutes to make changes related to organ donation and transplantation.

Sections 1 and 7 amends ss. 379.352 and 765.521, F.S., respectively, to require educational materials regarding organ donation and registration to be made available and displayed for the public at each location where hunting, fishing, or trapping licenses or permits are sold. Additionally, each person who applies for a hunting, fishing, or trapping license or permit over the Internet must be provided a link to the statewide donor registry. The bill also includes recreational licenses and permits in the current program designed to encourage persons to sign up as an organ donor when being issued a driver licenses or identification card and makes other technical changes.

Section 2 amends s. 395.1055, F.S., to require AHCA rules establishing licensure requirements for hospitals to provide tertiary care services⁴⁰ to include minimum volume standards for organ transplantation and neonatal intensive care services.

Section 3 amends s. 409.906, F.S., to allow the AHCA to pay, through Medicaid, for organ transplantation services including pre-transplant, transplant, and post-discharge services, and

³⁹ The law encourages the SBE to adopt standards and pursue assessment relating to the required instructional content. s. 1003.42(2), F.S.

⁴⁰ Including organ transplantation, neonatal intensive care services, inpatient psychiatric services, inpatient substance abuse services, or comprehensive medical rehabilitation.

treatment of complications after transplantation for transplants deemed necessary and appropriate within the guidelines set by the Organ Transplant Advisory Council under s. 765.53, F.S., or the Bone Marrow Transplant Advisory Panel under s. 627.4236, F.S.

Section 4 amends s. 627.6045, F.S., to prohibit a preexisting condition provision in a health insurance policy from excluding coverage solely on the basis that the insured is a living organ donor.

Sections 5 and 10 amend s. 765.5155 and 1003.42, F.S., respectively, to expand the donor registry education program to include federal law, to require the contractor providing the education program to work with the AHCA and the SBE to develop an instructional curriculum for students in grades 9 through 12 relating to organ donor registration, and to require public schools to teach organ donor registration to students in grades 9 through 12.

Section 6 amends s. 765.517, F.S., to prohibit an organ transplantation facility from charging a donor or his or her family member any fee for services relating to the procurement or donation of his or her organs.

Section 8 amends s. 765.522, F.S., to require any individual who requests the consent for an anatomical gift from the health care surrogate or family of a person who is, or will be, recently deceased in a hospital, to clearly explain to patients and living organ donors the protocols of the hospital and the federal and state laws regarding organ donation.

Section 9 amends s. 765.543, F.S., to require the OTPTAB to work with relevant public and private entities to develop the necessary professional qualifications, including continuing education, for licensed health care practitioners and other persons engaged in the various facets of organ and tissue procurement. The bill also requires the OTPTAB to submit to the AHCA, by September 1, 2022, recommendations that address the:

- Frequency of communication between patients and organ transplant coordinators.
- Monitoring of each organ transplantation facility and the annual reporting and publication of relevant information regarding the statewide number of patients placed on waiting lists and the number of patients who receive transplants, aggregated by facility.
- Establishment of a coordinated communication system between organ transplantation facilities and living organ donors for the purpose of minimizing the cost and time required for duplicative lab tests, including the sharing of lab results between facilities.
- Potential incentives for organ transplantation facilities to increase organ donation in this state.
- Creation of a more efficient regional or statewide living organ donor process.
- Potential opportunities and incentives for organ transplantation research.
- Best practices for organ transplantation facilities and organ procurement organizations which promote the most efficient and effective outcomes for patients.
- Monitoring of organ procurement organizations.

Section 11 provides an effective date of July 1, 2021.

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:

Article III, Section 6, of the State Constitution requires that “every law shall embrace but one subject and matter properly connected therewith, and the subject shall be briefly expressed in the title.” SB 1318 is entitled “An act relating to organ donation and transplantation.” As such, a portion of section 2 of the bill, requiring the AHCA to adopt minimum volume standards for neonatal intensive care services, may be found to be outside of the scope of the bill as titled and may be unconstitutional.

V. Fiscal Impact Statement:

A. Tax/Fee Issues:

None.

B. Private Sector Impact:

None.

C. Government Sector Impact:

SB 1318 may have a negative fiscal impact on the AHCA of approximately \$56,000 for the first year of implementation and \$20,000 for year two to hire one OPS position to implement the AHCA’s duties under the bill.⁴¹

VI. Technical Deficiencies:

None.

⁴¹ Agency for Health Care Administration, *House Bill 1009 Fiscal Analysis* (Mar. 5, 2021) (on file with the Senate Committee on Health Policy.)

VII. Related Issues:

None.

VIII. Statutes Affected:

This bill substantially amends the following sections of the Florida Statutes: 379.352, 395.1055, 409.906, 627.6045, 765.5155, 765.517, 765.521, 765.522, 765.543, and 1003.42.

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.
