

**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.)

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Prepared By: The Professional Staff of the Committee on Rules

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**BILL:** CS/CS/CS/SB 1516

**INTRODUCER:** Rules Committee; Judiciary Committee; Health Policy Committee; and Senator Harrell

**SUBJECT:** Organ Donation

**DATE:** February 27, 2020

**REVISED:** \_\_\_\_\_

	ANALYST	STAFF DIRECTOR	REFERENCE	ACTION
1.	<u>Looke</u>	<u>Brown</u>	<u>HP</u>	<b>Fav/CS</b>
2.	<u>Ravelo</u>	<u>Cibula</u>	<u>JU</u>	<b>Fav/CS</b>
3.	<u>Looke</u>	<u>Phelps</u>	<u>RC</u>	<b>Fav/CS</b>

**Please see Section IX. for Additional Information:**

COMMITTEE SUBSTITUTE - Substantial Changes

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**I. Summary:**

CS/CS/CS/SB 1516 amends multiple sections of law related to organ donations. The bill:

- Authorizes a human immunodeficiency virus (HIV)-positive patient to donate blood, plasma, organs, skin, or other human tissue to an HIV-positive recipient who knows the donor is HIV positive.
- Requires the Agency for Health Care Administration (AHCA) to adopt rules establishing specified ongoing minimum volume standards to maintain licensure to provide specified organ transplants.
- Prohibits a health insurance policy from limiting or excluding coverage for a living organ donor based on a preexisting condition.
- Prohibits an organ transplantation facility or procurement organization from charging a living or deceased organ donor or his or her family any fee for services relating to the procurement or donation of the donor's organs.
- Adds a statement on the uniform donor card application form that neither the donor nor his or her family is responsible for the payment of any fees associated with services relating to the procurement or donation of the donor's organs, tissues, or eyes.
- Expands the organ donation education program to include federal laws and information on the organ donation and transplantation process.
- Establishes additional requirements for the AHCA related to organ transplantation evaluation, reporting, and education.
- Renames the Organ Transplant Advisory Council as the Organ Transplant Technical Advisory Council (Council), and assigns duties to develop quality standards for programs.

- Requires the Organ and Tissue Procurement and Transplantation Advisory Board to submit specified recommendations to the AHCA by September 1, 2021.

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

## **II. Present Situation:**

### **Organ Transplant Advisory Council**

Section 765.53, F.S., establishes the Organ Transplant Advisory Council (OTAC) to consist of 12 physician<sup>1</sup> members who are appointed to represent the interests of the public and the clients of the Department of Health (DOH) or the AHCA. All members are appointed by the Secretary of Health Care Administration for two-year terms. The OTAC is responsible for recommending indications for adult and pediatric organ transplants to the AHCA and formulating guidelines and standards for organ transplants and for the development of End Stage Organ Disease and Tissue/Organ Transplant programs. The OTAC's recommendations, guidelines, and standards are limited in applicability to only those health programs funded through the AHCA.

The OTAC met 22 times with its first meeting held on August 27, 2007 and its last meeting held on April 14, 2015. Most actions of the OTAC revolved around approving guidelines for organ transplantations and reviewing and approving hospital transplant program applications for recommendation to the AHCA.

### **Organ and Tissue Procurement and Transplantation Advisory Board (Board)**

The Organ and Tissue Procurement and Transplantation Advisory Board consists of 14 members appointed by the Secretary for three-year terms.<sup>2</sup> The Board is tasked with:

- Assisting the AHCA in the development of necessary professional qualifications, including, but not limited to, the education, training, and performance of persons engaged in organ and tissue procurement, processing, preservation, and distribution for transplantation;
- Assisting the AHCA in monitoring the appropriate expenses associated with organ and tissue procurement, processing, and distribution for transplantation and developing methodologies to ensure uniform statewide reporting of data to facilitate the accurate and timely evaluation of the organ and tissue procurement and transplantation system;
- Providing 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;
- Developing with and recommending to the AHCA the necessary procedures and protocols required to assure that all residents of this state have reasonable access to available organ and tissue transplantation therapy and that residents of this state can be reasonably assured that the statewide procurement transplantation system is able to fulfill their organ and tissue requirements within the limits of the available supply and according to the severity of their medical condition and need; and

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<sup>1</sup> Licensed under chs. 458 and 459, F.S.

<sup>2</sup> Section 765.543, F.S.

- Developing with and recommending to the AHCA any changes to the laws of this state or administrative rules or procedures to ensure that the statewide organ and tissue procurement and transplantation system is able to function smoothly, effectively, and efficiently, in accordance with the Federal Anatomical Gift Act and in a manner that assures the residents of this state that no person or entity profits from the altruistic voluntary donation of organs or tissues.

The Board met five times between September of 2011 and January of 2014. The Board held its last meeting to conduct general business of the advisory board, including a review and discussion on recommendations for changes to the laws and administrative rules related to organ and tissue procurement activities in Florida.<sup>3</sup>

**Licensure Requirements**

*Volume requirements:*<sup>4, 5</sup>

Liver	5 transplants over 2 years
Kidneys	Adult – 15 transplants per year Pediatric – 5 transplants per year
Pediatric bone marrow	10 transplants per year of each type performed (allogenic or autologous)
Adult bone marrow	10 transplants per year of each type performed (allogenic or autologous)
Lung, Heart and Lung, Pancreas and Islet Cells, and Intestines	None
Proposed organ transplant volume requirements in 59A-3.246, F.A.R.	Each licensed organ transplant program must perform a minimum of 10 transplants per year averaged over 2 years. Hospitals providing adult and pediatric programs must meet the minimum volume requirement for each age group separately.

Currently, standards for licensure for organ transplant programs in Florida can be found in AHCA Rule 59C-1.044, F.A.C.<sup>6</sup> These standards include:

- General staffing requirements:
  - A staff of physicians with expertise in caring for patients having end-stage disease requiring transplantation. The staff must have medical specialties or sub-specialties appropriate for the type of transplantation program to be established. A physician having one year of experience in the management of infectious diseases in the transplant patient must be a member of the transplant team. The program must employ a transplant

<sup>3</sup> See meeting notice 14072583 in the Florida Administrative Register. Additional meeting minutes and recommendations are available at [https://ahca.myflorida.com/MCHQ/Health\\_Facility\\_Regulation/Lab\\_HomeServ/OrganTissueBoard.shtml](https://ahca.myflorida.com/MCHQ/Health_Facility_Regulation/Lab_HomeServ/OrganTissueBoard.shtml) (last visited on Jan. 28, 2020).

<sup>4</sup> Projected prior to grant of licensure.

<sup>5</sup> Volume requirements for liver and kidney transplants are included in the CON portions of the rule.

<sup>6</sup> For a discussion of the licensure requirements in a CON rule versus a licensure rule, see the CON overview below.

- physician, and a transplant surgeon, if applicable, as defined by the United Network for Organ Sharing (UNOS), June 1994.
- A program director who has a minimum of one year of formal training and one year of experience at a transplantation program for the same type of organ transplantation program proposed.
  - A staff of practitioners with experience in the special needs of children if pediatric transplantations are performed;
  - A staff of nurses and nurse practitioners with experience in the care of chronically ill patients and their families;
  - Contractual agreements with consultants who have expertise in blood banking and are capable of meeting the unique needs of transplant patients on a long-term basis;
  - Nutritionists having expertise in the nutritional needs of transplant patients;
  - Respiratory therapists having expertise in the needs of transplant patients; and
  - Social workers, psychologists, psychiatrists, and other individuals skilled in performing comprehensive psychological assessments, counselling patients, and families of patients, providing assistance with financial arrangements, and making arrangements for use of community resources.
- Coordination of services:
    - Staff and other resources necessary to care for a patient's chronic illness prior to transplantation, during transplantation, and in the post-operative period. Services and facilities for inpatient and outpatient care must be available on a 24-hour basis.
    - If cadaveric transplantation will be part of the transplantation program, a written agreement with an organ acquisition center for organ procurement is required. A system by which 24-hour call can be maintained for assessment, management, and retrieval of all referred donors, cadaver donors or organs shared by other transplant or organ procurement agencies is mandatory. Applicants for a bone marrow transplantation program are exempt from this requirement.
    - An age-appropriate (adult or pediatric) intensive care unit which includes facilities for prolonged reverse isolation when required.
    - A clinical review committee for evaluation and decision-making regarding the suitability of a transplant candidate.
    - Written protocols for patient care for each type of organ transplantation program including, at a minimum, patient selection criteria for patient management and evaluation during the pre-hospital, in-hospital, and immediate post-discharge phases of the program.
    - Detailed therapeutic and evaluative procedures for the acute and long term management of each transplant program patient, including the management of commonly encountered complications.
    - Equipment for cooling, flushing, and transporting organs. If cadaveric transplants are performed, equipment for organ preservation through mechanical perfusion is necessary. Applicants for a bone marrow transplantation program are exempt from this requirement. This requirement may be met through an agreement with an organ procurement agency.
    - An onsite tissue-typing laboratory or a contractual arrangement with an outside laboratory within the state which meets the requirements of the American Society of Histocompatibility.
    - Pathology services having the capability of studying and promptly reporting a patient's response to the organ transplantation surgery, and analyzing appropriate biopsy material.
    - Blood banking facilities.

- A program for the education and training of staff regarding the special care of transplantation patients.
- Education programs for patients, their families, and a patient's primary care physician regarding after-care for transplantation patients.
- Specialized requirements:
  - For heart transplant programs:
    - A board-certified or board-eligible adult cardiologist, or, in the case of a pediatric heart transplantation program, a board-certified or board-eligible pediatric cardiologist;
    - An anesthesiologist experienced in both open heart surgery and heart transplantation; and
    - A one-bed isolation room in an age-appropriate intensive care unit.
  - For liver transplant programs:
    - A department of gastroenterology, including clinics, and adequately equipped procedure rooms;
    - Radiology services to provide complex biliary procedures, including transhepatic cholangiography, portal venography, and arteriography;
    - A laboratory having the capability of performing and promptly reporting the results of liver function tests as well as required chemistry, hematology, and virology tests; and
    - A patient convalescent unit for further monitoring of patient progress for approximately one month post-hospital discharge following liver transplantation.
    - In addition to the general staffing requirements for all transplantation programs, program staff for liver transplantation programs must be trained in the care of patients with hepatic diseases, and liver transplantation.
  - For kidney transplant programs:
    - Coordination of services requirements:
      - Inpatient services must be available and must include renal dialysis and pre- and post operative care. There must be 24-hour availability of onsite dialysis under the supervision of a board-certified or board-eligible nephrologist. If pediatric patients are served, a separate pediatric dialysis unit must be established.
      - Outpatient services must be available and must include renal dialysis services and ambulatory renal clinic services.
      - Ancillary services must include pre-dialysis, dialysis, and post transplantation nutritional services; bacteriologic, biochemical, and pathological services; radiologic services; and nursing services having the capability of monitoring and support during dialysis and assisting with home care including vascular access and home dialysis management, when applicable.
    - Staffing requirements for adult programs:
      - The kidney transplantation program must be under the direction of a physician having experience in physiology, immunology, and immuno-suppressive therapy relevant to kidney transplantation.
      - The transplant surgeon must be board-certified in surgery or a surgical subspecialty and must have a minimum of 18 months training in a transplant center.

- The transplant team performing kidney transplantation must include physicians who are board-certified or board-eligible in the areas of anesthesiology, nephrology, psychiatry, vascular surgery, and urology.
- Additional support personnel which must be available include a nephrology nurse with experience in nursing care of patients with permanent kidney failure, and a renal dietician.
- A laboratory with the capability of performing and promptly reporting bacteriologic, biochemical, and pathologic analysis.
- An anesthesiologist experienced in kidney transplantation.
- Staffing requirements for pediatric programs:
  - A medical director who is sub-board-certified or sub-board-eligible in pediatric nephrology.
  - A dialysis unit head nurse with special training and expertise in pediatric dialysis.
  - Nurse staffing at a nurse-to-patient ratio of one-to-one in the pediatric dialysis unit.
  - A registered dietician with expertise in nutritional needs of children with chronic renal disease.
  - A surgeon with experience in pediatric renal transplantation.
  - A radiology service with specialized equipment for obtaining X-rays on pediatric patients.
  - Education services to include home and hospital programs to ensure minimal interruption in school education.
- For bone marrow transplant programs:
  - Staffing Requirements:
    - A program director who is a board certified hematologist or oncologist having experience in the treatment and management of pediatric acute oncological cases involving high dose chemotherapy or high dose radiation therapy. The program director must have formal training in pediatric bone marrow transplantation;
    - Clinical nurses having experience in the care of critically ill immuno-suppressed patients. Nursing staff must be dedicated full time to the program;
    - An interdisciplinary transplantation team having expertise in hematology, oncology, immunologic diseases, neoplastic diseases, including hematopoietic and lymphopoietic malignancies, and non-neoplastic disorders. The team must direct permanent follow-up care of the bone marrow transplantation patients, including the maintenance of immunosuppressive therapy and treatment of complications;
    - A radiation therapy division onsite which is capable of sub-lethal x-irradiation, bone marrow ablation, and total lymphoid irradiation. The division must be under the direction of a board-certified radiation oncologist;
    - An ongoing research program that is integrated either within the hospital or by written agreement with a bone marrow transplantation center operated by a teaching hospital. The program must include outcome monitoring and long-term patient follow-up; and
    - An established research-oriented oncology program.
  - Pediatric allogenic bone marrow transplant requirements:
    - A laboratory equipped to handle studies including the use of monoclonal antibodies, if this procedure is employed by the hospital, or T-cell depletion,

- separation of lymphocyte and hematological cell subpopulations and their removal for prevention of graft versus host disease. This requirement may be met through contractual arrangements;
- An onsite laboratory equipped for the evaluation and cryopreservation of bone marrow;
  - An age-appropriate patient convalescent facility to provide a temporary residence setting for transplant patients during the prolonged convalescence; and
  - An age-appropriate outpatient unit for close supervision of discharged patients.
- Adult allogenic bone marrow transplant program requirements:
    - Inpatient transplantation units for post-transplant hospitalization. Post-transplantation care must be provided in a laminar air flow room; or in a private room with positive pressure, reverse isolation procedures, and terminal high efficiency particulate aerosol filtration on air blowers. The designated transplant unit must have a minimum of two beds. This unit can be part of a facility that also manages patients with leukemia or similar disorders;
    - A radiation therapy division onsite which is capable of sub-lethal x-irradiation, bone marrow ablation, and total lymphoid irradiation. The division must be under the direction of a board-certified radiation oncologist;
    - A laboratory equipped to handle studies including the use of monoclonal antibodies, if this procedure is employed by the hospital, or T-cell depletion, separation of lymphocyte and hematological cell subpopulations and their removal for prevention of graft versus host disease. This requirement may be met through contractual arrangements;
    - An onsite laboratory equipped for the evaluation and cryopreservation of bone marrow;
    - An ongoing research program that is integrated either within the hospital or by written agreement with a bone marrow transplantation center operated by a teaching hospital. The program must include outcome monitoring and long-term patient follow-up;
    - An established research-oriented oncology program;
    - A patient convalescent facility to provide a temporary residence setting for transplant patients during the prolonged convalescence; and
    - An outpatient unit for close supervision of discharged patients.
  - Adult autologous bone marrow transplant program requirements:
    - Inpatient transplantation units for post-transplant hospitalization. Post-transplantation care must be provided in a laminar air flow room; or in a private room with positive pressure, reverse isolation procedures, and terminal high efficiency particulate aerosol filtration on air blowers. The designated transplant unit must have a minimum of two beds. This unit can be part of a facility that also manages patients with leukemia or similar disorders;
    - A radiation therapy division onsite which is capable of sub-lethal x-irradiation and total lymphoid irradiation. The division must be under the direction of a board-certified radiation oncologist;
    - An ongoing research program that is integrated either within the hospital or by written agreement with a bone marrow transplantation center operated by a teaching hospital; or the applicant may enter into an agreement with an outpatient provider having a research program, as defined in this rule. Under the agreement,

the outpatient research program may perform specified outpatient phases of adult autologous bone marrow transplantation, including blood screening tests, mobilization of stem cells, stem cell rescue, chemotherapy, and reinfusion of stem cells; and

- An established research-oriented oncology program.
- Lung, Heart and Lung, Pancreas and Islet Cells, and Intestines transplant programs have no additional requirements.

### **Ongoing Organ Transplant Volume Requirements**

Currently, under provisions in ch. 2019-136, L.O.F.,<sup>7</sup> licensure of organ transplantation programs in Florida is governed by Rule 59C-1.044, F.A.C., until the AHCA adopts licensure rules for organ transplant programs. As of January 23, 2020, the AHCA has begun the process of amending Rule 59A-3.246, F.A.C., to incorporate licensure requirements for organ transplant programs but no changes have yet been adopted. Additionally, the Federal Centers for Medicare and Medicaid Services recently repealed ongoing volume requirements for organ transplant centers to participate in the Medicaid and Medicare.<sup>8</sup>

### **HIV Positive Organ, Blood, Plasma, Skin, and Tissue Donation**

Due to increased life expectancy, the number of HIV-positive persons in need of organ transplants has increased.<sup>9</sup> However, the number of people on the organ transplant waiting list far outweighs the number of available organs.<sup>10</sup> This shortage disproportionately affects persons with HIV, who have a higher mortality rate than persons without HIV on the organ transplant waiting list.<sup>11</sup>

For decades, federal law prohibited persons with HIV from donating organs for transplantation, including to HIV-positive recipients.<sup>12</sup> However, in 2013, the HIV Organ Policy Equity (HOPE) Act legalized HIV-positive organ donations for transplantation into HIV-positive candidates under approved research protocols designed to evaluate the feasibility, effectiveness, and safety of such organ transplants.<sup>13</sup>

Although authorized by federal law, it is a third-degree felony in Florida for an HIV-positive person to donate blood, plasma, organs, skin, or other human tissue when he or she knew of the HIV infection and was informed that transmission could occur through such donation.<sup>14</sup>

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<sup>7</sup> Chapter 2019-136, L.O.F., eliminated Florida's certificate of need program for certain hospitals and tertiary services, including organ transplants. Under the provisions of the act, the AHCA's CON rules remain effective for licensure purposes until the AHCA replaces them with licensure rules.

<sup>8</sup> 83 FR 47686

<sup>9</sup> Christine Durand, M.D., *The Transformation of Transplantation*, HIV Specialist (July 2018), available at [https://aahivm.org/wp-content/uploads/2018/07/FINALHIVspecialist\\_July2018FINAL-1.pdf](https://aahivm.org/wp-content/uploads/2018/07/FINALHIVspecialist_July2018FINAL-1.pdf) (last visited Feb. 26, 2020).

<sup>10</sup> *Id.*

<sup>11</sup> *Id.*

<sup>12</sup> UNOS, *At Two Years, HOPE Act Still Offering Hope* (December 1, 2017), available at <https://unos.org/at-two-years-hope-act-still-offering-hope/> (last visited Feb. 26, 2020).

<sup>13</sup> *Id.*

<sup>14</sup> Section. 381.0041(11)(b), F.S.



### Florida Sovereign Immunity

Generally, the state has sovereign immunity from liabilities and lawsuits.<sup>15</sup> The Legislature has waived sovereign immunity for certain liabilities from the state, including tort claims for negligence.<sup>16</sup> However, individual state actors and employees are not personally liable unless they act in bad faith or with malicious purpose or in a manner exhibiting wanton and willful disregard of human rights, safety, or property. Moreover, there are limits on the collectability of a judgments of \$200,000 limit per claimant and \$300,000 limit per incident unless the Legislature approves a claim bill authorizing additional payments.

Sovereign immunity is not limited to government agencies. Some private entities, such as Community Based Care Agencies contracted with the Department of Children and Families,<sup>17</sup> share sovereign immunity as corporations primarily acting as instrumentalities of the state or its agencies.

Some advisory boards having both private and government purpose share sovereign immunity. The Florida Virtual School, for example, is governed by a board of trustees entitled to sovereign immunity.<sup>18</sup> The Board acts as the governing board of the Florida Virtual Schools and has the power to generate revenue and supervise employment matters. Similarly, the Nurse Licensure Compact, a national compact of different states making rules for multi-state nurse licensures, enjoys sovereign immunity under Florida law.<sup>19</sup>

### III. Effect of Proposed Changes:

This bill substantially amends and creates several sections of law relating to organ donations.

**Section 1** amends s. 381.0041, F.S., to authorize an HIV-positive patient to donate blood, plasma, organs, skin, or other human tissue to a HIV-positive recipient who knows the donor is HIV positive.

**Section 2** amends s. 395.1055, F.S., to require the AHCA to adopt in rule specified minimum volume standards for organ transplantation programs as follows:

- For heart transplants, performance of at least 12 such transplants per year.
- For liver transplants, performance of at least five such transplants per biennium.
- For adult kidney transplants, performance of at least 15 such transplants per biennium.
- For pediatric kidney transplants, performance of at least five such transplants per biennium.
- For adult allogenic and autologous bone marrow transplants, performance of at least 10 transplants per year of each such transplant it offers.
- For pediatric allogenic and autologous bone marrow transplants, performance of at least 10 transplants per year of each such transplant it offers.
- For any other transplant type not specified in subparagraphs 1.-6., performance of at least 10 transplants of such transplant per year.

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<sup>15</sup> FLA. CONST. art. X, s. 13.

<sup>16</sup> Section 768.28, F.S.

<sup>17</sup> Section 409.2564(6), F.S.

<sup>18</sup> Section 1002.37, F.S.

<sup>19</sup> Section 464.0095, F.S.

The minimum volume standards remain in effect until the AHCA has adopted rules based on recommendations from the Organ Transplant Technical Advisory Council.

**Section 3** amends s. 627.6045, F.S., to prohibit a health insurance policy from limiting or excluding coverage for a living organ donor under a preexisting condition provision.

**Section 5** amends s. 765.5155, F.S., to expand the organ donation education program to include federal laws and information on the organ donation and transplantation process.

**Sections 4 and 6** amend ss. 765.514 and 765.517, F.S., respectively, to prohibit an organ procurement organization from charging a deceased donor or his or her family any fee for services relating to the procurement or donation of the donor's organs and to add a statement on the uniform donor card form that neither the donor nor his or her family is responsible for the payment of any fees associated with services relating to the procurement or donation of the donor's organs, tissues, or eyes.

**Section 7** creates s. 765.5175, F.S., to prohibit an organ transplantation facility from charging a living donor or his or her family member, other than the recipient of the organ, any fee for services relating to the procurement or donation of his or her organs.

**Section 8** revises s. 763.53, F.S., to expand the duties of the existing OTAC and rename it as the Organ Transplant Technical Advisory Council (Council).

The bill establishes the Council within the AHCA to develop standards for quality and outcomes at adult and pediatric organ transplant programs. The Council is also tasked with advising the AHCA and the Legislature regarding the cost savings, trends, research, and protocols and procedures relating to organ donation and transplantation, including the availability of organs for donation and access to organ transplants for persons having disabilities. The bill specifies that unless otherwise stated, the Council must operate in accordance with s. 20.052, F.S.

The bill establishes the membership of the council to include eight voting members appointed by the CEO of each of the following hospitals:

- Jackson Memorial Hospital in Miami.
- Tampa General Hospital in Tampa.
- University of Florida Health Shands Hospital in Gainesville.
- AdventHealth Orlando in Orlando.
- Mayo Clinic in Jacksonville.
- Cleveland Clinic Florida in Weston.
- Largo Medical Center in Largo.
- Broward Health Medical Center in Fort Lauderdale

Each such member must have technical expertise in adult or pediatric organ transplantation and must be an organ transplant surgeon licensed under chs. 458 or 459, F.S., or an organ transplant nurse coordinator licensed under ch. 464, F.S. Each such member's appointment is contingent upon the appointing hospital's compliance with ch. 395, F.S., and related rules. If the hospital is

noncompliant, the member may serve only as a nonvoting member until the hospital comes into compliance.

Additionally, the Secretary of the AHCA, or his or her designee, must serve as the chair and a nonvoting member of the Council and must appoint the following to serve as voting members:

- The State Surgeon General or his or her designee.
- A parent of a child who has had an organ transplant.
- An adult who has had an organ transplant.
- An adult patient who is on an organ transplant waiting list.
- A representative from an organ procurement organization.
- An administrator of an organ transplant program.
- A licensed physician from each of the following organ transplantation areas:
  - Kidneys.
  - Lungs.
  - Heart.
  - Liver.
  - Pancreas.

Voting members of the Council are required to reflect the ethnic and gender diversity of the state. Members serve without compensation but may be reimbursed for per diem and travel expenses. Members of the Council who are performing their duties in good faith are considered agents of the state for the purpose of sovereign immunity. Members may be reappointed and each vacancy may be filled in the same manner as it was originally filled.

The Council must meet at least twice annually and additionally upon call of the chair. The meetings may be held using any method of telecommunications.

The Council's duties include:

- Recommending to the AHCA and the Legislature standards for quality care of adult and pediatric organ transplant patients including:
  - Recommendations on minimum volume of transplants by organ type;
  - Personnel;
  - Physical plant;
  - Equipment;
  - Transportation; and
  - Data reporting for hospitals that perform organ transplants.
- Reporting its recommendations to the Governor, the President of the Senate, the Speaker of the House of Representatives, the Secretary of Health Care Administration, and the State Surgeon General by October 1, 2021.

Additionally, the Council may, but is not required to, further advise the AHCA and the Legislature regarding research focused on improving overall organ availability. Voting members may only vote on a specific recommendation if the hospital which the member represents has a transplant program for that type of organ.

Based on the recommendations of the Council, the AHCA must develop and adopt rules for organ transplant programs so that such rules include, at a minimum:

- Quality of care standards for adult and pediatric organ transplants, including minimum volume thresholds by organ type, personnel, physical plant, equipment, transportation, and data reporting.
- Outcome and survival rate standards that meet or exceed nationally established levels of performance in organ transplantation.
- Specific steps to be taken by the AHCA and licensed facilities when the facilities do not meet the volume, outcome, or survival rate standards within a specified timeframe that includes the time required for detailed case reviews and the development and implementation of corrective action plans.

This requirement to adopt or amend rules is repealed on July 1, 2030.

**Section 9** amends s. 765.543, F.S., to require the Organ and Tissue Procurement and Transplantation Board to, by September 1, 2021, submit to the AHCA recommendations that address:

- The frequency of communication between patients and organ transplant coordinators.
- The 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 the facility.
- The 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.
- The potential incentives for organ transplantation facilities that may be necessary to increase organ donation in this state.
- The evaluation and encouragement of an efficient living organ donor process.
- The potential opportunities and incentives for organ transplantation research.
- The best practices for organ transplantation facilities and organ procurement organizations which promote the most efficient and effective outcomes for patients.
- The monitoring of organ procurement organizations.

Additionally, the bill specifies that the Board must collaborate with other relevant public or private entities in the development of necessary professional qualifications for persons engaged various facets of organ and tissue procurement.

**Section 10** creates s. 765.548, F.S., to require the AHCA to:

- Monitor the operation of each organ transplantation facility and organ procurement organization located in this state.
- Develop uniform statewide rules regarding organ donations, which:
  - Must include the requirement that each hospital that performs organ transplants designate at least one employee or representative of the hospital who is educated on the protocols of the hospital and federal and state regulations regarding organ donation, to provide a clear explanation of such subjects to any patient, or a patient's representative, who is considering posthumous or living organ donation; and
  - May include, but need not be limited to, procedures for maintaining a coordinated system of communication between organ transplantation facilities.

- Evaluate the current protocols and procedures used by organ transplantation facilities and make recommendations for improving such protocols and procedures.
- Establish annual reporting requirements for organ transplantation facilities and organ procurement organizations.
- In consultation with the state Board of Education and the contractor procured by the AHCA pursuant to s. 765.5155, F.S., develop a curriculum for educating high school students regarding the laws of this state relating to organ donation.
- Publish any data and other relevant information to adequately inform patients and potential donors about organ donation and organ transplantation by December 1, 2021, and each year thereafter.

**Section 11** amends s. 409.815, F.S., to make a conforming change

**Section 12** provides that the bill has an effective date of July 1, 2020.

#### **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 identified.

#### **V. Fiscal Impact Statement:**

A. Tax/Fee Issues:

None.

B. Private Sector Impact:

None.

**C. Government Sector Impact:**

CS/CS/CS/SB 1516 may have an indeterminate negative fiscal impact on the AHCA due to the requirement to reimburse Council members for per diem and travel expenses.

**VI. Technical Deficiencies:**

None.

**VII. Related Issues:**

None.

**VIII. Statutes Affected:**

This bill substantially amends the following sections of the Florida Statutes: 381.0041, 395.1055, 627.6045, 765.514, 765.5155, 765.517, 765.53, 765.543, 765.548, and 409.815.

The bill creates s. 765.5175 of the Florida Statutes.

**IX. Additional Information:****A. Committee Substitute – Statement of Substantial Changes:**  
(Summarizing differences between the Committee Substitute and the prior version of the bill.)**CS/CS/CS by Rules on February 26, 2020:**

The CS:

- Places the substance of CS/SB 626 into the bill which allows HIV positive blood, plasma, organ, and other human tissue donors to donate to recipients who are also HIV positive and who know the donor is HIV positive.
- Establishes ongoing minimum volume requirements in licensure for organ transplant programs that match the current minimum volume requirements established in AHCA's CON rules.
- Clarifies language regarding charges to living donors and family members, as opposed to a deceased donor or his or her family. Makes clarifying changes to the Organ Transplant Advisory Council.
- Makes other technical and clarifying changes.

**CS/CS by Judiciary on February 11, 2020:**

The CS:

- Clarifies that an organ transplantation facility may not charge a donor, deceased donor, or his or her family for services relating to the procurement or donation of the deceased donors organs.
- Requires the Organ Transplant Technical Advisory Council to advise the Agency for Healthcare Administration and the Legislature on organ donor benefits and access to organ transplants for persons having disabilities.

- Increases the membership of the Organ Transplant Technical Advisory Council to include a representative from an organ procurement organization, administrator of an organ transplant program.

**CS by Health Policy on January 27, 2020:**

The CS changes the title of the bill from “an act relating to organ transplant technical Advisory Council to “an act relating to organ donation” and amends and creates additional sections of law relating to organ donation as follows:

- Section 627.6045, F.S., is amended to prohibit a health insurance policy from limiting or excluding coverage for a living organ donor under a preexisting condition provision.
- Sections 765.517 and 765.514, F.S., are amended to prohibit an organ transplantation facility from charging an organ donor or his or her family any fee for services relating to the procurement or donation of the donor’s organs and to add a statement on the uniform donor card form that neither the donor nor his or her family is responsible for the payment of any fees associated with services relating to the procurement or donation of the donor’s organs, tissues, or eyes.
- Section 765.5155, F.S., is amended to expand the organ donation education program to include federal laws and information on the organ donation and transplantation process.
- Section 765.543, F.S., is amended to require the Organ and Tissue Procurement and Transplantation Board to, by September 1, 2021, submit to the AHCA recommendations that address:
  - The frequency of communication between patients and organ transplant coordinators.
  - The 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 the facility.
  - The 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.
  - The potential incentives for organ transplantation facilities that may be necessary to increase organ donation in this state.
  - The creation of a more efficient regional or statewide living organ donor process.
  - The potential opportunities and incentives for organ transplantation research.
  - The best practices for organ transplantation facilities and organ procurement organizations which promote the most efficient and effective outcomes for patients.
  - The monitoring of organ procurement organizations.
- Section 765.548, F.S., is created to require the AHCA to:
  - Monitor the operation of each organ transplantation facility and organ procurement organization located in this state.
  - Develop uniform statewide rules regarding organ donations, which must include the requirement that each hospital designate at least one employee or representative of the hospital who is educated on the protocols of the hospital and

federal and state regulations regarding organ donation, to provide a clear explanation of such subjects to any patient, or a patient's representative, who is considering posthumous or living organ donation; and may include, but need not be limited to, procedures for maintaining a coordinated system of communication between organ transplantation facilities.

- Evaluate the current protocols and procedures used by organ transplantation facilities and make recommendations for improving such protocols and procedures.
- Establish annual reporting requirements for organ transplantation facilities and organ procurement organizations.
- In consultation with the state Board of Education and the contractor procured by the AHCA pursuant to s. 765.5155, F.S., develop a curriculum for educating high school students regarding the laws of this state relating to organ donation.
- Publish any data and other relevant information to adequately inform patients and potential donors about organ donation and organ transplantation by December 1, 2021, and each year thereafter.

In addition, the CS amends requirements for the Council to:

- Require the Council to advise the AHCA and the Legislature regarding the cost savings, trends, research, and protocols and procedures relating to organ donation and transplantation, including the availability of organs for donation.
- Revise the membership of the Council to:
  - Allow the appointment of organ transplant nurses, in addition to physicians;
  - Reduce the members appointed by hospitals to eight;<sup>20</sup> and
  - Grant voting rights to members of the Council appointed by the secretary of the AHCA and revise the list of members appointed by the secretary;<sup>21</sup> and
  - Require voting members to reflect the ethnic and gender diversity of the state;
- Revise the duties of the Council to:
  - Require recommendations be presented to the Legislature as well as the AHCA;
  - Eliminate the duty to develop recommendations for improving education, outreach, and communication between hospitals, patients, and the public, with an emphasis on potential and prospective donors, including recommendations for clear explanations to the public of relevant laws, rules, and regulations; requirements for coordinated communication between hospitals, between hospitals and patients, and between hospitals and prospective donors; and recommendations for providing education to the public on the organ donation process, with an emphasis on educating potential living donors; and
  - Allow the Council to advise the AHCA and the Legislature regarding research focused on improving overall organ availability.

<sup>20</sup> Memorial Regional hospital in Hollywood, Halifax Health Medical Center in Daytona Beach, Sacred Heart Hospital in Pensacola, H. Lee Moffitt cancer Center and Research Institute in Tampa, and the University of Miami Hospital in Fort Lauderdale are removed from the list while Broward Health Medical Center in Fort Lauderdale is added.

<sup>21</sup> Representatives of the Florida Hospital Association, the Safety Net Hospital Alliance of Florida, and HCA Healthcare are removed from the underlying bill while an adult patient who is on an organ transplant waiting list and licensed physicians who specialize in organ transplantation of the kidneys, lungs, liver, heart, and pancreas are added.



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The CS also revises the automatic repeal date of the requirement that the AHCA adopt rules based on the Councils recommendations from an automatic repeal when the AHCA adopts such rules to a repeal on the set date of July 1, 2030.

**Amendments:**

None.

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

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