

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 1516

INTRODUCER: Senator Harrell

SUBJECT: Organ Transplant Technical Advisory Council

DATE: January 27, 2020

REVISED: _____

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

I. Summary:

SB 1516 substantially rewords s. 765.53, F.S., to expand the duties of the Organ Transplant Advisory Council (OTAC). The bill renames the OTAC as the Organ Transplant Technical Advisory Council (Council) and charges the Council with assisting the Agency for Health Care Administration (AHCA) in developing standards for quality and outcomes at adult and pediatric organ transplant programs. The bill specifies the Council's membership and requires the Council to meet at least annually.

The bill requires the Council to recommend standards for quality of care, minimum volumes, personnel, physical plant, equipment, transportation, and data reporting. The Council must also develop recommendations for improving education, outreach, and communications between hospitals, patients, and the public. When creating its recommendations, the Council must review any existing or proposed AHCA rules and may provide recommendations on amendments to such rules. By October 1, 2021, the Council must submit a report of its recommendations to the Legislature and to the Governor.

Based on the recommendations of the Council, the AHCA must amend or adopt rules for organ transplant programs that include criteria established by the bill.

Additionally, the bill specifies that certificate of need (CON) rules for minimum volume standards for organ transplantation and neonatal intensive care unit (NICU) services remain in effect until the AHCA has adopted corresponding licensure rules. The requirement to adopt rules expires upon the AHCA's adoption of such rules.

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

II. Present Situation:

Organ Transplant Advisory Council (OTAC)

Section 765.53, F.S., establishes the OTAC to consist of 12 physician¹ 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 the AHCA (a.k.a. the Secretary of Health Care Administration) and serve 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.

Licensure Requirements

Volume requirements (including NICU volume requirements):^{2, 3}

Liver	5 transplants over two 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.

Level II NICU	10 beds and the hospital must have at least 1,000 live births per year.
Level III NICU	15 beds and the hospital must have at least 1,500 live births per year.
Proposed rule 59A-3.249	Same as above.

¹ Licensed under chs. 458 and 459, F.S.

² Projected prior to grant of licensure.

³ Volume requirements for liver and kidney transplants are included in the CON portions of the rule.

Currently, standards for licensure for organ transplant programs in Florida can be found in AHCA Rule 59C-1.044, F.A.C.⁴ These standards include:

- General staffing requirements:
 - A staff of physicians with expertise in caring for patients with 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 with 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 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 with expertise in the nutritional needs of transplant patients;
 - Respiratory therapists with 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.

⁴ For a discussion of the licensure requirements in a CON rule versus a licensure rule, please see the CON overview below.

- 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 with 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 with 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 with 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 with 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 with 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 with experience in the care of critically ill immuno-suppressed patients. Nursing staff must be dedicated full time to the program;
 - An interdisciplinary transplantation team with expertise in hematology, oncology, immunologic diseases, neoplastic diseases, including hematopoietic and lymphopietic 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.

CON Overview

In Florida, a CON is a written statement issued by the AHCA evidencing community need for a new, converted, expanded, or otherwise significantly modified health care facility or health service, including hospices. The Florida CON program has three levels of review: full, expedited, and exempt.⁵ Florida's CON program has existed since July 1973. From 1974 through 1986, the specifics of the program were largely dictated by the federal National Health Planning and Resources Development Act of 1974 (Act), which established minimum requirements regarding the type of services subject to CON review, review procedures, and review criteria.⁶ Each state was required to have a CON program in compliance with the Act as a condition for obtaining federal funds for health programs. The Act was repealed in 1986. The Legislature repealed Florida's CON program for most hospitals and tertiary services, including organ transplantation, in 2019 with the passage of HB 21.⁷ However, HB 21 allowed the AHCA to continue to enforce the licensure portions of its CON rules for tertiary services until such time as the AHCA has adopted corresponding licensure rules.

Status of Certificate of Need Rules for Organ Transplant and Neonatal Intensive Care

Currently, licensure of organ transplantation programs in Florida is governed by Rule 59C-1.044, F.A.C., and licensure of NICUs is governed by Rule 59C-1.042, F.A.C. Although the CON program was repealed for tertiary services including organ transplantation and NICUs in 2019 (see CON Overview above), the AHCA was authorized to continue to enforce the licensure portions of its CON rules until such time as the AHCA has adopted corresponding licensure rules. As of January 23, 2020, the AHCA has proposed amending Rule 59A-3.246, F.A.C., to

⁵ Section 408.036, F.S.

⁶ Pub. Law No. 93-641, 42 U.S.C. s. 300k et seq.

⁷ Chapter 2019-136, L.O.F.

incorporate licensure requirements for organ transplant programs and has proposed creating Rule 59A-3.249, F.A.R.; however, these proposed changes have not yet been adopted.

III. Effect of Proposed Changes:

SB 1516 substantially 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 assist the AHCA in developing standards for quality and outcomes at adult and pediatric organ transplant programs. 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 12 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.
- 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, Inc., in Tampa.
- University of Miami Hospital in Miami.

Each voting 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. Each voting 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. Members may be reappointed and each vacancy may be filled in the same manner as it was originally filled.

Additionally, the Secretary of the AHCA must serve as the chair and a nonvoting member of the Council and may appoint any of the following to serve as nonvoting members:

- The State Surgeon General.
- A parent of a child who has had an organ transplant.
- An adult who has had an organ transplant.
- One representative from each of the following:
 - The Florida Hospital Association.⁸
 - The Safety Net Hospital Alliance of Florida.⁹
 - HCA Healthcare.¹⁰

⁸ See <http://www.fha.org/> (last visited Jan. 26, 2020)

⁹ See <http://safetynetsflorida.org/> (last visited Jan. 26, 2020)

¹⁰ See <https://hcahealthcare.com/> (last visited Jan. 26, 2020)

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.

The Council must meet at least 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 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.
- Developing 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 among 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.
- 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.

When developing its recommendations, the Council must review any relevant existing or proposed AHCA rules and may provide recommendations to the AHCA on amendments to such rules. 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 adopt or amend 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 expires upon the AHCA's adoption of such rules.

The bill also amends s. 408.0455, F.S., to specify that AHCA CON rules for minimum volume standards for organ transplantation and neonatal intensive care services remain in effect until the AHCA has adopted corresponding licensure rules.

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.

V. Fiscal Impact Statement:

A. Tax/Fee Issues:

None.

B. Private Sector Impact:

None.

C. Government Sector Impact:

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 sections 408.0455 and 765.53 of the Florida Statutes.

IX. Additional Information:

A. Committee Substitute – Statement of Changes:

(Summarizing differences between the Committee Substitute and the prior version of the bill.)

None.

B. Amendments:

None.

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