

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 Appropriations

BILL: CS/CS/SB 1556

INTRODUCER: Appropriations Committee; Banking and Insurance Committee; and Senator Bean

SUBJECT: Nondiscrimination in Organ Transplants

DATE: March 2, 2020

REVISED: _____

	ANALYST	STAFF DIRECTOR	REFERENCE	ACTION
1.	Rossitto-Van Winkle	Brown	HP	Favorable
2.	Palecki	Knudson	BI	Fav/CS
3.	Gerbrandt	Kynoch	AP	Fav/CS

Please see Section IX. for Additional Information:

COMMITTEE SUBSTITUTE - Substantial Changes

I. Summary:

CS/CS/SB 1556 prohibits insurers, and health maintenance organizations that provide transplant coverage, from denying coverage solely on the basis of an individual's disability.

The bill prohibits specified entities from denying, refusing to allocate, or lowering an individual's priority for organ transplant medical services solely based on an individual having a developmental or intellectual disability. The bill prohibits discrimination regarding access to anatomical gifts and organ transplants by:

- Defining certain terms and entities;
- Specifying when certain entities may consider an individual's disability and when they may not;
- Requiring certain entities to take steps to ensure that an individual with a disability is not denied services, with exceptions;
- Requiring certain entities to make reasonable modifications to transplant policies, practices, and procedures to accommodate individuals with a disability, with an exception;
- Prohibiting certain entities from denying transplant services due to an individual's lack of auxiliary aids and services, with an exception;
- Providing injunctive relief or other equitable relief for a qualified individual who are affected by violations of a covered entity.

The bill does not authorize transplants that are not medically necessary.

The bill does not have a fiscal impact on state revenues or expenditures.

The bill takes effect on July 1, 2020.

II. Present Situation:

Tissue Donation and Organ Transplantation

Organ and tissue donation and transplantation is the process of surgically removing an organ or tissue from one person (the donor) and transplanting it into another person (the recipient). Transplantation may be necessary because the recipient's organ or tissue has failed or has been damaged by disease or injury. Transplantable organs include the kidneys, liver, heart, lungs, pancreas, and intestine.¹ Transplantable tissue includes:

- Skin, which can be 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 in 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 to prevent amputation.²

The Organ Procurement and Transplantation Network (OPTN)

The National Organ Transplant Act (NOTA) established the Organ Procurement and Transplantation Network (OPTN) in 1984.³ In 2000, The U.S. Department of Health and Human Services (HHS) implemented a final rule establishing a regulatory framework for the structure and operations of the OPTN.⁴ HHS implemented the final rule that established the regulatory framework for the structure and operations of the OPTN.⁵

The OPTN policies are rules that govern the operation of all member transplant hospitals, organ procurement organizations (OPOs) and histocompatibility labs in the U.S.⁶ Currently, every transplant hospital program, OPO, and transplant histocompatibility laboratory in the U.S. is an OPTN member. Membership means that an institution meets OPTN requirements and that it plays an active role in forming the policies that govern the transplant community.⁷ The OPTN

¹ Donate Life Florida, *Frequently Asked Questions*, <https://www.donateliflorida.org/categories/donation/> (last visited February 8, 2018).

² *Id.*

³ 42 U.S.C. 274.

⁴ U.S. Department of Health & Human Services, Health Resources & Services Administration, Organ Procurement and Transplantation Network, *About the OPTN*, <https://optn.transplant.hrsa.gov/governance/about-the-optn/> (last visited Feb. 8, 2020).

⁵ *Id.*

⁶ U.S. Department of Health & Human Services, Health Resources & Services Administration, Organ Procurement and Transplantation Network, *Policies*, <https://optn.transplant.hrsa.gov/governance/policies/> (last visited Feb. 8, 2020).

⁷ U.S. Department of Health & Human Services, Health Resources & Services Administration, Organ Procurement and Transplantation Network, *Members*, <https://optn.transplant.hrsa.gov/members/> (last visited Feb. 8, 2020).

regulates how donor organs are matched and allocated to patients on the waiting list.⁸ On average, 95 transplants take place each day in the U.S.⁹

Oversight and Implementation of Florida’s Organ Donation and Transplantation System

The organ donation and transplantation system consists of an extensive network of federal, state, and local entities, as well as individual organ donors, recipients, and individuals on organ transplant waitlists. The process of organ donation relies on coordination among these entities to match organs from donors to individuals on organ transplant waitlists. The Legislature’s Office of Program Policy Analysis and Government Accountability’s (OPPAGA) January 22, 2020, research memo, *Reviewing Florida Organ Donation and Transplantation System*, lists the participants in Florida’s organ transplantation system as follows:¹⁰

Entity	Level	Role Within the Organ Donation and Transplantation System
U.S. Department of Health and Human Services	Federal	Oversees the two federal agencies responsible for organ procurement and transplantation regulation
Federal Centers for Medicare & Medicaid Services (CMS)	Federal	Monitors procurement and transplant program success and quality
Health Resources and Services Administration (HRSA)	Federal	Oversees the Organ Procurement and Transplantation Network and contractors (United Network for Organ Sharing and Scientific Registry of Transplant Recipients)

⁸ U.S. Department of Health & Human Services, Health Resources & Services Administration, U.S. Government Information on Organ Donation and Transplantation, *The Organ Transplant Process*, <https://organdonor.gov/about/process/transplant-process.html> (last visited Feb. 8, 2020).

⁹ U.S. Department of Health & Human Services, Health Resources & Services Administration, U.S. Government Information on Organ Donation and Transplantation, *Organ Donation and Transplantation Can Save Lives*, <https://optn.transplant.hrsa.gov/> (last visited Feb. 8, 2020).

¹⁰ Office of Program Policy Analysis and Government Accountability, Research Memo, *OPPAGA Review of Florida’s Organ Donation and Transplant System*, (Jan. 22, 2020) (on file with the Senate Committee on Health Policy).

Scientific Registry of Transplant Recipients	Private/ Nonprofit	Provides statistical and other analytic support to OPTN for the formulation and evaluation of organ allocation
Organ Procurement and Transplantation Network (OPTN)	Private/ Nonprofit	Maintains a national registry for organ matching and carries out numerous other responsibilities relating to organ procurement and transplantation
United Network for Organ Sharing (UNOS)	Private/ Nonprofit	Operates OPTN under contract with HRSA
Agency for Health Care Administration	State	Contracts with Donate Life Florida for online donor registration and education system; coordinates with DHSMV to obtain donor registry funding; certifies and monitors organ procurement organizations for compliance and collects fees
Donate Life Florida	Private/ Nonprofit	Contracts with AHCA to operate a statewide online donor registry and to provide donor education
Department of Highway Safety and Motor Vehicles	State	Coordinates with county tax collector offices where donor education and registration occur when issuing driver licenses and identification cards; encourages and registers organ donors when issuing identification cards and driver licenses; provides donor educational materials; collects voluntary financial contributions to donor registry
County Tax Collector Offices	Local	Encourage and register organ donors when issuing identification cards and driver licenses; may provide donor educational materials; collect voluntary financial contributions to donor registry
Organ Procurement Organizations (Certified by CMS)	Regional within the State	Follow policies set by CMS and OPTN; primarily responsible for procuring organs and matching donor organs to patients on waitlists and coordinating with hospital transplant centers for transport of matched organs
Transplant Centers	Local/Private/ Nonprofit	Evaluate patients to determine eligibility to be placed on waitlists and suitability of and procuring organs at donor hospitals after being contacted by an OPO; perform transplant surgeries and conduct pre- and post-transplant care
Entity	Level	Role Within the Organ Donation and Transplantation System
Donor Hospitals	Local/ Private/ Nonprofit	Responsible for timely notification of OPO in their region of death or imminent death of a patient who is a viable organ donor ²⁰

Organ Allocation

More than 120,000 people in the U.S. are waiting to receive an organ transplant. There are not enough donated organs to transplant everyone in need, so a balance of the following is sought:

- Justice (fair consideration of candidates' circumstances and medical needs); and
- Medical utility (trying to increase the number of transplants performed and the length of time patients and organs survive).¹²

Factors in Organ Allocation

Many factors are used to match organs with patients in need such as, proximity to donor, waiting time, immune system compatibility, survival benefit. Some factors are the same for all organs, but the system must accommodate some unique differences for each organ. Before an organ is allocated, all transplant candidates on the waiting list that are incompatible with the donor are automatically screened out from any potential match. Then the system determines the order in which the compatible candidates will receive offers, according to national policies.¹³

Each organ has different criteria for allocation, but federal policy dictates that wealth, social status, citizenship, residency, political influence, national origin, ethnicity, sex, or religion are never factors.¹⁴ Blood type and other medical factors weigh into the allocation of every donated organ, and other factors are unique to each organ-type.

Wait Times for Organ Transplants

The shortage of organs causes most patients to wait for a transplant. Some patients are more ill than others when they are put on the transplant waiting list. Some patients get sick more quickly than other patients or respond differently to treatments. Patients may have medical conditions that make it more difficult to find a good match.¹⁵

How long a patient waits depends on many factors. These can include:

- Blood type;
- Tissue type;
- Height and weight of transplant candidate;
- Size of donated organ;
- Medical urgency;
- Time on the waiting list;
- The distance between the donor's hospital and the potential donor organ;
- How many donors there are in the local area over a period of time; and

¹² U.S. Department of Health and Human Services, Health Resources & Services Administration, Organ Procurement and Transplantation Network, *How Organ Allocation Works* <https://optn.transplant.hrsa.gov/learn/about-transplantation/how-organ-allocation-works/> (last visited Feb. 8, 2020).

¹³ *Id.*

¹⁴ U.S. Department of Health and Human Services, Health Resources & Services Administration, Organ Procurement and Transplantation Network, *Policies, 5.4 Organ Offers* (Jan. 9, 2020), p. 92, https://optn.transplant.hrsa.gov/media/1200/optn_policies.pdf (last visited Feb. 14, 2020).

¹⁵ U.S. Department of Health & Human Services, Health Resources & Services Administration, Organ Procurement and Transplantation Network Transplant Process, *Wait Times* <https://optn.transplant.hrsa.gov/learn/about-transplantation/transplant-process/> (last visited Feb. 8, 2020).

- The transplant center's criteria for accepting organ offers.¹⁶

The Donor Matching System

The OPTN has policies regulating how donor organs are matched and allocated to patients on the waiting list. There are some common factors in how organs are matched, such as blood type and how severe the patient's illness is. However, depending on the organ, some factors become more important than others, so there is a different policy for each organ.¹⁷ The OPTN operates the national database of all patients in the U.S. waiting for a transplant. OPTN's computer system matches the donor's organs to potential recipients.¹⁸

For each organ that becomes available, the computer system generates a list of potential recipients ranked according to objective criteria (i.e. blood type, tissue type, size of the organ, medical urgency of the patient, time on the waiting list, and distance between donor and recipient). After printing the list of potential recipients, the procurement coordinator contacts the transplant surgeon caring for the top-ranked patient (i.e. patient whose organ characteristics best match the donor organ and whose time on the waiting list, urgency status, and distance from the donor organ adhere to allocation policy) to offer the organ. Depending on various factors, such as the donor's medical history and the current health of the potential recipient, the transplant surgeon determines if the organ is suitable for the patient. If the organ is turned down, the next listed individual's transplant center is contacted, and so on, until the organ is placed.

Organ Transplants and Florida Medicaid

Florida Medicaid coverage for organ transplants is restricted to those transplants currently accepted as therapeutic modalities and do not include experimental procedures. For children under 21, Florida Medicaid covers kidney, liver, cornea, heart, lung, pancreas, intestines, bone marrow, and multivisceral transplants that are medically necessary and appropriate.¹⁹

Discrimination in Access to Anatomical Gifts and Organ Transplants

On September 25, 2019, the National Council on Disability (NCD)²⁰ submitted a report to the President and Congress entitled, *Organ Transplant Discrimination against People with Disabilities*.²¹ The report found, among other things, that people with disabilities are frequently denied access to organ transplants based on a transplant center's written and unwritten policies

¹⁶ *Id.*

¹⁷ U.S. Department of Health & Human Services, Health Resources & Services Administration, Organ Procurement and Transplantation Network, *Donor Matching System* <https://optn.transplant.hrsa.gov/learn/about-transplantation/donor-matching-system/> (last visited Feb. 8, 2020).

¹⁸ *Id.*

¹⁹ Agency for Health Care Administration, *Florida Standards for the Coverage of Organ Transplant Services*, (effective April 1, 2015), p. 1, https://ahca.myflorida.com/medicaid/organ_transplant/pdfs/state_plan_standards_for_coverage_updated_2015.pdf (last visited Feb. 8, 2020).

²⁰ The NCD is an independent federal agency charged with advising the President, Congress, and other federal agencies on disability policy to advance the goals of the federal Americans with Disabilities Act (ADA): equal opportunity, full participation, independent living, and economic self-sufficiency for persons with disabilities

²¹ National Council on Disability, Bioethics and Disability Series, *Organ Transplant Discrimination against People with Disabilities*, https://ncd.gov/sites/default/files/NCD_Organ_Transplant_508.pdf (last visited Feb. 8, 2020).

excluding people with disabilities as candidates for a transplant, and even refusing to evaluate a particular person's medical suitability for an organ transplant because of the person's disability. The report stated that:²²

People with disabilities have been denied organ transplants as a result of unfounded assumptions about their quality of life and misconceptions about their ability to comply with post-operative care. Although the Americans with Disabilities Act (ADA) and Section 504 of the Rehabilitation Act of 1973 (Section 504) prohibit discrimination on the basis of disability, organ transplant centers and medical professionals are often unaware that this prohibition applies to the organ transplant process.

According to the NCD, the primary forms of disability discrimination occurring at organ transplant centers are:²³

- Refusal to evaluate a person with a disability as a candidate for transplant; and
- Refusal to place a person with a disability on the national organ transplant waiting list.

The Americans with Disabilities Act and The Rehabilitation Act of 1973

The Americans with Disabilities Act (ADA)²⁴ and section 504 of the Rehabilitation Act of 1973²⁵ prohibit discrimination on the basis of disability. The Rehabilitation Act specifically prohibits discrimination against otherwise qualified individuals on the basis of disability in:

- Programs and activities receiving financial assistance from HHS;²⁶ and
- Programs or activities conducted by HHS.²⁷

The ADA defines “disability” as:²⁸

- A physical or mental impairment²⁹ that substantially limits one or more of the major life activities;³⁰
- A record of such an impairment; or
- Being regarded as having such an impairment.

The ADA and Section 504 of the Rehabilitation Act also require reasonable modifications of policies, practices, and procedures when necessary to ensure that people with disabilities can access services on a nondiscriminatory basis.³¹

²² National Council on Disabilities, Letter to UNOS, OPTN, HRSA Regarding Organ Transplants (Sept. 25, 2019), <https://ncd.gov/publications/2019/ncd-letter-unos-optn-hrsa-regarding-organ-transplants> (last visited Feb. 14, 2020).

²³ *Id.*

²⁴ 42 U.S.C. ch. 126.

²⁵ 29 U.S.C. s. 701.

²⁶ 45 C.F.R. Part 84.

²⁷ 45 C.F.R. Part 85.

²⁸ 28 C.F.R. Part 35.104.

²⁹ The ADA specifies the meaning of the phrase “physical or mental impairment” to mean any physiological disorder or condition, cosmetic disfigurement, or anatomical loss affecting certain body systems and any mental or psychological disorder such as mental retardation, organic brain syndrome, emotional or mental illness, or specific learning disabilities.

³⁰ The ADA specifies the meaning of the phrase “major life activities” to include functions such as caring for oneself; performing manual tasks; walking; seeing; hearing; speaking; breathing; learning; and working.

³¹ 42 U.S.C. ch. 126.

ADA Enforcement

An individual who believes that he or she has been subjected to discrimination on the basis of his or her disability, by a public entity, may file a complaint with the Department of Justice (DOJ).³² The DOJ will investigate, and if discrimination on the basis of disability is found will issue a non-compliance letter of findings to the Assistant Attorney General and initiate negotiations with the public entity to secure compliance by voluntary means.³³ If the public entity declines to enter into voluntary compliance negotiations, or if negotiations are unsuccessful, the case is referred to the Attorney General with a recommendation for appropriate action.³⁴ If the complainant prevails, he or she may be awarded a reasonable attorney's fee, including litigation expenses and costs.³⁵

Cause of Action under the Florida Civil Rights Act of 1992

The general purposes of the Florida Civil Rights Act of 1992 (Act) is:

- To secure for all individuals within the state freedom from discrimination because of race, color, religion, sex, pregnancy, national origin, age, *handicap*, or marital status and thereby to protect their interest in personal dignity;
- To make available to the state their full productive capacities;
- To secure the state against domestic strife and unrest;
- To preserve the public safety, health, and general welfare; and
- To promote the interests, rights, and privileges of individuals within the state.³⁶

The Act creates both a state and individual cause of action for any violation of a Florida statute making unlawful discrimination because of race, color, religion, gender, pregnancy, national origin, age, *handicap*, or marital status in the areas of education, employment, housing, or public accommodations for relief and damages under s. 760.11(5), F.S., unless greater damages are expressly provided for.³⁷ [emphasis added]

Section 760.22(7), F.S., as created by the Florida Fair Housing Act defines “handicap” to mean:

- A person has a physical or mental impairment which substantially limits one or more major life activities, or he or she has a record of having, or is regarded as having, such physical or mental impairment; or
- A person has a developmental disability, as that term is defined in s. 393.063, F.S., which manifests itself before the age of 18 and constitutes a substantial handicap that can reasonably be expected to continue indefinitely, including:
 - A disorder or syndrome that is attributable to intellectual disability;
 - Cerebral palsy;
 - Autism;
 - Spina bifida;
 - Down syndrome;

³² 28 C.F.R. Part 35.170.

³³ 28 C.F.R. Part 35.173.

³⁴ 28 C.F.R. Part 35.174.

³⁵ 28 C.F.R. Part 35.175.

³⁶ Section 760.01, F.S.

³⁷ Section 760.07, F.S.

- Phelan-McDermid syndrome; or
- Prader-Willi syndrome.³⁸

Section 393.063(24), F.S., defines “intellectual disability” as a significantly subaverage general intellectual functioning existing concurrently with deficits in adaptive behavior which manifests before age 18 and can be expected to continue indefinitely.

III. Effect of Proposed Changes:

Requirements for Covered Entities

Section 1 creates s. 765.523, F.S., to prohibit specified covered entities from denying, refusing to allocate, or lowering an individual’s priority for organ transplant medical services, solely on the basis of an individual’s disability.

The bill defines the following terms:

- “Auxiliary aids and services” means effective methods of making aurally delivered materials available to individuals with hearing impairments; effective methods of making visually delivered materials available to individuals with visual impairments; and supported decisionmaking services;
- “Covered entity” means a licensed health care practitioner; a hospital, skilled nursing facility, hospice, or intermediate care facility for the developmentally disabled; or any other entity responsible for potential recipients of an anatomical gift;
- “Disability” means a developmental disability or intellectual disability as those terms are defined in s. 393.063, F.S.;
- “Organ transplant” means the transplantation or transfusion of a part of a human body into the body of another individual for the purpose of treating or curing a medical condition; and
- “Qualified individual” means an individual who has a disability and meets the clinical eligibility requirements for the receipt of an anatomical gift or an organ transplant.

The bill prohibits a covered entity from doing any of the following, solely on the basis of an individual’s disability:

- Consider a qualified individual ineligible for a transplant;
- Deny medical or other organ transplant services, including:
 - Evaluations;
 - Surgery;
 - Counseling; and
 - Post-transplant treatment and services;
- Refuse to refer the individual to an organ procurement organization or specialist for evaluation for an organ transplant;
- Refuse to place a qualified individual on an organ transplant waiting list;
- Place a qualified individual at a lower priority on an organ transplant waiting list; or
- Consider the individual’s inability to independently comply with the post-transplant medical requirements if the individual has the necessary support system to assist him or her with such compliance.

³⁸ Section 393.063(12), F.S.

The bill requires covered entities to make reasonable modifications to its policies, practices, or procedures, when necessary, to allow an individual with a disability access to services, unless it can demonstrate that making the modifications would fundamentally alter the nature of the services. The modifications must include communication with people responsible for supporting the patient with post-transplant care and consideration of support networks available to the patient.

The bill requires a covered entity to take additional steps to ensure that an individual with a disability is not denied services due to the absence of auxiliary aids and services, unless it can demonstrate that taking the steps would fundamentally alter the nature of the services being offered, or result in an undue burden on the covered entity.

The bill provides that a covered entity may consider an individual's disability, following an evaluation, if a physician finds the person's disability to be medically significant to the provision of the organ transplant or anatomical gift, but only to the extent that the covered entity is making treatment or coverage recommendations or decisions for the individual.

If a person has the necessary support system to assist him or her in complying with post-transplant medical requirements, a covered entity may not consider the individual's inability to independently comply with the post-transplant medical requirements to be medically significant.

The bill allows a person with a disability to file a civil action for injunctive or other equitable relief for violations of a covered entity.

Section 2, 3, 4, and 5 prohibit insurers (including small group health insurance policies), and health maintenance organizations that provide transplant coverage from denying coverage solely on the basis of an individual's disability.

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:

None.

VI. Technical Deficiencies:

None.

VII. Related Issues:

None.

VIII. Statutes Affected:

This bill creates the following sections of the Florida Statutes: 765.523, 627.64197, 627.65736, and 641.31075.

This bill substantially amends section 627.6699 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 by Appropriations on February 27, 2020:

The committee substitute:

- Provides a definition of the term “disability” relating to coverage for organ transplants under ss. 627.64197 (individual health insurance policies), 627.65736 (group health insurance policies), 627.6699 (small employer group policies), and 641.31075 (HMO contracts), F.S.
- Clarifies that health insurers and HMOs that provide major medical coverage and coverage for organ transplants (rather than health insurers, HMOs and non-profits that provide coverage for organ transplants on an expense-incurred basis) may not deny coverage solely based on a person having a disability.

- Prohibits a health benefit plan covering small employers that provides organ transplant coverage from denying coverage solely based on a person having a disability.

CS by Banking and Insurance on February 11, 2020:

- The CS amends the following definitions:
 - Replaces the reference to the Health Insurance Portability and Accountability Act (HIPAA) with a reference to “federal [laws]” within the definition of “auxiliary aids and services.”
 - Removes residential facilities licensed under ch. 393, F.S., and institutional medical units in correctional facilities from the definition of “covered entity.”
 - Narrows the definition of “disability” to include only the conditions contemplated by the terms “developmental disability” and “intellectual disability” as defined in s. 393.063, F.S.
 - Relocates the description of reasonable modifications to policies from the definition of “qualified individual” to subsection (4), which requires covered entities to make reasonable modifications.
- The CS expands the types of support networks to be considered to include any “community-based services coverage.”
- The CS amends titles to eliminate references to nondiscrimination.

B. Amendments:

None.