

**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 Health Policy

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BILL: SB 1556

INTRODUCER: Senator Bean

SUBJECT: Nondiscrimination in Organ Transplants

DATE: January 27, 2020

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

	ANALYST	STAFF DIRECTOR	REFERENCE	ACTION
1.	Rossitto-Van Winkle	Brown	HP	<b>Pre-meeting</b>
2.	_____	_____	BI	_____
3.	_____	_____	AP	_____

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**I. Summary:**

SB 1556 prohibits specified 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 certain terms and entities;
- Specifies when certain entities may consider an individual's disability and when they may not;
- Requires certain entities to take steps to ensure that an individual with a disability is not denied services, with exceptions;
- Requires certain entities to make reasonable modifications to transplant policies, practices, and procedures to accommodate individuals with a disability, with an exception;
- Prohibits certain entities from denying transplant services due to individual's lack of auxiliary aids and services, with an exception;
- Permits a civil action for injunctive or other equitable relief for violations;
- Prohibits insurers, nonprofit health care service plans, and health maintenance organizations that provide transplant coverage, from denying coverage solely on the basis of an individual's disability; and
- Does not authorize transplants that are not medically necessary.

The bill has an effective date of 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.<sup>1</sup> 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.<sup>2</sup>

### **The Organ Procurement and Transplantation Network (OPTN)**

The National Organ Transplant Act (NOTA) established the Organ Procurement and Transplantation Network (OPTN) in 1984.<sup>3</sup> 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.<sup>4</sup> HHS implemented the final rule that established the regulatory framework for the structure and operations of the OPTN.<sup>5</sup>

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.<sup>6</sup> 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.<sup>7</sup>

The OPTN is a unique public-private partnership that links all professionals involved in the U.S. donation and transplantation system. Also crucial to the system are individuals who sign organ donor cards, people who comment on policy proposals, and countless volunteers who support donation and transplantation, among many others. The OPTN regulates how donor organs are matched and allocated to patients on the waiting list.<sup>8</sup> On average, 95 transplants take place each day in the U.S.<sup>9</sup>

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<sup>1</sup> Donate Life Florida, *Frequently Asked Questions*, <https://www.donatelifeflorida.org/categories/donation/> (last visited Jan. 27, 2018).

<sup>2</sup> *Id.*

<sup>3</sup> 42 U.S.C. 274.

<sup>4</sup> 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 Jan. 22, 2020).

<sup>5</sup> *Id.*

<sup>6</sup> 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 Jan. 24, 2020).

<sup>7</sup> 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 Jan. 22, 2020).

<sup>8</sup> 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 Jan. 22, 2020).

<sup>9</sup> 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 Jan. 22, 2020).

### ***United Network for Organ Sharing (UNOS)***

The United Network for Organ Sharing (UNOS) serves as the OPTN under contract with the Health Resources and Services Administration (HRSA) of HHS. UNOS is a private, non-profit organization based in Richmond, Virginia.<sup>10</sup>

### ***Organ Procurement Organizations (OPOs) Serving Florida***

In Florida, four non-profit, federally designated OPOs work closely with hospitals and transplant centers to facilitate the organ donation and transplantation process:<sup>11</sup>

- Life Alliance Organ Recovery Agency;<sup>12</sup>
- LifeLink Florida;<sup>13</sup>
- LifeQuest Organ Recovery Services;<sup>14</sup> and
- Our Legacy.<sup>15</sup>

### ***Organ Transplant Centers (OTCs)***

There are currently 252 organ transplant centers (OCTs) in the United States.<sup>16</sup> Florida has 11 transplant centers to serve its citizens requiring organ transplants:

- The Miami Transplant Institute at the University of Miami/Jackson Memorial Medical Center;
- Broward General Medical Center/JMH Liver Transplant Program;
- Cleveland Clinic Florida;
- Memorial Healthcare System;
- Tampa General Hospital;
- Largo Medical Center;
- All Children's Hospital;
- Gulf Coast Medical Center, a Division of Lee Memorial Health System;
- University of Florida Health, Shands Transplant Center;
- Transplant Program at Mayo Clinic Hospital;

<sup>10</sup> Id.

<sup>11</sup> Donate Life Florida, Organ Procurement Organizations and Transplant Centers, Organ Procurement Organizations (OPOs) Serving Florida <https://www.donateliflorida.org/local-resources/transplant-centers/> (last visited Jan. 23, 2020).

<sup>12</sup> University of Miami, Miller College of Medicine, *Life Alliance Organ Recovery Agency* <http://surgery.med.miami.edu/laora> (last visited Jan. 22, 2020).

<sup>13</sup> The LifeLink Foundation, *Our Mission* <https://www.lifelinkfoundation.org/> (last visited Jan. 22, 2020). The LifeLink Foundation is a non-profit community service organization dedicated to the recovery of life-saving and life-enhancing organs and tissue for transplantation therapy. The Foundation works in a sensitive, diligent, and compassionate manner to facilitate the donation of desperately needed organs and tissues for waiting patients, support research efforts to enhance the available supply of organs and tissue for transplant patients, improve clinical outcomes of patients post transplantation and work closely with the United Network For Organ Sharing (UNOS) to support its goals.

<sup>14</sup> LifeQuest Organ Recovery Services, *Mission* <https://lifequestfla.org/about/> (last visited Jan. 22, 2020). The mission of LifeQuest is to honor individuals' donor designations, to ensure families' opportunities to donate and to maximize the Gift of Life through organ and tissue donation.

<sup>15</sup> OurLegacy, *Mission* <https://www.ourlegacyfl.org/mission> (last visited Jan. 22, 2020). The mission of OurLegacy is dedicated to saving and improving lives through organ and tissue donation and public education, while honoring all donors and their loved ones whose generosity makes the gift of life possible.

<sup>16</sup> 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 Jan. 23, 2020).

- Sacred Heart Health System, Pensacola;
- AdventHealth Transplant Institute; and
- Halifax Health Center for Transplant Services.

***The Organ Transplant Advisory Council (OTAC)***

The Florida Legislature established the Organ Transplant Advisory Council (OTAC) in 1985 to recommend indications for adult and pediatric organ transplants to Florida’s Agency for Health Care Administration (AHCA). The council consists of twelve members who are physicians.<sup>17</sup> The OTAC has met 22 times, with its first meeting held August 27, 2007; and its most recent meeting held on April 14, 2015.

The responsibilities of the council are to:

- Recommend to the AHCA indications for adult and pediatric organ transplants;
- Formulate guidelines and standards for organ transplants; and
- Development of End Stage Organ Disease and Tissue/Organ Transplant programs.

The recommendations, guidelines, and standards developed by the council are applicable only to those health programs funded through the AHCA.<sup>18</sup>

**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:<sup>19</sup>

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)

<sup>17</sup> Agency for Health Care Administration, *Organ Transplant Advisory Council*, available at [https://ahca.myflorida.com/medicaid/organ\\_transplant/index.shtml](https://ahca.myflorida.com/medicaid/organ_transplant/index.shtml) (last visited Jan. 23, 2020).

<sup>18</sup> Section 765.53, F.S.

<sup>19</sup> 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).

Entity	Level	Role Within the Organ Donation and Transplantation System
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
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 <sup>20</sup>

<sup>20</sup> Id.

### *The Organ Transplant Process*

**Step 1-** Get a physician referral or contact the transplant center directly as a self-referral to be evaluated by a transplant program as a potential transplant candidate.

**Step 2-** Select a Transplant Center. The OPTN has a list of member transplant centers. While a transplant candidate may be referred to a transplant center or program, he or she may want to make sure that it meets his or her need. Factors to consider are:

- Location;
- Compatibility with insurance;
- Financial arrangements; and
- Support group availability.

**Step 3-** Contact the transplant hospital to schedule an evaluation to find out if the candidate is a good candidate for transplant. The standard transplant evaluation usually includes the following tests and assessments:

- Blood typing;
- Tissue typing;
- Dental exam;
- Chest X-ray;
- Cardiac work-up;
- Pulmonary work-up;
- Infectious disease testing;
- Cancer screening;
- Gender-specific testing;
- Psychological evaluation to determine emotional preparedness;
- Evaluation of social and financial supports; and
- Ability to care for oneself and the new organ after transplant.

Other testing may be required depending on the needed organ and the individual's health history.<sup>21</sup>

The exact process varies among transplant centers, as each center determines its own criteria for evaluating patients. Each organ transplant center is required by law to provide its specific guidelines and criteria for inclusion and exclusion of patients as candidates for transplant.

**Step 4-** If the transplant team members determine that a candidate is suitable for a transplant, they will add him or her to the OPTN national waiting list of all people waiting for a transplant. The transplant team will contact the candidate in writing about ten days after he or she is listed to let the patient know the date and time his or her name was added to the national list.<sup>22</sup>

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<sup>21</sup> United Network for Organ Sharing, Talking About Transplantation, *What Every Patient Needs to Know*, 2019, p. 11, available at <https://www.unos.org/wp-content/uploads/unos/WEPNTK.pdf> (last visited Jan. 23, 2020).

<sup>22</sup> U.S. Department of Health and Human Services, Health Resources & Services Administration, *Organdonor.gov*, *The Organ Transplant Process* <https://www.organdonor.gov/about/process/transplant-process.html> (last visited Jan. 22, 2020).

### ***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).<sup>23</sup>

Many factors are used to match organs with patients in need. Some are the same for all organs, but the system must accommodate some unique differences for each organ.<sup>24</sup>

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.

There are 58 local Donation Service Areas, and 11 regions, that are used for United States organ allocation. Hearts and lungs have less time to be transplanted, so the OPTN uses a radius from the donor hospital, instead of regions, when allocating those organs.

### ***Factors in Organ Allocation***

Each organ has different criteria for allocation, but wealth, social status, citizenship, residency, political influence, national origin, ethnicity, sex, or religion are never factors.<sup>25</sup> Blood type and other medical factors weigh into the allocation of every donated organ, and other factors are unique to each organ-type. For example, to receive a kidney, the following additional medical factors weigh heavily in the allocation process:

- Waiting time;
- Donor/recipient immune system compatibility;
- Pediatric status;
- Prior living donor;
- How far the candidate lives from donor hospital; and
- Survival benefit.

For a heart or a liver transplant, the following medical factors weigh heavily in the allocation process:

- Medical need; and
- How far the candidate lives from donor hospital.

For a lung transplant, the following medical factors weigh heavily in the allocation process:

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<sup>23</sup> 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 Jan. 22, 2020).

<sup>24</sup> *Id.*

<sup>25</sup> 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, available at [https://optn.transplant.hrsa.gov/media/1200/optn\\_policies.pdf](https://optn.transplant.hrsa.gov/media/1200/optn_policies.pdf) (last visited Jan. 23, 2020).

- Survival benefit;
- Medical urgency;
- Waiting time; and
- How far the candidate lives from donor hospital.

### ***Wait Times for Organ Transplants***

Candidate wait times vary widely for many reasons. 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.<sup>26</sup>

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
- The transplant center's criteria for accepting organ offers.<sup>27</sup>

Depending on the kind of organ needed, some factors are more important than others.

### ***The Donor Matching System***

The OPTN has policies that regulate 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.<sup>28</sup> 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.<sup>29</sup>

When transplant hospitals accept patients onto the waiting list, the patients are registered in a centralized, national computer network that links all donors and transplant candidates. The UNOS center is staffed 24 hours a day throughout the year, and it assists with the matching, sharing, and transportation of organs via this computer network.

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<sup>26</sup> 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 Jan. 22, 2020).

<sup>27</sup> Id.

<sup>28</sup> 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 Jan. 22, 2020).

<sup>29</sup> Id.



Transplant centers, tissue typing laboratories, and OPOs are involved in the organ sharing process. When donor organs are identified, the procuring organization typically accesses the computerized organ matching system, enters information about the donor organs, and runs the match program. At times, when requested or when there is a need to identify perfectly matched kidney donors to recipients, the matching process is handled by organ center personnel at UNOS headquarters in Richmond, Virginia.

For each organ that becomes available, the computer program 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.

Once the organ is accepted for a potential recipient, transportation arrangements are made for the surgical teams to come to the donor hospital, and surgery is scheduled. For heart, lung, or liver transplantation, the recipient of the organ is identified prior to the organ recovery and called into the hospital where the transplant will occur to prepare for the surgery.

The recovered organs are stored in a cold organ preservation solution and transported from the donor to the recipient hospital. For heart and lung recipients, it is best to transplant the organ within six hours of organ recovery. Livers can be preserved up to 24 hours after recovery. For kidneys and typically the pancreas, laboratory tests designed to measure the compatibility between the donor organ and recipient are performed. A surgeon will not accept the organ if these tests show that the patient's immune system will reject the organ. Therefore, the recipient is usually not identified until after these organs are recovered.

For example, some organs can survive outside the body longer than others. So the distance between the donor's hospital and the potential recipient's hospital must be taken into consideration. How long individual organs can stay alive outside of the body is approximately the following:

- Hearts and Lungs: 4-6 hours;
- Livers: 8-12 hours;
- Pancreas: 12-18 hours;
- Kidney: 24-36 hours; and
- Intestines: 8-16 hours.

When matching organs from deceased donors to patients on the waiting list, many of the factors taken into consideration are the same for all organs. These usually include:

- Blood type;
- Body size;
- Severity of patient's medical condition;

- Distance between the donor's hospital and the patient's hospital;
- The patient's waiting time; and
- Whether the patient is available (for example, whether the patient can be contacted and has no current infection or other temporary reason that transplantation cannot take place).

### *Allocation Calculators*

The Calculated Panel Reactive Antibody (CPRA) calculator is used to evaluate candidates for kidney, pancreas, and kidney/pancreas transplants. This calculator uses the same formula as the UNet<sup>SM</sup> computer system. UNet is the computer system used by the transplant center to calculate kidney, pancreas, and kidney/pancreas allocation scores for candidates in need of a transplant. This calculator produces a value based on the unacceptable antigens.<sup>30</sup>

Estimated Post Transplant Survival (EPTS) score is assigned to all adult candidates on the kidney waiting list, as part of the new kidney allocation system. An EPTS score is assigned to all adult candidates on the kidney waiting list and is based on four factors:

- Candidate time on dialysis;
- Current diagnosis of diabetes;
- Prior solid organ transplants; and
- Candidate age.

A candidate's EPTS score can range from 0 percent to 100 percent. An EPTS score of 20 percent or less will receive offers for kidneys from donors with KDPI scores of 20 percent or less before other candidates at the local, regional, and national levels of distribution. The EPTS score is not used in allocation of kidneys from donors with KDPI scores greater than 20 percent.

The Kidney Donor Profile Index (KDPI) calculator summarizes the risk of graft failure after kidney transplant. The Kidney Donor Risk Index (KDRI) combines a variety of donor factors to summarize the risk of graft failure after kidney transplant into a single number. The KDRI expresses the relative risk of kidney graft failure for a given donor compared to the median kidney donor from last year.

The KDPI and KDRI are combined and put on a cumulative percentage scale. A donor with a KDPI of 80 percent or higher has a greater expected risk of graft failure. If diabetes or hypertension statuses are unknown, the calculator will assume the donor has the same chance as a randomly selected donor having the condition. If Hepatitis C Virus (HCV) status is unknown, the calculator will assume the donor is negative for HCV.

The Lung Allocation Score (LAS) is a numerical calculation used for allocating lungs to candidates age 12 and older to calculate lung allocation scores for patients in need of a lung transplant.<sup>31</sup>

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<sup>30</sup> See <https://unos.org/technology/unet/> (last visited Jan. 25, 2020)

<sup>31</sup> U.S. Department of Health & Human Services, Health Resources & Services Administration, Organ Procurement and Transplantation Network, Transplant Process, *Allocation Calculators* <https://optn.transplant.hrsa.gov/resources/allocation-calculators/> (last visited Jan. 22, 2020).

### ***Organ Transplant Costs***

The cost of transplantation and follow-up care varies across the country and by organ. Even before a transplantation, these costs can add up quickly. These costs may include:

- Medical costs
  - Pre-transplant evaluation and testing;
  - Hospital stay and surgery;
  - Additional hospital stays for complications;
  - Follow-up care and testing;
  - Anti-rejection and other drugs, which can cost more than \$10,000 per year;
  - Fees for surgeons, physicians, radiologist and anesthesiologist;
  - Fees for the surgical recovery (procurement) of the organ from the donor;
  - Physical, occupational, and vocational rehabilitation; and
  - Insurance deductibles and co-payments.
- Nonmedical costs
  - Transportation to and from the transplant center, before and after transplantation;
  - Food, lodging, long distance phone calls for the patient and his or her family;
  - Child care; and
  - Lost wages if the patient's employer does not pay for the patient's time away from work.<sup>32</sup>

The most common funding sources for organ transplants are:

- Insurance;
- Extending insurance coverage through COBRA;
- Medicare and Medicaid;
- TRICARE;
- Charitable organizations;
- Advocacy organizations;
- Fundraising campaigns; and
- Other sources of insurance.<sup>33</sup>

### ***Organ Transplants and Medicare***

Medicare Part B covers doctor services for certain organ transplants. Medicare Part A covers heart, lung, kidney, pancreas, intestine, and liver transplants under certain conditions at Medicare-certified facilities. Part A also covers some stem cell transplants under certain conditions. Part B covers cornea transplants, under some conditions. Stem cell and cornea transplants are not limited to Medicare-approved transplant centers. Organ transplant coverage under Medicare includes:

- Medically necessary tests, labs, and exams before surgery;
- Transplant immunosuppressive drugs (under certain conditions);
- Follow-up care, and

<sup>32</sup> U.S. Department Of Health And Human Services, Health Resources and Services Administration, Healthcare Systems Bureau, Division of Transplantation, *Partnering With Your Transplant Team: The Patient's Guide to Transplantation* (2008), p. 22, available at <https://www.unos.org/wp-content/uploads/unos/PartneringWithTransplantTeam.pdf> (last visited Jan. 23, 2020).

<sup>33</sup> Id.

- Procurement of organs.<sup>34</sup>

A Medicare recipient's out-of-pocket costs may include:

- Twenty percent of the Medicare-approved amount for doctors' services;
- The Part B deductible; and
- Various amounts for organ transplant facility charges.

Medicare does not pay for a living donor for a kidney transplant.<sup>35</sup>

### ***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<sup>36</sup>transplants that are medically necessary and appropriate.<sup>37</sup> The following are samples of the AHCA's Medicaid fee-for-service reimbursement rates for specific transplant surgery:

- Adult Heart: Facility \$135,000; physician \$27,000;
- Adult Liver: Facility \$95,600; physician \$27,000;
- Adult Lung: Facility \$205,000; physician \$33,000;
- Pediatric Lung: Facility \$280,000.00; physician \$40,800; and
- Adult and Pediatric Intestinel/Multivisceral: Facility \$450,000; physician: \$50,000.<sup>38</sup>

### **Discrimination in Access to Anatomical Gifts and Organ Transplants**

On September 25, 2019, the National Council on Disability (NCD) submitted a report to the President and Congress entitled, *Organ Transplant Discrimination Against People with Disabilities*.<sup>39</sup> 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 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 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

<sup>34</sup> Medicare.gov., The Official U.S. Government Site for Medicare; *Open Enrollment Is Over - Get Ready for A New Year of Coverage*, available at <https://www.medicare.gov/> (last visited Jan. 23, 2020).

<sup>35</sup> Id.

<sup>36</sup> A multivisceral transplant is the transplantation of three or more abdominal organs all at once, namely the liver together with the pancreatoduodenal complex, the stomach as well as the small bowel with/without the right hemicolon. Medical Dictionary by Farlex, available at <https://medical-dictionary.thefreedictionary.com/Multivisceral+Transplantation> (last visited Jan. 23, 2020).

<sup>37</sup> Agency for Health Care Administration, *Florida Standards for the Coverage of Organ Transplant Services*, (effective April 1, 2015), p. 1, available at [https://ahca.myflorida.com/medicaid/organ\\_transplant/pdfs/state\\_plan\\_standards\\_for\\_coverage\\_updated\\_2015.pdf](https://ahca.myflorida.com/medicaid/organ_transplant/pdfs/state_plan_standards_for_coverage_updated_2015.pdf), (last visited Jan. 23, 2020).

<sup>38</sup> Id.

<sup>39</sup> National Council on Disability, Bioethics and Disability Series, *Organ Transplant Discrimination Against People with Disabilities*, available at [https://ncd.gov/sites/default/files/NCD\\_Organ\\_Transplant\\_508.pdf](https://ncd.gov/sites/default/files/NCD_Organ_Transplant_508.pdf), (last visited Jan. 23, 2020).

Disabilities Act (ADA): equal opportunity, full participation, independent living, and economic self-sufficiency for persons with disabilities.<sup>40</sup>

### **The American’s with Disabilities Act & The Rehabilitation Act of 1973**

The ADA<sup>41</sup> and section 504 of the Rehabilitation Act of 1973<sup>42</sup> 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;<sup>43</sup> and
- Programs or activities conducted by HHS.<sup>44</sup>

According to the NCD, while there are few empirical studies analyzing how organ transplant centers actually evaluate patients for transplantation, particularly with respect to how any particular disability influences which patients are selected, the primary forms of disability discrimination occurring at organ transplant centers are:

- 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 ADA defines “disability” as:

- A physical or mental impairment that substantially limits one or more of the major life activities;
- A record of such an impairment; or
- Being regarded as having such an impairment.<sup>45</sup>

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 one or more of the following body systems:
  - Neurological;
  - Musculoskeletal;
  - Special sense organs;
  - Respiratory (including speech organs);
  - Cardiovascular;
  - Reproductive;
  - Digestive;
  - Genitourinary;
  - Hemic and lymphatic;
  - Skin;
  - Endocrine; or
- Any mental or psychological disorder such as:
  - Mental retardation;

<sup>40</sup> National Council on Disabilities, Letter to UNOS, OPTN, HRSA Regarding Organ Transplants (Sept. 25, 2019), *available at* <https://ncd.gov/publications/2019/ncd-letter-unos-optn-hrsa-regarding-organ-transplants> (last visited Jan. 23, 2020).

<sup>41</sup> 28 C.F.R. Part 35 and 36.

<sup>42</sup> 29 U.S.C. s. 794.

<sup>43</sup> 45 C.F.R. 84.

<sup>44</sup> 45 C.F.R. 85.

<sup>45</sup> 28 C.F.R., s. 35.104.

- Organic brain syndrome;
- Emotional or mental illness; or
- Specific learning disabilities.<sup>46</sup>

The phrase “physical or mental impairment” specifically includes, but is not limited to:

- Contagious and noncontagious diseases and conditions as orthopedic, visual, speech and hearing impairments;
- Cerebral palsy;
- Epilepsy;
- Muscular dystrophy;
- Multiple sclerosis;
- Cancer;
- Heart disease;
- Diabetes;
- Emotional illness;
- HIV disease (whether symptomatic or asymptomatic);
- Tuberculosis;
- Drug addiction; and
- Alcoholism.

The ADA also 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.

### ***Enforcement of the ADA and the Rehabilitation Act of 1973***

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) no later than 180 days from the date of the alleged discrimination, unless the time for filing is extended by the designated agency for good cause shown.<sup>47</sup> The DOJ, or designated agency, will then investigation, and if discrimination on the basis of disability is found, 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.<sup>48</sup> If the public entity declines to enter into voluntary compliance negotiations, or if negotiations are unsuccessful, the designated agency shall refer the matter to the Attorney General with a recommendation for appropriate

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<sup>46</sup> Id.

<sup>47</sup> 28 C.F.R. s. 35.170.

<sup>48</sup> 28 C.F.R. s. 35.173.

action.<sup>49</sup> If the complainant prevails, he or she may be awarded a reasonable attorney's fee, including litigation expenses and costs.<sup>50</sup>

### **A Cause of Action Under the Florida Civil Rights Act of 1992**

The general purposes of the Florida Civil Rights Act of 1992 (Act) were set out by the Legislature as follows:

- 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.<sup>51</sup>

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.<sup>52</sup> [emphasis added]

Section 760.22(12), 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 under s. 393.063, F.S.,<sup>53</sup> 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;
  - Phelan-McDermid syndrome;<sup>54</sup> or

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<sup>49</sup> 28 C.F.R. s. 35.174.

<sup>50</sup> 28 C.F.R. s. 35.175.

<sup>51</sup> Section 760.01, F.S.

<sup>52</sup> Section 760.07, F.S.

<sup>53</sup> Section 760.22(7), F.S.

<sup>54</sup> U.S. Department of Health and Human Services, National Institutes of Health, Genetic and Rare Disease Information Center, *22q13.3 deletion syndrome* <https://rarediseases.info.nih.gov/diseases/10130/phelan-mcdermid-syndrome> (last visited Jan. 23, 2020). 22q13.3 deletion syndrome, also known as Phelan-McDermid syndrome, is a chromosome disorder caused by the loss (deletion) of a small piece of chromosome 22. The deletion occurs near the end of the long arm (or q arm) of the chromosome at a location designated as q13.3. Not everyone with 22q13.3 deletion syndrome will have the same medical, developmental, or behavioral problems (features). Common problems include low muscle tone (hypotonia), intellectual disability, developmental delays especially delayed or absent speech, and tendency to overheat. Children may be tall and thin.

- Prader-Willi syndrome.<sup>55, 56</sup>

A Florida Civil Rights cause of action for discrimination based on a disability may apply to a violation of s. 501.2077(2), F.S., within the “Florida Deceptive and Unfair Trade Practices Act,” which creates civil liability and a penalty of not more than \$15,000 for each violation if a person willfully uses a method, act, or practice which victimized or attempted to victimize a person who has a disability, and if he or she knew that his or her conduct was unfair or deceptive.<sup>57</sup> If members of a transplant team intentionally discriminated against an otherwise qualified disabled person in a transplant decision, this may create a civil rights violation under the Florida Civil Rights Act.

### III. Effect of Proposed Changes:

SB 1556 creates sections 765.523, 627.64197, 627.65736, and 641.31075, F.S. The bill prohibits 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:

- Auxiliary aids and services;
- Covered entity;
- Disability;
- Organ transplant; and
- Qualified individual.

Under the bill, “covered entity” means any of the following:

- A licensed health care practitioner.
- A hospital, skilled nursing facility, hospice, or intermediate care facility for the developmentally disabled.
- A facility providing room and board and personal care for persons who have developmental disabilities.
- An institutional medical unit in a correctional facility.
- Any other entity responsible for potential recipients of an anatomical gift.

The bill mandates that a covered entity may not do 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:

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<sup>55</sup> U.S. Department of Health and Human Services, National Institutes of Health, U.S. National Library of Medicine, *Prader-Willi Syndrome* <https://ghr.nlm.nih.gov/condition/prader-willi-syndrome> (last visited Jan 23, 2020). Prader-Willi syndrome is a complex genetic condition. In infancy, this condition is characterized by weak muscle tone (hypotonia), feeding difficulties, poor growth, and delayed development. Beginning in childhood, affected individuals develop an insatiable appetite, which leads to chronic overeating (hyperphagia) and obesity. People with Prader-Willi syndrome typically have mild to moderate intellectual impairment and learning disabilities. Behavioral problems include temper outbursts, stubbornness, and compulsive behavior such as picking at the skin. Sleep abnormalities can also occur. Both affected males and females have underdeveloped genitals. Puberty is delayed or incomplete, and most affected individuals are infertile.

<sup>56</sup> Section 393.063(12), F.S.

<sup>57</sup> See ss. 501.2077(2), and 760.07, F.S.



- 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.

The bill also mandates that, unless the covered entity can demonstrate that making modifications to its policies, practices, or procedures to allow an individual with a disability access to services would fundamentally alter the nature of the services, a covered entity must:

- Make reasonable modifications to its policies, practices, or procedures to allow an individual with a disability access to services, including:
  - Transplant-related counseling;
  - Information;
  - Coverage; or
  - Treatment.

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

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 life of the transplant 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.

The bill prohibits insurers, nonprofit health care service plans, 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:**

The bill could be interpreted to conflict with federal law. The federal National Organ Transplant Act (NOTA) established the OPTN. The OPTN policies and procedures are rules that govern and control the operation of all member transplant hospitals, OPOs, and histocompatibility labs in the U.S. The OPTN rules have supremacy over any state law regarding transplant candidate selection and allocation criteria.

**VIII. Statutes Affected:**

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

**A. Committee Substitute – Statement of Changes:**

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

None.

**B. 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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