#### HOUSE OF REPRESENTATIVES STAFF ANALYSIS

# BILL #:CS/HB 677Organ DonationSPONSOR(S):Health & Human Services Committee, BerfieldTIED BILLS:IDEN./SIM. BILLS:SB 646

REFERENCE	ACTION	ANALYST	STAFF DIRECTOR or BUDGET/POLICY CHIEF
1) Health & Human Services Committee	21 Y, 0 N, As CS	Osborne	Calamas
2) Ways & Means Committee			
3) Infrastructure Strategies Committee			
4) Appropriations Committee			

#### SUMMARY ANALYSIS

Organ donation is the process of surgically removing an organ or tissue from one person (the donor) and transplanting it into another person (the recipient). Transplanting in such cases is necessary because the recipient's organ has failed or has been damaged by disease or injury. Transplantable organs include the liver, kidneys, pancreas, heart, lung, and intestine. Transplantable tissues include skin, bone, heart valves, tendons, veins, and corneas.

Although most organ donations occur after death of the donor, some donations come from living organ donors. A living-donor transplant is a surgical procedure to remove an organ or portion of an organ from a living person and place it another person whose organ is no longer functioning. Some living organ donors have difficulty obtaining various types of insurances.

CS/HB 677 amends multiple sections of law related to organ donation.

The bill creates a category of administrative leave for organ donation for employees of the state or a political subdivision thereof.

The bill requires locations where recreational licenses or permits are sold to display and make available to the public educational materials relating to organ donation and registration. The bill requires the Florida Fish and Wildlife Conservation Commission to maintain an integrated link on its website referring a visitor applying for a hunting, fishing, or trapping license to the organ donor registry.

The bill amends the Florida Insurance Code to prohibit preexisting condition exclusions that have the effect of limiting or denying coverage to a living organ donor.

The bill requires certain driver improvement schools and DUI programs provide students with information pertaining to organ donation. The bill directs the Department of Transportation to adopt rules to implement this provision.

The bill requires Donate Life to coordinate with the Department of Health to ensure that continuing education topics on organ donation are available to medical professionals.

The bill has an insignificant, negative fiscal impact on state government. The bill has no impact on local governments.

The bill provides an effective date of July 1, 2024.

#### FULL ANALYSIS

#### I. SUBSTANTIVE ANALYSIS

#### A. EFFECT OF PROPOSED CHANGES:

Background

#### **Organ and Tissue Donation**

Organ and tissue donation is the process of surgically removing an organ or tissue from one person (the donor) and transplanting it into another person (the recipient). Transplanting in such cases is necessary because the recipient's organ has failed or has been damaged by disease or injury.<sup>1</sup> Transplantable organs include the liver, kidneys, pancreas, heart, lung, intestine.<sup>2</sup> Transplantable tissue include skin used as a temporary dressing for burns, serious abrasions and other exposed areas; bone is used in orthopedic surgery to facilitate healing of fractures or prevent amputation; heart valves are used to replace defective valves; tendons are used to repair torn ligaments on knees or other joints; veins are used in cardiac by-pass surgery; and corneas can restore sight.<sup>3</sup> A single organ donor can save up to eight lives and over seventy-five more can be improved through organ donation.<sup>4</sup>

Despite advances in medicine and technology, and increased awareness of organ donation and transplantation, more donors are needed to meet the demand for transplants.<sup>5</sup> As of January 2022, 120,000 children and adults are waiting for a life-saving organ transplant, including 5,000 Floridians.<sup>6</sup> In 2021, 41,354 organ transplants were performed in the United States, reflecting an increase of 5.9 percent from 2020.<sup>7</sup> Living donor transplants on the other hand significantly decreased in 2020 due to COVID-19. While they increased in 2021, the numbers remain lower than in previous years. In 2021, a total of 6,541 living donor transplants were performed nationwide

## Living Organ Donation

Although most organ donations occur after the death of the donor, some donations come from living organ donors. A living-donor transplant is a surgical procedure to remove an organ or portion of an organ from a living person and place it in another person whose organ is no longer functioning properly.<sup>8</sup> Kidney and liver transplants are the most common living-organ procedures, though a living organ donor can also donate tissues for transplants such as skin, bone marrow, and stem cells to replace organs or tissue that have been damaged or destroyed by disease, drugs or radiation.<sup>9</sup>

Based on the limited data available on the long-term risks of living organ donors currently available, the overall risks are considered to be low and differ among donors depending on the organ donated.<sup>10</sup> Short-term risks of living organ donation involve risks associated with anesthesia and major surgeries, including pain, infection, blood loss, blood clots, allergic reactions to anesthesia, pneumonia, injury to surrounding tissue or organs, and death.<sup>11</sup>

<sup>&</sup>lt;sup>1</sup> Cleveland Clinic, Organ Donation and Transplantation. Available at <u>https://my.clevelandclinic.org/health/articles/11750-organ-donation-and-</u>

transplantation#:~:text=Organ%20donation%20is%20the%20process%20of%20surgically%20removing.one%20of%20the%20great%2 <u>Oadvances%20in%20modern%20medicine</u> (last visited January20, 2024).

<sup>&</sup>lt;sup>2</sup> Id.

<sup>&</sup>lt;sup>3</sup> Donate Life Florida, *Frequently Asked Questions* Available at <u>https://www.donatelifeflorida.org/categories/donation/</u> (last visited January 20, 2024).

<sup>&</sup>lt;sup>4</sup> Health Resources and Services Administration, *What Can Be Donated*? Available at <u>https://www.organdonor.gov/learn/what-can-be-donated</u> (last visited January 14, 2022). <u>https://optn.transplant.hrsa.gov/data/</u> (last visited January 20, 2024).

<sup>&</sup>lt;sup>5</sup> U.S. Department of Health and Human Services, *Organ Procurement and Transplantation Network*. Available at <u>All-time records</u> <u>again set in 2021 for organ transplants, organ donation from deceased donors - OPTN (hrsa.gov)</u> (last visited January 20, 2024). <sup>6</sup> *Supra*, note 3.

<sup>&</sup>lt;sup>7</sup> Supra, note 5.

<sup>&</sup>lt;sup>8</sup> Mayo Clinic, *Living-donor transplant*. Available at <u>https://www.mayoclinic.org/tests-procedures/living-donor-transplant/about/pac-20384787</u> (last visited January 20, 2024).

<sup>&</sup>lt;sup>9</sup> Id.

<sup>&</sup>lt;sup>10</sup> UNOS, *How do I become a living donor*? Available at <u>https://unos.org/transplant/living-donation/</u> (last visited January 20, 2024). <sup>11</sup> *Id.* 

#### National Organ Transplant Act of 1984

The National Organ Transplant Act of 1984, which regulates organ donations including living organ donors, prohibits the buying and selling of organs.<sup>12</sup> Living donation of an organ must be voluntary, and the donor cannot receive payment. While, the organ recipient's health insurance covers medical expenses such as evaluation, surgery, and limited follow-up test and medical appointments depending on the particular insurance, the recipient's insurance will not cover transportation, lodging, childcare, or lost wages.<sup>13</sup> In addition, treatment for conditions discovered during the evaluation portion of the donation process and some post-donation follow-up expenses are not covered.<sup>14</sup>

The United Network for Organ Sharing (UNOS), is a non-profit organization under contract with the federal government to manage the national transplant waiting list and maintaining the databases containing all organ transplant data for every transplant event occurring in the U.S.<sup>15</sup>, UNOS warns prospective donors that some donors report, "difficulty in getting, affording, or keeping health, disability, or life insurance."16

## Regulation of Organ Donation, Procurement, and Transplantation in Florida

The Agency for Health Care Administration (AHCA) oversees the various organizations and facilities involved in the organ procurement and transplant process in this state. AHCA licenses transplant facilities, contracts with an organization to educate the public on organ donation, sets requirements for training individuals who engage with families whose deceased relatives may be a good candidate for organ donation, and supports the Organ Transplant Advisory Council and the Organ and Tissue Procurement and Transplantation Advisory Board.

## Organ Donor Registry

In 2008,<sup>17</sup> Florida's Legislature found that a shortage of organ and tissue donors existed in Florida. Findings included a need for:

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

The online registry would afford more persons who are awaiting organ or tissue transplants the opportunity for a full and productive life.<sup>18</sup> As directed by the legislature, AHCA and the Department of Highway Safety and Motor Vehicles (DHSMV) jointly contracted for the operation of Florida's interactive web-based donor registry that allows for online donor registration and the recording of organ and tissue donation records submitted through the driver license identification program or through other sources. AHCA and the DHSMV selected Donate Life Florida, which is a coalition of Florida's organ, tissue, and eye donor programs, to run the donor registry and maintain donor records.

Floridians who are age 18 or older can join the donor registry either online, at the DHSMV (or their local driver license office), or by contacting Donate Life Florida for a paper application.<sup>19</sup> Children ages 13 to 17 may join the registry, but the final decision on any organ donation of a minor rests with the parent or guardian. The registry collects personal information from each donor including, but not limited to, his or her name, address, date and place of birth, race, ethnicity, and driver's license number.

- <sup>14</sup> Id.
- <sup>15</sup> Id. <sup>16</sup> *Id*.

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<sup>&</sup>lt;sup>12</sup> National Organ Transplant Act, 42 U.S.C. s. 274.

<sup>&</sup>lt;sup>13</sup> UNOS, Financial and Insurance Factors to Consider. Available at https://unos.org/transplant/living-donation/ (last visited January 20, 2024).

<sup>&</sup>lt;sup>17</sup> Ch. 2008-223, Laws of Fla.

<sup>&</sup>lt;sup>18</sup> S. 765.5155(1), F.S.

<sup>&</sup>lt;sup>19</sup> Donate Life Florida, Welcome to the Joshua Abbott Organ and Tissue Donor Registry. Available at http://www.donatelifeflorida.org/ (last visited January 20, 2024) STORAGE NAME: h0677a.HHS

As of March 3, 2021, there were 11,468,537 people registered in the donor registry.<sup>20</sup>

A person may make an anatomical gift of all or part of his or her body by:<sup>21</sup>

- Signing an organ and tissue donor card;
- Registering online with the donor registry;
- Signifying an intent to donate on his or her driver license or identification card issued by the DHSMV;<sup>22</sup>
- Expressing a wish to donate in a living will or other advance directive;
- Executing a will that includes a provision indicating that the testator wishes to make an anatomical gift;<sup>23</sup> or
- Expressing a wish to donate in a document other than a will.<sup>24</sup>

# Donor Education

When a patient dies in a hospital and is not a registered organ donor, but is determined to be a good candidate by the hospital's medical staff and the OPO, a representative of the OPO or a member of the hospital's staff may approach the patient's family about organ donation.<sup>25</sup> AHCA has developed rules for training and guidelines for the person making the request for organ donation.<sup>26</sup> The requestor is trained in explaining the process of organ donation to the patient's family, including their right to allow or refuse donation and for what purpose the organs would be donated (transplantation, research, or education).<sup>27</sup> The requestor is also specifically trained in the different types of approaches to deal with a family's grief and offering them the opportunity for organ donation.<sup>28</sup> The current rules require the requestor to explain the requirements needed to be met under Florida law in order for a donation to be allowed, but not federal regulations relating to organ donation.

# Organ Donation Fees

Generally, an organ donor and their family are not charged by a transplant facility for the medical care required to donate an organ.<sup>29</sup> Families pay for medical care and funeral costs, but costs related to living or deceased donation are paid by the recipient, usually through insurance, Medicare, or Medicaid.<sup>30</sup> Typically, any cost that falls outside of the transplant center's donor evaluation or actual surgery, such as travel, lodging, lost wages, and other non-medical expenses, is borne by the living donor or recipient.<sup>31</sup>

# Living Organ Donors and Insurance

## Obtaining and Affording Insurance

<sup>23</sup> The gift becomes effective upon the death of the testator without waiting for probate. If the will is not probated or if it is declared invalid for testamentary purposes, the gift is nevertheless valid to the extent that it has been acted upon in good faith.

<sup>31</sup> UNOS, *Living Donation Costs*. Available at <u>https://transplantliving.org/financing-a-transplant/living-donation-costs/</u> (last visited January 20, 2024).

<sup>&</sup>lt;sup>20</sup> Id.

<sup>&</sup>lt;sup>21</sup> S. 765.514(1), F.S.

<sup>&</sup>lt;sup>22</sup> Revocation, suspension, expiration, or cancellation of the driver license or identification card does not invalidate the gift.

<sup>&</sup>lt;sup>24</sup> The document must be signed by the donor in the presence of two witnesses who shall sign the document in the donor's presence. If the donor cannot sign, the document may be signed for him or her at the donor's direction and in his or her presence and the presence of two witnesses who must sign the document in the donor's presence. Delivery of the document of gift during the donor's lifetime is not necessary to make the gift valid.

<sup>&</sup>lt;sup>25</sup> Health Resources and Services Administration, *The Deceased Donation Process*. Available at

https://www.organdonor.gov/about/process/deceased-donation.html#authorize (last visited January 20, 2024). See also s. 765.522, F.S.

<sup>&</sup>lt;sup>26</sup> Ch. 59A-3.274, F.A.C.

<sup>&</sup>lt;sup>27</sup> Id.

<sup>&</sup>lt;sup>28</sup> Id.

<sup>&</sup>lt;sup>29</sup> Health Resources Services Administration, Organ Donation Frequently Asked Questions. Available at <u>https://www.organdonor.gov/about/facts-terms/donation-fags.html</u> (last visited January 20, 2024).

<sup>&</sup>lt;sup>30</sup> Id. See also UNOS, Living Donation Costs. Available at <u>https://transplantliving.org/financing-a-transplant/living-donation-costs/</u> (last visited January 20, 2024).

A 2014 survey of 1,046 donors who underwent living kidney donation at Johns Hopkins Hospital found that, 25 percent of those who reported attempting to obtain new or revised life insurance policies post-procedure reported difficulty in doing so. The difficulties reported included outright denials in obtaining coverage, higher premiums, and the notation of a pre-existing condition relating to the kidney donation. The same survey also noted that of the donors who reported attempting to obtain new or revised health insurance policies post-procedure, seven percent reported difficulties in doing so.<sup>32</sup>

Another study, which reviewed different studies over a 35-year period concluded that a significant number of living kidney donors encounter difficulties in obtaining or maintaining insurance (with anywhere between three percent to eleven percent of those surveyed reporting difficulties).<sup>33</sup> That same study also found that insurability issues caused significant stress for between 11 percent and 13 percent of kidney donors and that "insurability may negatively influence one's decision to become a living organ donor."<sup>34</sup> This same study also found that these insurability issues are not isolated to kidney donors.<sup>35</sup> The National Kidney Foundation also advises potential donors, in assessing the risk of donation, that "some donors have reported difficulty in getting, affording, or keeping disability or life insurance."

There is some evidence that these increased difficulties and costs in obtaining life insurance is not always based on the actual additional loss risk that organ donation presents. A 2015 study of living kidney donors found that such donation "does not appear to increase long-term mortality compared with controls;" however, the study did advise that it was limited in scope and more research was needed.<sup>36</sup> A study of living kidney donors in Korea, published in 2019, found that," the risk of all-cause mortality was comparable between live kidney donors and matched non-donor healthy controls with similar health status."<sup>37</sup> A 2012 study of live liver donors found that while 90-day mortality rates were elevated for such donors, the rates of long-term mortality were essentially the same for live liver donors, for live kidney donors, and for healthy controls.<sup>38</sup>

Florida insurance law does not expressly address insurance discrimination against living organ donors.

## The Patient Protection and Affordable Care Act

The federal Patient Protection and Affordable Care Act (PPACA), signed into law in 2010 made sweeping changes to the U.S. health insurance system.<sup>39</sup> The PPACA imposes extensive requirements on health insurance and health insurance policies relating to required benefits, rating and underwriting standards, review of rate increase, and other requirements.<sup>40</sup>

The PPACA prohibits health insurers from denying coverage or increasing health insurance premiums due to a pre-existing condition,<sup>41</sup> which would include having made a living organ donation.

#### **Recreational Licenses and Permits**

The Florida Fish and Wildlife Conservation Commission (FWC) regulates hunting and fishing seasons, means of take, bag limits, and areas authorized for hunting or fishing. Florida residents and visitors are required to possess a Florida hunting, freshwater fishing, or saltwater fishing license when engaged in

<sup>37</sup> Y. Kim, et al, Long-term Mortality Risks Among Living Kidney Donors in Korea. 75(6) Am J Kidney Dis. 925 (2019).

<sup>&</sup>lt;sup>32</sup> B.j. Boyarsky, et al, Experiences Obtaining Insurance After Live Kidney Donation, 14(9) AM J Transplant. 2168-72 (2014).

 <sup>&</sup>lt;sup>33</sup> R.C. Yang, et al, Insurability of Living Organ Donors: A Systematic Review, 7(6) AM J TRANSPLANT. 1547-48 (2007).
<sup>34</sup> Id.

<sup>&</sup>lt;sup>35</sup> *Id.* and Nissing MH & Hayashi PH, *Right hepatic lobe donation adversely affects donor life insurability up to one year after donation*, 11 LIVER TRANSPL 843–847 (2005).

<sup>&</sup>lt;sup>36</sup> K.L. Lentine & A. Patel, *Risks and outcomes of living donation*, 19(4) ADV CHRONIC KIDNEY DIS. 220-8 (2012).

<sup>&</sup>lt;sup>38</sup> 1 A.D. Muzaale, et al, *Estimates of early death, acute liver failure, and long-term mortality among live liver donors, 142(2) Gastroenterology* 273-80 (2012).

<sup>&</sup>lt;sup>39</sup> Patient Protection and Affordable Care Act (PPACA), Pub. L. No. 111-148, March 23, 2010, 124 Stat 119.

<sup>&</sup>lt;sup>40</sup> Most of the insurance regulatory provisions in PPACA amend Title XXVII of the Public Health Service Act (PHSA), 42 U.S.C. 300 gg et seq.

fishing and hunting activities.<sup>42</sup> Fees for licenses and permits typically range from \$17 to \$151<sup>43</sup> depending on the type and duration of the license, as well as if the individual is a Florida resident.<sup>44</sup> Certain individuals are exempt from the permitting requirements.<sup>45</sup> Individuals can obtain hunting and fishing permits online,<sup>46</sup> in person at a license agent<sup>47</sup> or tax collector's office, by calling toll-free numbers, and through the FWC Fish|Hunt FL app.<sup>48</sup> Licenses expire a year from the date they are issued.<sup>49</sup>

## Effect of the Bill

## Administrative Leave for Organ Donation

CS/HB 677 creates a category of administrative leave for organ donation for employees of the state or a political subdivision thereof.

## **Recreational Licenses and Permits**

The bill requires FWC to maintain an integrated link on its website referring a visitor applying for a hunting, fishing, or trapping license to the organ donor registry. It also requires locations where recreational licenses or permits are sold to display and make available to the public educational materials relating to organ donation and registration. The bill allows applicants for recreational licenses and permits to sign up to make anatomical gifts and requires a notation that the licensee is an organ donor on such license.

## **Driver Improvement Schools or DUI Programs**

The bill requires certain driver improvement schools and DUI programs provide students with information pertaining to organ donation. The bill directs the Department of Transportation to adopt rules to implement this provision.

#### **State Regulation of Health Insurance**

The bill amends the Florida Insurance Code to prohibit preexisting condition exclusions that have the effect of limiting or denying coverage to a living organ donor.

## **Continuing Medical Education**

The bill requires Donate Life to coordinate with the Department of Health to ensure that continuing education topics on organ donation are available to medical professionals.

<sup>49</sup> FWC, FAQs: Recreational Licenses. Available at https://myfwc.com/license/recreational/faqs/ (last visited January 8, 2024)

<sup>&</sup>lt;sup>42</sup> This includes individuals who are aiding in the take. FWC, *Exemptions*. Available at https://myfwc.com/license/recreational/do-i-need-one/ (last visited January 23, 2024).

<sup>&</sup>lt;sup>43</sup> Outside of this range, FWC offers a five-year resident gold sportsman's license that includes freshwater fishing, hunting, and saltwater fishing licenses and wildlife management area, archery, muzzleloading gun, crossbow, deer, turkey, Florida waterfowl, snook, and lobster permits for \$494.

<sup>&</sup>lt;sup>44</sup> See, FWC, Recreational Freshwater Licenses & Permits. Available at https://myfwc.com/license/recreational/freshwater-fishing/ (last visited January 8, 2024); FWC, Recreational Saltwater Licenses & Permits. Available at

https://myfwc.com/license/recreational/saltwater-fishing/ (last visited January 8, 2024); FWC, *Recreational Hunting Licenses & Permits*. Available at https://myfwc.com/license/recreational/hunting/ (last visited January 8, 2024).

<sup>&</sup>lt;sup>45</sup> See s. 379.353, F.S., for a list of individuals who are exempt from permitting requirements. See also, FWC, Exemptions. Available at https://myfwc.com/license/recreational/do-i-need-one/ (last visited January 8, 2024).

<sup>&</sup>lt;sup>46</sup> FWC, Go Outdoors Florida – The official Licensing and Permitting site of the FWC! Available at

https://license.gooutdoorsflorida.com/Licensing/CustomerLookup.aspx(last visited January 8, 2024).

<sup>&</sup>lt;sup>47</sup> Licensing agents often include bait-and-tackle shops and sports retailers like Wal-Mart and Bass Pro Shop. FWC, FAQs:

Recreational Licenses. Available at https://myfwc.com/license/recreational/faqs/ (last visited January 8, 2024). Individuals can look up local agents through FWC's locate an agent portal. FWC, Locate an Agent. Available at

https://license.gooutdoorsflorida.com/Licensing/LocateAgent.aspx(last visited January 8, 2024).

<sup>&</sup>lt;sup>48</sup> FWC, How to Order. Available at https://myfwc.com/license/recreational/how-to-order/(last visited January 8, 2024).

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

#### B. SECTION DIRECTORY:

- Section 1: Creates s. 110.1185, F.S., relating to administrative leave for organ donation.
- **Section 2:** Creates s. 220.197, F.S., relating to tax credit for expenses related to employee organ donation.
- Section 3: Amends s. 322.291, F.S., relating to driver improvement schools or DUI programs.
- **Section 4:** Amends s. 379.352, F.S., relating to recreational licenses, permits, and authorization numbers to take wild animal life, freshwater aquatic life, and marine life; issuance; costs; reporting.
- Section 5: Amends s. 627.6045, F.S., relating to preexisting condition.
- Section 6: Amends s. 765.5155, F.S., relating to donor registry; education program.
- **Section 7:** Amends s. 765.521, F.S., relating to donations as part of driver license or identification card process.
- Section 8: Provides an effective date of July 1, 2024.

# II. FISCAL ANALYSIS & ECONOMIC IMPACT STATEMENT

- A. FISCAL IMPACT ON STATE GOVERNMENT:
  - 1. Revenues:

None.

2. Expenditures:

Government agencies would need to update their employee leave policies to include the administrative leave for organ donation. This will have an insignificant, negative fiscal impact on state government.

- B. FISCAL IMPACT ON LOCAL GOVERNMENTS:
  - 1. Revenues:

None.

2. Expenditures:

None.

- C. DIRECT ECONOMIC IMPACT ON PRIVATE SECTOR: None.
- D. FISCAL COMMENTS:

None.

## **III. COMMENTS**

- A. CONSTITUTIONAL ISSUES:
  - 1. Applicability of Municipality/County Mandates Provision:

Not Applicable. This bill does not appear to affect county or municipal governments.

2. Other:

None.

B. RULE-MAKING AUTHORITY:

Current law and the bill provide sufficient rule-making authority to implement the provisions of the bill.

C. DRAFTING ISSUES OR OTHER COMMENTS:

None.

# IV. AMENDMENTS/COMMITTEE SUBSTITUTE CHANGES

On January 23, 2024, the Health & Human Services Committee adopted two amendments and reported the bill favorably as a committee substitute. The amendments:

- Deleted a section of the bill relating to tax credits; and
- Made a technical change to correct a reference to the "Department of Business and Professional Regulation" to the "Department of Health."

The analysis is drafted the committee substitute as approved by the Health & Human Services Committee.