

HOUSE OF REPRESENTATIVES STAFF ANALYSIS

BILL #: CS/CS/HB 429 Donation and Transfer of Human Tissue
SPONSOR(S): Health & Human Services Committee; Health Quality Subcommittee; Pigman
TIED BILLS: **IDEN./SIM. BILLS:** SB 514

REFERENCE	ACTION	ANALYST	STAFF DIRECTOR or BUDGET/POLICY CHIEF
1) Health Quality Subcommittee	13 Y, 0 N, As CS	Langston	McElroy
2) Health & Human Services Committee	20 Y, 0 N, As CS	Langston	Calamas

SUMMARY ANALYSIS

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). Transplantation in such cases is necessary because the recipient's organ has failed or has been damaged by disease or injury.

It is important to determine if the potential donor has an infection that could be transmitted to recipients through the transplanted organs and tissues. Currently, between one and two percent of recipients acquire an unexpected disease transmission, including malignancies, as a result of transplant. Section 381.0041, F.S., requires every donation of blood, plasma, organs, skin, or other human tissue be tested for HIV and other communicable diseases prior to transfusion or transplantation.

CS/CS/HB 429 requires DOH to develop and publish on its website an educational pamphlet on the risks and benefits of human cells, tissue, and cellular and tissue-based product transplants. At a minimum, the pamphlet must include:

- An overview of the risk of infectious disease transmission;
- An overview of the standards for donor testing and screening;
- An overview of processing methods intended to reduce the risk of disease or bacterial transmission in donated human cells, tissue, or cellular or tissue-based products;
- The importance of providing limited recipient transplant information to the supplier of the human cells, tissue, or cellular or tissue-based product; and
- Information about the generosity of the human donor who provided the human cells, tissue, or cellular or tissue-based product.

DOH must electronically notify physicians of the availability of this pamphlet.

The bill will have an insignificant negative fiscal impact on DOH, which can be absorbed within existing resources. The bill does not have a fiscal impact on local governments.

The bill provides an effective date of July 1, 2018.

FULL ANALYSIS

I. SUBSTANTIVE ANALYSIS

A. EFFECT OF PROPOSED CHANGES:

Present Situation

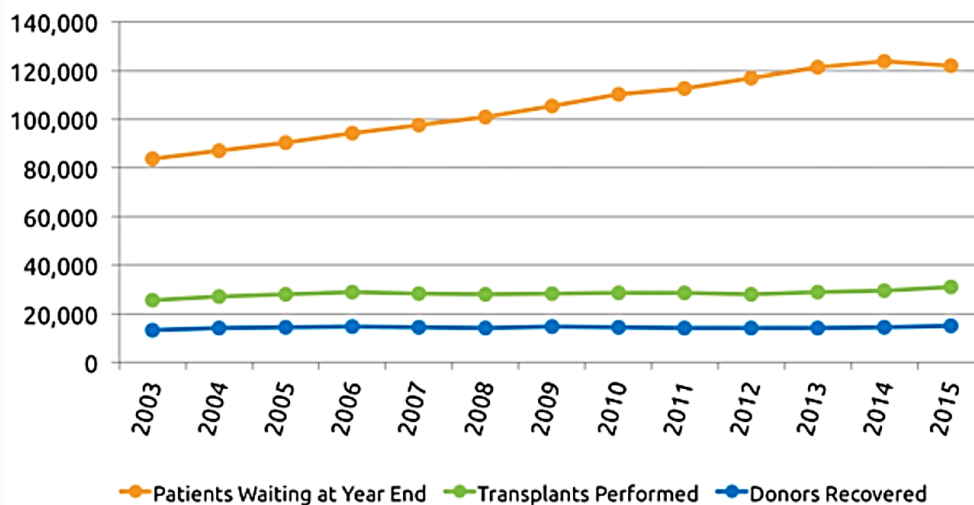
Tissue Donation and Transfer

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). Transplantation in such cases is necessary because the recipient's organ has failed or has been damaged by disease or injury. Transplantable organs include the kidneys, liver, heart, lungs, pancreas and intestine.¹ Transplantable tissue include skin 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 on knees or other joints; veins used in cardiac by-pass surgery; corneas used to restore sight; and bone used in orthopedic surgery to facilitate healing of fractures or prevent amputation.²

A single person can save up to eight lives through organ donation, and dozens more lives may be improved through tissue donation.³ While most organ and tissue donations occur after the donor has died, some organs, including a kidney or part of a liver or lung, and tissues can be donated while the donor is alive.⁴ There are about as many living donors every year as there are deceased donors.⁵

Despite advances in medicine and technology, and increased awareness of organ donation and transplantation, more donors are needed to meet the demand for transplants.⁶

National Organ Shortage 2003-2015⁷



¹ DONATE LIFE FLORIDA, *Frequently Asked Questions*, <https://www.donateliflorida.org/categories/donation/> (last visited January 12, 2018).

² *Id.*

³ *Id.*

⁴ U.S. GOVERNMENT INFORMATION ON ORGAN DONATION AND TRANSPLANTATION, U.S. DEPARTMENT OF HEALTH & HUMAN SERVICES, *How Organ Donation Works*, <https://organdonor.gov/about/process.html> (last visited January 12, 2018).

⁵ *Id.*

⁶ ORGAN PROCUREMENT AND TRANSPLANTATION NETWORK, U.S. DEPARTMENT OF HEALTH & HUMAN SERVICES, <https://optn.transplant.hrsa.gov/> (last visited January 12, 2018).

⁷ *Id.*

Today, there are nearly 120,000 children and adults are waiting for organ transplants, including 5,000 in Florida.⁸

The Organ Procurement and Transplantation Network (OPTN) regulates how donor organs are matched and allocated to patients on the waiting list.⁹ Non-profit, federally designated organ procurement organizations (OPOs) work closely with OPTN, hospitals, and transplant centers to facilitate the organ donation and transplantation process,¹⁰ including conducting a thorough medical and social history of the potential donor to help determine the suitability of his or her organs for transplantation.¹¹

Risk of Infectious Disease Transmission

Currently, between one and two percent of recipients acquire an unexpected disease transmission, including malignancies, through organ and tissue transplants.¹² Possible transmissions include virus transmissions, such as Hepatitis B and C, the human immunodeficiency virus (HIV), and West Nile Virus; bacteria transmissions; fungus transmissions; and parasite transmissions.¹³

Screening and Testing

It is important to determine if the potential donor has an infection that could be transmitted to recipients through the transplanted organs and tissues.¹⁴ This is accomplished through donor interviews and testing.

OPTN policy requires OPOs¹⁵ to conduct a medical and social history interview of the living donor or the deceased donor's next-of-kin to gather information about behaviors that may have exposed the potential donor to certain diseases.¹⁶ OPTN also requires OPOs and living donor recovery centers to test potential donors for:

- HIV
- Hepatitis B
- Hepatitis C
- Syphilis
- Cytomegalovirus
- Epstein Barr Virus
- Tuberculosis (living kidney donors only)

The U.S. Food and Drug Administration (FDA) requires tissue and eye banks to conduct donor screening interviews similar to those required by the OPTN.¹⁷ The FDA also requires donors be tested

⁸ *Supra*, note 3.

⁹ U.S. GOVERNMENT INFORMATION ON ORGAN DONATION AND TRANSPLANTATION, U.S. DEPARTMENT OF HEALTH & HUMAN SERVICES, *The Organ Transplant Process*, <https://organdonor.gov/about/process/transplant-process.html> (last visited January 12, 2018).

¹⁰ DONATE LIFE FLORIDA, *Organ Procurement Organizations and Transplant Centers*, <https://www.donateliflorida.org/local-resources/transplant-centers/> (last visited January 12, 2018).

¹¹ ORGAN PROCUREMENT AND TRANSPLANTATION NETWORK, U.S. DEPARTMENT OF HEALTH & HUMAN SERVICES, *The Basic Path of Donation*, <https://optn.transplant.hrsa.gov/learn/about-donation/the-basic-path-of-donation/> (last visited January 12, 2018).

¹² CENTERS FOR DISEASE CONTROL AND PREVENTION, *Transplant Safety: Outbreak Investigations*, https://www.cdc.gov/transplantsafety/outbreak_investigations.html (last visited January 12, 2018).

¹³ *Id.*

¹⁴ CENTERS FOR DISEASE CONTROL AND PREVENTION, *Transplant Safety: Donor Screening and Testing*, https://www.cdc.gov/transplantsafety/screening_testing.html (last visited January 12, 2018).

¹⁵ U.S. FOOD AND DRUG ADMINISTRATION, U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES, *Vaccines, Blood & Biologics: Tissue Guidances*, <https://www.fda.gov/BiologicsBloodVaccines/GuidanceComplianceRegulatoryInformation/Guidances/Tissue/default.htm>

¹⁶ *Supra*, note 14.

¹⁷ *Id.* The FDA recommends that blood collection centers screen all donations using a screening test authorized for use under an FDA investigational new drug application or use an FDA-approved pathogen-reduction device for plasma and certain platelet products. *Revised Recommendations for Reducing the Risk of Zika Virus Transmission by Blood and Blood Components: Guidance for Industry*, U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES, FOOD AND DRUG ADMINISTRATION, CENTER FOR BIOLOGICS EVALUATION AND RESEARCH,

for HIV, Hepatitis B and C, and syphilis,¹⁸ and tissues that may contain live white blood cells, such as skin, be tested for human T-lymphotropic virus and cytomegalovirus.¹⁹

Section 381.0041, F.S., requires every donation of blood, plasma, organs, skin, or other human tissue be tested for HIV and other communicable diseases,²⁰ prior to transfusion²¹ or transplantation. Additionally, the institution or physician responsible for overseeing the procedure warn the prospective recipient as to the risks of contracting HIV prior to the transplant of an organ or artificial insemination.²²

Sterilization and Inactivation

Once screened, OPOs, tissue banks, and donor recovery centers take additional steps to rid tissue of pathogens that might be present on or within the tissue.²³ Corneas are stored in a solution to reduce bacterial growth.²⁴ Some tissues, such as corneas, blood vessels, heart valves and skin cannot be sterilized because the treatment could damage the tissue; however, other tissues go through a disinfection process.²⁵ Various sterilization techniques have been used to prevent infection include gamma irradiation,²⁶ ethylene oxide gas,²⁷ thermal treatment with moist heat,²⁸ beta-propiolactone, chemical processing, and antibiotic soaks.²⁹

Recipient Follow-Up

It is important that other recipients of organs and tissues from the same donor be quickly traced when a donor-derived disease transmission is suspected or confirmed in a recipient.³⁰ OPTN requires reporting of suspected donor-derived disease transmission in a recipient or new information regarding a donor that indicates risk of disease transmission to recipients.³¹ OPTN requires OPOs to notify the United Network for Organ Sharing (UNOS), who then notifies transplant centers and requests follow up with

(Aug. 2016), available at,

<https://www.fda.gov/downloads/BiologicsBloodVaccines/GuidanceComplianceRegulatoryInformation/Guidances/Blood/UCM518213.pdf>

(last visited January 12, 2018).

¹⁸ *Supra*, note 14.

¹⁹ *Id.*

²⁰ Other communicable diseases must be specified in Department of Health (DOH) rules. S. 381.004(1), F.S. DOH requires donated blood, organs and tissue to be tested for infectious diseases identified in 21 CFR s. 610.40 (which also includes hepatitis B and C) and in the Federal Health Resources and Services Administration's Organ Procurement and Transplantation Network Policy 2.2, as revised 9-1-2012. Rule 64D-2.005(1), F.A.C.

²¹ A blood transfusion is a safe, common procedure in which blood is given to you through an intravenous (IV) line in one of your blood vessels. Blood transfusions are typically done to replace blood lost during surgery or due to a serious injury. NATIONAL HEART, LUNG, AND BLOOD INSTITUTE, U.S., DEPARTMENT OF HEALTH AND HUMAN SERVICES, *What is a Blood Transfusion?*, <https://www.nhlbi.nih.gov/health/health-topics/topics/bt> (last visited January 12, 2018).

²² S. 381.0041(12), F.S.

²³ *Supra*, note 14.

²⁴ *Id.*

²⁵ *Id.*

²⁶ Radiation sterilization is one of the most widespread and successful applications of radiation. Radiation is an acceptable method for sterilization and is based on the ability of ionizing radiation to kill microorganisms. There are two mechanisms for the cell damage and inactivation of bacteria, fungi and viruses due to the direct effect and indirect effect of gamma radiation.

²⁷ Ethylene oxide is a chemical sterilization method which provides both bactericidal and virucidal effects at appropriate concentrations that is widely used commercially for sterilization of health care products. Ethylene oxide is thus not a suitable method of sterilization for tissue allografts; however, peracetic acid-ethanol sterilization procedure has been used for sterilization of bone grafts. Although the peracetic acid treatment is an established sterilization method of bone, dermis and amniotic membrane transplants with no evidence to impair the transplants properties, it has caused significantly reduced biomechanical strength and decreased remodeling activity in anterior cruciate ligament reconstruction tendon grafts.

²⁸ Thermodesinfection has been used for femoral heads excised during hip joint surgery. Thermodesinfection of cancellous bone was found to preserve tensile strength necessary for clinical purposes. Additionally, the process of microwave sterilization was found to be effective for sterilization of bone allografts processed from femoral heads contaminated with Gram-positive and Gram-negative bacteria.

²⁹ Rita Singh, Durgeshwer Singh, and Antaryami Singh, *Radiation sterilization of tissue allografts: A review*, WORLD JOURNAL OF RADIOLOGY, (Apr. 28, 201), available at, <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4840193/> (last visited January 12, 2018).

³⁰ CENTERS FOR DISEASE CONTROL AND PREVENTION, *Transplant Safety: Investigating, Tracking and Reporting Findings*, https://www.cdc.gov/transplantsafety/tracking_infections.html (last visited January 12, 2018).

³¹ CENTERS FOR DISEASE CONTROL AND PREVENTION, *Transplant Safety: CDC's Transplant-Transmitted Infection Toolkit*, <https://www.cdc.gov/transplantsafety/TTI-toolkit.html> (last visited January 12, 2018).

STORAGE NAME: h0429c.HHS

DATE: 1/19/2018

potentially impacted recipients.³² These reports are reviewed by UNOS's Disease Transmission Advisory Committee to determine the likelihood of transplant transmission, educate the transplant community, and inform policy.³³ Additionally, UNOS notifies the Centers for Disease Control and Prevention (CDC)³⁴ and requests that the reporting transplant center or OPO notify local public health authorities.³⁵ Early identification and treatment improves recipient outcomes.³⁶ Additionally, the ability to easily trace unused tissue to storage locations for immediate quarantine can prevent further transplantation of potentially infected tissues.³⁷

Effect of the Bill

CS/CS/HB 429 requires DOH to develop and publish on its website an educational pamphlet relating to the risks and benefits of human cells, tissue, and cellular and tissue-based product transplants. At a minimum, the pamphlet must include:

- An overview of the risk of infectious disease transmission;
- An overview of the standards for donor testing and screening;
- An overview of processing methods intended to reduce the risk of disease or bacterial transmission in donated human cells, tissue, or cellular or tissue-based products;
- The importance of providing limited recipient transplant information to the supplier of the human cells, tissue, or cellular or tissue-based product; and
- Information about the generosity of the human donor who provided the human cells, tissue, or cellular or tissue-based product.

DOH must electronically notify physicians of the availability of the pamphlet.

The bill provides an effective date of July 1, 2018.

B. SECTION DIRECTORY:

Section 1: Amends s. 381.0041, F.S., relating to donation and transfer of human tissue; testing requirements.

Section 2: Provides an effective date.

II. FISCAL ANALYSIS & ECONOMIC IMPACT STATEMENT

A. FISCAL IMPACT ON STATE GOVERNMENT:

1. Revenues:

None.

2. Expenditures:

The bill will have an insignificant negative fiscal impact on DOH related to the cost of publishing the pamphlet on its website, which can be absorbed within existing resources.³⁸

³² Id.

³³ Id.

³⁴ UNOS staff notifies CDC for cases that involve disease clusters, unknown diseases, or nationally notifiable diseases. CDC works first to establish recipient safety and then to determine residency of all involved; relevant health departments are notified promptly should a donor or recipient be within their jurisdiction.

³⁵ *Supra*, note 31.

³⁶ *Supra*, note 30.

³⁷ Id.

³⁸ Email from Paul Runk, Director, Office of Legislative Planning, Florida Department of Health, RE: HB 429 – Amendment Fiscal, (Jan. 16, 2018) (on file with Health and Human Services Committee staff).

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:

None.

C. DRAFTING ISSUES OR OTHER COMMENTS:

None.

IV. AMENDMENTS/ COMMITTEE SUBSTITUTE CHANGES

On December 6, 2017, the Health Quality Subcommittee adopted an amendment that requires DOH to develop and publish on its website an educational pamphlet relating to the risks and benefits of human cells, tissue, and cellular and tissue-based product transplants.

On January 18, 2018, the Health and Human Services Committee adopted an amendment that required that the pamphlet include information on the processing methods intended to reduce the risk of disease or bacterial transmission.

The bill was reported favorably as a committee substitute. The analysis is drafted to the committee substitute as passed by the Health and Human Services Committee.