The Florida Senate

BILL ANALYSIS AND FISCAL IMPACT STATEMENT

(This document is based on the provisions contained in the legislation as of the latest date listed below.)

Prepared By: The Professional Staff of the Committee on Rules

BILL:	CS/SB 514
INTRODUCER:	Health Policy Committee and Senator Young
SUBJECT:	Transplant of Human Tissue
DATE:	February 6, 2018 REVISED:

	ANALYST	STAFF DIRECTOR	REFERENCE	ACTION
1.	Rossitto-Van Winkle	Stovall	HP	**Fav/CS**
2.	Stallard	Cibula	JU	**Favorable**
3.	Rossitto-Van Winkle	Phelps	RC	**Pre-meeting**

Please see Section IX. for Additional Information:

COMMITTEE SUBSTITUTE - Substantial Changes

I. Summary:

CS/SB 514 requires the Department of Health to develop a pamphlet that contains the following information on the risks and benefits of human cell and tissue transplants:

- An overview of the risks of transmission of infectious diseases associated with a transplant;
- A summary of the standards of testing and screening of donors;
- A summary of processing methods used to reduce the risk of the transmission of bacteria and disease;
- A statement acknowledging the importance of limiting information provided to the supplier about the recipient; and
- A statement acknowledging the generosity of donors.

The Department must publish the pamphlet on its website and electronically notify physicians when it is available.

II. Present Situation:

Tissue Donation and Transplantation

Organ and tissue donation and transplantation is the process of surgically removing an organ or tissue from one person (the donor) and transplanting it into another person (the recipient).

Transplantation may be necessary because the recipient's organ or tissue has failed or has been damaged by disease or injury. Transplantable organs include the kidneys, liver, heart, lungs, pancreas and intestine.[1] And 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 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 to prevent amputation.[2]

The Organ Procurement and Transplantation Network (OPTN) regulates how donor organs are matched and allocated to patients on the waiting list.[3] Non-profit, federally designated organ procurement organizations (OPOs) work closely with the OPTN, hospitals, and transplant centers to facilitate the organ donation and transplantation process,[4] including conducting a thorough medical and social history of the potential donor to help determine the suitability of his or her organs for transplantation.[5]

The Department of Health (DOH) is responsible for the state's public health system to promote, protect, and improve the health of all people in the state. This includes regulating human tissue donation and transplantation.[6] Absent limited exceptions, every donation of human tissue, cells, skin, organs, blood, or plasma for transfusion or transplantation to another person must be tested for HIV infection[7] and any other communicable diseases specified by rule of the DOH or undergo a DOH approved process capable of killing the causative agent of those diseases.[8, 9] The DOH, by rule,[10] requires that blood, organs, and tissue be tested for the following additional infectious disease agents, as identified by the federal regulation:

- Hepatitis B virus;
- Hepatitis C virus;
- Human T-lymphotropic virus, type I; and
- Human T-lymphotropic virus, type II.[11]

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[1] Donate Life Florida, *Frequently Asked Questions*, https://www.donatelifeflorida.org/categories/donation/ (last visited Jan. 27, 2018).
[2] *Id*.
[3] 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 Jan. 27, 2018).
[4] Donate Life Florida, *Organ Procurement Organizations and Transplant Centers*, https://www.donatelifeflorida.org/local-resources/transplant-centers/ (last visited Jan. 17, 2018).
[5] Organ Procurement and Transplantation Network, U.S. Department of Health and Human Services, *The Basic Path of Donation*, https://optn.transplant.hrsa.gov/learn/about-donation/the-basic-path-of-donation/ (last visited Jan. 27, 2018).
[6] Section 381.001, F.S.
[7] Testing for HIV infection is required for both type 1and type 2 HIV. *See* 21 C.F.R. §§ 610.40 and 1270.21 (2017).
[8] Section 381.0041(3), F.S.
[9] Section 381.0041(1), (3), F.S.
[10] Rule 64D-2.005, F.A.C.
[11] *See* 21 C.F.R. §§ 610.40 and 1270.21 (2017).

The Zika Virus and Transplant Tissue Testing

In March 2016, the U.S. Department of Health and Human Services, Food and Drug Administration (FDA), Center for Biologics Evaluation and Research issued non-binding recommendations on donor screening to reduce the risk of the Zika virus's transmission to human cells, tissues, and cellular products. The recommendations included the review of a potential donor's medical records for any clinical evidence of the Zika virus. Under the recommendations, a donor was considered ineligible if he or she:

- Had a medical diagnose of a Zika virus infection in the past six months;
- Was a resident of, or traveled to, an area with active Zika virus transmission within the past six months; or
- Had sex with a male diagnosed with a Zika virus infection in the past six months who had resided in, or traveled to, an area with active Zika virus transmission within the past six months.[12]

III. Effect of Proposed Changes:

The bill requires the Department of Health to develop a pamphlet that contains the following information on the risks and benefits of human cell and tissue transplants:

- An overview of the risks of transmission of infectious diseases associated with a transplant;
- A summary of the standards of testing and screening of donors;
- A summary of processing methods used to reduce the risk of the transmission of bacteria and disease;
- A statement acknowledging the importance of limiting information provided to the supplier about the recipient; and
- A statement acknowledging the generosity of donors.

The Department must publish the pamphlet on its website and electronically notify physicians when it is available.

The effective date of the bill is July 1, 2018.

IV. Constitutional Issues:

A. Municipality/County Mandates Restrictions:

None.

B. Public Records/Open Meetings Issues:

None.

[12] The FDA has authority to issue guidance to industry in accordance with 21 CFR 10.115(g)(2). *See* U.S. Department of Health and Human Services, Food and Drug Administration, Center for Biologics Evaluation and Research, *Donor Screening Recommendations to Reduce the Risk of Transmission of Zika Virus by Human Cells, Tissues, and Cellular and Tissue-Based Products - Guidance for Industry*, https://www.fda.gov/downloads/biologicsbloodvaccines/guidancecomplianceregulatoryinformation/guidances/tissue/ucm488582.pdf (last visited Jan. 27, 2018).

C. Trust Funds Restrictions:

None.

V. Fiscal Impact Statement:

A. Tax/Fee Issues:

None.

B. Private Sector Impact:

None.

C. Government Sector Impact:

The Department of Heath will incur an unknown cost in developing the educational pamphlet, in publishing it on the website, and in notifying physicians of the pamphlet's availability.

VI. Technical Deficiencies:

None.

VII. Related Issues:

None.

VIII. Statutes Affected:

This bill substantially amends section 381.0041 of the Florida Statutes.

IX. Additional Information:

A. Committee Substitute – Statement of Substantial Changes:
(Summarizing differences between the Committee Substitute and the prior version of the bill.)

CS/SB 514 by Health Policy on January 23, 2018:
The CS removed the requirement for health care providers to warn potential transplant recipients of the risks of contracting ZIKV. Instead, the DOH must develop a pamphlet addressing the risks and benefits of human cells and tissue transplants; publish the pamphlet on its website; and electronically notify physicians when the pamphlet is available.

B. Amendments:

None.