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 Health Policy

BILL:	CS/SB 514
INTRODUCER:	Health Policy Committee and Senator Young
SUBJECT:	Transplant of Human Tissue
DATE:	January 23, 2018
REVISED:	

	ANALYST	STAFF DIRECTOR	REFERENCE	ACTION
1.	Rossitto-Van Winkle	Stovall	HP	**Fav/CS**
2.			JU	
3.			RC	

Please see Section IX. for Additional Information:

COMMITTEE SUBSTITUTE - Substantial Changes

I. Summary:

CS/SB 514 requires the Department of Health (DOH) to develop a pamphlet that contains certain information on the risks and benefits of human cell and tissue transplants. The DOH must publish the pamphlet on its website, and electronically notify physicians when it is available.

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

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] Transplantable tissue includes 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

[1] Donate Life Florida, *Frequently Asked Questions* https://www.donatelifeflorida.org/categories/donation/ (last visited Jan. 17, 2018).

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 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 human immunodeficiency virus (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] has required 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]

The Zika Virus (ZIKV) and Transplant Tissue Testing

In March 2016, 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 ZIKV 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 ZIKV; and the donor was considered ineligible if he or she had any of the following:

- A medical diagnose of a ZIKV infection in the past six months;
- Was a resident of, or traveled to, an area with active ZIKV transmission within the past six months; or

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[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. 17, 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. 17, 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. ss. 610.40 and 1270.21 (2013).
[8] Section 381.0041(3), F.S.
[9] Section 381.0041(1) and 3, F.S.
[10] Rule 64D-2.005, F.A.C.
[11] See 21 C.F.R. ss. 610.40 and 1270.21 (2013).

- Had sex with a male diagnosed with a ZIKV infection in the past six months who had resided in, or traveled to, an area with active ZIKV transmission within the past six months. [12]

The CDC further recommended that cadaveric donors be ineligible for donation if the cadaver has had a medical diagnosis of the ZIKV in the past six months.[13]

III. Effect of Proposed Changes:

CS/SB 514 requires the DOH to develop a pamphlet on the risks and benefits of human cells and tissue transplants. The DOH must publish the pamphlet on its website, and electronically notify physicians when it is available. The pamphlet must include the following:

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

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

IV. Constitutional Issues:

A. Municipality/County Mandates Restrictions:

None.

B. Public Records/Open Meetings Issues:

None.

C. Trust Funds Restrictions:

None.

V. Fiscal Impact Statement:

A. Tax/Fee Issues:

None.

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[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. 17, 2018).

[13] *See* note 31.

B. Private Sector Impact:

None.

C. Government Sector Impact:

The DOH will incur a cost in developing the educational pamphlet, in publishing it on the website, and in notifying physicians of the pamphlet's availability. The cost is undeterminable at this time.

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.