

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: SB 514

INTRODUCER: Senator Young

SUBJECT: Transplant of Human Tissue

DATE: January 22, 2018

REVISED: _____

	ANALYST	STAFF DIRECTOR	REFERENCE	ACTION
1.	Rossitto-Van Winkle	Stovall	HP	Pre-meeting
2.	_____	_____	JU	_____
3.	_____	_____	RC	_____

I. Summary:

SB 514 requires an institution or physician responsible for transplanting an organ or an allograft,¹ or for artificial insemination, to warn the recipient of the risks of contracting the Zika virus (ZIKV) from the organ, allograft or sperm. The bill provides an exception to the warning requirement for an organ or allograft that has been virally inactivated. The term virally inactivated means the organ or allograft has undergone a validated process to eliminate viral contamination.

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

II. Present Situation:

Tissue Donation and Transplantation

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.² 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 surgery, corneas used to restore

¹ "Allograft" means human tissue that is surgically transplanted from one person to another. See ALLOGRAFT.com available at <http://www.allograftinfo.com/> (last visited Jan. 17, 2018).

² Donate Life Florida, *Frequently Asked Questions* <https://www.donateliflorida.org/categories/donation/> (last visited Jan. 17, 2018).

sight, and bone used in orthopedic surgery to facilitate healing of fractures or prevent amputation.³

The Organ Procurement and Transplantation Network (OPTN) regulates how donor organs are matched and allocated to patients on the waiting list.⁴ Non-profit, federally designated organ procurement organizations (OPOs) work closely with OPTN, hospitals, and transplant centers to facilitate the organ donation and transplantation process,⁵ including conducting a thorough medical and social history of the potential donor to help determine the suitability of his or her organs for transplantation.⁶

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.⁷ Every donation of human tissue, cells, organs, blood, or plasma for transfusion or transplantation to another person must be tested for human immunodeficiency virus (HIV) infection⁸ and any other communicable diseases specified by rule of the DOH.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

Absent limited exceptions, it is impermissible to collect blood, organs, skin, or other human tissue from a human being and hold it for, or actually perform, an implantation, transplantation, transfusion, grafting, or any other method of transfer to another human being without first testing the tissue for HIV and any other communicable disease specified by DOH rule; or without performing a DOH approved process capable of killing the causative agent of those diseases.¹²

The Zika Virus (ZIKV) and Testing

The ZIKV was first isolated in 1947 from a rhesus monkey in the Zika Forest of Uganda, and isolated from a human in 1968 in Nigeria.¹³ In 2007 the ZIKV illness was first detected outside

³ See note 2.

⁴ 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).

⁵ Donate Life Florida, *Organ Procurement Organizations and Transplant Centers* <https://www.donateliflorida.org/local-resources/transplant-centers/> (last visited Jan. 17, 2018).

⁶ 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).

⁷ Section 381.001, F.S.

⁸ Testing for HIV infection is required for both type 1 and type 2 HIV. See 21 C.F.R. ss. 610.40 and 1270.21 (2013).

⁹ Section 381.0041(1), F.S.

¹⁰ Rule 64D-2.005, F.A.C.

¹¹ See 21 C.F.R. ss. 610.40 and 1270.21 (2013).

¹² Section 381.0041(3), F.S.

¹³ Hayes EB. *Zika Virus Outside Africa*, *Emerging Infectious Diseases*, 2009; 15(9):1347-1350. <https://dx.doi.org/10.3201/eid1509.090442>

of Africa and Asia causing an outbreak in Micronesia.¹⁴ According to the Centers for Disease Control and Prevention (CDC) as of February 23, 2016, 34 countries and territories had reported active transmission of the ZIKV.¹⁵

Only about one in five people infected with the ZIKV become symptomatic. The ZIKV fever is a mild illness. Severe disease, requiring hospitalization, is uncommon. Signs and symptoms of the ZIKV may include: acute onset of low-grade fever, rash, joint pain, conjunctivitis (reddening of eye), body aches, headache, eye pain, and vomiting. Treatment is symptomatic since there is no specific treatment against the virus. Illness typically resolves within a week.¹⁶

In early 2016, the first travel-related cases of the ZIKV were identified in Florida. The DOH established an incident management team (IMT) to prepare and respond to the threat of the ZIKV; and is still active. Governor Scott used his executive authority to invest \$62 million to prepare, and attempt to protect, Florida's residents and guests from the ZIKV. The DOH distributed \$25 million in competitive grants for research for better diagnostics, vaccine studies, and to expand knowledge on the short and long term impacts of the ZIKV. Each suspected case of the ZIKV infection is tested at the state public health laboratory.

The ZIKV spreads to people primarily through the bite of an infected *Aedes* species mosquito (*Ae. aegypti* and *Ae. albopictus*). The ZIKV can also be passed through sex from a person who has the ZIKV, to his or her sex partners, and it can be spread from a pregnant woman to her fetus.¹⁷ The ZIKV infection during pregnancy can cause serious birth defects, including microcephaly.¹⁸ Microcephaly has been linked with the following problems:

- Seizures;
- Developmental delay, such as problems with speech or other developmental milestones (like sitting, standing, and walking);
- Intellectual disability (decreased ability to learn and function in daily life);
- Problems with movement and balance;
- Feeding problems, such as difficulty swallowing;
- Hearing loss; and
- Vision problems.¹⁹

These problems can range from mild to severe and are often lifelong. Because a baby's brain is small and underdeveloped, babies with severe microcephaly can have more of these problems than babies with milder microcephaly. Severe microcephaly can also be life-threatening. Because it is difficult to predict at birth what problems a baby will have from microcephaly, babies with

¹⁴ Mark R. Duffy et al., *Zika Virus Outbreak on Yap Island, Federated States of Micronesia*, *N. Engl. J. Med.*, 2009, 360(24): p. 2536-43. <http://www.nejm.org/doi/pdf/10.1056/NEJMoa0805715>.

¹⁵ Centers for Disease Control and Prevention, *Zika Virus: Areas with Zika*, <http://www.cdc.gov/zika/geo/index.html> (last visited Jan. 17, 2018).

¹⁶ See note 25.

¹⁷ Center for Disease Control and Prevention, *Zika: The Basics of the Virus and How to Protect Against It* (June 27, 2017), <https://www.cdc.gov/zika/pdfs/fs-zika-basics.pdf> (last visited Jan. 17, 2018).

¹⁸ Microcephaly is a birth defect where a baby's head is smaller than expected when compared to babies of the same sex and age. Babies with microcephaly often have smaller brains that might not have developed properly. Center for Disease Control and Prevention, *Facts about Microcephaly*, <https://www.cdc.gov/ncbddd/birthdefects/microcephaly.html> (last visited Jan. 17, 2018).

¹⁹ See note 28.

microcephaly often need close follow-up through regular check-ups with a healthcare provider to monitor their growth and development.

Congenital Zika syndrome is a unique pattern of birth defects found among fetuses and babies infected with ZIKV during pregnancy. Congenital Zika syndrome is described by the following five features:

- Severe microcephaly where the skull has partially collapsed;
- Decreased brain tissue with a specific pattern of brain damage;
- Damage (i.e., scarring, pigment changes) to the back of the eye;
- Joints with limited range of motion, such as clubfoot; and
- Too much muscle tone restricting body movement soon after birth.

Not all babies born with congenital ZIKV infection will have all of these problems. Some infants with congenital ZIKV infection who do not have microcephaly at birth may later experience slowed head growth and develop postnatal microcephaly.

Recognizing that the ZIKV is a cause of certain birth defects does not mean that every pregnant woman infected with the ZIKV will have a baby with a birth defect. It means that infection with the ZIKV during pregnancy increases the chances for these problems. Scientists continue to study how the ZIKV affects mothers and their children to better understand the full range of potential health problems that the ZIKV infection during pregnancy may cause.

The ZIKV can also cause other problems. Several countries that have experienced the ZIKV outbreaks have reported increases in people who have Guillain-Barré syndrome (GBS).²⁰ Current CDC research suggests that GBS is strongly associated with the ZIKV; however, only a small proportion of people with the ZIKV infection get GBS.

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
- 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.²¹

²⁰ Guillain-Barré syndrome (GBS) is an uncommon sickness of the nervous system in which a person's own immune system damages the nerve cells, causing muscle weakness, and sometimes, paralysis. Symptoms of GBS include weakness of the arms and legs and, in severe cases, can affect the muscles that control breathing. These symptoms can last a few weeks or several months. Most people fully recover from GBS, though some people have permanent damage. Very few people die from GBS. Center for Disease Control and Prevention, *Zika and Guillain-Barre' Syndrome* (August 9, 2016), <https://www.cdc.gov/zika/healtheffects/gbs-qa.html> (last visited Jan. 17, 2018).

²¹ 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*,

- 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.²²

Currently there are no federal or Florida statutes, or administrative rules that require an institution, or physician responsible for overseeing a tissue or organ transplant to test the blood, plasma, organs, skin or other human tissue for transplant or transfusion for the ZIKV.

III. Effect of Proposed Changes:

The bill requires an institution, or physician, responsible for transplanting an organ, an allograft, or semen during artificial insemination, to warn the recipient of the tissue of the risks of contracting ZIKV from the organ or allograft being transplanted into them.

The bill provides an exception to the recipient warning requirement if the organ or allograft²³ has been virally inactivated. The bill defines “virally inactivated” as an organ or allograft that has undergone a validated process to eliminate viral contamination.²⁴

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.

<https://www.fda.gov/downloads/biologicsbloodvaccines/guidancecomplianceregulatoryinformation/guidances/tissue/ucm488582.pdf> (last visited Jan. 17, 2018).

²² See note 31.

²³ See note 1.

²⁴ “A validated process to eliminate viral contamination” is a scientifically validated, method of viral inactivation or viral removal. Well recognized methods of viral inactivation include pasteurization, dry heat, vapor heat, solvent/detergent and low (acid) pH. Well recognized methods of viral removal are precipitation, chromatography and nanofiltration. The selection of the method to be employed for viral inactivation and removal depends on the size and lability of the protein being prepared, the method(s) of purification the manufacturer wishes to use, and the nature and titer of the viruses of concern. Each method of inactivation and removal has special characteristics that need to be taken into account. From a virus safety perspective, the best procedures will use a combination of complementary methods because combinations have the advantage of increasing the spectrum of viruses covered as well as increasing the total quantity of virus that is eliminated. See World Health Organization, WHO Technical Report, Series No. 924, 2004, *Guidelines on viral inactivation and removal procedures intended to assure the viral safety of human blood plasma products* (Nov. 19, 2004), http://www.who.int/bloodproducts/publications/WHO_TRS_924_A4.pdf (last visited Jan. 17, 2018).

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:

None.

VIII. Statutes Affected:

This bill substantially amends section 381.0041 of the Florida Statutes.

IX. Additional Information:

A. Committee Substitute – Statement of Changes:

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

None.

B. Amendments:

None.