HOUSE OF REPRESENTATIVES STAFF ANALYSIS

BILL #: CS/HB 1155 Anatomical Gifts

SPONSOR(S): Health Quality Subcommittee; La Rosa TIED BILLS: IDEN./SIM. BILLS: SB 1086

REFERENCE	ACTION	ANALYST	STAFF DIRECTOR or BUDGET/POLICY CHIEF
1) Health Quality Subcommittee	14 Y, 0 N, As CS	Gilani	McElroy
2) Health & Human Services Committee			

SUMMARY ANALYSIS

Part V of ch. 765, F.S., regulates the procurement, donation, and use of anatomical gifts. An anatomical gift is the donation of all or part of a human body after the donor's death, which is only used for transplantation, therapy, research, or education.

Any person may make an anatomical gift by executing a document or using some other mechanism to verify the intent to do so. Examples include a signed organ and tissue card, registering online with the donor registry, a driver's license signifying an intent to donate, or an executed will.

Currently, only the following entities may receive an anatomical gift:

- Any procurement organization (e.g. tissue bank, eye bank) or accredited medical or dental school, college, or university for education, research, therapy, or transplantation.
- Any individual specified by name for therapy or transplantation needed by that individual.
- The anatomical board or a nontransplant anatomical donation organization (a tissue bank or other organization that facilitates nontransplant anatomical donations) for donation of the whole body for medical or dental education or research.

Donors may specify by name which of these entities they wish to donate their human remains.

HB 1155 expands the list of entities that may receive anatomical gifts to include a nonprofit surgical training center that meets certain conditions. The bill defines a nonprofit surgical training center as a nonprofit center owned by a statutory teaching hospital, which offers multidisciplinary learning opportunities, including at least 100 hours of certified continuing medical education courses. The bill prohibits a nonprofit surgical training center from giving an anatomical gift to another facility and requires the nonprofit surgical training center to contract with a licensed funeral director to dispose of or transport the anatomical gifts. Additionally, a nonprofit surgical training center must limit its advertisement of its anatomical gift program to hospitals, nursing homes, or hospice programs owned or controlled wholly by its parent company.

The bill has no fiscal impact on state or local governments.

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

This document does not reflect the intent or official position of the bill sponsor or House of Representatives. STORAGE NAME: h1155a.HOS

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FULL ANALYSIS

I. SUBSTANTIVE ANALYSIS

A. EFFECT OF PROPOSED CHANGES:

Present Situation

Anatomical Gifts

Part V of ch. 765, F.S., regulates the procurement, donation, and use of anatomical gifts. An anatomical gift is the donation of all or part of a human body after the donor's death, which is to only be used for transplantation, therapy, research, or education.¹

Any person may make an anatomical gift by:2

- 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 an identification card issued by the Department of Highway and Motor Vehicles.³
- 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.⁴
- Expressing a wish to donate in a document other than a will, so long as the document is signed by the donor in the presence of two witnesses who also 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 also sign the document in the donor's presence.

Section 765.513(1), F.S., limits the persons or entities that may receive an anatomical gift and the conditions for such gift:

- Any procurement organization⁵ or accredited medical or dental school, college, or university for education, research, therapy, or transplantation.
- Any individual specified by name for therapy or transplantation needed by him or her.
- The anatomical board or a nontransplant anatomical donation organization⁶ for donation of the whole body for medical or dental education or research.

Donors may select by name which eligible person or entity to whom they gift their human remains.⁷ Donors who list multiple purposes for their human remains in their gifting document⁸ will have their donation prioritized first for transplantation or therapy, if suitable, and then for research or education.⁹

⁹ S. 765.513(2), F.S.

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¹ S. 765.511(2), F.S.

² S. 765.512(1), S. 765.514(1), F.S.

³ Revocation, suspension, expiration, or cancellation of the driver license or identification card does not invalidate the gift, s. 765.514(c), F.S.

F.S.

⁴ The gift becomes effective upon the death of the testator without waiting for probate. If the will is not probated or declared invalid for testamentary purposes, the gift is nevertheless valid to the extent that it has been acted upon in good faith. S. 765.514(1)(e), F.S.

⁵ "Procurement organization" means an organ procurement organization, eye bank, or tissue bank, s. 765.511(19), F.S.

⁶ "Nontransplant anatomical donation organization" means a tissue bank or other organization that facilitates nontransplant anatomical donation, including referral, obtaining informed consent or authorization, acquisition, traceability, transport, assessing donor acceptability, preparation, packaging, labeling, storage, release, evaluating intended use, distribution, and final disposition of nontransplant anatomical donations, s. 406.49, F.S.

⁷ S. 765.514(2), F.S.

⁸ A gifting document or "document of gift" is any of the documents or mechanisms used in making an anatomical gift under s. 765.514, F.S. S. 765.511(8), F.S.

Nontransplant Anatomical Donation Organizations

The American Association of Tissue Banks (AATB) is an organization that promulgates industry standards and accredits tissue banks in both the United States and Canada. ¹⁰ In 2012, the AATB also developed an accreditation standard for nontransplant anatomical donation organizations (NADO). ¹¹ A NADO, commonly referred to as a body broker, stores human remains for the purposes of research, rather than transplant.

An accredited NADO facilitates a nontransplant anatomical donation (NTAD) by overseeing referrals, obtaining informed consent or authorization, acquisition, traceability, transport, assessing donor acceptability, preparation, packaging, labeling, storage, release, evaluating intended use, distribution, and final disposition of an NTAD. ¹² Currently, the AATB has accredited seven NADOs in the U.S. and at least three of these operate in Florida. ¹³

According to media reports, prices for human remains obtained through a NADO can range from \$3,000 to \$10,000.¹⁴ Such prices may reflect the costs of final disposition, paid by NADOs on behalf of families. According to media reports, funeral home directors will often refer families to NADOs if they are unable to afford after-life expenses, and in some instances, will also receive monetary incentives for their referrals.¹⁵

Anatomical Board

Body donor programs were first created in Florida in the 1950s as medical schools were being established in the state. ¹⁶ In 1970, the University of Florida College of Medicine (UF) received authorization from the Board of Regents ¹⁷ to create an anatomical board that would oversee the donation and use of bodies for anatomical education and medical research. ¹⁸ In 1996, the Legislature created the state Anatomical Board (Board), codifying this program in statute. ¹⁹ The Board is headquartered at the UF Health Center and is comprised of representatives from the medical schools in the state. ²⁰

The Board is authorized to receive human remains from different sources throughout the state and is responsible for the equitable distribution of human remains among the medical and dental schools, teaching hospitals, medical institutions, and health-related teaching programs that require human remains for study.²¹

²¹ Ss. 406.57(1); 406.56; 406.50, F.S.

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¹⁰ AMERICAN ASSOCIATION OF TISSUE BANKS, *About Us*, https://www.aatb.org/?q=about-us (last visited Jan. 22, 2018). The AATB has produced best practice standards for the operation of tissue banks since 1984. The association also provides an educational network for member organizations to encourage the dissemination of new practices.

¹¹AMERICAN ASSOCIATION OF TISSUE BANKS, *Policies for Non-Transplant Anatomical Donation Organizations*, https://www.aatb.org/?q=content/policies-non-transplant-anatomical-donation-organizations (last visited Jan. 22, 2018).

¹³ AMERICAN ASSOCIATION OF TISSUE BANKS, *Accredited Bank Search*, https://www.aatb.org/?q=content/accredited-bank-search (last visited Jan. 22, 2018).

¹⁴ Brian Grow and John Shiffman, *The Body Trade: Body Brokers*, REUTERS (Oct. 24, 2017), https://www.reuters.com/investigates/special-report/usa-bodies-brokers/ (last visited Jan. 22, 2018). Additionally, some NADOs will divide the human remains and sell parts separately for similar prices.

¹⁶ ANATOMICAL BOARD OF THE STATE OF FLORIDA, About Us, http://anatbd.acb.med.ufl.edu/about-us/ (last visited Jan. 17, 2018).

¹⁷ The Florida Board of Regents governed the state university system of Florida from 1965 to 2001. These powers are now held by the Florida Board of Governors.

¹⁸ Supra note 16.

¹⁹ S. 406.49(1), F.S.; ch. 96-251, Laws of Fla. Prior to 1996, the Division of Universities of the Department of Education was responsible for these functions.

²⁰ Supra note 16. Medical schools represented include: University of Florida, University of Miami, University of South Florida, University of Central Florida, Florida State University, and Nova Southeastern University Osteopathic School of Medicine.

The Board inspects the institutions prior to distribution of any human remains, and the human remains cannot be used for anything other than medical education or research.²² The Board may also loan the remains to accredited colleges of mortuary science or to medical or dental examining boards for educational or research purposes.²³

Distribution of Human Remains

The Board receives its human remains solely from anatomical gifts since unclaimed human remains are often unsuitable for distribution.²⁴ The number of anatomical donations made to the Board has consistently decreased in the past several years, and that trend is projected to continue.²⁵

The Board first distributes human remains to the medical schools, then to other entities such as the research institutions or teaching hospitals.²⁶ The Board is currently unable to meet the schools' demands for human remains, and with new medical schools and programs opening in the state, the Board expects this disparity to increase.²⁷ Due to the prioritization in distribution and the shortage of human remains, the Board does not have enough human remains to supply research institutions or teaching hospitals.28

Statutory Teaching Hospitals

A statutory teaching hospital is any Florida hospital that:²⁹

- Is officially affiliated with an accredited Florida medical school;
- Actively offers at least seven different graduate medical education programs accredited by the Accreditation Council for Graduate Medical Education or the Council on Postdoctoral Training of the American Osteopathic Association; and
- Has at least 100 or more full-time equivalent resident physicians.

The Director of the Agency for Health Care Administration is responsible for determining which hospitals meet this definition and giving this designation.³⁰ Currently, there are at least 27 statutory teaching hospitals in Florida.31

Effect of the Bill:

HB 1155 expands the list of entities that may receive anatomical gifts to include a nonprofit surgical training center that meets certain conditions:

- Does not provide human remains to another facility;
- Contracts with a licensed funeral director to dispose of and transport human remains: and
- Only promotes its anatomical gift program in hospitals, nursing homes, or hospice programs that are wholly owned or controlled by its parent company.

²³ S. 406.57(2), F.S.

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²² S. 406.59, F.S.

²⁴ S. 406.50, F.S., authorizes the Anatomical Board to receive unclaimed human remains in certain circumstances. However, citing health concerns (unknown health conditions, risk of infectious diseases), the Board rejects most unclaimed human remains and has not accepted any unclaimed human remains in the past five or more years. Email from Dr. William Dunn, Executive Director, Anatomical Board, RE: Inquiry on Anatomical Gifts (Jan. 23, 2018)(on file with staff in the House Health and Human Services Committee).

Email from Dr. William Dunn, Executive Director, Anatomical Board, RE: Inquiry on Anatomical Gifts (Jan. 23, 2018)(on file with staff in the House Health and Human Services Committee). Beginning in FY 14-15, the anatomical donations have been as follows: 393; 366; 342; 320 (projected). 26 Id.

ld. There is a projected shortage of at least 30 human remains for FY 2018-19.

²⁹ S. 408.07(45), F.S.

³⁰ S. 408.07(45), F.S.

³¹ AGENCY FOR HEALTH CARE ADMINISTRATION, Facility/Provider Search http://www.floridahealthfinder.gov/FacilityLocator/ListFacilities.aspx (last visited Jan. 24, 2018).

Currently, anatomical gifts may only be made to the anatomical board, a specific person for transplantation or therapy, a nontransplant anatomical donation organization or a procurement organization (i.e. a tissue bank, eye bank, organ procurement organization), or an accredited medical or dental school.

The bill defines a nonprofit surgical training center as a nonprofit center, which is owned by a statutory teaching hospital, and offers multidisciplinary learning opportunities, including at least 100 hours of certified continuing medical education courses.

There are currently at least 27 statutory teaching hospitals in Florida which may have a nonprofit center that meets the bill's definition of a nonsurgical training center. 32 The bill allows any of these entities that qualify to solicit and receive anatomical gifts from patients or other individuals that previously could have only been donated to a transplant patient, the anatomical board, an accredited medical or dental school, nontransplant anatomical donation organization or other tissue bank.

The bill prohibits a nonprofit surgical training center from giving an anatomical gift to another facility, meaning these entities will not be able to give or sell these human remains to any other facilities or organizations, even if the human remains are no longer of use to them.

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

B. SECTION DIRECTORY:

Section 1: Amends s. 765.513(1), F.S., relating to donees of anatomical gifts.

Section 2: Provides an effective date.

II. FISCAL ANALYSIS & ECONOMIC IMPACT STATEMENT

A. FISCAL IMPACT ON STATE GOVERNMENT:

1. Revenues:

None.

2. Expenditures:

None.

B. FISCAL IMPACT ON LOCAL GOVERNMENTS:

1. Revenues:

None.

2. Expenditures:

None.

C. DIRECT ECONOMIC IMPACT ON PRIVATE SECTOR:

To the extent that nonsurgical training centers, as defined in the bill, currently purchase human remains through a NADO, the bill will have an indeterminate, positive impact. According to media reports, prices for human remains obtained through a NADO can range from \$3,000 to \$10,000.33 The bill authorizes individuals to donate their human remains directly to a nonsurgical training center. This potentially reduces the number of human remains that a nonsurgical training center will have to purchase.

33 Supra note 14.

³² Id.

The bill may have an indeterminate, negative impact on medical and dental schools and other educational institutions that currently receive human remains from the Board. The Board charges these institutions \$2,600 per body.³⁴ The Board is currently unable to meet the schools' demands for human remains, and with new medical schools and programs opening in the state, the Board expects this disparity to increase. 35 There are currently 27 statutory teaching hospitals which may own a nonprofit center that qualifies as a nonsurgical training center under the bill. This could potentially reduce the number of human remains that the Board receives. To the extent that this bill reduces the number of anatomical gifts the Board receives and distributes, these educational institutions may have to purchase human remains from other sources, the prices for which can range from \$3,000 to \$10,000 per body.³⁶

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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 January 24, 2018, the Health Quality Subcommittee adopted an amendment that:

- Narrows the type of entities eligible to receive anatomical gifts from hospital owned entities that provide learning opportunities to statutory teaching hospital owned entities that provide learning opportunities, including at least 100 hours of certified continuing medical education.
- Requires nonprofit surgical training centers to contract with a licensed funeral director to dispose of and transport anatomical gifts.
- Limits a nonprofit surgical training center's advertising of its anatomical gift program to hospitals. nursing homes, or hospice programs owned or controlled by its parent company.

The bill was reported favorably as a committee substitute. The analysis is drafted to the committee substitute as passed by the Health Quality Subcommittee.

³⁶ Supra note 14.

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Supra note 25. See also ANATOMICAL BOARD OF THE STATE OF FLORIDA, General Information, http://anatbd.acb.med.ufl.edu/donorpacket/general-information/ (last visited Jan. 22, 2018). These costs are determined by the funeral home directors and not the Anatomical Board.

ld. There is a projected shortage of at least 30 human remains for FY 2018-19.