HOUSE OF REPRESENTATIVES STAFF ANALYSIS

BILL #: HB 289 w/CS Nick Oelrich Gift of Life Act/Organ Donation

SPONSOR(S): Cretul, Clarke and others

TIED BILLS: None. IDEN./SIM. BILLS: 1st ENG/SB 530

REFERENCE	ACTION	ANALYST	STAFF DIRECTOR	
1) Health Care	12 Y, 7 N w/CS	Chavis	Collins	
2) Judiciary	13 Y, 1 N w/CS	Birtman	<u>Havlicak</u>	
3)		· -		
4)				
5)	·			

SUMMARY ANALYSIS

Organ transplantation takes place when an organ from one person is surgically removed, and placed into another person. It is a treatment in situations where a person's organ has failed because of illness or injury. Replacing the organ may be the only treatment choice for the patient or the best among several options. Since the 1970s, when organ transplantation became an established medical procedure, the number of organ transplants performed each year in the United States has grown from 12,618 in 1988 to 20,961 in 1998; and the number of centers performing this surgery has grown from 235 in 1988 to 278 today. Nationally, according to the United Network for Organ Sharing, the number of patients awaiting transplantation, as of March 28, 2003, was 80,769. While the need for organ transplant has grown dramatically, the donation of organs has grown much more slowly and, according to the U.S. Department of Health and Human Services, 15 Americans die each day while waiting for an organ to become available.

HB 289/CS creates the "Nick Oelrich Gift of Life Act," revising Part V of chapter 765, F.S., governing anatomical gifts, as follows:

- Prohibits a family member, guardian, representative ad litem, or health care surrogate of an adult donor
 who has made an anatomical gift from modifying, denying, or preventing a decedent's prior wish or
 intent to donate his or her organs;
- Specifies that when a decedent has executed an agreement concerning an anatomical gift, the document is evidence of legally sufficient informed consent to donate an anatomical gift;
- Authorizes a decedent's medical provider or family member or other third party to furnish medical records, upon request, regarding the decedent's medical and social history;
- Eliminates the option of amending or revoking an anatomical gift through an oral statement made to a spouse;
- Specifies that one of the two witnesses to an oral amendment or revocation of a written document making an anatomical gift must not be a family member; and
- Eliminates the validity of a signed document amending or revoking a donor's anatomical gift if the document is found in his or her effects in lieu of on or about his or her person.

The act takes effect on July 1, 2003.

FULL ANALYSIS

I. SUBSTANTIVE ANALYSIS

A. DOES THE BILL:

1.	Reduce government?	Yes[]	No[]	N/A[x]
2.	Lower taxes?	Yes[]	No[]	N/A[x]
3.	Expand individual freedom?	Yes[]	No[x]	N/A[]
4.	Increase personal responsibility?	Yes[x]	No[]	N/A[]
5.	Empower families?	Yes[]	No[x]	N/A[]

For any principle that received a "no" above, please explain:

To the extent that this bill makes it more difficult for an individual to revoke a decision regarding an anatomical gift, it appears that individual freedom is not expanded. To the extent that donors may no longer revoke an anatomical gift by an oral statement made to a spouse, it would appear that this bill does not empower families.

B. EFFECT OF PROPOSED CHANGES:

This bill creates the "Nick Oelrich Gift of Life Act," relating to anatomical gifts, as follows:

- Prohibits a family member, guardian, representative ad litem, or health care surrogate of an adult donor who has made an anatomical gift from modifying, denying, or preventing a decedent's prior wish or intent to donate his or her organs;
- Specifies that the executed agreement is evidence of legally sufficient informed consent to donate an anatomical gift;
- Authorizes the decedent's medical provider, family, or a third party to furnish medical records requested concerning the decedent's medical and social history;
- Eliminates the option of amending or revoking an anatomical gift through an oral statement made to a spouse;
- Specifies that one of the two witnesses to an oral amendment or revocation of a written document making an anatomical gift must not be a family member; and
- Eliminates the validity of a signed document amending or revoking a donor's anatomical gift if the document is found in his or her effects in lieu of on or about his or her person.

The act takes effect on July 1, 2003.

Nick Oelrich

Nick Oelrich was the son of Alachua County Sheriff Stephen Oelrich. He was a high school football player and an avid golfer. In 1995, Sheriff Oelrich's 18-year old son died shortly after his graduation from Gainesville High School as a result of a fatal fall. Apparently, 108 people benefited from the donation of the son's organs and tissues. As a result of his experience, Sheriff Oelrich proposed the formation of the Gift of Life Foundation to the National Sheriffs' Association (NSA) in March 1997. The NSA voted to establish the NSA Gift of Life Foundation for the purpose of promoting organ and tissue donation awareness on national, regional, and local levels. The NSA Gift of Life Committee was established with the goal of enlisting the assistance of every Sheriff's Office in the United States in educating the law enforcement community and our society on the importance of giving the gift of life. Sheriff Oelrich serves as the NSA's national spokesperson for organ and tissue donation, as well as chairman of the Gift of Life Foundation.¹

STORAGE NAME: DATE:

h0289c.ju.doc April 22, 2003

Gift of Life Foundation. [http://www.nsagiftoflife.org]

Florida Law

In an effort to encourage organ and tissue donation, the 1969 Legislature enacted legislation modeled after the national Uniform Anatomical Gift Act. Part V of ch. 765, F.S., establishes the process by which individuals, their families, or others may donate organs and tissue.² One of the underlying expressions of legislative intent is to encourage and aid the development of reconstructive medicine and surgery and the development of medical research by regulating the gift of the body, or parts of the body, after the death of a donor.

Any person able to make a will may donate all or part of his or her body for the purpose of transplantation or for medical research.³ An adult donor's anatomical gift unless revoked by the donor is irrevocable. The consent or concurrence of another person prior to the procurement of the organ or tissue is not required. However, it is common practice for those entities procuring organs or tissues to acquiesce to the wishes of the family or quardian even if it modifies or overrides a decedent's expressed wish to make an anatomical gift. The donee is prohibited from accepting the gift if the donee has actual notice of contrary indications by the decedent, or if the spouse made the gift, an objection by an adult son or daughter.⁴ Reportedly, out of compassion and respect for the donor's family/guardian at a very stressful or emotional time, and out of concern for public perception and potential legal ramifications, organ procurement organizations are reluctant to procure organs without that concurrence or additional consent from the family member or guardian.

In the absence of a written document to make an anatomical gift, and provided there is no evidence to the contrary of the deceased donor's wishes, any family member from the specified classes of relatives or persons may make an anatomical gift of a decedent's body or part thereof, unless there is opposition from a member of the same or higher specified class of relatives. Persons who may donate all or part of a decedent's body include the spouse, an adult son or daughter, either parent, an adult brother or sister, a grandparent, the guardian of the person at the time of death, or a representative ad litem appointed by the court.5

A person may make an anatomical gift by a will or another signed document including a designation made during the application or renewal for a state-issued driver's license. If the donation is included within the donor's will, the donation becomes effective upon the donor's death without waiting for probate. The document must be executed in the presence of two witnesses.⁶

A person may actually specify a hospital, a physician, a school, facility or even an individual as a donee of an anatomical gift. However, the law prohibits restrictions on possible recipients if based on race, color, religion, sex, national origin, age, physical handicap, health status, marital status, or economic status. A person may also designate the surgeon or physician to carry out his or her donation wish but that physician or surgeon who serves as the recipient of the donation cannot participate in the actual removal or transplantation process.

An amendment or revocation of an anatomical gift can be made through:

A signed statement delivered to the donee:

STORAGE NAME: h0289c.ju.doc PAGE: 3 April 22, 2003

DATE:

² Organs encompass the heart, lung, liver, kidney, pancreas, and intestine. Tissue refers to cornea, bone, cartilage, skin, heart valves, and saphenous vein.

See s. 765.512, F.S.

⁴ See s. 765.512(4), F.S.

⁵ See s. 765.512(3), F.S.

⁶ See s. 765.514, F.S.

⁷ See s. 765.513, F.S., for the comprehensive list of donees: 1) hospital, surgeon, or physician for medical or dental education, research, therapy, or transplantation; 2) medical or dental school, college, or university; 3) bank or storage facility for medical or dental science, therapy, or transplantation; or 4) specified individual.

- An oral statement to his or her spouse:
- An oral statement in the presence of two persons and communicated to the donor's family or attorney or to the donee;
- An oral statement to the attending physician during the person's terminal illness or injury; or
- A signed document found on the donor's person or in the donor's effects.⁸

Other legal obligations have differing requirements regarding revocation. A will or codicil may be revoked by writing or by act;⁹ an advance directive or designation of a surrogate may be revoked by writing, by act, or by oral expression; 10 consent to place a child for adoption must be revoked in writina.11

The Agency for Health Care Administration (agency) oversees the organ procurement program in Florida. The agency certifies procurement organizations¹² to conduct business in Florida, provides donor education, and maintains an organ and tissue donor registry in cooperation with the Department of Highway Safety and Motor Vehicles (DHSMV). The agency provides DHSMV with the donor registration forms. DHSMV provides a weekly electronic transfer of these executed forms to the agency for the registry. 13 These forms are paid for from the Organ and Tissue Donor Education and Procurement Trust Fund. Moneys deposited into the trust fund must be used exclusively for the implementation, administration, and operation of the certification program and the advisory board, for maintaining the organ and tissue donor registry, and for organ and tissue donor education.

Organ Donation

Researchers began experimenting with organ transplantation on animals and humans in the 18th century. Over the years, scientists have experienced many failures, but by the mid-20th century, they were performing successful organ transplants. Transplants of kidneys, livers, hearts, pancreata, intestine, lungs, and heart-lungs are now considered routine medical treatment. In the last 20 years, important medical breakthroughs such as tissue typing and immunosuppressant drugs have allowed for a larger number of organ transplants and a longer survival rate for transplant recipients. Unfortunately, the need for organ transplants continues to exceed the supply of organs. ¹⁴ As medical technology improves and more donors become available, the number of people who live longer and healthier lives continues to increase each year.

By federal mandate, all states must have legislation, requiring hospitals to set up protocols for discussing the possibility of organ donation with the families of deceased patients. This is called "Required Request" or "Routine Inquiry." By signing a "Uniform Donor Card," an individual indicates his or her wish to be a donor.

While traditionally, deceased donors were young adults with traumatic head injuries, the trend in recent vears has been to older people dving from cerebrovascular event, such as strokes. Since 1996. deceased donors have been older on average than the general population. The percentage of

STORAGE NAME: h0289c.ju.doc PAGE: 4 April 22, 2003

DATE:

⁸ See s. 765.516, F.S.

⁹ See ss. 732.505 and 732.506, F.S. Neither section allows for oral revocation.

¹⁰ See s. 765.104, F.S. Oral revocation must be made in the presence of a third person.

¹¹ See s. 63.082, F.S.

¹² Fifty-nine organ procurement organizations (OPOs) across the United States identify donors and coordinate organ retrieval by surgical teams. OPOs and tissue banks recover, preserve, and distribute organs and tissues for transplant. Each OPO has a geographic region within which it serves hospitals where potential donors have been identified. Procurement and Transplantation Network, under a government contract, establishes allocation policy based on input from transplant professionals, patients, donor groups, and the public. Ultimately, these policies determine, for any given donor, which waiting patient has the highest priority. [http://www.unos.org and http://www.hrsa.gov] As of March 2003, 3.4 million of the 16 million active Florida driver's licensees carry an organ donor notation.

¹⁴ United Network for Organ Sharing, "The national waiting list for most transplantable organs has continued to grow, with the exception of the heart, where the wait list growth has leveled somewhat in recent years, and heart-lung, which has decreased." [http://www.unos.org]

transplant recipients over fifty has steadily grown as well. In addition, living kidney donors now account for nearly 52 percent of all kidney donors and the number of living donors has grown as well.¹⁵

How Organ Donation Works

Each year, tens of thousands of people in the U.S. die from accidental head trauma, gunshot wounds to the head, cerebral vascular accidents (strokes), or other conditions like heart attacks which result in prolonged lack of oxygen to the brain. Many of these people are admitted to a hospital for observation and treatment prior to their death. Sometimes, their brain function progressively deteriorates over several days, culminating in the determination of brain death. The diagnosis of brain death is made when a patient with a known cause of brain injury shows no sign of responsiveness, requires a mechanical ventilator to breathe, and has no evidence of blood flow or electrical activity in the brain over an extended period of time. Tests such as an electroencephalogram (EEG) or a cerebral blood flow study are often performed to confirm the diagnosis.

During this evaluation process, doctors and nurses may identify these patients as possible organ donors and contact the local organ procurement organization (OPO). The OPO staff are available 24 hours a day to consult with the medical team and to come to the hospital to meet with the families of these patients. The OPO staff first attempts to determine if the patient has made a designation of an anatomical gift and then discusses with the family their finding. OPO staff are experts at presenting the family the appropriate information regarding organ donation. Organ donation is only considered when there is irreversible and non-survivable brain injury.

The OPO staff conducts an extensive review of the patient's medical and social history. Great care is taken to ensure that no diseases such as cancer or AIDS will be transmitted to the organ transplant recipients. Additional testing to determine the medical condition of specific organs such as the heart or the pancreas is performed. Laboratory tests to screen for hepatitis and AIDS are also performed prior to the actual surgery to recover the organs.

While the potential donor is being evaluated further, the OPO staff contact the transplant programs to coordinate the timing and plans for organ recovery surgery. Organs are allocated according to predetermined policies that consider the medical urgency of the patients waiting, the length of time waiting, blood type and size matching, and various other factors.

Once all suitable organs have been accepted by transplant programs, the surgical teams travel to the hospital to perform the organ recovery procedure. The ventilator continues to provide oxygen to the donor's bloodstream, which in turn allows the heart to keep beating and the blood to circulate. The organ recovery surgery is performed in the same fashion as any other operation, in the operating room, under sterile conditions, using standard surgical instruments and techniques. The operation may take from one to four hours, or longer, depending on which organs are recovered for transplantation. The organs are flushed with cold preservation solution which lower their temperature and ensure safe preservation until the time of transplantation. Blood samples and lymph nodes are also removed for tissue typing to ensure compatibility between the donor and the recipients. When the organs have been removed from the body, the ventilator is turned off. The surgical incisions are closed and the donor's body is prepared for transfer to the morgue. Throughout this process, the donor's body is treated with respect and dignity.

The transplant teams transport the recovered organs to their respective hospitals where the recipients are prepared and awaiting the transplant operation. Following the organ transplant operations, the recipients are placed on immunosuppressive medication to prevent their immune system from rejecting

¹⁵ Ibid.

¹⁵

¹⁶ The top 3 OPOs of the state which consistently rank in the top 10 of the nation report that less than 1% of family members or other authorized persons modify, prevent or deny a donor's validly executed organ and tissue designation.

the new organ. Barring serious complications, most patients are discharged home within five to fifteen days following their transplant.

The donor family receives a letter from the OPO staff several weeks later, describing in general terms the outcome of their loved one's donation. At all times, confidentiality of the donor and the recipients is maintained.

Statistics – Nationally

Each month, 1,000 people are added to the national organ transplant waiting list, which tops more than 75,000. Nearly half of the patients die waiting for a life-saving transplant. Although 89 percent of the U.S. population favors donation, only 1 in 4 consent - leaving the rate of donation around 5,000 a year, far below the demand.¹⁷ As of March 28, 2003, nationally, there were 80,769 candidates waiting for organ transplantation throughout the United States.¹⁸ As of March 21, 2003, the year-to-date total of transplants performed was 25,765 with organs provided from 12,794 donors.¹⁹

Statistics - Florida

As of March 14, 2003, in Florida, there was a waiting list for 3,005 organs. From January 1, 2002 to December 31, 2002, there were a total of 598 organ donors (439 deceased donors and 159 living donors) for a total of 1,487 transplants (1,328 from deceased donors and 159 from living donors).²⁰

C. SECTION DIRECTORY:

Section 1. Creates the "Nick Oelrich Gift of Life Act."

Section 2. Amends s. 765.512, F.S., relating to anatomical gifts, as follows: prohibits certain modifications; provides that a donor document is legally binding; and authorizes specified persons to furnish a donee's medical records upon request.

Section 3. Amends s. 765.516, F.S., relating to ways to amend or revoke an anatomical gift.

Section 4. Provides an effective date of July 1, 2003.

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:

STORAGE NAME: DATE:

¹⁷ Vanderbilt Medical Center. [http://www.mc.vanderbilt.edu/reporter/index.html]

¹⁸ The Organ Procurement and Transplantation Network, "[t]he waiting list reflects the current number of candidates on the waiting list. A candidate has multiple registrations if they are waiting at more than one center, or for multiple organs. The waiting list count is continuously updated throughout the day." [http://www.optn.org/]

The Organ Procurement and Transplantation Network, "Data," March 28, 2003. [http://www.optn.org]

²⁰ The Organ Procurement and Transplantation Network, "Florida Data," March 14, 2003. [http://www.optn.org]

None.

2. Expenditures:

None.

C. DIRECT ECONOMIC IMPACT ON PRIVATE SECTOR:

The bill may facilitate greater participation by those willing to execute pre-death organ and tissue donor designations.

The bill makes it much clearer that concurring or additional consent is not required to effectuate an anatomical gift. It will be more difficult for family members and other specified individuals to modify, override or otherwise challenge the validity of a written designation of an anatomical gift.

D. FISCAL COMMENTS:

None.

III. COMMENTS

A. CONSTITUTIONAL ISSUES:

1. Applicability of Municipality/County Mandates Provision:

This bill does not require counties or municipalities to spend funds or to take an action requiring the expenditure of funds. This bill does not reduce the percentage of a state tax shared with counties or municipalities. This bill does not reduce the authority that municipalities have to raise revenues.

2. Other:

Constitutionality of presumptions: The bill appears to create a presumption that a document making an anatomical gift is legally binding and will constitute evidence of a legally sufficient informed consent. Other than the public awareness and education campaign²¹ and the two witness requirement for proper execution of a designation,²² there are no other established standards for the minimum amount of information necessary to qualify someone's decision as one of informed consent to donate an anatomical gift.²³ Evidentiary presumptions are constitutional if there is a rational connection between the facts proved and the ultimate fact presumed, and there is a right to rebut the presumption in a fair manner.²⁴ It appears that the language in HB 289/CS which states that a document indicating a person's wish to make an anatomical gift is evidence of legally sufficient informed consent to donate an anatomical gift may not be rationally connected if the person was not in fact informed. The right to rebut the presumption is evidenced by actual notice of contrary

STORAGE NAME: h0289c.ju.doc DATE: h0289c.ju.doc April 22, 2003

²¹ See ss. 765.5215 and 765.5216, F.S., which require the Agency for Health Care Administration (AHCA) to develop a continuing program to educate and inform the public regarding the laws relating to anatomical gifts, and creates an organ and tissue donor education panel within AHCA.

²² See s. 765.514(2) (a), F.S.

²³ See s. 766.103(3), F.S., which provides immunity for physicians in actions brought for treating, examining, or operating on a patient without his or her informed consent when the action of the physician in obtaining the consent of the patient or another person authorized to give consent for the patient was in accordance with an accepted standard of medical practice among members of the medical profession with similar training and experience in the same or similar medical community; and a reasonable individual, from the information provided by the physician would have a general understanding of the procedure, the medically acceptable alternative procedures, and the substantial risks and hazards inherent in the treatment which are recognized among other physicians in the same or similar community who perform similar treatments or procedures, or the patient would have reasonably, under all the surrounding circumstances, have undergone such treatment or procedure had he or she been advised.

²⁴ See Straughn v. K & K Land Management, Inc., 326 So.2d 421 (Fla. 1976).

indications by the decedent, which is limited, but not eliminated, by the bill's deletion of a spouse as someone to whom a donor may orally revoke an anatomical gift.

B. RULE-MAKING AUTHORITY:

None.

C. DRAFTING ISSUES OR OTHER COMMENTS:

None.

IV. AMENDMENTS/COMMITTEE SUBSTITUTE CHANGES

The Committee on Health Care adopted two amendments on April 2, 2003, and reported the bill favorably with a CS. The first amendment clarifies that the prohibition to modify, deny, or prevent a donor's wish or intent applies only to adult donors and makes a grammatical change for the purpose of consistency. The second amendment specifies that in the event of an oral revocation or modification of the gift by a donor, that one of the two required witnesses must not be a member of the donor's family.

The Judiciary Committee adopted an amendment on April 22, 2003, which deleted language that provided that a document indicating a person's intent or wish to make an anatomical gift is legally binding. This analysis is drafted to the bill as amended.

h0289c.ju.doc PAGE: 8 STORAGE NAME: April 22, 2003

DATE.