

Organ and Tissue Donation and Transplantation Legislation

DATE	FEDERAL AND STATE LEGISLATION AND REGULATIONS
2021	<p>State – HB Improve Anatomical Gift Donation Process</p> <ul style="list-style-type: none"> • Effective October 1, 2021 • Requires the DMV examiners to not ask registered organ, eye and tissue donors to re-register their decisions when obtaining a drivers license or state ID.
2019	<p>State – SB 210 – Heart Heroes (an amendment to Heart Prevails)</p> <ul style="list-style-type: none"> • Effective October 1, 2019 and makes the gift of tissue first person authorization. • Heart symbol on NC drivers’ licenses an ID represents organ, eye and tissue donation for those saying “yes” to donation at the DMV. • Registrants prior to Oct. 1, 2019, must register online at DonateLifeNC to become <u>registered tissue donors</u>. • North Carolina is uniform with the rest of the nation regarding the donation of organ, eyes and tissues at the DMV.
2007	<p>State - HB 1372 The Heart Prevails</p> <ul style="list-style-type: none"> • Effective October 1, 2007 converts the heart-on-license and the correlating names in the donor registry to legal first person authorization. • The heart indicates organ and eye donation ONLY, not tissue. • Those names already on the registry will be grandfathered and the heart on their license/name in registry will convert to first person consent. • Registry database is confidential- only the Organ Procurement Organizations and the Eye Banks will be granted access. <p>JCAHO (Joint Commission on Accreditation of Healthcare Organizations) Standard LD.3.110 revisions</p> <p>The organization works with the Organ Procurement Organizations (OPO) and tissue and eye banks to do the following:</p> <ul style="list-style-type: none"> • Ensure that the necessary testing and placement of potential donated organs, tissues and eyes takes place in order to maximize the viability of donor organs for transplant and maintain potential donors while preliminary suitability is determined. • Develop a donation policy that addresses opportunities for asystolic recovery (Donation after cardiac death – DCD) based on an organ potential for donation that is mutually agreed upon by the designated OPO, hospital and medical staff.
2005	<p>State – HB 967 Healthcare Power of Attorney/Disposition of Remains</p>

- Enables those with a legal healthcare power of attorney document to designate a specific person as having primary decision making rights regarding their healthcare when unable to express wishes. This law extends beyond death to organ donation and disposition of the body.
- Provides healthcare power of attorney holder with rights to supersede wishes of next-of-kin regardless of relationship with patient.

2004

State – SB 852 Organ Procurement Organizations and Eye banks Access to DMV Records

- Establishes a North Carolina donor registry of intent. Effective January 1, 2005 federally-designated OPOs and eye banks operating in North Carolina can check via internet the Department of Motor Vehicles secure database (Organ Donor Internet site) to determine if someone wanted to be a donor at the time of their death. The Organ Donor Internet site will be used for the sole purpose of seeking consent from the individual's next of kin for organ, tissue or eye donation.
- Requires driver's license offices to offer donor information and a donor card to each applicant for a driver's license including the type of information that will be made available by DMV on the Organ Donor Internet site and how that information will be used by OPOs and eye banks.
- Establishes A License to Give Trust Fund and Commission to promote organ and tissue donation and health care decision-making at life's end.

Federal - Organ Donation and Recovery Improvement Act (ODRIA)

- Focuses on strengthening efforts to increase donation rates, including ways to make living donation an easier and more financially appealing option.
- Authorizes \$25 million in program development, grants, and direct funding for public awareness studies and demonstration projects; assistance for living donors; grants for hospital-based donation programs; and studies relating to organ donation recovery, preservation and transportation.

2001

State – SB 907 Session Law 2001-481 Organ, Eye and Tissue Donor Registry

- Effective January 1, 2002, a gift made in accordance with G.S. 130A-406 (see below) shall be sufficient legal authority for procurement without additional authority from the donor, donor's family or estate.
- Requires driver's license offices to offer a donor card to each applicant for a driver's license or special identification.

1998

Federal - HCFA Regulation 42 CFR 482.45 Hospital Conditions of Participation; Identification of Potential Organ, Tissue and Eye Donors

- Requires hospitals to notify, in a timely manner, their designated organ procurement organization of individuals whose death is imminent or who have died in the hospital.
- Requires that the individual designated by the hospital to initiate the request to the family must be an organ procurement representative or a trained designated requestor.

- 1997 **North Carolina - G.S. 130A - 412.2 - Amendments to the Anatomical Gift Act "Gift of Life Act"**
- Specifies that hospitals are to notify the organ procurement organization (OPO) of all cardiac deaths and impending brain deaths up to age 75. The hospital also must provide the OPO with reasonable access to patients' charts to determine donation potential and conduct record reviews for evaluation of educational needs.
 - Establishes OPO's as the responsible party for evaluating all referrals for donation potential and making the families of donors aware of their option to donate.
- 1993 **The Federal Food and Drug Administration (FDA) initiates regulation of all U.S. tissue banks.**
- 1992 **Baboon liver transplanted into man dying of liver failure resulting from hepatitis.**
- 1991 **First successful small intestine transplants reported by surgeons at University of Pittsburgh.**
- 1990 **Dr. Joseph Murray, who performed the first kidney transplant, was awarded the Nobel Prize for Medicine.**
- First lung transplant from a living related donor.**
- 1989 **First liver transplant from a living related donor.**
- 1988 **Federal - PL100-608 Health Omnibus Programs Extension Act**
- Expands prohibition of sale to include fetuses and organ subparts.
 - Modifies OPO certification requirements to include 50 actual organ donors per year.
 - Extends Medicare coverage for immunosuppressive drugs.
- FDA approval of Viaspan or UW solution, greatly extends preservation time for organs.**
- The Joint Commission on Accreditation of Healthcare Organizations (JCAHO) sets standards for policies and procedures for identification and referral of potential donors to organ procurement organizations.**
- 1987 **Federal - PL100-203 Omnibus Budget Reconciliation Act**
- Provides Medicare reimbursement to pediatric heart transplant centers which are affiliated with approved adult centers.
- Federal - HCFAR 87-1**
- Established Medicare coverage for heart transplants performed at approved centers.

1986

Federal - PL99-509 Omnibus Budget Reconciliation Act

- Requires hospitals receiving reimbursement from Medicare and Medicaid to establish protocols to insure the approach of potential donor families and notification of an OPO.
- Requires transplant hospitals to become members of the Organ Procurement Transplantation Network (OPTN) and abide by Network rules.
- Establishes "designation" of OPOs.
- Provides Medicare coverage for immunosuppressive drugs.

North Carolina - Omnibus Reconciliation Act

- Assures that families of potential organ and tissue donors are informed of their option to consent to or decline donation.
- Encourages discretion and sensitivity with respect to the circumstances, views, and beliefs of such families.
- Requires that the organ procurement organization designated by the Secretary of the Department of Health and Human Services be notified of all potential donors.

1985

Federal - PL99-272 Consolidated Omnibus Budget Reconciliation Act

- Encourages DHHS to reconsider Medicare coverage of liver transplantation.
- Requires state Medicare plans to address equity of access to organ transplant procedures.

1984

Federal - HCFA Pub. 635-53

- Provides Medicare coverage for liver transplantation in children with extrahepatic Biliary Atresia or other form of end stage liver disease.

Federal - PL98-507 National Organ Transplant Act

- Establishes a task force for organ transplantation.
- Provides special grants for planning, establishing, and expanding organ procurement organizations (includes standards for OPOs).
- Mandates a contract to establish and operate the organ procurement and transplantation network.
- Mandates a grant or contract to develop and maintain a scientific registry of organ transplant recipients.
- Mandates the designation and maintenance of an identifiable administrative unit in the public health office (Office of Transplantation).
- Prohibits buying/selling of organs.

1983

FDA approves cyclosporine, the most successful anti-rejection medication developed to date.

1981

First successful heart/lung transplant done by Dr. Norman Shumway, Stanford University Medical Center, Palo Alto, CA.

1980

The Uniform Determination of Death Act, which recognizes death as either a determination of irreversible cessation of circulatory and respiratory functions or

irreversible cessation of all functions of the entire brain, including the brain stem, was adopted by American Medical Association.

1978

Federal - 413.178 Freestanding OPOs and Histo Labs

- Provides mechanism for the establishment and reimbursement of independent organ procurement agencies and histocompatibility labs

Immunosuppressive drug Cyclosporin was introduced to control the body's immune systems from rejecting a transplanted organ.

1972

Federal - PL92-603 End Stage Renal Disease Program

- Provides reimbursement under Medicare for dialysis, kidney acquisition, and kidney transplantation.

1966

First pancreas transplant by Dr. Lillehei, University Minnesota, Minneapolis.

1968

The Uniform Anatomical Gift Act established the Uniform Organ Donor Card as a legal document in all 50 states making it possible for anyone 18 years or older to legally donate his or her organs upon death.

1967

First successful heart transplant, Dr. Christian Bernard, Groote Shure Hospital, South Africa.

1967

First successful liver transplant, Dr. Thomas Starzl, University of Colorado, Denver, CO.

1963

First lung transplant by Dr. James Hardy, University of Mississippi Medical Center, Jackson, MS.

1962

First successful post-mortem kidney transplant by Dr. Joseph Murray and Dr. David Hume at Brigham Hospital, Boston.

1954

First successful living-related donor kidney transplant (between identical twin brothers) was performed by Dr. Joseph Murray and Dr. David Hume at Brigham Hospital, Boston.

1905

First successful cornea transplant by Eduard Zirm, Austria.