

Guidelines, Regulations and Laws Governing the Organ and Tissue Donation Process: Collaboration with Funeral Home Colleagues

**ONLINE EDUCATIONAL COURSE PROVIDED BY THE
MARYLAND STATE FUNERAL DIRECTORS ASSOCIATION
1.0 CEU approved by the Maryland Board of Morticians & Funeral Directors**

Course created for MSFDA's online continuing education program by
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Program Objectives

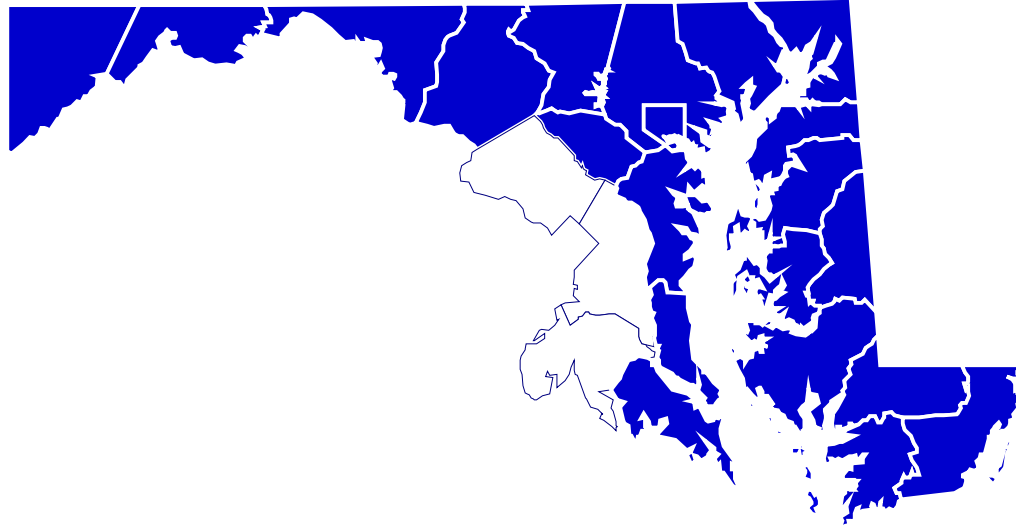
At the end of this program, the participant will be able to:

- Verbalize knowledge of key federal and state laws and regulations related to donation.
- Highlight national best practices that guide donor processes.
- Cite examples of how these laws and practices aid funeral directors in their practice.
- Describe the importance of collaboration between donor programs and funeral directors in meeting family needs.

The Living Legacy Foundation's Commitment to Excellence

- Assure adherence to all local, state and national laws and regulations related to organ, tissue and eye donation.
- Attain and maintain accreditation through appropriate oversight entities.
- Establish and maintain collaborative relationships with professional colleagues with whom our program interacts.

LLF Service Area



- 34 Acute Care Hospitals
- 2 Solid Organ Transplant Centers: The Johns Hopkins Hospital and University of Maryland
- White areas indicate counties served by the Washington Regional Transplant Community (WRTC)

Highlights of National Laws, Guidelines and Regulatory Bodies

National Organ Transplant Act (NOTA)

- Approved in 1984; amended in 1988 and 1990
- Outlawed sale of human organs for transplant
- Established Organ Procurement Organizations (OPO) to coordinate deceased donation process.
- Created the Organ Procurement and Transplantation Network (OPTN) and Scientific Registry of Transplant Recipients (SRTR).

Federal Oversight of Donation

- Centers for Medicare and Medicaid Services (CMS) provides oversight for organ donation.
- Food and Drug Administration (FDA) provides oversight for tissue donation.
- Each entity audits donor programs to ensure compliance with regulations.

The HOPE Act: HIV Organ Policy Equity Act

The 2013 HOPE Act

- Signed into law by President Obama
- Foundation for advancing research related to HIV and transplantation
- Allows transplants from HIV+ donors
- Antiretroviral therapy is enhancing quality of life for HIV+ patients
- Some individuals with HIV, like others with liver failure and renal disease, face end-stage organ disease

HOPE
IN ACTION →



The Joint Commission



- The Joint Commission requires that hospitals have a written agreement with their OPO as part of their Transplant Safety Standard TS 01.01.01
- LLF works collaboratively with our hospital partners to ensure this standard is met and upheld

Development of Model Donation Related National Legislation



Uniform Law Commission

The National Conference of Commissioners on Uniform State Laws



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Diversity of Thought, Uniformity of Law

The Uniform Law Commission provides states with non-partisan, well conceived, and well drafted legislation that brings clarity and stability to critical areas of state statutory law.

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- The Uniform Law Commission, established in 1892, provides states with non-partisan legislation to bring clarity and stability to critical areas of state statutory law.
- In 1968, ULC drafted model donation related legislation, known as the Uniform Anatomical Gift Act, for dissemination to state legislatures for passage.

Maryland Legislation



Revised Uniform Anatomical Gift Act (UAGA)

- Maryland's donation statutes were developed from the draft model legislation created by ULC in 1968 and revised over in the ensuing years.
- In an earlier update to the UAGA, Maryland's revisions were known as the William Amoss Act.
- The most recent revisions were in 2011 and are known as the Revised Uniform Anatomical Gift Act.

Maryland's RUAGA Provisions

- Reaffirms autonomy of donor designation
- Establishes hierarchy for legal next of kin who can authorize donation
- Outlines collaborative relationship for Office of the Chief Medical Examiner and Living Legacy Foundation
- Includes provisions whereby Medical Examiners can authorize permission for organs and tissues for donation

Maryland RUAGA Provisions

- Requires that the hospital continues measures necessary to ensure the medical suitability of a prospective donor.
- Establishes that the OPO be allowed the opportunity to conduct a reasonable medical examination and conduct a reasonable search for next of kin.

Organ and Tissue Donor Program Professional Organizations

American Association of Organ Procurement Organizations (AOPO)

- Membership organization for Organ Procurement Organizations (OPOs)
- Administers accreditation program via standards encompassing all aspects of operations and practices
- Assesses compliance with AOPO standards and federal regulations
- Upholds tenets of maintaining public trust in donation, and honoring every Gift of Life and every donor to the fullest



Mission Statement

- Help member OPOs maximize availability of organs and tissues for transplantation and enhance the quality, effectiveness and integrity of the donation process

Vision Statement

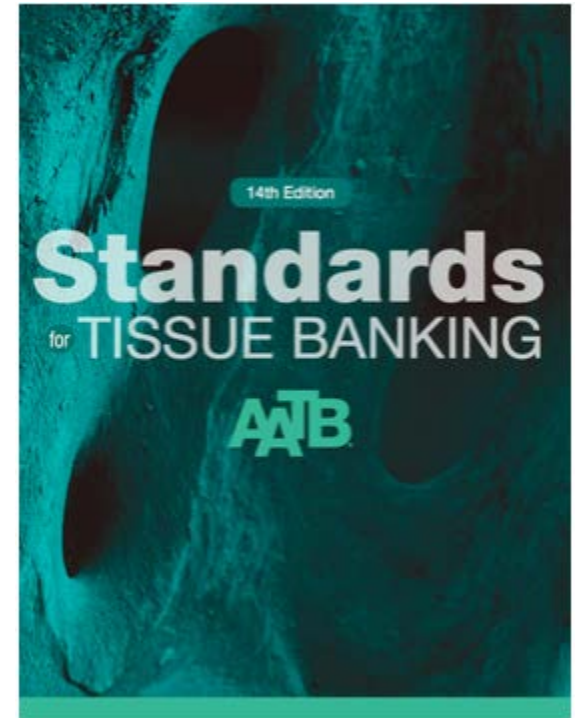
- Help those in need of a transplant receive donated organs or tissues in a timely manner to end deaths on the waiting list

American Association of Tissue Banks (AATB)

- Professional organization dedicated to leadership, education, service, research, and integrity involving tissue donation and transplantation practices.
- All members pledge to adhere to AATB's Codes, Principles and Good Faith Practices.

AATB Accreditation Program

- Provides assurance that member tissue banks comply with AATB Standards
- Standards are extensive and address all areas of tissue banking process, including evaluation and recovery
- Standards developed in collaboration with FDA and other regulatory entities



Best Practices for Cooperation Among OPOs, Tissue Banks and Funeral Service Professionals

Best Practices for Cooperation in Organ and Tissue Donation

- Guidelines developed jointly by:
 - The National Funeral Directors Association (NFDA)
 - American Association of Tissue Banks (AATB)
 - Association of Organ Procurement Organizations (AOPO)

Best Practices for Cooperation in Organ and Tissue Donation

- Highlighted aspects include:
 - Notification
 - Disclosure
 - Recovery Procedures
 - Reimbursement
 - Support and Communication



Notification – Best Practices

- Recovery agencies should provide timely notification to Funeral Homes regarding key aspects of the donation process, to include:
 - Once consent for donation is given by the next of kin
 - Estimated timeframe in which recovery will occur
 - Regular updates regarding any changes in planned timeframes

Disclosure – Best Practices

- Organ and tissue related recovery agencies will make the necessary disclosure to families regarding the donation process, to include:
 - Confirmation that the program utilized trained professional staff
 - Information regarding recovery programs and processors For Profit vs. Not for Profit status
 - The organ and tissue gifts that can be donated to help others

Recovery Processes – Best Practices

- Organ Procurement Organizations (OPO) commit to the following:
 - Provide an estimated time for completion of the surgical recovery of organs and give timely updates
 - Logistics
 - Ligation of vessels
 - Respectfully reconstruction of donor

Reimbursement – Best Practices

- Each OPO should establish a policy regarding compensation of funeral directors should additional time and materials be required.
- LLF's Tax Deduction policy was created as a best practice to support the funeral homes with whom there is collaboration for donation cases.

Support and Communication

Best Practices

Highlights of this best practice include:

- NFDA and AATB publicly support and encourage their members to reinforce the concept of donation
- Members of each organization respect donor and donor family wishes and collaborate to facilitate donation processes
- Recovery Agencies have obligation to be mindful of manner in which donation and effects on decedent are discussed with families
- Donation programs ensure awareness of the timing of the donation process and its effects on funeral home staff

How do These Laws and Best Practices Support the Funeral Director?

- Provides greater insight into the organ and tissue donation process
- Supports the creation of collaborative relationships among OPOs, Tissue Banks and the Funeral Home Community
- Ensures an overall awareness of the importance of donation and how it enhances and saves the lives of those in need of a life saving transplant

Resources and Links

- American Association of Tissue Banks (AATB); <http://www.aatb.org/>
- Association of Organ Procurement Organizations (AOPO); <http://www.aopo.org/>
- Centers for Medicare and Medicaid Services (CMS) Guidance; <https://www.cms.gov/Regulations-and-Guidance/Legislation/CFCsAndCoPs/OPOs.html>
- Food and Drug Administration (FDA) Tissue Resources; <http://www.fda.gov/BiologicsBloodVaccines/GuidanceComplianceRegulatoryInformation/Guidances/Tissue/>
- HIV Organ Policy Equity (HOPE) Act; <https://optn.transplant.hrsa.gov/learn/professional-education/hope-act/>
- Joint Commission Standards Highlights; <http://www.hcpro.com/ACC-304209-4634/Joint-Commission-clarifies-organ-procurement-requirements.html>
- Maryland Revised Uniform Anatomical Gift Act (RUAGA); <http://mgaleg.maryland.gov/webmga/frm1st.aspx?tab=home>
- National Organ Transplant Act (NOTA); <https://optn.transplant.hrsa.gov/governance/about-the-optn/history-nota/>