

# 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**

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# Program Objectives

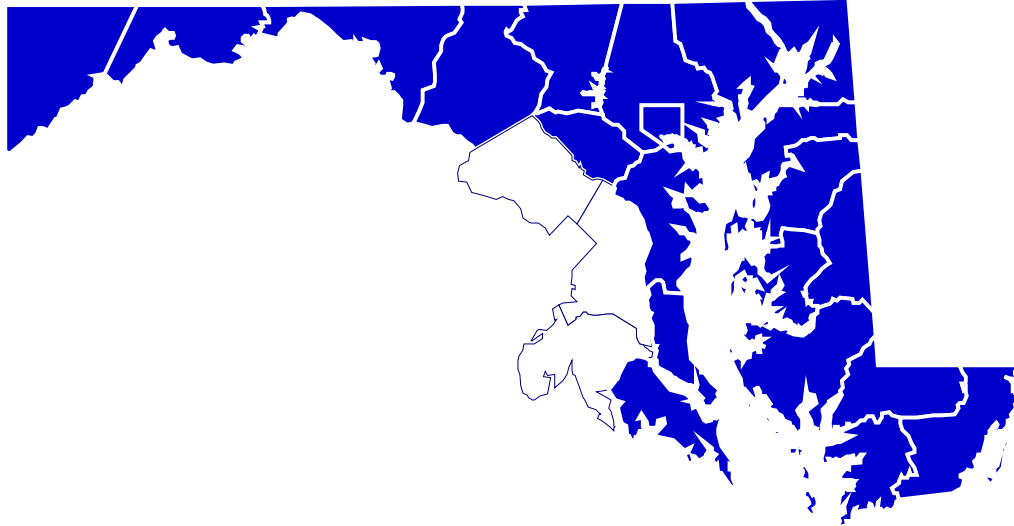
At the end of this program, the participant will be able to:

- 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

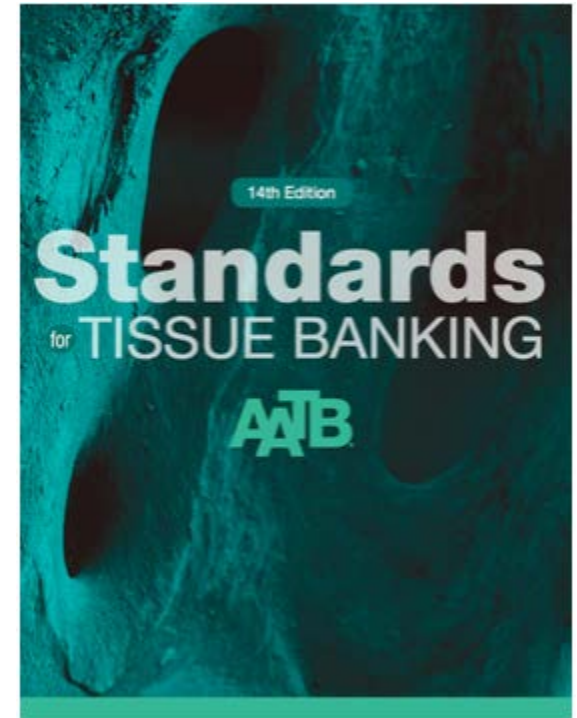
- Help those in need of a transplant receive donated organs or tissues in a timely manner to end deaths on the waiting list

# 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)





# 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/>