

REPORT TO THE COMMITTEE OF THE WHOLE
REVISED UNIFORM ANATOMICAL GIFT ACT (200__)

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and

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BACKGROUND

A. History of Act. The original Act was proposed immediately following the heart transplantation in November 1967 by Dr. Christian Bernard and was drafted and promulgated in one reading in the summer of 1968. The Act was uniformly enacted by all jurisdictions within several years; a demonstration that prompt drafting responsive to new developments can on occasion be extraordinarily successful.

In 1987, a revised Act was promulgated to address changes in circumstances and in practice. However, only twenty-six (26) jurisdictions have enacted the 1987 revision. Consequently, there is substantial non-uniformity not only between the 1968 Act states and 1987 revision states, but also because of extensive federal statutes and regulations and state law changes promulgated since 1987.

Currently state anatomical gift laws (either the 68' or 87' version) largely governs the ability to procure organs through the donation process and federal law (see below) largely controls how donated organs are donated to recipients.

B. Scope The Act is limited in scope to donations from deceased donors. Donations by living donors are not included, as distinct and difficult issues are raised by living donations.

C. Federal Regulation In addition to state regulation and licensing, the federal government has substantially expanded its role including:

1. With respect to organs the Department of Health and Human Services (HHS) has implemented:
 - (i) a Federal allocation system under the National Organ Transplantation Act of 1984 (NOTA), 42 U.S.C. § 273 – 4 and regulations thereunder;
 - (ii) a certification system on outcome and process measures under the Organ Procurement Organization Certification Act of 2000 amending 42 U.S.C. § 273 and regulations thereunder;
 - (iii) standards for hospitals and health care providers under Medicare and Medicaid, under authority granted by the Omnibus Budget Reconciliation Act of 1986.
2. With respect to Tissue and Eye Banks, the Department of Health and Human Services (HHS) has implemented:
 - (i) standards for hospitals and health care providers under Medicare and Medicaid, under authority granted by the Omnibus Reconciliation Act of 1986;
 - (ii) standards to prevent the transmission of communicable disease and/or infectious agents under the Public Health Service Act, 42 USC Section 264 and regulations pursuant thereto, 21 CFR parts 1270 and 1271.

D. Donation Process In a hospital setting, a majority of potential donors are candidates for donation of eye or tissue. Only a small percentage of potential donors die under circumstances that permit organ donation. For organs, after the donor is declared brain dead, the

body must be kept on a respirator and life support until the organs are procured. When a death occurs, or a death is imminent, the OPO and/or Eye/Tissue Banks are notified by federal law of a potential donor, and they begin developing a medical and family history to determine whether the dying or deceased person is a suitable donor. If a dying or deceased person is a suitable donor, these organizations check for a donation card, and seek, when necessary, a consent to donation from authorized persons. If a donation can be secured for organs, an organ procurement organization will ascertain with the federal OPO Network whether there is a match on the priority list; arrange teams of surgeons at both the donor and recipient hospitals; arrange transport; and effect the transplantation. If a donation can be secured for eye and tissue gifts, the appropriate procurement organization procures the eye or portions of human eyes and/or other tissues and undertakes steps to begin the screening, testing, processing, storage, or distribution of the eye or portions of human eyes and/or other tissues as required for each type of anatomical gift for transplantation. All must be done expeditiously.

E. Need for More Donations.

Organs

Continuing innovations have increased the types of organs that can be transplanted and the range of individuals that can donate or receive an organ thereby increasing the numbers of transplantations that occur each year. However, the number of deaths for lack of available organs has also generally increased:

Year	Deaths While Waiting	Suitable Deceased Donors	On Waiting List
1988	1502	4084	16026
1996	3916	5416	50047
2002	6746	6182	80792
2004	6324	7150	88142

Harvard School of Public Health estimates that 10,500 to 22, 000 deaths occur in the United States every year that could yield suitable organs for transplantation.. The average donor provides three (3) organs for transplant. By far the most common reason for loss of an otherwise transplantable organ is denial of consent of the donor's family. Approximately seventy (70) people receive an organ transplant every day. However, another seventeen (17) die due to the lack of transplantable organs.

Currently (as of April 2005), there are 88,187 on the waiting list for organs of which 61,627 need a kidney and 17,272 a liver, with the remaining 9,288 waiting for a pancreas, kidney and pancreas, heart, lung or intestine.

Tissue and Eye.

Currently there are in excess of 25,000 eye and tissue donors annually and in excess of 1,000,000 tissue and eye transplants annually. While donations are presently nearly adequate, the need for eye and tissue transplants increases every year.

F. Uniformity and Revision. Transplantation occurs across state boundaries. Thus, uniformity of state law is highly desirable. Transplantation requires speed and efficiency. The current state laws are out of harmony and the Uniform Act is not harmonized with federal law. If the Conference comes up with the right product, our deliberations to date indicate that all of the stakeholders are willing to support enactment of a revised Act on a uniform basis.

PRINCIPAL CHANGES AND ISSUES.

A. Harmonizing with Federal Law:

- Definitions for “organ procurement organization,” “eye bank,” “tissue bank,” and “procurement organization” (Section 2 (9), (15) and (22)) and their use throughout the revised Act.
- Deleted hospital request process (part of old Section 5) since federal law preempts procedures for requesting consent (see proposed regulations Vol. 70 of Federal Register 02/04/05 at page 6136 (revising 42 CFR §486 342 et. seq.)
- Adds OPOs to the list of “donees” and clarifies that the OPO will serve the geographical area in which the decedent died.

B. Consent:

- If the donor acts by a document or gift including a symbol on a Drivers License, that “precludes” others (including the family) from acting contrary to Donor’s intent (Section 6).
- A gift may be made by registering on a “donor registry” (Definition, Section 2 (7) and Section 3 (d)).
- If an individual refuses to make a gift, (Section 5) that precludes others from later making a gift of that individual’s organs (Section 6).
- If the donor has not created a record to make or refuse to make a gift, the gift may be made by:
 - the agent under an advance medical directive (Section 2 (1) and Section 7 (a)(1));

- the majority of the members of a class (e.g. children of decedent)(Section 7 (a));
- the first person(s) “readily available in order of priority” (defined in Section 2 (16));
- thereby facilitating the process of ascertaining consent or denial of consent within the limited time available for successful transplantation;
- N.B. Federal regulation prescribes the process and procedure for obtaining consent from others, 42 CFR 486 (Proposed Requirements for Certification)

- Consent by Donor or others is always required (Old Section 5 deleted)

C. Medical Examiners. Old Section 4 has been deleted and a new Section 8 inserted that sets forth a different concept providing for coordination and cooperation between OPOs and Medical Examiners who perform investigative autopsies . The Committee has made contact with the National Association of Medical Examiners and hopes to have this stakeholder interest represented in our deliberations in 2005 – 06.

D. Electronic signature and record.

- The definition of “Record” and “sign” are added in standard Conference form ((Section 2(18) and (19) and the terms are used throughout the Act).
- Adds Section 21 to comply with “E-Sign” federal act.

E. Choice of Law. This Section was added to facilitate interstate recognition of gifts (Section 16).

8. Sections unchanged in substance.

OLD SECTION

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NEW SECTION

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Attachment: Reporter's Chart

<p>Reporter’s Note: The Revised UAGA preserves many of the policies reflected in the 1987 version of the act. The revisions largely relate to changes in who may make anatomical gifts on behalf of donors, the development of the donor registry as a device for the making of gifts, and changes in federal law that affect the manner in which organs are solicited from patients at or near death. The Revised Act also strengthens the autonomy interest of donors by not only making their gifts irrevocable but precluding other from making or revoking gifts when they die.</p>	
1987 Act	Revised UAGA
Section 1 Definitions (12)	Section 2 (22) There are new definitions for “agent,” “decedent,” “donee,” “donor registry,” “enucleator,” “eye bank,” “organ procurement organization,” “reasonably available,” “recipient,” “record,” “sign,” and “tissue bank”
Section 2 Making, Amending, Revoking and Refusing to Make an Anatomical Gift	<p>Section 3 Making Anatomical Gifts</p> <p>Section 4 Amending or Revoking Anatomical Gifts</p> <p>Section 5 Refusal to Make an Anatomical Gift</p> <p>Section 6 Preclusive Effects of Amendments, Revocations or Refusals</p> <p>The new provisions allow for gifts by agents, parents and guardians, permits gifts to be made on a donor registry, and preclude all others from making, revoking, or objecting to gifts when a donor has made a refusal under Section 5.</p>
Section 3 Making, Revoking, and Objecting to Anatomical Gifts, By Others	<p>Section 7 Making, Revoking, and Objecting to Anatomical Gifts by Others</p> <p>Assuming decedent made no record of a gift or refusal, expands prior law to allow gifts by agents, majority of members of a class (e.g., children) and close friends. Allows for procurement organization to proceed down the list of potential gift givers when others higher on the list are unavailable or unwilling to make a decision</p>
Section 4 Authorization by [Coroner][Medical Examiner] or [Local Public Health Official]	<p>Concept deleted.</p> <p>Section 8 Cooperation between [Coroner][Medical Examiner] and Procurement Organizations and Donees</p> <p>Section substantially revised to delete ability of coroner to make gifts absent donor or family consent in light of consistent line of adverse 1983 actions against coroners. But, provides for ongoing cooperation between coroners and procurement organizations to preserve bodies and parts where the</p>

	procurement organization has otherwise solicited a gift from families or where the decedent was a donor.
Section 5 Routine Inquiry and Required Request; Search and Notification	Section 9 Search and Notification (Routine Inquiry and Required Request deleted as co-opted by federal law)
Section 6 Persons Who May Become Donees; Purposes for Which Anatomical Gifts May be Made	Section 10 Persons Whom May Become Donees Modernizes the rules as to who may be a donee to take account of National Organ Transplant Act and the role of organ procurement organizations in the obtaining of parts for transplantation.
Section 7 Delivery of Document of Gift	Section 11 Delivery of Document of Gift
Section 8 Rights and Duties at Death	Section 12 Rights and Duties of Procurement Organizations and Donees
Section 9 Coordination of Procurement and Use	Section 13 Coordination of Procurement and Use
Section 10 Sale or Purchase of Parts Prohibited	Section 14 Sale or Purchase of Parts Prohibited
Section 11 Examination, Autopsy, Liability	Section 15 Liability (Material on examination and autopsy moved to Section 12)
Section 12 Transitional Provisions	Section 17 Transitional Provisions
Section 13 Uniformity of Application and Construction	Section 18 Uniformity of Application and Construction
Section 14 Severability	Section 19 Severability
Section 15 Short Title	Section 2 Short Title
Section 16 Repeals	Section 22 Repeals
Section 17 Effective Date	Section 23 Effective Date
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