Proposed AOPO Amendments

to the UNIFORM ANATOMICAL GIFT ACT (1987)

AOPO EXPLANATORY COMMENTS ARE IN RED. PROPOSED AMENDMENTS ARE IN BLUE

FOR PURPOSES OF EASE OF READING, DELETIONS ARE SUMMARIZED BUT NOT SHOWN.

SECTION 1. DEFINITIONS. As used in this [Act]:

- (1) "Anatomical gift" means a donation of all or part of a human body to take effect upon or after death.
- (2) "Decedent" means a deceased individual and includes a stillborn infant or fetus.
- (3) "Designated requestor" means a designated organ procurement organization representative or an individual who has completed a course offered or approved by a designated organ procurement organization pursuant to 42 CFR 482.45. For purposes of this Act, the term "Designated Requestor" shall also include individuals requesting tissue and eyes only who have received training in the consent process;
- (4) "Document of gift" means a card, a statement attached to or imprinted on a motor vehicle operator's or chauffeur's license, a will, or designation on a donor registry, including an electronic donor registry established in accordance with state or federal law or regulation, or other writing used to make an anatomical gift.
- (5) "Donor" means an individual who makes an anatomical gift of all or part of the individual's body.
- (6) "Enucleator" means an individual who is [licensed] [certified] by the [State Board of Medical Examiners] to remove or process eyes or parts of eyes.
- (7) "Hospital" means a facility licensed, accredited, or approved as a hospital under the law of any state or a facility operated as a hospital by the United States government, a state, or a subdivision of a state.
- (8) "Part" means an organ, tissue, eye, bone, artery, blood, fluid, or other portion of a human body.

- (9) "Person" means an individual, corporation, business trust, estate, trust, partnership, joint venture, association, government, governmental subdivision or agency, or any other legal or commercial entity.
- (10) "Physician" or "surgeon" means an individual licensed or otherwise authorized to practice medicine and surgery or osteopathy and surgery under the laws of any state.
- (11) "Procurement organization" means a person licensed, accredited, or approved under the laws of any state or the federal government, for procurement, distribution, or storage of human bodies or parts.
- (12) "Designated organ procurement organization" means an organ procurement organization designated pursuant to 42 CFR 486 for the coordination and provision of organ donation, recovery and transplantation services for a hospital.
- (13) "State" means a state, territory, or possession of the United States, the District of Columbia, or the Commonwealth of Puerto Rico.
- (14) "Technician" means an individual who is [licensed] [certified] by the [State Board of Medical Examiners] to remove or process a part.

AOPO COMMENT: 1(12) The Medicare Conditions of Participation for Hospitals, 42 CFR 482.45 (henceforth "COP", attached hereto) as well as other regulations promulgated pursuant to the Social Security and Public Health Services Acts create a mandatory system for all Medicare participating hospitals. (Veterans Administration hospitals are not covered by these regulations, but most have contractually agreed to work with designated organ procurement organizations). Thus, designated organ procurement organizations (OPOs) coordinate the process of referral, consent, medical suitability screening, and distribution of cadaveric anatomical gifts, even when the OPO is not the eventual donee. Some states license their OPOs, others don't. OPOs are nonetheless empowered to operate by federal mandate.

- 1(3) In 1987, most in the transplant community agreed that families were not having the option of organ donation communicated to them in an effective manner. Hence, "routine inquiry" was incorporated into the Uniform Anatomical Gift Act. Subsequent research and experience has shown, however, that inquiry at the time of admission to a hospital is not likely to elicit a thoughtful or accurate response, and may in fact lead to unnecessarily binding "false negatives". This is due not only to the timing of the inquiry, but the training of the person making the inquiry. Hence the COP rules define the qualifications of a person who may make the request of a family, ("designated requestor") and in comments to these rules, the concept of routine inquiry is discouraged.
- 1(4) Finally, many states, OPOs and other private organizations are creating donor registries, whereby people may record their wish to make an anatomical gift. In some states, such as New Jersey, registration is a legally valid documentation of a gift. In other states, such as New York, registration is "an expression of intent". Often, these registries

are operated within or by the motor vehicles agencies, and increasingly, internet registration is desired.

SECTION 2. MAKING, AMENDING, REVOKING, AND REFUSING TO MAKE ANATOMICAL GIFTS BY INDIVIDUAL.

- (a) An individual who is at least [18] years of age may (i) make an anatomical gift for any of the purposes stated in Section 6(a), (ii) limit an anatomical gift to one or more of those purposes, or (iii) refuse to make an anatomical gift.
- (b) An anatomical gift may be made only by a document of gift signed by the donor. Signing by means of electronic signature is valid if permitted in the donor's state of residence. If the donor cannot sign, the document of gift must be signed by another individual and by two witnesses, all of whom have signed at the direction and in the presence of the donor and of each other, and state that it has been so signed.
- (c) If a document of gift is attached to or imprinted on a donor's motor vehicle operator's or chauffeur's license, revocation, suspension, expiration, or cancellation of the license does not invalidate the anatomical gift. [Note deletion of two witness requirement]
- (d) A document of gift may designate a particular physician or surgeon to carry out the appropriate procedures. In the absence of a designation or if the designee is not available, the donee or other person authorized to accept the anatomical gift may employ or authorize any physician, surgeon, technician, or enucleator to carry out the appropriate procedures.
- (e) An anatomical gift by will takes effect upon death of the testator, whether or not the will is probated. If, after death, the will is declared invalid for testamentary purposes, the validity of the anatomical gift is unaffected.
- (f) A donor may amend or revoke an anatomical gift, not made by will, only by:
- (1) a signed statement;
- (2) an oral statement made in the presence of two individuals; removal or written or electronic request to be removed from a donor registry;
- (3) any witnessed form of communication during a terminal illness or injury addressed to a physician or surgeon; or
- (4) the delivery of a signed statement to a specified donee to whom a document of gift had been delivered.
- (g) The donor of an anatomical gift made by will may amend or revoke the gift in the manner provided for amendment or revocation of wills, or as provided in subsection (f).

- (h) An anatomical gift that is not revoked by the donor before death is irrevocable and does not require the consent or concurrence of any person after the donor's death.
- (i) An individual may refuse to make an anatomical gift of the individual's body or part by (i) a writing signed in the same manner as a document of gift, (ii) a statement attached to or imprinted on a donor's motor vehicle operator's or chauffeur's license, or (iii) any other writing used to identify the individual as refusing to make an anatomical gift. During a terminal illness or injury, the refusal may be an oral statement or other form of communication.
- (j) In the absence of contrary indications by the donor, an anatomical gift of a part is neither a refusal to give other parts nor a limitation on an anatomical gift under Section 3 or on a removal or release of other parts under Section 4.
- (k) In the absence of contrary indications by the donor, a revocation or amendment of an anatomical gift is not a refusal to make another anatomical gift. If the donor intends a revocation to be a refusal to make an anatomical gift, the donor shall make the refusal pursuant to subsection (i).

The proposed amendments to this section arise from two practical concerns: The first is that there is no need to make the process of expressing the wish to make an anatomical gift upon death more difficult. Hence, as the Uniform Electronic Transactions Act is adopted and followed in more states, along with accompanying federal law, electronic signatures should be acceptable means of verification. Similarly, at least one state has eliminated the "two signature" requirement for driver's license documents of gift, because the validity of information on a license has already been verified by checking identity, photo, etc.

Permitting amendment or revocation of a gift by oral statement threatens the donors rights of self-determination. Such an option invites an argument over whether the potential donor did or did not amend or revoke a previously expressed wish to be a donor. Nothing would prevent family members from claiming oral revocation if they were uncomfortable with the potential donor's wishes. A person must make a gift in writing. It should not be easier to amend or revoke a gift than it is to make one in the first place and therefore, gifts should only be able to be amended or revoked in writing (except if terminally ill). Therefore, we recommend the deletion of the current 2(f)(2), replacing it with an recognition of revocation by means of voluntary removal from a donor registry.

SECTION 3. MAKING, REVOKING, AND OBJECTING TO ANATOMICAL GIFTS, BY OTHERS.

(a) Any member of the following classes of persons, in the order of priority listed, may make an anatomical gift of all or a part of the decedent's body for an authorized purpose,

unless the decedent, at the time of death, has made an unrevoked refusal to make that anatomical gift:

- (1) The agent under a power of attorney for health care, or health care proxy that expressly authorizes or does not limit the authority of the agent to make an anatomical gift of all or part of the principal's body.
- (2) the spouse of the decedent;
- (3) an adult son or daughter of the decedent;
- (4) either parent of the decedent;
- (5) an adult brother or sister of the decedent;
- (6) a grandparent of the decedent;
- (7) a guardian of the person of the decedent at the time of death.
- (8) any other person authorized or under obligation to dispose of the body.
- (b) An anatomical gift may not be made by a person listed in subsection (a) if:
- (1) a person in a prior class is available at the time of death to make an anatomical gift. For purposes of this section, "available" shall mean accessible for telephonic, electronic or other direct means of communication within a time frame compatible with donation. An anatomical gift shall not be made by a person described in (3)(a)(8) above until the completion of a search of at least twelve hours duration for a person in a higher category.
- (2) the person proposing to make an anatomical gift knows of a refusal or contrary indications by the decedent;

Note (b)(3) deletion, "knowledge of contrary indications from same or prior class".

- (c) An anatomical gift by a person authorized under subsection (a) must be made by (i) a document of gift signed by the person or (ii) the person's telegraphic, telecopied, recorded telephonic, electronic or other recorded message, or other form of communication from the person that is contemporaneously reduced to writing and signed by the recipient.
- (d) An anatomical gift by a person authorized under subsection (a) may be revoked by any member of the same or a prior class if, before procedures have begun for the removal of a part from the body of the decedent, the physician, surgeon, technician, or enucleator removing the part knows of the revocation.

(e) A failure to make an anatomical gift under subsection (a) is not an objection to the making of an anatomical gift.

AOPO Comment: 3(a)(1) Many people believe that when they designate an individual to make health care decisions, particularly those at the end of life, that the designated individual is also empowered to determine whether or not an anatomical gift is made. The decision of how to dispose of the body is not a health care decision, and thus health care proxies are not enabled under the 1987 UAGA to make anatomical gift decisions. Since 1987, most states have adopted statutes allowing individuals to designate proxies for the most intimate of decisions, and often, these proxies are not reflected in the UAGA table of consanguinity. Thus, the autonomy of the individual is preserved by allowing them to designate an individual to exercise the right, should they fail to exercise it themselves, while living.

3(a)(8) The earliest UAGA contained a final category of individual who was empowered to exercise the right to donate. That final class consisted of those "authorized or under an obligation to dispose of the body". While the original intent of this language may have been to allow medical examiners to authorize donation, many states utilized this provision, and even defined it further, to include those who, in the absence of all others, might consent to donation. Thus, a hospital administrator or public welfare body might authorize life- saving donation from a verified John Doe, as might the close friend of a person who dies without family. State agencies which assume the care for, if not the guardianship of, developmentally disabled individuals are authorized to consent to donation under this residual paragraph. The 1987 UAGA deleted this section; it needs to be reinserted to give the statute flexibility, and to maximize the right to donate.

3(b)(2) Again, there is no justifiable reason to allow the unverified wishes of a third party to trump the wishes of an available consenting party. This is especially true where the unverified wish of a third party to donate could not possibly cancel a refusal. Given that most states and the federal government have expressed a legislative policy in favor of organ donation, and the preservation of life, it seems odd that the power of one negative voice can overrule one or more assents. This contradiction is especially stark given that there is no self-interest being served by the donor of an anatomical gift. Consider this analogy: If two beneficiaries jointly inherited the formula for a life-saving elixir, would we allow one of the beneficiaries to burn the formula, when the other wished to use the formula to benefit all mankind?

3(b)(2)(c) There is considerable confusion over the meaning of the term "telegraphic", and whether telecopied consent forms may be used.

SECTION 4. AUTHORIZATION BY [CORONER] [MEDICAL EXAMINER] OR [LOCAL PUBLIC HEALTH OFFICIAL].

(a) The [coroner] [medical examiner] may release and permit the removal of a part from a body within that official's custody, for transplantation or therapy or research, if:

- (1) the official has received a request for the part from a hospital, physician, surgeon, or procurement organization;
- (2) the official has made a reasonable effort, taking into account the useful life of the part, to locate and examine the decedent's medical records and inform persons listed in Section 3(a) of their option to make, or object to making, an anatomical gift;
- (3) the official does not know of a refusal or contrary indication by the decedent or objection by a person having priority to act as listed in Section 3(a);
- (4) the removal will be by a physician, surgeon, or technician; but in the case of eyes, by one of them or by an enucleator;
- (5) the removal will not interfere with any autopsy or investigation;
- (6) the removal will be in accordance with accepted medical standards; and
- (7) cosmetic restoration will be done, if appropriate.
- (b) If the body is not within the custody of the [coroner] [medical examiner], the [local public health officer] may release and permit the removal of any part from a body in the [local public health officer's] custody for transplantation or therapy or research if the requirements of subsection (a) are met.
- (c) An official releasing and permitting the removal of a part shall maintain a permanent record of the name of the decedent, the person making the request, the date and purpose of the request, the part requested, and the person to whom it was released.

Subsection (b) is a companion provision to subsection (a) to cover similar situations but in cases where the [coroner] [medical examiner] is not authorized to act. Under both subsections, the removal and release is limited to transplant or therapeutic purposes.

SECTION 5. REFERRAL, SEARCH AND NOTIFICATION

(a) At or around the time of death of a patient in a hospital, the hospital shall notify its designated organ procurement organization of the patient's death or potential for removal from life support. If the patient has a validly executed donor card, donor designation on a driver's license, advance directive, will, other document of gift, or registration with an organ and tissue donor registry, the organ procurement organization representative or the hospital's designated requestor shall attempt to notify a person listed in this subsection of the gift. If no document of gift is known to the organ procurement organization representative or the designated requestor, one of those two individuals shall ask the persons listed in this subsection whether the decedent had a validly executed document of gift. If there is no evidence of an anatomical gift or actual notice of contrary indications

by the decedent, the organ procurement organization representative or the designated requestor shall attempt to notify a person listed in Section 3 of the option to donate organs or tissues. Consent need only be obtained from an available person in the highest priority class applicable. If no available member of a class will make a decision, the organ procurement organization representative or the designated requestor shall approach a member of the next class

- (b) If the death takes place outside of a hospital, a reasonable search for a document of gift shall be made, as described in paragraph (c) of this section.
- (c) The following persons shall make a reasonable search for a document of gift or other information identifying the bearer as a donor or as an individual who has refused to make an anatomical gift:
- (1) a law enforcement officer, fireman, paramedic, or other emergency rescuer finding an individual who the searcher believes is dead or near death; and
- (2) a hospital, upon the admission of an individual at or near the time of death, if there is not immediately available any other source of that information.
- (c) If a document of gift or evidence of refusal to make an anatomical gift is located by the search required by subsection (c)(1), and the individual or body to whom it relates is taken to a hospital, the hospital must be notified of the contents and the document or other evidence must be sent to the hospital.

AOPO COMMENT: 5(a)— This paragraph replaces the first two paragraphs of the 1987 section with language mirroring the protocol in the COP. The proposed new 5(b) reflects the fact that gifts of eyes and tissues may be made when the potential donor dies outside of a hospital. Further, the COP regulations do not apply to this scenario.

SECTION 6. PERSONS WHO MAY BECOME DONEES; PURPOSES FOR WHICH ANATOMICAL GIFTS MAY BE MADE.

- (a) The following persons may become donees of anatomical gifts for the purposes stated:
- (1) a designated organ or other procurement organization, hospital, physician, surgeon, for transplantation, therapy, medical or dental education, research, or advancement of medical or dental science;
- (2) an accredited medical or dental school, college, or university for education, research, advancement of medical or dental science; or
- (3) a designated individual for transplantation or therapy needed by that individual.

- (b) An anatomical gift may be made to a designated donee or without designating a donee. If a donee is not designated or if the donee is not available or rejects the anatomical gift, the anatomical gift may be accepted by the designated organ procurement organization or other procurement organization.
- (c) If the donee knows of the decedent's refusal or contrary indications to make an anatomical gift or that an anatomical gift by a member of a class having priority to act is opposed by a member of the same class or a prior class under Section 3(a), the donee may not accept the anatomical gift.

AOPO Comment: These revisions more accurately reflect the federally mandated role of the OPO is this portion of the process.

SECTION 7. DELIVERY OF DOCUMENT OF GIFT.

- (a) Delivery of a document of gift during the donor's lifetime is not required for the validity of an anatomical gift.
- (b) If an anatomical gift is made to a designated donee, the document of gift, or a copy, may be delivered to the donee to expedite the appropriate procedures after death. The document of gift, or a copy, may be deposited in any hospital, procurement organization, or registry office that accepts it for safekeeping or for facilitation of procedures after death. On request of an interested person, upon or after the donor's death, the person in possession shall allow the interested person to examine or copy the document of gift.

SECTION 8. RIGHTS AND DUTIES AT DEATH.

- (a) Rights of a donee created by an anatomical gift are superior to rights of others. A donee may accept or reject an anatomical gift. If a donee accepts an anatomical gift of an entire body, the donee, subject to the terms of the gift, may allow embalming and use of the body in funeral services. If the gift is of a part of a body, the donee, upon the death of the donor and before embalming, shall cause the part to be removed without unnecessary mutilation. After removal of the part, custody of the remainder of the body vests in the person under obligation to dispose of the body. Note deletion of autopsy language.
- (b) The time of death must be determined by a physician or surgeon who attends the donor at death or, if none, the physician or surgeon who certifies the death. Neither the physician or surgeon who attends the donor at death nor the physician or surgeon who determines the time of death may participate in the procedures for removing or transplanting a part unless the document of gift designates a particular physician or surgeon pursuant to Section 2(d).
- (c) If there has been an anatomical gift, a technician may remove any donated parts and an enucleator may remove any donated eyes or parts of eyes, after determination of death by a physician or surgeon.

AOPO Comment: Many states have adopted laws which require that autopsies be performed in a time and manner compatible with organ donation, and not the other way around. Prominent medical examiners have publicly testified that there is seldom if ever a reason for the needs of forensic autopsy and the need for donor organs to conflict. The UAGA is not the appropriate place to determine the relative value of the need to determine the cause of death versus the need to preserve life.

SECTION 10. SALE OR PURCHASE OF PARTS PROHIBITED.

- (a) A person may not knowingly, for valuable consideration, purchase or sell an anatomical gift made pursuant to this act part for transplantation or therapy, if removal of the part is intended to occur after the death of the decedent.
- (b) Valuable consideration does not include reasonable payment for the removal, processing, disposal, preservation, quality control, storage, transportation, or implantation of a part.
- (c) A person who violates this section is guilty of a [felony] and upon conviction is subject to a fine not exceeding [\$50,000] or imprisonment not exceeding [five] years, or both.

AOPO Comment: We are not aware of any reason why the prohibition of sale should not apply to research organs and tissues as well.

SECTION 11. EXAMINATION, AUTOPSY, LIABILITY.

- (a) If, at or near the time of death, an anatomical gift has been made or there is no evidence of a refusal to make an anatomical gift, reasonable examinations, tests or procedures necessary to preserve the right to make a gift and to assure medical acceptability the gift for the purposes intended may be performed, including but not limited to serological and compatibility testing. Notwithstanding any law to the contrary, OPOs, tissue banks and eye banks may access and review the medical record of the potential donor for purposes of assessing medical suitability for donation.
- (b) The provisions of this [Act] are subject to the laws of this State governing autopsies.
- (c) A hospital, physician, surgeon, [coroner], [medical examiner], [local public health officer], enucleator, technician, procurement organization or other person, who acts in accordance with this [Act] or with the applicable anatomical gift law of another state [or a foreign country] or attempts in good faith to do so is not liable for that act in a civil action or criminal proceeding.
- (d) An individual who makes an anatomical gift pursuant to Section 2 or 3 and the individual's estate are not liable for any injury or damage that may result from the making or the use of the anatomical gift.

AOPO COMMENT: Since 1987 there have been considerable changes in how decisions are made at the end of life. The decision of whether or not to remove ventilators from non-brain- dead, but still terminal patients is one of those decisions. Such patients are also potential organ donors, should the removal from a ventilator result in their cardiac death. The recovery of organs from an individual who dies in these circumstances requires careful adherence to clinical and ethical protocols. The families of such patients also need to have the time and information necessary to decide, not only if their loved one will donate organs, but if it is time to remove the loved one from the ventilator. The Act needs to allow physicians the flexibility to institute medically accepted medical procedures to preserve the ability of the family to donate until these decisions are made.

Federal privacy regulations promulgated pursuant to the Health Insurance Portability and Accountability Act ("HIPAA") explicitly permit pre-consent disclosure of medical records for potential donors. In fact, in its published commentary accompanying the HIPAA regulations, the Department of Health and Human Services noted that "[w]e agree that organ and tissue donation is a special situation due to the need to protect potential donor families from the stress of considering whether their loved one should be a donor before a determination has been made that donation would be medically suitable."(65 Fed Reg. 82688 (December 28, 2000)). There are some states, however, which do not recognize this area of exemption from privacy statutes. HIPAA does not preempt state privacy laws that are more protective of a patient's privacy. Thus, again, state laws should be amended to be in line with federal policy on organ donation.

SECTION 12. TRANSITIONAL PROVISIONS. This [Act] applies to a document of gift, revocation, or refusal to make an anatomical gift signed by the donor or a person authorized to make or object to making an anatomical gift before, on, or after the effective date of this [Act].

SECTION 13. UNIFORMITY OF APPLICATION AND CONSTRUCTION. This [Act] shall be applied and construed to effectuate its general purpose to make uniform the law with respect to the subject of this [Act] among states enacting it.

SECTION 14. SEVERABILITY. If any provision of this [Act] or its application thereof to any person or circumstance is held invalid, the invalidity does not affect other provisions or applications of this [Act] which can be given effect without the invalid provision or application, and to this end the provisions of this [Act] are severable.

SECTION 15. SHORT TITLE. This [Act] may be cited as the "Uniform Anatomical Gift Act (1987)."