



POSITION STATEMENT

The Eye Bank Association of America (EBAA) supports hospitals' right and obligation to independently select and contract with the recovery organizations they choose to recover eyes and tissues for transplant and research purposes. This authority is granted to them by the Uniform Anatomical Gift Act and by CMS' Conditions of Participation. EBAA opposes any effort to interfere with the relationship between hospitals and their preferred recovery partners.

DEFINITIONS AND BACKGROUND

The Centers for Medicare and Medicaid Services (CMS) develops Conditions of Participation (CoPs) that health care organizations must meet in order to participate in the Medicare and Medicaid programs. These health and safety standards have been in place since 1986 and are the foundation for improving outcomes and protecting beneficiaries' health and safety.¹ Failure to adhere to the CoPs can result in a hospital being barred from Medicare and Medicaid reimbursement.

The Uniform Law Commission (ULC) is a non-profit association comprised of commissioners appointed by every U.S. state and territory. The ULC aims to provide well-researched and well-drafted legislation to bring stability to critical areas of statutory law across jurisdictions. The ULC promotes enactment of uniform acts in areas of state law where uniformity is desirable and practical.²

In 1968, the ULC drafted the country's first Uniform Anatomical Gift Act (UAGA). This act facilitated making an anatomical gift (commonly called organ, eye and tissue donation) by harmonizing the laws and processes in the various states. The 1968 UAGA was enacted by all 50 states. It has been updated twice, in 1987 and 2006, to respond to changes in medical and information technology. The UAGA is the foundational legislation on which the nation's organ, eye and tissue donation and transplantation professions rest.

EYE BANKS' TISSUE RECOVERY PROCESS

Eye banks recover corneas from deceased donors and prepare them for transplantation by corneal surgeons; over 79,000 corneas were provided for sight-restoring surgeries in 2018. A further 23,000 corneas were used for educational or research purposes. These tissues were recovered from over 68,000 individual donors, the majority of whom were referred to the eye bank by the hospitals in which these donors were treated and died.

As per the CoPs, eye banks sign recovery service contracts with hospitals in their area to recover ocular tissues from their deceased patients. These agreements establish the eye bank's right to recover corneas from the hospital's donors. They dictate the processes the hospital will use to notify the eye bank of a potential donor and the steps the hospital will follow to maintain the donor until the recovery can be completed. They also detail the eye bank technician's workflow within the

¹ <https://www.cms.gov/Regulations-and-Guidance/Legislation/CFCsAndCoPs/index.html?redirect=/cfcsandcops/> - retrieved March 13, 2019

² <http://www.uniformlaws.org/aboutulc/overview> - retrieved March 13, 2019

hospital to ensure swift and effective corneal recovery, as well as the eye bank's obligation to protect the hospital by maintaining appropriate accreditations, licensures and liability insurance.

Corneas, unlike organs, are recovered after the donor's death. There are fewer medical rule outs for eye donation than for organs donation and there is no need to match donors to recipients to reduce the risk of rejection. As a result, the supply of donor corneas currently exceeds demand in the United States. This has led to competition among eye banks to establish relationships with corneal surgeons with whom they can place tissue.

Surgical advances require more sophisticated transplant procedures; these call for more technically demanding preparation techniques. Concurrently, new federal regulations have increased eye banks' costs to provide tissue for transplant. This has led to a decrease in the number of eye banking organizations operating in the United States, from 82 in 2012 to 57 in 2018³. This consolidation has come about through mergers, acquisitions and the dissolution of some eye banks.

To obtain a competitive advantage, some eye banks have partnered with organ procurement organizations (OPOs) located in distant parts of the country to provide cornea recoveries in the OPOs' service areas. In most cases, OPOs are given first notification of potential donors because of the scarcity and time-sensitivity of donated organs. If the OPO has partnered with an eye bank outside their recovery area, that OPO will use its gatekeeper status, and its political and financial influence, to encourage hospitals to designate its partner eye bank, rather than the eye bank serving that community, as its cornea recovery organization. Alternately, the OPO's staff will recover the corneas and ship them to their client eye bank for evaluation, processing and placement with surgeons.

Through these partnerships, eye banks serving as OPO clients can bypass the local eye bank to obtain corneal tissue from donors located hundreds of miles from their bases of operations. This deprives the local bank of its primary source of donor tissue, severely hampering its operations and its ability to serve its local community.

EBAA believes that these and similar strategies are inappropriate and contradict the letter and the intent of the legislative and regulatory foundations of America's donation and transplantation system.

In response to the diversion of donor tissue to out-of-state eye banks, some eye banks have endorsed efforts to amend their states' anatomical gift acts to stipulate that only their eye banks may recover corneal tissue from donors within their state. EBAA believes that the transplantation community is best served when each eye bank competes on a level playing field. Without external influences, each eye bank's success will be determined by their ability to serve the needs of all their partners, from recovery hospitals to transplant surgeons. In such an environment, seeking protection by legislative means would be unnecessary.

THE BASIS FOR EBAA'S OBJECTIONS

As noted above, the UAGA has been established in every U.S. state and territory to increase the number of organ, eye and tissue transplants by streamlining and standardizing the process of donating one's body parts. Attempts to amend a state's anatomical gift act to give preference to certain eye banks over others interfere with that standardization and complicate the organ, eye and

³ 2018 Eye Banking Statistical Report, Eye Bank Association of America

tissue donation and recovery process. This could result in unnecessary delays in recovering donated body parts, leading to poor transplant outcomes, and could lead to declines in donation consent rates.

The UAGA is clear about the obligation and authority of each of the organ, eye and tissue recovery organizations:

Section 11. Persons that May Receive Anatomical Gift; Purpose of Anatomical Gift.

(a) An anatomical gift may be made to the following persons named in the document of gift:

- (1) a hospital; accredited medical school, dental school, college, or university; organ procurement organization; or other appropriate person, for research or education;
- (2) subject to subsection (b), an individual designated by the person making the anatomical gift if the individual is the recipient of the part;
- (3) an eye bank or tissue bank.

(c) If an anatomical gift of one or more specific parts or of all parts is made in a document of gift that does not name a person described in subsection (a) but identifies the purpose for which an anatomical gift may be used, the following rules apply:

- (1) If the part is an eye and the gift is for the purpose of transplantation or therapy, the gift passes to the appropriate eye bank.
- (2) If the part is tissue and the gift is for the purpose of transplantation or therapy, the gift passes to the appropriate tissue bank.
- (3) If the part is an organ and the gift is for the purpose of transplantation or therapy, the gift passes to the appropriate organ procurement organization as custodian of the organ.

Section 11 comments: "...organs passing to organ procurement organizations under this [act] for the purpose of transplantation or therapy pass to them in a custodial capacity. There is no expectation that the organ procurement organization will retain the organ. Eyes and tissue pass to the appropriate eye or tissue bank under no similar restrictions; therefore, eye and tissue banks do not properly take as a custodian."

The UAGA's text and intent are clear that eye banks and tissue banks are on an equal basis with organ procurement organizations. Donated eyes and tissues are to be received by the appropriate eye or tissue bank, while donated organs are provided to an OPO on a custodial basis. The explanatory comments, intended for legislators in the various states considering adoption of the UAGA, further emphasize that OPOs' custodial role over eyes and tissue pertains to the referral of donated gifts to the contracted recovery banks, and not to the organs, eyes or tissues themselves. The legal definition of custodian is, "a person with whom some article is left, usually pursuant to a contract, who is responsible for the safe return of the article to the owner when the contract is fulfilled"⁴. In the case of corneas, the organ procurement organization does not take ownership of the ocular tissue, but merely facilitates its transfer from the donor to the appropriate eye bank.

Further on in the text, the UAGA, Section 15, "Coordination of Procurement and Use" states in its entirety:

Each hospital in this state shall enter into agreements or affiliations with procurement organizations for coordination of procurement and use of anatomical gifts.

⁴ <https://legal-dictionary.thefreedictionary.com/custodian> - retrieved March 13, 2019

This explicitly establishes that the responsibility for selecting an eye bank to serve as its recovery partner rests solely with each individual hospital.

Similarly, CMS' Conditions of Participation read as follows (emphasis added):

Section 486.322(c) Standard: Cooperation with tissue banks.

(1) The OPO must have arrangements to cooperate with tissue banks that have agreements with hospitals and critical access hospitals with which the OPO has agreements. The OPO must cooperate in the following activities, as may be appropriate, to ensure that all usable tissues are obtained from potential donors:

(i) Screening and referral of potential tissue donors.

(ii) Obtaining informed consent from families of potential tissue donors.

(iii) Retrieval, processing, preservation, storage, and distribution of tissues.

(iv) Providing designated requestor training.

(2) An OPO is not required to have an arrangement with a tissue bank that is unwilling to have an arrangement with the OPO.

This was commented upon in the publication of the final rule as follows (emphasis added):

“...when an OPO receives a referral of a death or an imminent death from the hospital with which it has an agreement, the OPO must cooperate with the tissue bank with which the hospital has an agreement to ensure that the referral is screened for tissue donation potential and, as appropriate, referred to the tissue bank. Additionally, as proposed at 486.322(c)(ii), an OPO must cooperate with tissue banks with which a hospital has an agreement in obtaining informed consent for tissue donation.”⁵

The Interpretive Guidelines for 42 CFR §486.322(c)(1) state (emphasis added):

“Verify that the OPO has identified the eye bank and tissue bank agreements between each hospital/critical access hospital located in the service area.”⁶

Furthermore, Section 486.322(c)2 above, which exempts an OPO from working with an unwilling tissue bank, is illogical unless the selection of a partner tissue bank was the provenance of the hospital, rather than the OPO.

Each of these citations makes clear that the OPO is required to cooperate with the tissue banks selected by the hospital, and makes no allowance for the OPO to unilaterally select or favor one recovery organization over another.

CONCLUSION

Competition among eye banks, as within any profession, can lead to innovation and improved outcomes for all involved. America's eye banks recognize this and embrace it as part of their ongoing quest to provide safe, quality tissue for sight-restoring ocular surgeries. However, agreements between OPOs and eye banks to send recovered tissue to distant eye banks for evaluation and placement distort the distribution of corneal tissue. This represents an overreach of the OPO's custodial authority and substantially harms affected local eye banks.

⁵ Federal Register Volume 63, Number 119 (Monday, June 22, 1998), p. 31007

⁶ Appendix Y - Organ Procurement Organization (OPO) Interpretive Guidance (Rev. 180, 08-24-18)

As illustrated above, both the Uniform Anatomical Gift Act and CMS's Conditions of Participation grant to each hospital the authority to select its recovery agencies. Hospitals should be free to make this decision based on their own needs and circumstances, and not have it imposed on them by outside entities over which they have no control.

The organ, eye and tissue donation system in the United States depends on the cooperation and shared expertise of many participants; hospitals, eye banks, tissue banks and organ procurement organizations. Each contributes to the process to ensure that the greatest number of anatomical gifts are safely recovered and provided for transplant. Interfering in the process, whether by permitting OPOs to favor certain recovery organizations over others or through legislative efforts to protect certain banks, undermines the entire system and threatens to hamper donation, recovery and transplantation efforts. EBAA opposes any activity that would threaten our ability to recover anatomical donations and provide life-transforming organ, eye and tissue transplants.

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ABOUT EBAA

The Eye Bank Association of America, established in 1961, is the oldest transplant association in the nation and sets standards, provides education, and engages in advocacy to support eye donation, and cornea transplantation and research. EBAA is widely recognized for leading the transplantation field with the establishment of medical standards for eye banking, and comprehensive training and certification programs for eye bank personnel.