



American Association of Tissue Banks®

January 31, 2022

Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-3409-NC
P.O. Box 8010
Baltimore, MD 21244-8010

In Re: [CMS-3409-NC](#), Request for Information: Health and Safety Requirements for Transplant Programs, Organ Procurement Organizations, and End-Stage Renal Disease Facilities

Submitted electronically at www.regulations.gov

Dear Madams and Sirs:

The American Association of Tissue Banks (AATB or Association) submits these comments related to the request for information (RFI) by the Centers for Medicare and Medicaid Services (CMS) related to health and safety requirements for transplant programs, organ procurement organizations (OPOs), and other facilities. In particular, the AATB comments will focus on those questions related to the procurement of tissue and items specific to tissue banking.

In formulating our response to the RFI, AATB focused on several key principles. First, the AATB recognizes the urgency of reducing the waiting list for organs in the United States and supports all policies that will improve the system of organ donor identification, recovery, and transplantation. The AATB strongly encourages, supports, and promotes organ recovery and recognizes that organ recovery should be prioritized over tissue -- without limitation. One of our core principles is to maximize the gift of life and to save as many human lives as possible by prioritizing organs, eye, and tissue donation, in that order. Finally, our efforts in collaboration with OPOs and others in the transplantation field are to prioritize organ recovery and support the donor family as they grieve the loss of their loved one.

The AATB is a professional, non-profit, scientific, and educational organization. AATB is the only national tissue banking organization in the United States, and its membership totals more than 125 accredited tissue banks and over 6,000 individual members. These banks recover tissue from more than 58,000 donors and distribute over 3.3 million allografts for more than 2.5 million tissue transplants performed annually in the US. The overwhelming majority of the human tissue distributed for these transplants comes from AATB-accredited tissue banks. For more information about tissue banking and its impact on patients, please visit <https://www.aatb.org/why-tissue>.

Below are the AATB's responses to key questions within the RFI related to the procurement of tissue and items specific to tissue banking:

OPO Tissue Banking Activity and Relationships with Other Tissue Banking Organizations

- *To what level have OPOs developed their own tissue banks and is this currently standard practice across OPOs?*

While the AATB cannot directly address the question concerning the practice of OPOs, we would like to take this opportunity to highlight two important issues: (1) The OPO Conditions of Participation ([CoPs](#)) specifically requires OPO collaboration with tissue banks; and (2) While the CoPs acknowledge the key role that OPOs should have with tissue banks, it is also important to acknowledge that tissue banks have differing roles.

Concerning the CoPs, the key requirement related to tissue banking is detailed under § 486.322(C)(1), which states the following:

- (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.*

In discussing the rationale for requiring the cooperation, CMS noted that OPOs have become the “de facto gatekeepers for information about potential tissue donors”,¹ while further noting that “[c]ooperation between OPOs and tissue banks often results in more efficient operations, such as shared referral lines for hospitals to use when calling about deaths and collaboration between OPOs and tissue banks in training hospital designated requestors. Further, as we stated in the preamble to the proposed rule, collaboration and cooperation between donation organizations promote a positive public opinion about donation.” Thus, to the extent that the CoPs have encouraged collaboration to promote synergies and greater collaboration, while also ensuring that families are only approached once by a trained “designated requestor,” the overall donation system benefits.

¹ Direct quote: The hospital CoP for organ, tissue, and eye procurement at § 482.45, which went into effect in August 1998, requires hospitals to refer all deaths and imminent deaths (rather than just potential organ donors) to an OPO or a third party designated by the OPO. Critical access hospitals also have a CoP for organ, tissue, and eye procurement. (See § 485.643.) The hospital and critical access hospital CoPs state that in the absence of alternative arrangements between a hospital and a tissue bank, the OPO will determine suitability for tissue donation. It has been our experience that very few hospitals have been willing to have alternative arrangements that would require them to make two phone calls: one to the OPO to report a death or imminent death and one to the tissue bank to report a potential tissue donor. Thus, in most areas of the country, OPOs became the de facto gatekeepers for information about potential tissue donors even though our regulations permit alternative arrangements.

Unfortunately, as detailed within the CoPs and within this RFI, CMS seems to have a narrow view of tissue banks, assuming that all banks perform all of the duties within the industry (i.e., donor screening and testing, retrieval, processing, preservation, storage, and distribution of tissues). Perhaps a better description of tissue banks would be that of the Food and Drug Administration (FDA). The FDA [requires](#) the registration and listing of certain tissue establishments. As part of that process, a tissue establishment designates which functions it performs within the process. Then the FDA makes publicly available [information](#) about tissue establishments and their particular functions within tissue banking.² Similarly, the AATB provides [information](#) on its accredited banks based on certain functions.³ For the most part, the CoPs encourage the collaboration between tissue banks and OPOs for certain functions, and to the extent that CMS may have concerns with certain OPO functions that overlap with tissue bank responsibilities (as this question implies), it may be best for CMS to fully articulate what, if any, tissue banking functions may be inappropriate for OPOs.

- *How has the increase in OPOs participating in tissue banking impacted the collection of usable tissue from donors?*

Before implementation of the CoPs, the hospital staff was routinely asked to notify multiple donation agencies dependent upon if a patient was a potential organ, eye, or tissue donor. This could result in hospital staff confusion and reduce or delay donor referrals in the healthcare setting and is particularly problematic for staff when hospitals are resource and staff constrained, as is occurring today. The AATB's position is that the OPO CoPs have promoted a system whereby the OPO would be the primary recipient of all hospital referrals for potential organ, eye, and tissue donors. That cooperation and collaboration between organ, eye, and tissue donation organizations have resulted in value-added efficiencies within healthcare facilities, and ensured families are not approached by multiple entities concerning the donation while overall sending a positive message about donation.

- *Are there areas for improvement in the relationship between OPOs, hospitals, and tissue banks that would facilitate increasing the collection of usable tissue?*

As with all complex systems involving multiple parties working in concert for ultimate success, there is always room for improvement. And, as such, AATB would support participating in a blue-ribbon panel or another appropriate group to address additional opportunities to positively impact the organ waiting list.

² FDA asks tissue establishments to identify activities in one or more of the following categories: distribute, donor testing, label, package, process, recover, screen, and store.

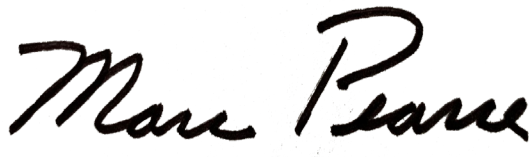
³ AATB identifies tissue bank activities as one or more of the following categories: acquisition, collection or recovery, authorization or informed consent, distribution or dispensing service, donor eligibility assessment, preparation or processing, and storage.

- *For OPOs that do have active tissue banks, how does this service impact or intersect with the OPOs primary mission of recovering and distributing organs?*

While the AATB cannot directly speak on behalf of OPOs, the question suggests that additional information may be helpful. First, as noted above, tissue banks have a variety of roles, and some of those roles are explicitly encouraged by the OPO CoPs. The clinical reality of how organ and tissue donation occurs inherently prioritizes organ donation. Unlike organ donation, tissue recovery is not dependent upon a potential donor being maintained on life support, and tissue can be recovered up to 24 hours after cardiac cessation (i.e. asystolic). For the subset of non-heart-beating organ donors (30% of total deceased organ donors or 4,187 donors in 2021) time from cardiac cessation to the recovery of organs is so critical that it would preclude any other tissue or eye recovery until the organs had been collected. Unlike organs, tissue can be stored for months or even years before being used for transplantation. In contrast, donated organs have a narrow window in which the organ can be implanted in the recipient. Given the diverse requirements, tissue banks acknowledge that organ donation should always have precedence over tissue donation.

We hope that you will find this information helpful in your deliberations. The AATB welcomes the opportunity to assist CMS in any way you deem appropriate.

Respectfully,

A handwritten signature in black ink that reads "Marc Pearce". The signature is written in a cursive, flowing style.

Marc Pearce, MBA
President & CEO
American Association of Tissue Banks