



American Association of Tissue Banks®

February 12, 2020

Seema Verma, MPH  
Administrator  
Centers for Medicare & Medicaid Services  
Department of Health and Human Services  
7500 Security Boulevard  
Baltimore, MD 21244

**RE: [CMS-3380-P] Medicare and Medicaid Programs; Organ Procurement Organizations Conditions for Coverage; Revisions to the Outcome Measure Requirements for Organ Procurement Organizations**

Dear Administrator Verma:

The American Association of Tissue Banks (AATB) welcomes the opportunity to comment on the above-captioned Centers for Medicare and Medicaid Services (CMS) proposed rule addressing Organ Procurement Organizations (OPOs) Conditions for Coverage and Outcome Measure Requirements (Proposed Rule). AATB is aligned with the Agency in its stated objectives to increase procurement opportunities for transplantation, increase organ utilization, and ultimately saving lives.<sup>1</sup> It is with that in mind that we provide additional input below and request additional clarification prior to finalization of any of the Agency's proposals.

The American Association of Tissue Banks (AATB) is a professional, non-profit, scientific, and educational organization. The Association was founded in 1976 by a group of doctors and scientists who in 1949 had started our nation's first tissue bank, the U.S. Navy Tissue Bank. Recognizing the increasing use of human tissue for transplant, the founders saw the need for a national organization to develop standards, promote ethics, and increase human tissue donations. Since its beginning, the AATB has been dedicated to improving and saving lives by promoting the safety, quality, and availability of donated human tissue. To fulfill that mission, the AATB publishes standards and accredits tissue banks. In support of the efforts The Association also regularly interacts with regulatory agencies, like FDA, and conducts educational meetings.

AATB is the only national tissue banking organization in the United States, and its membership totals 120 accredited tissue banks, 32 of which are OPO's. These organizations recover tissue from more than 58,000 donors annually. The overwhelming majority of the 3.3 million human tissue allografts prepared annually for transplantation and distributed for transplant comes from a wide array of AATB-accredited tissue banks including OPOs that are registered with the FDA to perform designated tissue banking functions.

The tissue donation process involves three distinct and regulated entities: donor hospitals, tissue procurement organizations (TPOs) which may also be OPOs, and tissue processors. Donor hospitals have standards of performance that are set out in the conditions of participation (CoPs). Donor hospital CoPs require them to maintain supportive measures to allow for organ, eye, and tissue donation by making timely referral (defined by affiliation agreements between TPOs/OPOs and donor hospitals) for **every death** and **imminent death**. In addition, under the CoPs, donor hospitals must preserve the option of organ, eye, and tissue donation for the family decision and have a designated requestor – the TPO/OPO or someone at the hospital trained by the TPO/OPO – to discuss the option of donation with the family.

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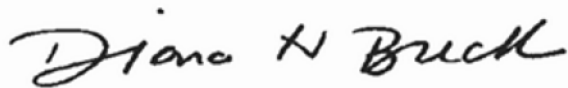
<sup>1</sup> 84 Fed. Reg. 70628, 70630 (Dec. 23, 2019).

While the Proposed Rule is focused on increasing availability of organs for transplantation through OPO performance, we also urge CMS to consider the OPO's role and obligations in support of tissue and eye donation. The vast majority of the 58 OPOs serve as tissue procurement organizations, receiving potential tissue referrals from donor hospitals and coordinating the procurement of tissue from organ donors, as well as from tissue-only donors.

In light of the interaction between tissue and organ donation, the AATB urges CMS to provide further rationale for setting a required performance threshold at the top 25%, especially given that it redefines above average performing OPOs (as a matter of math) as "low performing" and automatically puts the majority of OPOs at risk of decertification without opportunity to present mitigating factors or an improvement plan. As a result, the proposed measure if implemented could result in a large number of OPO de-certifications, which could significantly disrupt the existing system for tissue donation and procurement. The AATB is concerned that this type of destabilization to the existing system of OPOs may create an immediate and unnecessary shortage of tissue grafts available to heal people in need.

AATB would support program and measure changes that otherwise accurately assess OPO performance, increase organ and tissue donation and transplant, and provide an opportunity for OPOs not meeting the measure to present mitigating factors and a performance improvement plan, ultimately ensuring a consistent and well performing infrastructure to support tissue donation in all areas of the country. We are concerned, however, that the current proposals would not achieve those goals and could instead result in unintended delays and shortages of allograft tissue for transplant.

Respectfully submitted,

A handwritten signature in black ink that reads "Diana H. Buck". The signature is written in a cursive, flowing style.

Diana H. Buck, M.Ed., MBA, CTBS  
Chairperson, AATB Board of Governors  
Interim CEO, AATB