

January 8, 2026

Re: *Information Collection Request Title: Membership Forms for Organ Procurement and Transplantation Network*, OMB No. 0915-0184—Revision.

(Sent via www.reginfo.gov/public/do/PRAMain)

I am writing on behalf of the Association of Organ Procurement Organizations (AOPO) to seek clarification regarding the requirement that an Organ Procurement Organization (OPO) have a written agreement with a histology laboratory that is owned by the OPO.

AOPO collectively represents 46 federally designated, non-profit OPOs in the United States, which together serve millions of Americans. As an organization, AOPO is dedicated to providing education, information sharing, research, technical assistance, and collaboration with OPOs, other stakeholders, and federal agencies to continue this nation's transplantation success while consistently improving towards the singular goal of saving as many lives as possible.

By way of background, a *Federal Register* notice was published in the *Federal Register* on August 20, 2025, Vol. 90, No. 15, entitled *ICR -- Membership Forms for Organ Procurement and Transplantation Network*. In response to the request for comments, AOPO expressed support for the necessity and utility of the proposed information collection, noting that it provides critical information to assess whether applicants meet OPTN membership requirements. AOPO also sought clarification on whether a written agreement is required between an OPO and its laboratory when the two entities operate under separate Centers for Medicare & Medicaid Services Certification In Numbers.

Subsequently, in the December 9, 2025 *Federal Register*¹ HRSA responded "Laboratories are required to maintain written agreements with each OPO they serve, unless clinical urgency prevents such an agreement. These agreements delineate the respective responsibilities and expected procedures of the OPO and the laboratory to ensure compliance with OPTN membership standards and support the integrity of the organ procurement process. This requirement is outlined in OPTN Bylaw C.2.D (OPO Affiliation), which specifies the elements that must be included in OPO-laboratory agreements."

¹ Agency Information Collection Activities: Submission to OMB for Review and Approval; Public Comment Request; Membership Forms for Organ Procurement and Transplantation Network, OMB No. 0915-0184-Revision

AOPO is requesting HRSA clarify this language to indicate that each OPO must either contract with a laboratory or meet the requirements of Appendix C (Membership Requirements for Histocompatibility Laboratories). This would allow for OPOs and laboratories that operate under separate CMS Certification Numbers but are legally one entity. Currently, AOPO is aware that all hospital-based OPOs and OPOs that own and operate a histocompatibility laboratory would need this clarification.

Thank you for your consideration.

Sincerely,

A handwritten signature in black ink, appearing to read 'Jeffrey Trageser', with a long horizontal flourish extending to the right.

Jeffrey Trageser

AOPO President

Executive Director, Lifesharing