

September 18, 2025

John Magee, M.D.
President, Board of Directors
Organ Procurement and Transplantation Network
c/o AIR

Dear Dr. Magee:

Pursuant to the authority at 42 C.F.R. 121.10(a), the Department of Health and Human Services' (HHS) Health Resources and Services Administration (HRSA) has received multiple reports of ongoing practices presenting potential risk to the safety of patients referred to organ procurement organizations (OPOs) for the purpose of potential organ donation and procurement. In reviewing these reports, HRSA has validated threats to patient safety in multiple OPOs.

The information and data provided by the Organ Procurement and Transplantation Network (OPTN), OPTN members, and incident reporters, upon independent assessment and analysis by HRSA, have demonstrated potentially widespread safety concerns for those patients for whom an OPO engages in evaluation, examination, and coordination of care with hospitals for the purpose of potential organ donation and procurement.

Therefore, pursuant to the Secretary's authority under 42 C.F.R. 121.4(a)(6), HRSA is directing the OPTN to develop a new OPTN policy that requires OPOs to designate a patient safety officer. The OPTN is directed to complete the following actions by December 17, 2025:

- (1) Draft, for review by HHS, an OPTN policy that requires the designation of a patient safety officer by each OPO member. The proposed policy must include the following core responsibilities of the patient safety officer role, which should include but are not limited to:
 - (a) Monitoring and investigating alleged patient safety events in real time;
 - (b) Ensuring 24/7/365 coverage of this role by the OPO;
 - (c) Serving as the first point of contact for patients, patient families, hospital partners, OPTN, and HRSA regarding potential safety concerns and complaints;
 - (d) Documenting and reporting alleged safety incidents, complaints, near misses, and adverse events to the OPTN;
 - (e) Leading root cause analyses and ensuring corrective actions are implemented; and
 - (f) Fostering a culture of patient safety within OPOs through training, transparency, and continuous improvement.

After HHS review of the proposed policy, and after the completion of the OPTN policymaking process described in the OPTN Membership and Management Policies at Policy E, this letter directs the OPTN to:

- (2) Provide final policy language to HRSA for publication in the Federal Register, such that the policy will be made enforceable by the Secretary under the process described at 42 C.F.R. 121.4(b)(2)].

HRSA, with authority delegated by the Secretary, will provide additional guidance and technical support to the OPTN in the successful and timely completion of (1) and (2).

In closing, the Department is acting to ensure that every patient and family engaged by an OPO is protected by clear accountability, real-time oversight, and a learning system worthy of the public's trust. We appreciate the OPTN's partnership and expect timely execution of this directive. HRSA will provide technical assistance to support implementation and will monitor progress closely. Our shared obligation, to donor patients and families who make the gift of life possible and to patients awaiting transplant who depend on safe, reliable systems, requires nothing less.

Sincerely,

A handwritten signature in black ink, reading "Thomas J. Engels". The signature is fluid and cursive, with the first name "Thomas" and last name "Engels" clearly legible.

Thomas J. Engels
Administrator