OPTN OPO Patient Safety Officer (PSO) Policy

Kyle Herber, *Member, OPO PSO Workgroup*

VOTING ITEM

1:25 – 1:40 p.m.

OPO PSO Workgroup Composition

Meelie DebRoy
Workgroup Chair
Transplant Hospital Representative

Kyle Herber
OPO Representative

Martha Stipsits
Quality Improvement Representative

Ariane Lewis
Neurocritical Care Representative

Jullie Hoggan
Patient Safety Advocate

OPO PSO Policy Development Timeline

September 18, 2025

Health and Human Services (HHS) Secretary directed the OPTN to develop a new OPTN policy that requires OPOs to designate a PSO.

April 1, 2026

Workgroup convened and began its development of a PSO framework.

June 3, 2026

Workgroup began drafting OPO PSO policy elements.

September 2, 2026

Workgroup reviewed and approved the draft public comment proposal.

September 9, 2026

HHS and Board Leadership began their review of the proposal.

October 26, 2026

Workgroup reviewed and approved the revised public comment proposal.

November 6, 2026

Board votes to advance the policy to public comment.

November 13, 2026

Public comment period opens through December 28, 2026.

OPO PSO Workgroup Objective and Charges

Objective

- Develop the role, responsibilities, infrastructure and policy language for requiring each OPO member of the OPTN to designate a PSO

Charges

- Define the PSO role, eligibility, qualifications, and organizational placement
- Define a PSO reportable event framework, reporting mechanisms, and oversight
- Deliver draft policy language

Summary of Proposed Policy: PSO Role

PSO serves as a central point of contact for addressing **acute patient safety issues**

- Promotes **physical and psychological safety**
- **Intervenes in active cases** when safety risks are identified; initiates notification to executive leadership; and halts or redirects operational processes when patient safety is threatened
- Serves as a **central point of contact** for patients, families, hospitals, third party contractors, and OPO personnel

PSO and their designee provide **continuous coverage** for real time oversight, identification, reporting, mitigation, escalation, and documentation of patient safety risks across all OPO operations

- Requires **standardized handoffs** at all shift changes

Summary of Proposed Policy: PSO Eligibility and Requirements

Must meet the requirements for at least one of two pathways:

- **Advanced degree,** with at least three years of clinical experience related to patient safety, transplant, and/or organ donation
- **License to practice as a licensed healthcare worker,** with at least five years of clinical experience related to patient safety, transplant, and/or organ donation

Must be able to use safety data and trends to **formulate system-level improvements** based on event analysis

Must be a **full-time employee** of the OPO and not employed by an accountable care organization or a subcontractor to the OPO

Summary of Proposed Policy: Reporting

OPO and PSO will instruct individuals to contact the PSO directly about safety inquiries and reporting safety events through a publicly available reporting channel

- At a minimum, the OPO and PSO provide individuals with the following publicly available reporting channels to report safety events: OPTN Complaints, the OPTN support service, or the Office of Inspector General hotline

OPO and PSO must instruct individuals to contact the PSO directly to the extent possible, so long as the PSO's involvement does not limit or conflict with the event or report

PSO submits their own report through the OPTN Patient Safety Portal and updates the report as needed

PSO reports patient safety events in accordance with OPTN Policies 2.2, 2.14, 2.15, and 18.5

- PSO will report the following minimum mandatory reportable events: (1) A donor declared brain-dead who is suspected of having brain function; and (2) a patient in the DCD pathway shows signs of neurological improvement (e.g., respiratory effort) post-surgical incision for organ recovery

Summary of Proposed Policy: Reporting (cont'd)

OPOs and the OPTN **share PSOs' contact information** on their public-facing websites

- OPOs will designate **standardized contact information** for the PSO and designee

PSO has **direct clinical escalation access** to the OPO Medical Director and all other C-suite-level OPO executives to escalate patient safety reporting

PSO must **connect with other OPO personnel** about reportable events, serving as a facilitator

PSO is **responsible for communicating with the original reporter** about any changes or other outcomes of reports that include the PSO as a contact

Policies to be Updated

OPTN Policies

- **Policy 1.2** Definitions
- **Policy 2.2** OPO Responsibilities
- **Policy 2.14** Organ Procurement
- **Policy 2.15** Requirements for Controlled Donation after Circulatory Death (DCD) Protocols
- **Policy 15.1** Patient Safety Contact
- **Policy 15.4.A** Host OPO Requirements for Reporting Post-Procurement Donor Results and Discovery of Potential Disease Transmissions
- **Policy 15.4.B** Host OPO Requirements for Reporting Post-Procurement Discovery of Recipient Disease or Malignancy
- **Policy 15.5.B** Transplant Program Requirements for Reporting Discovery of Potential Transmission of Unexpected Recipient Pathogen, Disease or Malignancy

OPTN Management and Membership (M&M) Policies

- **Appendix B.5** OPO Personnel
- **Appendix B.7** ***(New)*** OPO Patient Safety Officer
- **Appendix M** Definitions

Discussion

Voting Recitals

- WHEREAS, on September 18, 2025, the HHS Secretary directed the OPTN to develop new policies requiring each organ procurement organization (OPO) to designate a Patient Safety Officer (PSO) to support patient safety and compliance with applicable OPTN obligations;
- WHEREAS, the Board established the OPO PSO Workgroup (the "Workgroup"), which developed proposed revisions to the OPTN Management and Membership Policies (the "M&M Policies") to implement the PSO requirement, by defining the PSO's role, qualifications, organizational placement, and reporting responsibilities, through revisions to OPTN Policies 1.2, 2.2, 2.14, 2.15, 15.1, 15.4.A, 15.4.B, and 15.5.B and to Appendices B.5, B.7 (new), and M of the M&M Policies (collectively, the "PSO Revisions"); and
- WHEREAS, the Board has reviewed the PSO Revisions and believes that distributing them for public comment is in the best interests of the OPTN.

Voting Resolution Language

- NOW THEREFORE, BE IT RESOLVED, that the Board hereby approves the distribution of the PSO Revisions, as developed by the Workgroup, for public comment; and
- RESOLVED FURTHER, that the President and/or their designees are authorized to take all actions necessary to implement this resolution.