Public Comment Proposal

OPTN
Organ Procurement & Transplantation Network

Proposed Organ Procurement Organization (OPO) Patient Safety Officer (PSO) Policy

Sponsor Committee	OPTN Board of Directors
Public Comment	Nov. 13 – Dec. 28, 2026
Board Approved	TBD
Effective Date	TBD

Executive Summary

After receiving reports of practices presenting potential risks to the safety of patients referred to organ procurement organizations (OPOs) for potential organ donation and procurement, the Health Resources and Services Administration (HRSA) directed the Organ Procurement and Transplantation Network (OPTN) to develop a new policy that requires OPOs to designate a Patient Safety Officer (PSO) to support patient safety and compliance with applicable OPTN obligations. As directed by HRSA in September 2025, the OPTN Board of Directors ("Board") established the OPO PSO Workgroup. The Workgroup's objective is to define the role and responsibilities of the OPO PSO, and the PSO's placement in OPO infrastructure, such that there will be an established position at each OPO to support patient safety and compliance with applicable OPTN obligations.

This document serves to present the motivation and authority for this proposed policy, explain how the proposed policy would be implemented, and detail how the proposed policy would be incorporated into existing OPTN policies. This proposal defines the PSO role and responsibilities across OPOs to support patient safety oversight, escalation, reporting, collaboration, corrective action, and shared learning across OPO operations.

Purpose of Policy Development

The OPO PSO Workgroup was motivated by the concerns raised and validated by HRSA regarding multiple reports of ongoing practices that presented potential risks to the safety of patients who were referred to OPOs for potential organ donation and procurement. The OPTN is responsible for establishing and maintaining systems, standards, and policies intended to promote the safe, equitable, and effective procurement, allocation, transportation, and transplantation of organs. The PSO Workgroup is charged with developing the role, responsibilities, infrastructure, and policy language for requiring each OPO member of the OPTN to designate a PSO.

Policies Affected

Policy Number	*Policy Name*
OPTN Policy 1.2	Definitions
OPTN Policy 2.2	OPO Responsibilities

Policy Number	*Policy Name*
OPTN Policy 2.14	Organ Procurement
OPTN Policy 2.15	Requirements for Controlled Donation after Circulatory Death (DCD) Protocols
OPTN Policy 15.1	Patient Safety Contact
OPTN Policy 15.4.A	Host OPO Requirements for Reporting Post-Procurement Donor Results and Discovery of Potential Disease Transmissions
OPTN Policy 15.4.B	Host OPO Requirements for Reporting Post-Procurement Discovery of Recipient Disease or Malignancy
OPTN 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
OPTN M&M Policies, Appendix B.7	OPO Patient Safety Officer
OPTN M&M Policies, Appendix M	Definitions

Proposal History

Background

In a letter to the OPTN Board of Directors on September 18, 2025, HRSA reported it "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." HRSA conducted an independent assessment and analysis that validated concerns about threats to patient safety. Upon review of OPTN data, and information provided by OPTN members and incident reporters, HRSA determined that it "demonstrated potentially widespread safety concerns for patients for whom an OPO engages in evaluation, examination, and coordination of care with hospitals for the purpose of potential organ donation and procurement."

Pursuant to the Secretary of the U.S. Department of Health and Human Services' (HHS) authority under 42 C.F.R. 121.4(a)(6), HRSA directed the OPTN to develop a new OPTN policy that requires OPOs to designate a PSO. To develop this policy, the OPTN Board of Directors formed the OPO PSO Workgroup, comprised of OPO representatives, a patient safety advocate, a transplant hospital partner representative, and other patient safety and compliance experts, including quality improvement and neurocritical care representatives.

Legal Authority for OPO PSO Policy

The OPTN is obligated to create policy requirements necessary for its operation, as described under 42 U.S.C. 274(b)(2)(E), which requires that the OPTN "adopt and use standards of quality for the acquisition and transportation of donated organs." In addition, the OPTN is authorized to establish "membership

criteria and medical criteria for allocating organs" under 42 U.S.C. § 274(b)(2)(B). Further, under 42 U.S.C. 274(b)(2)(I) and (J), the OPTN is required to:

> "(I) collect, analyze, and publish data concerning organ donation and transplants, (J) carry out studies and demonstration projects for the purpose of improving procedures for organ procurement and allocation"

In addition, the OPTN, the OPTN Board of Directors, and OPTN members—including transplant centers and OPOs that procure deceased donor organs—are subject to specific requirements under the National Organ Transplant Act of 1984, codified at 42 U.S.C. §§ 273–274e, and the regulations at 42 C.F.R. part 121 (2026).

OPTN Governance and Compliance Framework

In addition to the statutory and regulatory framework described above, OPTN governance, policy development, and member compliance are further addressed in the OPTN Bylaws and the OPTN Management and Membership Policies (M&M Policies). The OPTN Bylaws address the governance structure and roles of the OPTN, while the M&M Policies address administrative aspects of the OPTN, the policy-development process, and requirements and standards for OPTN membership. The M&M Policies establish requirements applicable to OPTN members, including OPOs. Pursuant to *Policy B.4.e Organ Allocation Plans* of the OPTN Management and Membership (M&M) Policies, OPOs must have policies and procedures demonstrating compliance with OPTN Obligations:

> *An OPO must demonstrate it has policies and procedures that meet or exceed OPTN obligations. An OPO's failure to comply with these requirements will be considered a noncompliance with OPTN Obligations that may result in an OPTN action according to Appendix L Reviews and Actions.*

Oversight of the implementation of policies includes the review of potential noncompliance with OPTN Obligations, developing the process for review delegation as specified in the OPTN Policies and Bylaws, and the actions the OPTN may take in response. The OPTN Board delegated the task of reviewing reports of noncompliance to the Membership and Professional Standards Committee (MPSC). In carrying out its role and responsibilities, the OPTN Board must also ensure that the OPTN Policies comply with NOTA and the OPTN Final Rule, in addition to the conditions defined in the OPTN Bylaws and M&M Policies.

Under *Policy E Adoption of Policies* of the M&M Policies, "The Board of Directors is responsible for approving and implementing policies that reflect the mission of the OPTN." In carrying out its role and responsibilities, the OPTN Board must also ensure that the OPTN Policies comply with NOTA and the OPTN Final Rule, in addition to the conditions defined in the OPTN Bylaws and M&M Policies.

Summary of Changes

- **Change 1:** Would add a new definition for the Patient Safety Officer under OPTN *Policy 1.2 Definitions*.
- **Change 2:** Would revise OPTN *Policy 2.2 OPO Responsibilities* to note OPOs' responsibilities for reporting safety events to PSOs.
- **Change 3:** Would revise OPTN *Policy 2.14 Organ Procurement* to note OPOs' responsibilities for reporting safety events to PSOs throughout the deceased organ procurement process.
- **Change 4:** Would revise OPTN *Policy 2.15 Requirements for Controlled Donation after Circulatory Death (DCD) Protocols* to identify the types of events or points when OPO personnel and other individuals must report safety events to the PSO and the types of events that PSOs are required to report.
- **Change 5:** Would revise OPTN *Policy 15.1 Patient Safety Contact* to retitle the Patient Safety Contact as the Transmissible Disease Reporting Contact, thereby delineating this contact's role and responsibilities from those of the PSO.
- **Change 6:** Would replace references to Patient Safety Contact with Transmissible Disease Reporting Contact in OPTN *Policy 15.4.A Host OPO Requirements for Reporting Post-Procurement Donor Results and Discovery of Potential Disease Transmissions* to align with the proposed revisions to OPTN *Policy 15.1 Patient Safety Contact*.
- **Change 7:** Would replace references to Patient Safety Contact with Transmissible Disease Reporting Contact in OPTN *Policy 15.4.B Host OPO Requirements for Reporting Post-Procurement Discovery of Recipient Disease or Malignancy* to align with the proposed revisions to OPTN *Policy 15.1 Patient Safety Contact*.
- **Change 8:** Would replace references to Patient Safety Contact with Transmissible Disease Reporting Contact in OPTN *Policy 15.5.B Transplant Program Requirements for Reporting Discovery of Potential Transmission of Unexpected Recipient Pathogen, Disease or Malignancy* to align with the proposed revisions to OPTN *Policy 15.1 Patient Safety Contact*.
- **Change 9:** In *Appendix B.5 OPO Personnel* of the M&M Policies, would expand the list of key OPO personnel to include the PSO and remove the requirement for an OPO to notify the MPSC if it has not filled a vacant administrative or medical director position within six months, as well as the suggestion that the MPSC could recommend that the Board notify the HHS Secretary of the OPO's failure to fill the position.
- **Change 10:** Would add *Appendix B.7 OPO Patient Safety Officer* of the M&M Policies, which addresses eligibility, qualifications, responsibilities, and organizational requirements for the PSO role.
- **Change 11:** Would add a new definition for the Patient Safety Officer under *Appendix M Definitions* of the M&M Policies.

Specific Proposed Requirements

The OPO PSO Workgroup proposed requirements for the OPO PSO policy related to (1) the PSO role, eligibility qualifications, and organizational placement; and (2) reporting.

PSO Role, Eligibility, Qualifications, Responsibilities, and Organizational Placement

- The PSO serves as a central point of contact for patients, families, hospitals, third party contractors, and OPO personnel to address acute patient safety issues. The PSO role is responsible for promoting patient safety, consistent with OPTN Obligations as described at OPTN M&M Policies *Policy F.1.e Member Compliance*. The PSO will promote physical and psychological safety and a just culture with zero tolerance for unreported safety risks. The PSO (1) intervenes in active cases when safety risks are identified; and (2) initiates notification to executive leadership; and (3) halts or redirects operational processes when patient safety is threatened.
- The PSO role requires continuous coverage with standardized handoffs within the OPO at all shift changes for real time oversight, identification, mitigation, escalation, and documentation of patient safety risks across all OPO operations 24 hours a day, 7 days a week, 365 days a year. The PSO role is filled at all times by the primary PSO or their designee. No gaps in coverage are permitted.
- The PSO must meet the requirements for at least one of the following pathways:
    - Pathway 1 (with master's or doctoral degree):
        - Have an advanced degree (e.g., nursing, healthcare administration, quality, or related field).
        - Have at least three years of clinical experience relating to patient safety, transplant, and/or organ donation (including ICU or OPO experience).
    - Pathway 2 (without master's or doctoral degree):
        - Have a license to practice as a licensed healthcare worker.
        - Have at least five years of clinical experience relating to patient safety, transplant, and/or organ donation (including ICU or OPO experience).
- To sufficiently support corrective actions and learning, the PSO must be able to use safety data and trends to formulate system-level improvements based on event analysis.
- The PSO must be a full-time employee of the OPO. The PSO must not be employed by an accountable care organization or a subcontractor to the OPO. The PSO is independent from existing quality, compliance, and operations hierarchies to avoid conflicts of interest and ensure objective safety oversight.

Reporting

- The OPO and PSO will instruct individuals to contact the PSO directly about safety inquiries that the individual wishes to report and the PSO will instruct individuals to report safety events through one of the publicly available reporting channels. At a minimum, the OPO and PSO will provide individuals with the following avenues to report safety events: the OPTN Complaints (OPTNComplaints@hrsa.gov), the OPTN support service (1-866-OPTN-411 or optn411@hrsa.gov), or the Office of Inspector General hotline (1-800-447-8477).
- The PSO will report patient safety events in accordance with OPTN *Policy 18 Data Submission Requirements*. The PSO will report the following minimum mandatory reportable events: (1) a

brain-dead donor is suspected of having brain function; and (2) an unplanned pause in the DCD process is requested due to an unresolved difference of opinion as to whether a patient meets the donor hospital's criteria for withdrawal of life sustaining therapies.

- In addition to the individual's report, the PSO will submit their own report about a safety event through the OPTN Patient Safety Portal to ensure the safety event is reported through at least one reporting channel. The PSO will include the minimum mandatory reportable events in this report. Once the event is initially reported, the PSO will update the portal with new information as needed.
- Individuals should notify the PSO about events of unresolved pauses, or unresolved differences of opinion as to whether a patient meets the donor hospital's criteria for withdrawal of life sustaining therapies[1], including but not limited to rescissions of brain death declaration and other deviations from the procurement plan that can be reported through the OPTN Patient Safety Portal.
- The 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 (e.g., a complaint about the PSO's actions). Under existing federal reporting mechanism, if an individual other than a PSO submits directly to a reporting system (i.e., complaints or reports made to HRSA or the Office of the Inspector General), the PSO will not automatically be included in communications. Therefore, an individual who reports an event through any of the publicly available reporting channels should copy the PSO if the PSO has determined the safety event is within their reporting responsibility. However, an individual should not copy a PSO when the individual is concerned that the PSO's involvement would limit or conflict with the report they want to make.
- The PSO will have direct clinical escalation access to the OPO Medical Director and all other C-suite-level OPO executives to escalate patient safety reporting. The PSO will also notify and liaise with the relevant external entities, including hospitals, the OPTN, and HRSA, as appropriate.
- The OPO will designate standardized contact information for the PSO and designee through which individuals can reach either the PSO or the designee. The OPO and the OPTN will share PSO contact information on their public-facing websites.
- The OPTN will contact the PSO with any questions or inquiries related to reported events.
- The PSO must connect with other OPO personnel about reportable events, serving as a facilitator, to provide guidance, education, and support that can prevent similar events in the future. The PSO will collaborate with OPO operations, quality, and compliance personnel to review event analyses, identify and require corrective actions, and support cross-hospital learning.

[1] Health Resources and Services Administration, HRSA Directive for OPTN Donation after Circulatory Death Policy Development, September 2026. Available at: https://www.hrsa.gov/sites/default/files/hrsa/optn/hrsa-directive-for-optn-dcd-policy-development-policy-proposal.pdf

- The PSO is responsible for communicating with the original reporter about any changes or other outcomes of reports that include the PSO as a contact. The PSO must make at least two attempts to contact the reporter through each communication channel provided. The PSO must document each attempt, specifying whether the PSO is able to reach the reporter or why the PSO was unable to reach the reporter (e.g., the reporter was anonymous, provided faulty contact information, or was unreachable).

Post-implementation Monitoring

Member Compliance

The OPTN regulations at 42 C.F.R. part 121 (2026) require that policies "include appropriate procedures to promote and review compliance." Per *Appendix B.1 OPO Compliance* of the M&M Policies, by accepting OPTN membership, "OPOs agree to comply with all OPTN Obligations according to *the policy on Membership*." In *Appendix B.5 OPO Personnel of the M&M Policies*, OPOs are required to have personnel who are qualified to effectively recover organs from all donors in their Donation Service Area (DSA) and distribute organs according to OPTN obligations. This proposal expands the list of specified key personnel to include the PSO.

Accordingly, this proposal will expand the routine monitoring of OPOs that are OPTN members to incorporate the review of the new PSO role as key personnel and to assign the reporting of patient safety events to the PSO. An OPTN Contractor, on behalf of the OPTN, will review OPOs' records of key personnel and the availability and communication of reporting channels for contacting the PSO for compliance with the PSO key personnel requirements. This process may include verification that:

- The PSO meets at least one of two education and experience pathways described under the PSO role in *Appendix B.5 OPO Personnel* of the M&M Policies, including documentation of their curriculum vitae.
- The PSO is a full-time employee of the OPO and is not employed by an accountable care organization or a subcontractor to the OPO.
- The PSO is independent from existing quality, compliance, and operations hierarchies to avoid conflicts of interest and ensure objective safety oversight.
- The OPO notifies the OPTN of any changes in the PSO position, as required under M&M Policies *Appendix B.5.f Failure to Report Changes in Key OPO Personnel*.
- The contact information for the PSO and their designee is publicly available via OPTN and OPO websites and is standardized across the OPO.
- Reporting channels are available for individuals to use 24 hours a day, 7 days a week, 365 days a year.
- There is a documented coverage plan, which demonstrates that the primary PSO or their designee are providing coverage at all times, including during the entire application process for changes in key personnel, regardless of the status of the application.

In addition to the verification of PSO personnel and reporting pathways, the OPTN Contractor may also review patient safety reporting across publicly available reporting channels and the OPTN Patient Safety Portal to determine the extent of the PSO's involvement in reporting, as specified in OPTN *Policy 2.2 OPO Responsibilities*, *Policy 2.14 Organ Procurement*, *Policy 2.15 Requirements for Controlled Donation after Circulatory Death (DCD) Protocols*, and *Policy 18.5 Reporting of Patient Safety Events*. This process may include:

- Comparison of patient safety reports that OPO personnel, other than the PSO, and non-OPO-affiliated individuals submit through publicly available reporting channels to the reports submitted to the OPTN Patient Safety Portal by the PSO.
- Documentation of the PSO's attempts to contact these event reporters through each communication channel provided as required in the proposed OPTN M&M Policies *Appendix B.7 OPO Patient Safety Officer.*
- Verification that the PSO sufficiently supports corrective actions and learning through system-level improvements to address safety events that occurred.

Policy Evaluation

When evaluating the impact of the proposed PSO policy, the Membership & Professional Standards Committee (MPSC) will leverage the documentation and data that the OPTN already collects on OPO personnel and reported patient safety events. These data would offer insight into the safety events that individuals report compared to the safety events that PSOs report, the extent to which PSOs can communicate with individuals about the safety events they reported, and the degree to which PSOs can use safety events to promote learning within OPOs and/or transplant hospitals. The metrics described below are a sample of potential metrics of interest to examine the PSO's ability to fulfill their role. The MPSC will compare the safety event reports that OPTN receives through OPTN Complaints, Office of Inspector General hotline, and other publicly available reporting channels with the safety events that PSOs report through the OPTN Patient Safety Portal. Based on the reported safety events, the MPSC will also review corrective actions that OPOs or hospitals implement as a result of reported safety events.

The following are samples of potential metrics of interest that the MPSC may use to examine the PSO's ability to fulfill their role:

- Number of contacts made between individuals and the PSO about safety inquiries
- Number and type of safety events received through public reporting channels
- Number and type of safety events reported through the Patient Safety Portal by the PSO
- Number and nature of corrective actions supported by the PSO

The MPSC will review metrics at approximately six months, one year, and two years post-implementation.

Appendices

Appendix A – Affected Language in OPTN Policy and the OPTN Management and Membership Policies

Appendix A: Affected Language in OPTN Policy and the OPTN Management and Membership Policies

Affected OPTN Policy Language

Proposed new language is underlined (example) and language that is proposed for removal is struck through (~~example~~). Heading numbers, table and figure captions, and cross-references affected by the numbering of these policies will be updated, as necessary.

1.2 Definitions

P

Patient Safety Officer
An OPO's central patient safety point of contact for patients, families, hospitals, third-party contractors, and other OPO personnel to address acute patient safety issues. The PSO is responsible for promoting patient safety, consistent with OPTN Obligations as described at OPTN Management and Membership Policies *Policy F.1.e Member Compliance* by (1) intervening in active cases when safety risks are identified; (2) initiating notification to executive leadership; and (3) halting or redirecting operational processes when patient safety is threatened.

2.2 OPO Responsibilities

Reporting, and instructing individuals to report, safety events to the OPO Patient Safety Officer (PSO) or their designee in accordance with *Appendix B.7 OPO Patient Safety Officer* of the OPTN Management and Membership Policies.[2]

2.14 Organ Procurement

When an unplanned or unresolved pause occurs during the organ procurement process, OPO personnel must report these pauses to the PSO or their designee. Refer to *Appendix B.7 OPO Patient Safety Officer* of the OPTN Management and Membership Policies for more guidance on reporting safety events to the PSO or their designee.

2.14.A Conflicts of Interest
The organ recovery procedure and the transplantation of organs must not be performed by the donor hospital healthcare team member who declares the death of the potential deceased donor. Death is declared in accordance with hospital policy and applicable state and local statutes or regulations.

2.15 Requirements for Controlled Donation after Circulatory Death (DCD) Protocols

Donation after Circulatory Death (DCD) describes the organ recovery process that may occur following death by irreversible cessation of circulatory and respiratory functions. Potential DCD donors are limited

[2] This item will be added to the list of OPO responsibilities. Due to concurrent revisions to the OPTN Policy, the language to be added under *Policy 2.2 OPO Responsibilities* will be numbered according to the policy that is in effect at the time this policy takes effect.

to patients who have died, or whose death is imminent, whose medical treatment no longer offers a medical benefit to the patient as determined by the patient, the patient's agent, or the patient's advance directive if applicable, in consultation with the patient's healthcare team. Any planned withdrawal of life sustaining therapies will be carried out in accordance with hospital policy. Prior to the OPO initiating any discussion with the patient's agent about organ donation, the host OPO must confirm with the patient's healthcare team and document that end-of-life discussions have been initiated with the patient or patient's agent. The timing of a potential DCD donor evaluation and donation discussion will be coordinated with the OPO and the patient's healthcare team, in accordance with hospital policy. The decision to withdraw life sustaining therapies should not be influenced by the donation decision. Death is declared by a healthcare team member in accordance with hospital policy and applicable state and local statutes or regulations. A DCD donor may also be called a non-heart beating, asystolic, or donation after cardiac death donor.

These policies will help OPOs and transplant hospitals develop necessary DCD protocols. These set the minimum requirements for DCD recovery but do not address local practices, cultural and resource issues, and therefore should not be the only resource consulted when developing DCD protocols. DCD protocols should continue to be developed through collaboration between OPOs, transplants hospitals, and donor hospitals.

OPO personnel must report unplanned or unresolved pauses that arise during organ procurement for a potential patient in the DCD pathway to the PSO or their designee. Refer to *Appendix B.7 OPO Patient Safety Officer* of the OPTN Management and Membership Policies for more guidance on reporting safety events to the PSO or their designee.

15.1 Transmissible Disease Reporting ~~Patient Safety~~ Contact

Each OPO and transplant program must identify a primary and secondary Transmissible Disease Reporting ~~Patient Safety~~ Contact and develop and comply with a written protocol for the Transmissible Disease Reporting ~~patient safety~~ contact to fulfill all the following responsibilities:

1. A Transmissible Disease Reporting ~~Patient Safety~~ Contact must be available 24 hours a day.
2. The OPO's primary or secondary Transmissible Disease Reporting ~~Patient Safety~~ Contact must communicate medical information that may affect recipient care to the Transmissible Disease Reporting ~~Patient Safety~~ Contact at the recipient's transplant program as soon as possible, but no later than 24 hours after receipt.
3. The transplant program's primary or secondary Transmissible Disease Reporting ~~Patient Safety~~ Contact must communicate medical information that may affect recipient care to the medical staff responsible for the recipient's clinical care at the transplant program as soon as possible, but no later than 24 hours after receipt.
4. The receiving primary or secondary Transmissible Disease Reporting ~~Patient Safety~~ Contact must acknowledge the receipt of any information that may affect or change recipient care within 24 hours of receipt.

5. The transplant program's Transmissible Disease Reporting ~~Patient Safety~~ Contact must acknowledge receipt of post-procurement donor results, through the OPTN Donor Data and Matching System, within 24 hours of notification of post-procurement donor results reported in accordance with OPTN *Policy 15.4.A Host OPO Requirements for Reporting Post-Procurement Donor Results and Discovery of Potential Disease Transmissions*.
6. OPOs and transplant programs must report to the OPTN a valid phone number and email address for both the primary and secondary Transmissible Disease Reporting ~~Patient Safety~~ Contacts.
7. OPOs and transplant programs must verify their primary and secondary Transmissible Disease Reporting ~~Patient Safety~~ Contacts are accurate through the OPTN Computer System during the biannual OPTN audit.

15.4.A Host OPO Requirements for Reporting Post-Procurement Donor Results and Discovery of Potential Disease Transmissions

The host OPO must report all positive test results and other relevant information received post-procurement for each donor to all the receiving transplant programs' Transmissible Disease Reporting ~~Patient Safety~~ Contacts through the OPTN Donor Data and Matching System as soon as possible but no later than 24 hours after receipt.

1. All results indicating Pathogens of Special Interest must also be reported through the OPTN Improving Patient Safety Portal. The OPTN Contractor provides a list of Pathogens of Special Interest, including any results that can be excluded from reporting. The OPTN Contractor reviews and updates this list at least annually
2. All other positive test results and relevant information must be reported according to *Table 15-2* below.

Table 15-2: Host OPO Reporting Requirements for Positive Post-Procurement Donor Results and Discovery of Potential Disease Transmissions

The host following OPO must report *all* of the *positive* results:		**To:**
Samples relevant to all recipients	Serologic, NAT, or antigen results indicating presence of parasites, virus, or fungi	The receiving transplant program's transmissible disease reporting ~~patient safety~~ contact
	Cultures from the following specimens: • Ascites • Blood • Cerebrospinal fluid (CSF) • Deep wound • Genital • Pericardial • Pleural fluid	The receiving transplant program's transmissible disease reporting ~~patient safety~~ contact

The host following OPO must report *all* of the *positive* results:		To:
	Mycobacterial smears and cultures Fungal smears and cultures with the exception of *Candida* species	The receiving transplant program's transmissible disease reporting ~~patient safety~~ contact
		The receiving transplant program's transmissible disease reporting ~~patient safety~~ contact
Relevant information	Respiratory samples (bacterial or *Candida species) only* to transplant programs receiving lungs or covered head and neck VCAs	The receiving transplant program's transmissible disease reporting ~~patient safety~~ contact
	Urine cultures (bacterial or *Candida species) only* to transplant programs receiving kidneys or covered genitourinary organ VCAs	The receiving transplant program's transmissible disease reporting ~~patient safety~~ contact
	Malignancy or other findings highly suggestive of malignancy recognized after procurement	1. The receiving transplant program's transmissible disease reporting ~~patient safety~~ contact 2. The OPTN Improving Patient Safety Portal
	Histopathology results reported post-procurement	The receiving transplant program's transmissible disease reporting ~~patient safety~~ contact
	All *final* culture information for any culture results that were reported according to these requirements	The receiving transplant program's transmissible disease reporting ~~patient safety~~ contact
	Other psycho-social history, medical history, autopsy, testing, and laboratory findings identifying infectious conditions that may adversely affect a potential transplant recipient	The receiving transplant program's transmissible disease reporting ~~patient safety~~ contact

15.4.B Host OPO Requirements for Reporting Post-Procurement Discovery of Recipient Disease or Malignancy

If the host OPO is notified that an organ recipient is suspected to have, is confirmed positive for, or dies from a potential transmissible disease, infection, or malignancy and there is substantial concern that it could be from the transplanted organ, then the host OPO must do all of the following:

1. Communicate the suspected donor's and affected organ recipient's test results and diagnosis that may be relevant to acute patient care, as soon as possible but no more than 24 hours after receipt, to all transplant programs' primary Transmissible Disease Reporting ~~Patient Safety~~ Contacts and

tissue banks that received organs or tissue from the donor. This includes any test results that were not available at the time of procurement or that were performed after procurement. If the transplant program's primary Transmissible Disease Reporting ~~Patient Safety~~ Contact does not acknowledge receipt of the information within 24 hours, then the host OPO must notify the transplant program's secondary Transmissible Disease Reporting ~~Patient Safety~~ Contact.

2. Document that this information is shared with all receiving transplant programs and tissue banks.

15.5.B Transplant Program Requirements for Reporting Discovery of Potential Transmission of Unexpected Recipient Pathogen, Disease or Malignancy

Transplant programs are required to report the discovery of a potential transmission for the following recipients:

- A non-lung organ recipient who:
  1. Is suspected to have, is confirmed positive for, or has died from any unexpected potential transmissible pathogen, disease, or malignancy, and
  2. There is substantial concern that the suspected or confirmed pathogen, disease, or malignancy could be from the transplant organ
- A lung recipient who:
  1. Is suspected to have, is confirmed positive for, or has died from an unexpected potential transmissible pathogen, disease, or malignancy, and
  2. There is substantial concern that the suspected or confirmed disease, malignancy, or infection could be from the transplanted organ and
  3. There is clinical evidence of infection. A lung recipient is considered to have clinical evidence of infection based on the clinical judgment of the treating physician or team if:
     1. An organism is isolated from the respiratory tract or other site and
     2. There is substantial concern that the organism is donor-derived and contributes to the lung recipient's illness
- A lung recipient who:
  1. Shows evidence of colonization but not clinical evidence of infection and
  2. Respiratory tract testing reveals an unexpected positive result identifying a Pathogen of Special Interest or malignancy, and
  3. There is substantial concern that the unexpected positive result is from the transplanted organ.

When an organ recipient is suspected to have, is confirmed positive for, or has died from potential transmissible disease, infection, or malignancy and there is substantial concern that it could be from the transplanted organ, then the transplant program must do all of the following:

1. Notify the primary Transmissible Disease Reporting ~~Patient Safety~~ Contact at the host OPO of the deceased donor or transplant program at which the living donor was recovered and provide available documentation within 24 hours of learning of the event. If the primary Transmissible Disease Reporting ~~Patient Safety~~ Contact of the host OPO of the deceased donor or transplant program at which the living donor was recovered does not acknowledge receipt of the information

within 24 hours, then the transplant program must notify the secondary Transmissible Disease Reporting ~~Patient Safety~~ Contact.
2. Report the event through the OPTN Patient Safety Reporting Portal within 24 hours after learning of the event.
3. Provide additional related information or specimens if requested.

Affected OPTN Management and Membership Policies Language

Proposed new language is underlined (example) and language that is proposed for removal is struck through (~~example~~). Heading numbers, table and figure captions, and cross-references affected by the numbering of these policies will be updated, as necessary.

Appendix B: Membership Requirements for Organ Procurement Organizations (OPOs)

B.5 OPO Personnel

Each OPO must have personnel who are qualified to effectively recover organs from all donors in its DSA. Each OPO must have the necessary staff to recover and distribute organs according to OPTN obligations, including an administrative director, a medical director, an organ donation coordinator, and an organ procurement specialist.

a. OPO Administrative Director

Each OPO must identify an individual that serves as the administrative director. The administrative director, together with other OPO staff, is responsible for effective organ recovery and placement according to OPTN obligations.

b. Medical Director

The OPO medical director must be a physician licensed in at least one of the states within the OPO's DSA. The OPO must submit the medical director's credentials to the OPTN. The medical director is responsible for the medical and clinical activities of the OPO.

c. Patient Safety Officer (PSO)

The PSO serves as a central point of contact for OPO personnel and other individuals to address acute patient safety issues. The PSO, together with their designee, will provide continuous coverage for real time oversight, identification, reporting, mitigation, escalation, and documentation of patient safety risks across all OPO operations, as well as support corrective actions and learning to formulate system-level improvements. Refer to *Appendix B.7 OPO Patient Safety Officer* for the specific roles and requirements of this role.

~~c.~~ d. Board of Directors

Each OPO must have a board of directors or an advisory board with members selected according to the Code of Federal Regulations. The board of directors or advisory board has the authority to recommend policies that guide the donation, procurement, and equitable distribution of organs.

~~d.~~ e. Changes in Key Personnel

When the OPO learns that the administrative or medical director plans to leave, it must notify the OPTN immediately, within 30 days of departure, if possible. The OPO must also submit to the OPTN at this time the replacement's name and curriculum vitae.

~~e.~~ f. Failure to Report Changes in Key OPO Personnel

An OPO's failure to notify the OPTN of a change in the administrative or medical director will be considered a noncompliance with OPTN Obligations that may result in an OPTN action according to *Appendix L: Reviews and Actions.*

~~The OPO must notify the MPSC if it has not filled a vacant administrative or medical director position within six months. The MPSC could then recommend that the OPTN Board of Directors notify the Secretary of HHS of the OPO's failure to fill the position.~~

B.7 OPO Patient Safety Officer

The PSO serves as a central point of contact for patients, families, hospitals, third party contractors, and OPO personnel to address acute patient safety issues. The PSO role is responsible for promoting patient safety, consistent with OPTN Obligations as described at OPTN Management and Membership Policies *Policy F.1.e Member Compliance*. The PSO will promote physical and psychological safety and a just culture with zero tolerance for unreported safety risks. The PSO (1) intervenes in active cases when safety risks are identified; (2) initiates notification to executive leadership; and (3) halts or redirects operational processes when patient safety is threatened.

a. Coverage Requirements

The PSO role requires standardized handoffs within the OPO at all shift changes for real time oversight, identification, reporting, mitigation, escalation, and documentation of patient safety risks across all OPO operations.

The PSO role is filled at all times by the primary PSO or a dedicated designee to provide continuous coverage with 24 hours a day, 7 days a week, 365 days a year. No gaps in coverage are permitted.

b. Qualification Requirements

The PSO must meet the requirements for at least one of the following pathways:

- Pathway 1 (with master's or doctoral degree):
    - Have an advanced degree (e.g., nursing, healthcare administration, quality, or related field).
    - Have at least three years of clinical experience relating to patient safety, transplant, and/or organ donation (including ICU or OPO experience).
- Pathway 2 (without master's or doctoral degree):
    - Have a license to practice as a licensed healthcare worker.
    - Have at least five years of clinical experience relating to patient safety, transplant, and/or organ donation (including ICU or OPO experience).

c. Using Data to Inform System-Level Improvements

To sufficiently support corrective actions and learning, the PSO must be able to use safety data and trends to formulate system-level improvements based on event analysis.

d. Position in OPO Infrastructure

The PSO must be a full-time employee of the OPO. The PSO must not be employed by an accountable care organization or a subcontractor to the OPO. The PSO is independent from existing quality, compliance, and operations hierarchies to avoid conflicts of interest and ensure objective safety oversight.

e. Reporting Safety Events

The OPO and PSO are responsible for instructing individuals to report safety events to the PSO by contacting the PSO directly about safety inquiries and reporting safety events through a publicly available reporting channel. The 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 (e.g., a complaint about the PSO's actions). Under existing federal reporting mechanisms, if an individual other than a PSO submits directly to a reporting system (i.e., complaints or reports made to HRSA or the Office of the Inspector General), the PSO will not automatically be included in communications. Therefore, an individual who reports an event through any of the publicly available reporting channels should copy the PSO if the PSO has determined the safety event is within their reporting responsibility. However, an individual should not copy a PSO when the individual is concerned that the PSO's involvement would limit or conflict with the report they want to make. The OPTN will contact the PSO with any questions or inquiries related to reported events.

At a minimum, the OPO and PSO provide individuals with the following publicly available reporting channels to report safety events: OPTN Complaints (OPTNComplaints@hrsa.gov), the OPTN support service (1-866-OPTN-411 or optn411@hrsa.gov), or the Office of Inspector General hotline (1-800-447-8477).

In addition to the individual's report, the PSO submits their own report about a safety event through the OPTN Patient Safety Portal to ensure the safety event is reported through at least one reporting channel. The PSO will include the minimum mandatory reportable events in this report. Once the event is initially reported, the PSO will update the portal with new information as needed.

The PSO reports patient safety events in accordance with OPTN *Policy 2.2 OPO Responsibilities*, *Policy 2.14 Organ Procurement*, *Policy 2.15 Requirements for Controlled Donation after Circulatory Death (DCD) Protocols*, and *Policy 18.5 Data Submission Requirements*. The 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.

The OPO and the OPTN share PSOs' contact information on their public-facing websites. The OPO will designate standardized contact information for the PSO and designee through which individuals can

reach either the PSO or the designee. The PSO has direct clinical escalation access to the OPO Medical Director and all other C-suite-level OPO executives to escalate patient safety reporting. The PSO will also notify and liaise with the relevant external entities, including hospitals, OPTN, and HRSA, as appropriate.

The PSO must connect with other OPO personnel about reportable events, serving as a facilitator, to provide guidance, education, and support that can prevent similar events in the future. The PSO will collaborate with OPO operations, quality, and compliance personnel to review event analyses, identify and require corrective actions, and support cross-hospital learning.

The PSO is responsible for communicating with the original reporter about any changes or other outcomes of reports that include the PSO as a contact. The PSO must make at least two attempts to contact the reporter through each communication channel provided. The PSO must document each attempt, specifying whether the PSO is able to reach the reporter or why the PSO was unable to reach the reporter (e.g., the reporter was anonymous, provided faulty contact information, or was unreachable).

Appendix M: Definitions

P

Patient Safety Officer

An OPO's central patient safety point of contact for patients, families, hospitals, third-party contractors, and other OPO personnel to address acute patient safety issues. The PSO is responsible for promoting patient safety, consistent with OPTN Obligations as described at OPTN Management and Membership Policies *Policy F.1.e Member Compliance* by (1) intervening in active cases when safety risks are identified; (2) initiating notification to executive leadership; and (3) halting or redirecting operational processes when patient safety is threatened.