OPTN

Notice of OPTN Policy Changes

Require Reporting of Patient Safety Events

Sponsoring Committee:	**Membership and Professional Standards**
Policies Affected:	***16.2: Packaging and Labelling Responsibilities***
	18.5: Reporting of Living Donor Events
Public Comment:	**July 27, 2023 – September 19, 2023**
Board Approved:	**December 4, 2023**
Effective Date:	**January 10, 2024**

Purpose of Policy Changes

The purpose of this policy change is to align OPTN members' patient safety reporting requirements with the OPTN Contractor's requirements to report certain patient safety events to Membership and Professional Standards Committee (MPSC) leadership and Health Resources and Services Administration (HRSA). By aligning these requirements, the MPSC will improve its ability to fulfill its charge to review events that present a potential risk to patient health, public safety, or the integrity of the OPTN. In addition, the policy change consolidates patient safety reporting requirements into a centralized location in policy. While this is not a data collection project for quality improvement purposes, the MPSC will also be able to use available information from these reports to evaluate the frequency of these concerning patient safety events and, provide guidance regarding effective practices to the transplant community to limit risk to transplant candidate, recipient, and living donor safety.

Proposal History

- MPSC identified that OPTN members were not required by OPTN policy to report certain identified patient safety events that are required by the OPTN Contract to be reported to MPSC Leadership and HRSA within 24 hours of receipt (HRSA criteria). The MPSC decided it was important to include required reporting of these concerning patient safety events in policy: October 2022
- MPSC developed the proposal to require OPTN members to report the patient safety events that are required to be reported to HRSA and MPSC leadership following receipt, as well as a couple additional concerning patient safety events identified through MPSC case reviews: February 2023 – June 2023
- MPSC requested feedback from the Operations and Safety Committee and the Living Donor Committee. The Living Donor Committee suggested the broadening of reports of listing of living donors from only when listed for the organ donated to listing for any organ: April 2023
- The overall proposal was widely supported during public comment, but there were requests for clarification of specific provisions of the proposal. Based on feedback, the MPSC made several changes to the original proposal including the removal of some proposed provisions for additional consideration. The OPTN Board of Directors approved the proposal at the December 4, 2023 meeting.

Summary of Changes

Transplant hospitals will be required to report the following patient safety events to the OPTN through the OPTN Patient Safety Reporting Portal within 72 hours of becoming aware of the incident:

- A transplant of the incorrect organ into an organ recipient occurs.
- A transplant of an organ into the incorrect organ recipient occurs.
- A donor organ is identified as incorrect during pre-transplant processes conducted according to either Policy 5.8.A: *Pre-Transplant Verification Prior to Organ Receipt* or Policy 5.8.B: *Pre-Transplant Verification Upon Organ Receipt.*
- The potential transplant recipient is identified as incorrect during pre-transplant processes conducted according to either Policy 5.8.A: *Pre-Transplant Verification Prior to Organ Receipt* or Policy 5.8.B: *Pre-Transplant Verification Upon Organ Receipt.*
- An organ was delivered to the incorrect transplant hospital and resulted in non-use of the organ.
- The incorrect organ was delivered to the transplant hospital and resulted in non-use of the organ.
- An ABO typing error or discrepancy is caught before or during pre-transplant processes conducted according to either Policy 5.8.A: *Pre-Transplant Verification Prior to Organ Receipt* or Policy 5.8.B: *Pre-Transplant Verification Upon Organ Receipt*

Organ Procurement Organizations (OPOs) will be required to report ABO typing errors or discrepancies that are caught after the OPO's deceased donor blood type and subtype verification process, as outlined in *Policy 2.6.C: Reporting of Deceased Donor Blood Type and Subtype*, and after the OPO has executed a match run to the OPTN through the OPTN Patient Safety Reporting Portal within 72 hours of becoming aware of the incident. The existing requirement that OPOs submit a report when transplant hospital procurement staff leave the operating room without allowing the host OPO to package and label deceased donor organs and typing specimens has been moved from Policy 16.2 to Policy 18 so that all required reports of patient safety events are located in Policy 18.

Recovery Hospitals will be required to report when a living donor is placed on the waiting list for any organ regardless of the organ that was donated within 72 hours of becoming aware of the listing.

Implementation

Members will need to become familiar with the proposed patient safety reporting requirements and will be required to report the events, as outlined in the proposal, within 72 hours after becoming aware of the event.

The OPTN will update the instructions in the OPTN Patient Safety Reporting Portal to reflect the new safety events that must be reported to the OPTN. The OPTN will continue to review and investigate events reported through the OPTN Patient Safety Reporting Portal and notify HRSA and MPSC leadership of reported events that meet the HRSA Criteria.

Affected Policy Language

New language is underlined (example) and language that is deleted is struck through (~~example~~).

16.2 Packaging and Labeling Responsibilities

The host OPO or recovery hospital is responsible for packaging and labeling organs and tissue typing materials that travel outside the recovery facilities.

The host OPO must complete labeling and packaging using the OPTN organ tracking system. The OPO must develop and comply with a written protocol for an alternative labeling and packaging process if, for any temporary reason, the OPTN organ tracking system is not used. This written protocol must fulfill all the requirements according to *Policy 16: Organ and Extra Vessels Packaging, Labeling, Shipping, and Storage* and the host OPO must document the reasons the OPTN organ tracking system was not used.

Transplant hospital staff may not leave the operating room without allowing the host OPO to package and label deceased donor organs and tissue typing specimens as required~~, or the host OPO will be required to submit a report about the event through the OPTN Improving Patient Safety Portal.~~ OPOs are required to report these events according to *Policy 18.5: Reporting of Patient Safety Events*.

If a transplant hospital repackages an organ for transport, it must package, label, and transport the organ according to Policy 16: Organ and Extra Vessels Packaging, Labeling, Shipping, and Storage, except that the use of the OPTN organ tracking system is not required. The transplant hospital must immediately notify the host OPO of the repackaging.

18.5 Reporting of ~~Living Donor Events~~ Patient Safety Events

18.5.A Required Reporting by Transplant Hospitals

Transplant hospitals must report the following events to the OPTN according to *Table 18-3* below.

Table 18-3: Required Reporting by Transplant Hospitals

Transplant hospitals must report if:	To the:	Within 72 hours after:
A transplant of the incorrect organ into an organ recipient occurs	OPTN Patient Safety Reporting Portal	The transplant hospital becomes aware
A transplant of an organ into the incorrect organ recipient occurs	OPTN Patient Safety Reporting Portal	The transplant hospital becomes aware

Transplant hospitals must report if:	To the:	Within 72 hours after:
A donor organ is identified as incorrect during pre-transplant processes conducted according to either Policy 5.8.A: *Pre-Transplant Verification Prior to Organ Receipt* or Policy 5.8.B: *Pre-Transplant Verification Upon Organ Receipt*	OPTN Patient Safety Reporting Portal	The transplant hospital becomes aware
The potential transplant recipient is identified as incorrect during pre-transplant processes conducted according to either Policy 5.8.A: *Pre-Transplant Verification Prior to Organ Receipt* or Policy 5.8.B: *Pre-Transplant Verification Upon Organ Receipt*	OPTN Patient Safety Reporting Portal	The transplant hospital becomes aware
An organ was delivered to the incorrect transplant hospital and resulted in non-use of the organ	OPTN Patient Safety Reporting Portal	The transplant hospital becomes aware
The incorrect organ was delivered to the transplant hospital and resulted in non-use of the organ	OPTN Patient Safety Reporting Portal	The transplant hospital becomes aware
An ABO typing error or discrepancy is caught before or during pre-transplant processes conducted according to either Policy 5.8.A: *Pre-Transplant Verification Prior to Organ Receipt* or Policy 5.8.B: *Pre-Transplant Verification Upon Organ Receipt*	OPTN Patient Safety Reporting Portal	The transplant hospital becomes aware

18.5.B Required Reporting of Living Donor Events by Recovery Hospitals

Recovery hospitals must report living donor events through the ~~Improving~~OPTN Patient Safety Reporting Portal or the OPTN according to *Table 18-4* below.

Table 18-4: Living Donor Event Reporting

Recovery hospitals must report if:	To the:	Within 72 hours after:
A living donor organ recovery procedure is aborted after the donor has begun to receive general anesthesia.	~~Improving~~OPTN Patient Safety Reporting Portal and the OPTN	The aborted organ recovery procedure
A living donor dies within 2 years after organ donation	~~Improving~~OPTN Patient Safety Reporting Portal	The hospital becomes aware
A living ~~liver~~ donor is listed on the ~~liver~~ wait list within 2 years after organ donation	~~Improving~~OPTN Patient Safety Reporting Portal	The hospital becomes aware

Recovery hospitals must report if:	To the:	Within 72 hours after:
A living kidney donor ~~is listed on the kidney wait list or~~ begins regularly administered dialysis as an ESRD patient within 2 years after organ donation	~~Improving~~OPTN Patient Safety Reporting Portal	The hospital becomes aware
A living donor organ is recovered but not transplanted into any recipient	~~Improving~~OPTN Patient Safety Reporting Portal and the OPTN	Organ recovery
A living donor organ is recovered and transplanted into someone other than the intended recipient	~~Improving~~OPTN Patient Safety Reporting Portal	Organ recovery

~~The Membership and Professional Standards Committee will review all cases reported according to *Table 18-4* above and report to the OPTN Board of Directors.~~

18.5.C Required Reporting by OPOs

OPOs must report the following events to the OPTN according to *Table 18-5* below.

Table 18-5: Required Reporting by OPOs

Host OPOs must report if:	To the:	Within 72 hours after:
Transplant hospital procurement staff leave the operating room without allowing the host OPO to package and label deceased donor organs and tissue typing specimens as required	OPTN Patient Safety Reporting Portal	The OPO becomes aware
An ABO typing error or discrepancy is caught after the OPO's deceased donor blood type and subtype verification process, as outlined in Policy 2.6.C: *Reporting of Deceased Donor Blood Type and Subtype*, and after the OPO has executed a match run	OPTN Patient Safety Reporting Portal	The OPO becomes aware