Require Reporting of Patient Safety Events

OPTN Membership and Professional Standards Committee (MPSC)

Purpose of Proposal

- The OPTN contract requires that the OPTN notify MPSC leadership and HRSA of certain types of safety events within a specific time frame
- OPTN policy does not specifically require members to report some of these specific patient safety events, including "near misses"
- Align OPTN members' reporting requirements with the requirement for the OPTN to notify MPSC leadership and HRSA of certain patient safety events

Proposal

- Add specific patient safety reporting requirements to Policy 18
  - MPSC can further fulfill their charge of reviewing events identified as presenting a risk to patient safety, public health or the integrity of the OPTN
  - Over time, the MPSC can provide guidance about effective practices to limit risk to transplant candidate, recipient, and living donor safety
  - Consolidate reporting requirements into one area for members to easily reference
- Update OPTN Improving Patient Safety Portal Safety Situation and Living Donor Event form instructions
  - Streamline the reporting process for members and create a single reference point when submitting a report

Transplant Hospital Requirements

- The proposal requires transplant hospitals to report the following events through the Patient Safety Portal within 24 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*

Transplant Hospital Requirements

- The proposal requires transplant hospitals to report the following events through the Patient Safety Portal within 24 hours of becoming aware of the incident:
  - 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 organ did not arrive when expected and resulted in the intended candidate not receiving a transplant from the intended donor because of the transportation issue
  - 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*

Recovery Hospital Requirements

- This proposal will broaden the current living donor requirement to report a liver living donor listed on the liver wait list or a kidney living donor listed on the kidney wait list within two years after donation.
- Recovery hospitals will now be required to report when a living donor is listed on the wait list within two years after donation.

OPO Requirements

- The proposal requires OPOs to report the event, “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*”, through the Patient Safety Portal within 24 hours of becoming aware of the incident

OPTN Member Requirements

- The proposal requires all OPTN members to report the following events through the Patient Safety Portal within 24 hours of becoming aware of the incident:
  - Any sanction is taken by a state medical board or other professional body against a transplant professional working for an OPTN member
  - Evidence is discovered of an attempt to deceive the OPTN or the Department of Health and Human Services (HHS)

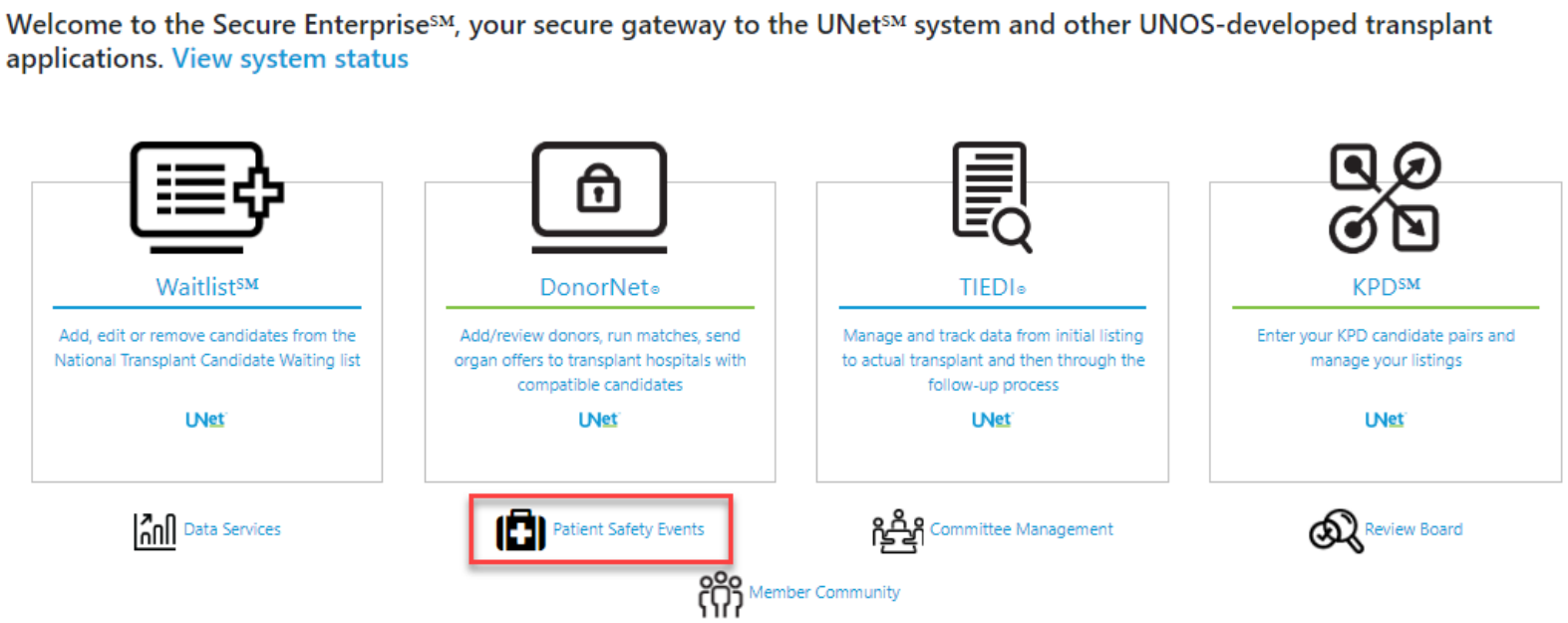
Rationale

- If these patient safety events are considered important enough for purposes of notification to MPSC leadership and HRSA, these events should specifically be required by OPTN policy to be reported to the OPTN

- Should not result in a significant increase in member burden
  - From August 2022 through May 2023, the OPTN has received about 17 reports (N=578) that would meet this proposed criteria, and would be required rather than voluntary reporting
  - The MPSC expects these events to be infrequent; however, it is important that the MPSC is aware when these events occur so they can help provide feedback.
  - If members are reporting multiple of these events a year, it further supports the need for MPSC review.

Member Actions

- Become familiar with the proposed patient safety reporting requirements
- Report these events within 24 hours after becoming aware of the incident through the OPTN Improving Patient Safety Portal



What do you think?

- Based on the “near miss” definitions considered for incorrect organ or incorrect potential transplant recipient, do you have any concerns with the proposed definition?
- Do you agree with requiring reporting for living donors placed on the wait list for any organ within two years after donation?
- Do you think the transportation events included in this proposal as required reports are appropriate?
- Are there other definitions for ABO typing errors or discrepancies that the MPSC should consider?