OPTN

Briefing to the OPTN Board of Directors on

Require Reporting of Patient Safety Events

OPTN Membership and Professional Standards Committee

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Require Reporting of Patient Safety Events

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Executive Summary

The Organ Procurement and Transplantation Network (OPTN) contract requires the OPTN to notify leadership of the OPTN Membership and Professional Standards Committee (MPSC) and Health Resources and Services Administration (HRSA) of certain types of safety events within a specific time frame. However, OPTN policy does not explicitly require members to report some of these specific patient safety events. To ensure MPSC leadership and HRSA are aware of and can review potential patient safety situations, this proposal suggests updating OPTN policy to require members to report certain safety events. This proposal will also update the OPTN Patient Safety Reporting Portal form instructions to list the events members will be required to report, making it easier for members to reference the events during the reporting process.

This proposal was issued for public comment from July 27, 2023 to September 19, 2023. The Committee reviewed the public comments and made changes to the document to incorporate feedback, discussed below.

Purpose

The purpose of this proposal is to align OPTN members' patient safety reporting requirements with the OPTN Contractor's requirements to report certain patient safety events to MPSC leadership and HRSA, to better allow the MPSC 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 proposal will consolidate 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 data from these reports to assess the prevalence 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.

Background

In 2011, a letter from the HRSA Administrator, Mary Wakefield, to the OPTN President clarified expectations for the OPTN to report concerning patient safety events to HRSA.[1] These are referred to in this proposal as "HRSA criteria." The OPTN contract now requires the OPTN to notify HRSA of these concerning safety events within specified time frames, usually within 24 hours or one business day.[2] HRSA has asked that staff also include MPSC leadership on HRSA criteria notifications. Given the short notification timeframe, the report to HRSA and MPSC leadership typically occurs before an investigation; however, an investigation still occurs to gather more information regarding the event and to determine if there were any violations of OPTN Obligations by a member. Additionally, these criteria do not affect whether a case is later referred to the MPSC, which is a separate decision-making process that happens after an investigation.

By accepting membership in the OPTN, each member agrees to comply with all OPTN Obligations, which includes acting to "[a]void risks to patient health or public safety".[3] *OPTN Bylaws, Article 1.1.G* states that "[a]ny member who becomes aware of a potential noncompliance of OPTN Obligations must inform the OPTN as soon as the member becomes aware of the issue, including potential noncompliance by the member itself." Additional OPTN policies require members to report certain specific events to the OPTN Contractor; however, not all "HRSA criteria" are explicitly defined as events that members must report to the OPTN.

Proposal for Board Consideration

The MPSC proposes adding certain "HRSA criteria" and additional specific concerning patient safety events to OPTN policy as required reports by OPTN members to ensure that the OPTN is aware of all incidences of these serious patient safety events.

This proposal clarifies specific patient safety events that members will be required to report through the OPTN Patient Safety Reporting Portal. While this proposal specifies certain safety events members must report to the OPTN, the proposal does not absolve members from informing the OPTN of other types of

[1] Wakefield, Mary K., Administrator, Department of Health and Human Services; Letter to Jack Lake, M.D., President, Organ Procurement and Transplantation Network, August 5, 2011.
[2] OPTN Performance Work Statement, Task 3.6.7, 2022.
[3] OPTN Bylaws, Article 1.1.E

potential non-compliance with OPTN Obligations when they become aware of the issue. So, if an event occurs that poses a risk to patient health or public safety but is not specifically listed in policy as a required report by members, the member must still report this event to the OPTN.

Once an event is reported, it will follow the same investigative process that currently exists.[4] The OPTN Contractor will notify key stakeholders in a timely fashion and investigate the event. OPTN members must comply with any requests for information from the OPTN Contractor during this investigative process. If appropriate, the OPTN Contractor will consult with the MPSC during the investigation and/or submit the results of the investigation to the MPSC for review and action according to the OPTN Bylaws, Appendix L: *Reviews and Actions*.

The following are the proposed patient safety events transplant hospitals will be required to report through the OPTN Patient Safety Reporting Portal within 72 hours after 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*

The following are the proposed patient safety events OPOs will be required to report through the OPTN Patient Safety Reporting Portal within 72 hours after becoming aware of the incident:

- 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.

The proposal also moves the 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 from *Policy 16.2* to *Policy 18* so that all required reports of patient safety events are located in *Policy 18*.

Finally, at the request of the OPTN Living Donor Committee, MPSC proposes to broaden the reporting of instances where a living donor is placed on a waiting list for transplant. Currently, recovery hospitals are required to report if a living kidney donor is placed on a kidney waiting list or a living liver donor is placed on a liver waiting list. The proposed revision would require reporting if a living donor is placed on a waiting list for any organ regardless of the organ that was donated.

[4] OPTN Member Monitoring Processes.
https://optn.transplant.hrsa.gov/media/gqrbxjba/optn_member_monitoring_processes.pdf

Overall Sentiment from Public Comment

The proposal was available for public comment from July 27 through September 19, 2023. During that time, it received 267 comments. The MPSC requested specific feedback on the "near miss" definitions for incorrect organ or incorrect potential transplant recipient, the broadening of the requirement to report a living donor being placed on a waiting list for any organ, the inclusion of transportation events and the definitions for ABO typing errors or discrepancies. The community expressed support for this proposal overall due to the emphasis placed on transparency and knowledge sharing as a result of the proposal. Patients were very supportive of this proposal as it relates to patient safety and public health; however, understandably stakeholder organizations and transplant hospitals raised some concerns over potential increased burden of additional required reporting.

Figure 1 shows the sentiment by Member, which was supportive overall, with an average score of 4.1/5 on the Likert Sentiment scale.

Figure 1: Sentiment by Member Type

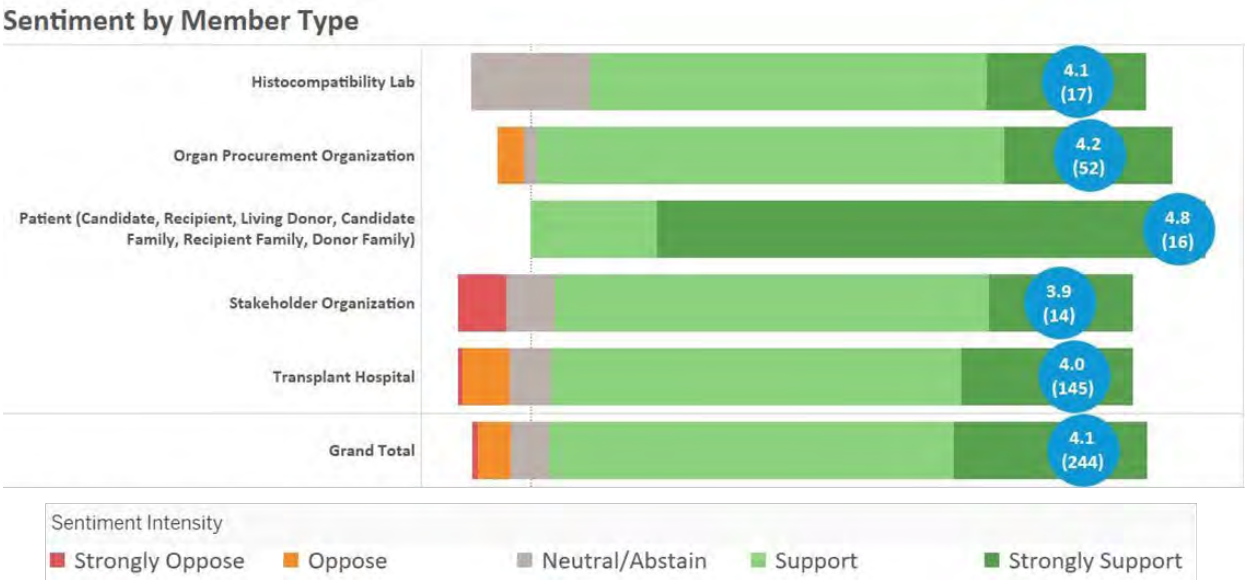
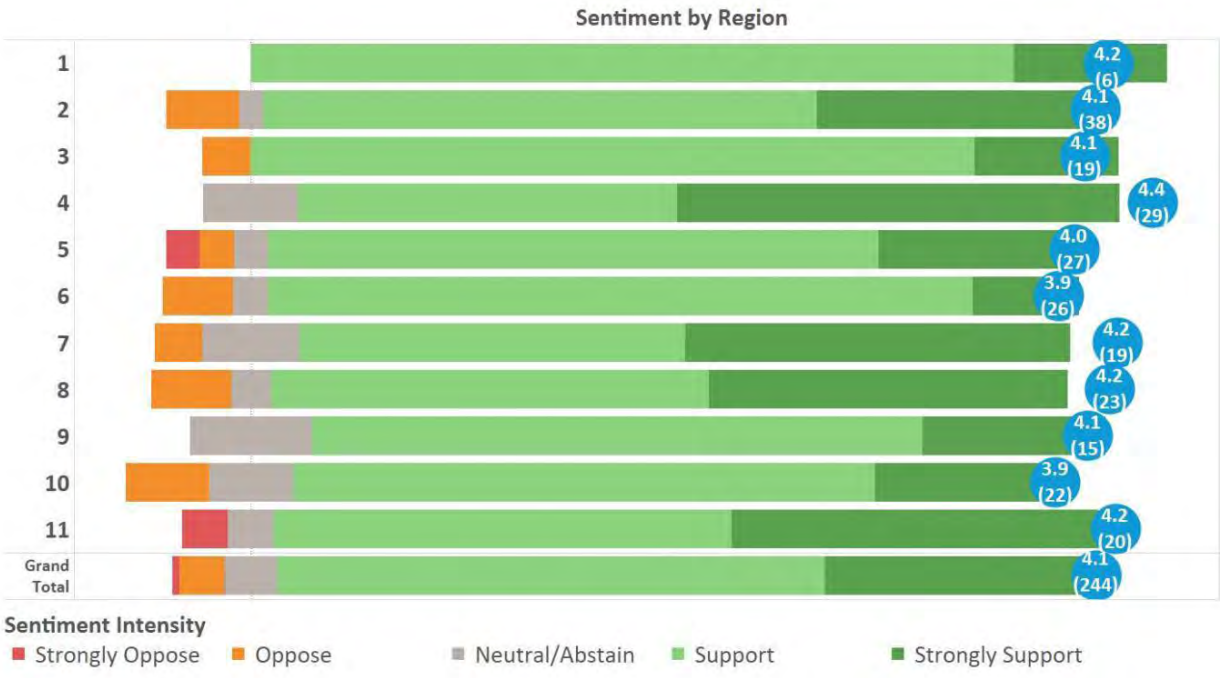


Figure 2 shows the sentiment received at regional meetings.

Figure 2: Sentiment by Region



The American Society of Transplantation (AST) supported the proposal agreeing that a broader safety event reporting structure will help guide future policy making and improve patient outcomes. The AST raised concerns about the lack of clear definitions of "sanction" and "other professional body" in the proposed requirement that members report "any sanction taken by a state medical board or other professional body against a transplant professional working for an OPTN member" noting that the term "sanction" could mean a wide range of actions taken by a board or hospital committee and "a professional body" could include an institution's internal medical staffing and performance committees. The AST expressed concern that such a requirement may undermine a provider's right to a fair internal peer review process, open up the institution to claims of defamation, or require an institution to monitor the often prolonged deliberations of a state medical board even if the provider is no longer employed at the institution. The AST also expressed concerns with the definitions of "near miss" noting that heterogeneity in transplant hospital practice may lead to the same occurrence being classified a near miss at one institution and not at another. The AST suggests that "near miss" should only include those instances where an error is caught by chance after all check points and safety measures have occurred. Finally, the AST suggested that there should be reporting requirements for all causes of non-use of organs not just transportation issues.

The ASTS strongly opposed this proposal noting a concern that the proposal markedly broadens the type and number of events that must be reported to the OPTN within 24 hours. ASTS also raised concerns regarding duplication of reporting to the OPTN and the Centers for Medicare and Medicaid Services (CMS). The ASTS supports the required reporting of ABO typing errors or discrepancies and the modification of the living donor reporting requirements. The ASTS opposes the required reporting of sanctions against a transplant professional noting it should be the responsibility of the OPTN or the

MPSC to identify when sanctions are taken. ASTS also opposes the required reporting of transportation events, noting that these events are out of the control of the transplant hospital and should be the responsibility of the OPO to report rather than the transplant hospital. The ASTS opposes the required reporting of near miss events contending that review of near miss events are important components of internal quality programs to help prevent safety events, they should not be reportable and potentially punishable by the OPTN.

The Association of Organ Procurement Organizations (AOPO) supported the proposal noting that AOPO members are committed to donor and recipient safety and review of safety events as a tool for continuous performance improvement. AOPO supported data collection on events that lead to non-use of organs. AOPO felt that the MPSC's focus on transportation, excluding other events that more significantly contribute to non-use such as avoidable late declines and surgical errors, was too narrow. Specifically, AOPO recommended that transplant hospitals communicate with the OPO prior to reporting transportation events and further suggested that the requirement for reporting when an organ did not arrive when expected should be changed to within a reasonable time of the scheduled arrival, noting expected arrival is subjective. AOPO also expressed concern that the required reporting of ABO typing errors and discrepancies could result in reporting of events that do not deviate from OPTN policy such as discordant results. Finally, AOPO expressed similar concerns to other comments about the 24-hour time frame and the requirement to report sanctions against transplant professionals.

The OPTN Patient Affairs, Transplant Administrators, Living Donor, Histocompatibility, Data Advisory Committee, Organ Procurement Organization, Pediatric Transplantation, Operations and Safety Committee and Vascularized Composite Allograft Committees provided feedback on the proposal that is reflected in the themes noted below.

Public Comment Feedback and Themes

The major themes on which the OPTN received feedback were:

- The requirement to report all of these events within 24 hours may be too rigid, and that it would be reasonable to require some or all of the events to be reported within 48 or 72 hours.
- No concerns were expressed about the proposed identification timeframe for near miss transplant of the incorrect organ or the incorrect potential transplant recipient. It was suggested that it could be clarified whether incorrect organ also means incorrect laterality.
- Support was expressed for the broadening of the living donor reporting requirement to capture any living donor who is added to the waiting list. The main feedback suggested that the MPSC should monitor living donors added to any waiting list greater than two years after donation and that this reporting could be automated within the OPTN Computer System rather than recovery hospitals being required to report this.
- Support was expressed for the inclusion of the transportation events and supported beginning to capture this data. There was general feedback that these transportation events were concerning enough by themselves that they should not only be required to be reported if they result in non-use. There were also suggestions to clarify the timeframe for "did not arrive when expected."
- Support was expressed for the inclusion of the ABO typing error or discrepancy as a required report. Members did provide feedback that the definition could be made clearer; however, no potential solutions were provided. It was also suggested that the time point, after allocation has begun, be added to the timeframe for the OPO ABO typing or discrepancy event.

- Support was expressed for requiring reporting of "any sanction taken by a state medical board or professional body against a transplant professional working for an OPTN member" or "evidence is discovered of an attempt to deceive the OPTN or the Department of Health and Human Services (HHS)." However, commenters believed that more clarity could be provided for definitions of "sanction" and "professional body" and the scope of the requirement for reporting an "attempt to deceive the OPTN or Department of Health and Human Services (HHS)."
- The community also felt that the MPSC should consider requiring reporting of events, other than transportation issues, that result in non-use, for example late organ declines, as well as requiring the reporting of HLA discrepancies by Histocompatibility labs.
- Commenters raised some concerns regarding member burden and the usability of the OPTN Patient Safety Reporting Portal.

24-Hour Reporting Timeframe

The public comment proposal required members to report the patient safety events within 24 hours of becoming aware of the event. Initially, the MPSC chose the 24-hour timeframe since it aligned with the OPTN's requirement to report these events to HRSA and MPSC leadership within 24 hours. During public comment, the MPSC received feedback suggesting an extension of this reporting timeframe to either 48 or 72 hours. While the requirement to report an event does not mean that a full root cause analysis or corrective action plan needs to be completed prior to the report, the MPSC agreed that 72 hours would be more reasonable to allow members time to assess the situation when they become aware and ensure that they are reporting accurate information still in a timely manner.[5] There is precedent for having different timeframes with the required reporting of living donor events currently contained in OPTN policy. The living donor events are required to be reported within 72 hours as well, some of which are included in the "HRSA Criteria" as events that must be reported to HRSA and MPSC leadership within 24 hours. Changing the reporting timeframe to 72 hours for the new required patient safety events promotes consistency for all required patient safety events in *Policy 18.5: Reporting of Patient Safety Events*.

Near Misses of Transplant of Wrong Organ or Wrong Recipient

The "HRSA criteria" include a requirement for the OPTN Contractor to report within 24 hours either "a near-miss transplant of the wrong organ into an organ recipient" or "a near-miss transplant into the wrong organ recipient" and state "an event should be considered a 'near-miss' if the error is not caught before the recipient is brought to the surgery holding area." The MPSC felt this definition of a "near-miss" was too ambiguous and would not be consistent between transplant hospitals. The MPSC also noted this definition may not capture errors that are caught after the patient has been taken into the operating room (OR) and, depending on organ type or hospital practice, some potential transplant recipients may go straight into the OR bypassing the surgery holding area.[6] The MPSC considered multiple definitions to clarify when a donor organ or potential transplant recipient is identified as incorrect would be considered a "near miss." The MPSC decided to adopt the near miss definition that "an error caught during pre-transplant processes conducted according to either Policy 5.8.A: *Pre-*

[5] MPSC Meeting Summary, September 27, 2023, OPTN, accessed October 19, 2023, https://optn.transplant.hrsa.gov/media/q2zmlhc1/20230927_mpsc_meeting_minutes_public.pdf
[6] MPSC Meeting Summary, May 4, 2023. https://optn.transplant.hrsa.gov/media/d5sf1py4/20230504_mpsc_meeting_minutes_public.pdf.

Transplant Verification Prior to Organ Receipt or Policy 5.8.B: *Pre-Transplant Verification Upon Organ Receipt*" noting that these steps in the process are the last safety nets to identify incorrect organ or incorrect potential transplant recipient error.

Commenters generally supported the proposed near miss definitions. Some comments suggested clarifying that the incorrect organ also means incorrect laterality. However, incorrect organ is not defined to include laterality for purposes of reporting to HRSA and MPSC leadership since the transplant of a kidney that is different laterality than the organ accepted is generally done intentionally by the program and transplant of incorrect laterality for lung does not occur.

The American Society of Transplant Surgeons (ASTS) did not support the near miss definition because they thought it would decrease hospitals' willingness to self-report these events due to potential punitive measures. Others expressed opposition to this definition as practices can vary drastically between transplant hospitals. It was suggested that the MPSC use the final checkpoint for the correct organ and the correct potential transplant recipient as the timeframe in which a near miss be identified.

This logic is exactly why the MPSC proposed near misses to be "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 processes outlined in these policies are required final check points of the correct organ or the correct potential transplant recipient that every transplant hospital must conduct in their pre-transplant processes; therefore, eliminating any potential issues with differing practices across hospitals.

The MPSC is aware that the proposed definition of a "near-miss" will include instances where the transplant hospitals' pre-transplant verification protocols and procedures worked as intended to identify and prevent the transplant of the incorrect organ or incorrect potential transplant recipient. However, the MPSC noted that these steps are intended to be the final safety checks and believes hospital processes should identify the correct organ and/or intended recipient prior to the final verifications.

While the MPSC may take an action if the Committee's review identifies a specific noncompliance with OPTN Obligations, the existence of a "near miss" report would not automatically result in an action from the MPSC beyond the required notice to HRSA. While reviewing "near miss" events, the MPSC will evaluate all processes leading up to the final verifications and identify effective preventive measures to minimize chances of the "near miss" error happening again. Identification of these improvements is consistent with the MPSC's charge to evaluate and support OPTN members by providing feedback on and recommendations to improve members' performance, compliance, and quality systems and disseminate effective preventive measures to the community.

Transportation Events

The public comment proposal contained three patient safety events related to transportation. In addition to delivery of the organ to the wrong hospital and delivery of the wrong organ to the hospital that results in the non-use of an organ, the public comment proposal included a required report when "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." Though the "HRSA criteria" do not specifically include transportation-related events, the Wakefield letter does note that an organ that goes to the wrong destination might lead to the transplant of the wrong organ or wrong patient. Additionally, the MPSC is aware of ongoing discussions in the transplant community about the impact of

transportation-related events on the utilization of recovered organs. The MPSC discussed the types of transportation-related events that should require reporting and based its decisions on its observations that (1) transportation-related events should never be the reason a donated organ is not used for transplant and (2) non-utilization is a patient safety event because a candidate who should have received a transplant did not.

Public comment generally supported the inclusion of transportation events as required reports noting an interest in acquiring data on transportation issues. However, commenters noted that clarification was needed for the language that "an organ did not arrive when expected." Commenters noted that not arriving when expected is subjective and could mean fifteen minutes, hours or even days. Many of the comments expressed an interest in data collection on transportation issues to evaluate causes of delay and the consequences of delay beyond non-use or the intended candidate not receiving a transplant.

Based on public comment feedback, the MPSC considered alternatives that would have required reporting if an organ arrived too late resulting in the intended candidate not receiving a transplant from the intended donor or resulted in the non-use of the organ. The Committee generally supported the more inclusive language represented by the intended candidate not receiving a transplant from the intended donor. However, the alternative language did not necessarily remove the subjectiveness noted in public comments. During its discussions, the MPSC noted the desire of the community to have more comprehensive data on the effect of transportation issues or delays and expressed a desire to be able to understand the scope of effect of transportation issues prior to determining the appropriate scope for a patient safety-based reporting requirement other than non-use due to the organ arriving at the wrong hospital or wrong organ arriving at the hospital. The MPSC concluded that reporting through the OPTN Patient Safety Reporting Portal is not an adequate avenue for collection of data that could be used to evaluate transportation issues and determine how to address these issues effectively. The information collected through the OPTN Patient Safety Reporting Portal form is limited and would require inquiry of the involved OPTN members to gather the circumstances of the transportation issue. Therefore, the MPSC decided to remove the required report when "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" from the proposal.[7] The MPSC will pursue a referral to an appropriate OPTN committee for data collection on transportation issues to determine the scope of the issue that can then be used to determine the scope of a required report for patient safety purposes.

The ASTS also did not support the inclusion of any transportation events because it is outside of hospitals' control. While the MPSC recognized that these events are outside of the transplant hospital's control, the hospital is the member that is most likely to know whether the transportation issue resulted in non-use of the organ. In the proposal, the MPSC also emphasizes that they understand in the majority of cases these events will not be the fault of hospitals, but the delivery of an organ to the wrong hospital or the wrong organ to a hospital resulting in non-use of the organ are events that they would still like to investigate and evaluate the causes.

ABO Typing Error or Discrepancy

Currently, OPTN members are not required to report the identification of ABO typing errors or discrepancies; however, MPSC review of past reported ABO typing errors or discrepancies have raised serious patient safety concerns. As a result, the MPSC believes that these events should be required

[7] MPSC Meeting Summary, October 16, 2023.

reports and determined that OPOs and transplant hospitals should be required to report these events since they are both required to perform and report ABO typing.[8] This error is also alluded to in the HRSA letter as an error that could contribute to the transplant of the incorrect organ or other safety events.

The public comment proposal included requirements for both transplant hospitals and OPOs to report ABO typing errors or discrepancies when discovered at or after a required verification process contained in policy. There was overall support for the inclusion of the ABO typing error or discrepancy as a required report. Members provided feedback that the definition could be made clearer; however, no potential solutions were provided. Several commenters noted that, for OPOs, a patient safety concern does not arise until a match run has been executed, allocation has begun, and after the verification process outlined in *Policy 2.6.C*: *Reporting of Deceased Donor Blood Type and Subtype*. In the public comment proposal, OPOs would be required to report "an ABO typing error or discrepancy that was caught after the OPO's deceased donor blood type and subtype verification process, outlined in *Policy 2.6.C*: *Reporting of Deceased Donor Blood Type and Subtype*. The MPSC agreed with these comments and has revised the proposal to require reporting when "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." Therefore, OPO reporting would be dependent on discovering the error or discrepancy after the occurrence of two events, the verification process outlined in policy and the execution of a match run.

OPTN Member Reporting Requirements

The "HRSA criteria" in the OPTN contract requires that the OPTN Contractor report to MPSC leadership and HRSA when it becomes aware of sanctions taken against a transplant professional working for an OPTN member and any evidence of an attempt to deceive the OPTN or the Department of Health and Human Services (HHS). The MPSC believed that these events posed a risk to patient safety and included them in the public comment proposal to gather feedback. The public comment proposal included requirements for OPTN members to report when:

- 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)

These two proposed provisions mirror requirements contained in the HRSA criteria in the OPTN Contract. However, it became clear during public comment that significant clarification to these two provisions was needed. Although commenters recognized that these two events were patient safety events, they noted that the provisions were vague and broad and do not provide sufficient guidance to members regarding what should be reported. Commenters noted that the failure to define the term "sanctions" and "other professional body" could result in the requirement to report confidential actions such as agreements to participate in substance abuse programs and less serious sanctions such as failure to meet a board continuing medical education (CME) requirement in a timely fashion or discipline by a hospital's credentialing committee for failure to complete patient care notes in a timely fashion. Commenters also noted that it is unclear what "other professional body" means. Clarification of this provision is also complicated by the fact that criteria for sanctions, the process for evaluating potential

[8] MPSC Meeting Summary, May 4, 2023.
https://optn.transplant.hrsa.gov/media/d5sf1py4/20230504_mpsc_meeting_minutes_public.pdf.

sanctions, and how those sanctions are reported varies by state. Additionally, commenters noted that the broad language for the requirement to report attempts to deceive the OPTN could conceivably require reporting of any attempt to deceive the Department of HHS that occurs in any service line within the hospital. The commenters noted that transplant program staff are unlikely to know of or become aware of or have the ability to gather information on these attempts to deceive. Therefore, it was suggested that this requirement to report to the OPTN be limited to attempts to deceive that are related to transplant. In addition, since hospitals are obligated under other federal agency regulations to report fraud, the MPSC felt this requirement should be narrow in scope to avoid overlap. The MPSC agreed that both of these provisions needed clarification. After discussion of several alternative language options for each of these proposed requirements, the MPSC was unable to draft appropriate replacement language prior to a final vote on the proposal to be sent to the Board. Therefore, these two provisions were removed from the proposal so that the other important patient safety event reporting requirements could move forward. The MPSC will continue to evaluate language for consideration in a future proposal. [9]

Living Donors Added to Waiting List Within Two Years After Donation

The MPSC sought feedback from the OPTN Living Donor Committee (LDC) about any modifications to the living donor reporting requirements that are currently in *Policy 18.5: Reporting of Living Donor Events*. The LDC noted that *Policy 18.5* currently requires members to report when a living liver donor is listed on the liver waitlist within two years of organ donation or when a living kidney donor is listed on the kidney waitlist or begins regularly administered dialysis as an end-stage renal disease (ESRD) patient within two years of organ donation. The LDC recommended modifying the requirements to require reporting any time any living donor is added to any wait list, regardless of the organ type, within two years of donation. The MPSC unanimously agreed to change the requirement to "a living donor is listed on the waitlist within two years after organ donation."

Overall, the community supported the broadening of the reporting requirement to capture any living donor who is added to the waiting list. The main feedback suggested that the MPSC should monitor living donors added to any waiting list for more than two years after donation and that this reporting could be automated within the OPTN Computer System rather than recovery hospitals being required to report this. While the MPSC voiced support for creating an automated report to alert the OPTN when a living donor is added to a waiting list within two years after donation, it will have to be a future enhancement. Once reporting is automated, it will be easier to see when a living donor is added to a waiting list even after two years post-donation. There was also a comment suggesting broadening the requirement to report when a living kidney donor begins regularly administered dialysis to all living donors as well; however, these policies were created by the OPTN Living Donor Committee and that Committee would be better suited to address that suggestion and is currently reviewing living donor follow-up as a project. The Committee reviewed and discussed the results of public comment and concluded the public sentiment supports sending this portion of the proposal to the Board with no changes.

[9] MPSC Meeting Summary, October 16, 2023.

Update to OPTN Patient Safety Reporting Portal Instructions

Additionally, the MPSC proposes updating the OPTN Patient Safety Reporting Portal Safety Situation and Living Donor Event form instructions to include the list of safety events members will be required to report. This should help streamline the reporting process and provide an immediate reference for members when submitting a report. The proposed changes are outlined in **Appendix A**.

Reporting of Additional Events

Some commenters suggested the required reporting of additional patient safety events such as human leukocyte antigen (HLA) discrepancies or other events that result in non-use of the organ, such as late decline of organs. Adding other patient safety events was out of scope for this proposal based on the feedback requested in the public comment proposal. The addition of HLA discrepancies as a required report is something that the OPTN Histocompatibility Committee is considering including in one of their projects. The MPSC, however, would support future enhancements and additions to this required patient safety reporting to ensure they are fulfilling their charge of reviewing events identified as presenting a risk to patient safety, public health, or the integrity of the OPTN.[10]

Compliance Analysis

NOTA and OPTN Final Rule

The Committee submits this proposal under the authority of the National Organ Transplant Act (NOTA), which states that "[t]he OPTN shall design appropriate plans and procedures, including survey instruments, a peer review process, and data systems, for purposes of: . . . (iii) Conducting ongoing and periodic reviews and evaluations of each member OPO and transplant hospital for compliance with these rules and OPTN policies."[11] Further, the 2011 HRSA letter to the OPTN stated that '[t]he OPTN may wish to include new reporting requirements, if appropriate, consistent with this letter and in the interest of protecting patient safety."[12] This proposal will require member organizations to report events that may impact patient safety to the OPTN. Doing so will improve the MPSC's ability to identify and investigate risks to patient safety, public health or integrity of the OPTN; support the MPSC's charge to evaluate and provide feedback on and recommendations to improve members' performance, compliance, and quality systems; and promote patient safety by informing the MPSC of how often these safety events occur so that the MPSC can provide guidance and communication to the transplant community regarding best practices to limit risks to patient safety.

[10] MPSC Meeting Summary, September 27, 2023, OPTN, accessed October 19, 2023, https://optn.transplant.hrsa.gov/media/q2zmlhc1/20230927_mpsc_meeting_minutes_public.pdf
[11] 42 U.S.C. §274(b)(2)(E), (I)); OPTN Final Rule (42 C.F.R. §121.10(b)(1)(iii).
[12] Wakefield, Mary K., Administrator, Department of Health and Human Services; Letter to Jack Lake, M.D., President, Organ Procurement and Transplantation Network, August 5, 2011.

One component of the OPTN's ongoing and periodic reviews and evaluations of OPOs and transplant hospitals is monitoring and reviewing reported potential patient safety issues. This responsibility is further defined by the OPTN Contract Task 3.6 OPTN member compliance and performance monitoring, quality improvement, and sanctioning, which states:

> "The OPTN Contractor shall monitor OPTN member performance, including threats to patient health and public safety, maintain and develop efforts to improve OPTN member performance, and impose sanctions when warranted.
>
> The OPTN Contractor shall develop processes to:
> - monitor and review OPTN member performance, including threats to patient health and public safety;
> - evaluate, assess, and monitor over time all OPTN members for compliance with the requirements of NOTA, the OPTN final rule, OPTN Bylaws and policies;
> - educate and encourage OPTN member compliance with the requirements of NOTA, the OPTN final rule, OPTN Bylaws, and OPTN policies; and
> - Promote member performance improvement to meet OPTN strategic planning goals as identified in Task 3.2.7.
>
> The Contractor shall ensure that these processes encourage member self-reporting of potential compliance problems and provide incentives to report issues by assisting members in identifying root causes of issues and developing appropriate corrective actions.
>
> In the event OPTN members are unable to increase compliance, improve performance, or mitigate threats to patient health or public safety, or unless otherwise determined to be appropriate, the Contractor shall develop processes consistent with the requirements of NOTA, the OPTN final rule, OPTN Bylaws, and OPTN policies to:
> - impose OPTN sanctions as determined by the OPTN MPSC and BOD; and
> - refer members to the Secretary when federal sanctions may be warranted."

Requiring OPTN members to report potential patient safety events is the OPTN's approach to identifying issues at OPOs and transplant programs that may implicate a patient safety concern. To efficiently identify and evaluate the transplant programs most likely in need of assistance to avoid potential risks to patient health and public safety, the MPSC proposes requiring reporting of the aforementioned patient safety events so the OPTN can inquire with the member, determine the root causes of the event, and help prevent the event from occurring again.

OPTN Strategic Plan

Promote living donor and transplant recipient safety: Since some of the HRSA criteria are not currently required to be reported in policy, the MPSC does not know the prevalence of these events. By adding these requirements to policy, the MPSC will be able review these events and provide guidance and communication to the transplant community regarding best practices to limit risks to living donor and transplant recipient safety.

Implementation Considerations

Transplant Programs

Operational Considerations

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.

Fiscal Impact

There were no significant fiscal impacts indicated with this proposal; however, additional training of staff may be necessary to ensure comprehension of definitions, policy, and procedure relating to patient safety events. It was noted that some transplant hospitals already report similar items, so their additional reporting burden would not be of real fiscal or temporal significance. This proposal was positively received.

Organ Procurement Organizations

Operational Considerations

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.

Fiscal Impact

There were no significant fiscal impacts indicated with this proposal; however, there could be an increased cost associated with response time and investigation. Additional training of OPO staff may also be necessary to ensure comprehension of definitions, policy, and procedure relating to patient safety events. Furthermore, efforts should be made to communicate patient safety events to other OPTN members so that potential errors or mistakes can be avoided, enabling these members to continuously improve and prevent future patient safety events before they occur.

Histocompatibility Laboratories

Operational Considerations

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.

Fiscal Impact

There is no expected fiscal impact on Histocompatibility Laboratories.

OPTN

Operational Considerations

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." The OPTN can expect to receive an increased number of reports that meet the "HRSA Criteria;" however, the MPSC does not anticipate a significant increase. From August 2022 through May 2023, there have been approximately seventeen reports that would meet the proposed requirements, which are more expansive than the "HRSA Criteria." Typically, the OPTN receives approximately fifteen reports per year that meet "HRSA Criteria."

The OPTN will provide members with a notice of pending implementation after Board approval, which will be 30 days prior to implementation, and a communication the day of implementation.

Resource Estimates

The OPTN contractor estimates 280 hours for implementation. This will include instruction updates, internal education, and education development for the community. Additionally, creation of targeted member emails, news articles, training and education, a toolkit, FAQ, and web design. Finally, processing of events in the organ center, and answering member questions.

The OPTN contractor estimates 505 hours for ongoing support for this project. This will include an increase in required reporting events and case review, finally, data request support.

Post-implementation Monitoring

Member Compliance

OPTN Contractor staff will continue to send inquiries on behalf of the MPSC to OPTN members who report these patient safety events and will request information about the program/safety event, such as:

- Procedures and protocols
- Quality review processes
- Plans for improvement

The MPSC will continue to review the information submitted by the program and may request that the member submit additional information about certain aspects of the program or submit a plan for quality improvement. The MPSC may also request that a member participate in additional engagement with the MPSC, such as an informal discussion or a peer visit. In rare circumstances where the MPSC identifies a potential ongoing risk to patient health or public safety, the MPSC may request that a member inactivate or withdraw a transplant program or a component of a program to mitigate the risk.

Policy Evaluation

The Committee will be provided with the volumes of these patient safety events following implementation every six months for up to two years. The Committee may also request any subsequent metrics.

Conclusion

By aligning OPTN members' reporting requirements with the OPTN Contractor's requirement to report specific concerning patient safety events to HRSA and MPSC leadership, the MPSC will better understand the prevalence of these events and will continue to fulfill their charge of reviewing events identified as presenting a risk to patient safety, public health, or the integrity of the OPTN. Based on feedback from public comment, the MPSC extended the reporting timeframe from 24 hours after becoming aware of the event to 72 hours to allow more time for members to evaluate whether the event needs to be reported and gather information needed to report. In addition, the MPSC removed proposed required reports for an organ that does not arrive when expected and results in the intended candidate not receiving a transplant from that donor, any sanctions against transplant professionals, and attempts to deceive the OPTN or the Department of Health and Human Services (HHS). Public comment requested clarification of these three provisions. The MPSC was not able to determine adequate replacements for these provisions so the MPSC removed these provisions to allow the rest of the proposal to go to the OPTN Board of Directors. The MPSC will continue to evaluate appropriate language for the removed provisions and pursue a referral for data collection on additional transportation events to determine which events need to be required reports for purposes of patient safety.

Over time, the MPSC will be able to provide guidance to the community regarding effective practices to limit risks to living donor, transplant candidate, and recipient safety. The MPSC does not anticipate that these new requirements will pose a significant increased burden to members since, historically, the OPTN received about fifteen reports per year that must be reported to HRSA and MPSC leadership. And from August 2022 to May 2023, the OPTN has received about seventeen reports that would meet the proposed requirements, which are more expansive than the "HRSA Criteria." While this number is expected to slightly increase with these new requirements, the MPSC believes these events are concerning enough that they must be reported and investigated to limit risks to patient safety. There will be no change in the MPSC's investigative process or decision-making process. The MPSC will make decisions and take actions based on its assessment of member compliance with OPTN Obligations, a member's actions in response to any potential noncompliance, the likelihood of recurrence, and documentation of mitigating factors.

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.

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

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OPTN

Appendix A: Update to OPTN Patient Safety Reporting Portal Instructions

Safety Situation Event Form Instructions

What is a Safety Situation?
A situation or activity that affected or could have affected patient safety.
What to report:
Transplant hospitals must report the following events within 72 hours of becoming aware of the event:

- 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*

OPOs must report the following events within 72 hours of becoming aware of the event:

- 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
- 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

In general:

- Any patient safety situation
- Any other situation that causes a safety concern from a transplantation, donation, and/or quality perspective.

Please report such situations in a timely manner.

Living Donor Event Form Instructions

What is a Living Donor Event?
Situations or activities that affected a living donor.

All required donor and recipient information must still be submitted through TIEDI

This information must be reported within 72 hours of the aborted recovery procedure:

- A living donor organ recovery procedure is aborted after the donor has begun to receive general anesthesia.

This information must be reported within 72 hours of the transplant program's knowledge of the event:

- A living donor dies within two years after organ donation
- A living ~~liver~~ donor is listed on the ~~liver~~ waitlist within two years after organ donation
- A living kidney donor ~~is listed on the kidney waitlist or~~ begins regularly administered dialysis as an ESRD patient within two years after organ donation

This information must be reported within 72 hours of organ recovery:

- A living donor organ is recovered but not transplanted into any recipient
- A living donor organ is recovered and transplanted into someone other than the intended recipient

Please reference OPTN policy for more information on living donor event reporting requirements.

All reported Living Donor Events falling into the above categories will be reviewed by the Membership and Professional Standards Committee and reported to the OPTN Board of Directors. Situations or events that are related to living donors but not listed above, but cause concern from a transplantation, donation, and/or quality perspective should be reported to the Safety Situation Portal.

Appendix B: Post-Public Comment Changes

New language that was proposed following public comment is underlined and highlighted (example); language that is proposed for removal following public comment is struck through and highlighted (~~example~~).

16.2 Packaging and Labeling Responsibilities

No changes proposed following public comment.

18.5 Reporting of 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 ~~24~~72 hours after:
A transplant of the incorrect organ into an organ recipient occurs	~~Improving~~ OPTN Patient Safety Reporting Portal	The transplant hospital becomes aware
A transplant of an organ into the incorrect organ recipient occurs	~~Improving~~ OPTN Patient Safety Reporting Portal	The transplant hospital becomes aware
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*	~~Improving~~ 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*	~~Improving~~ 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	~~Improving~~ 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	~~Improving~~ OPTN Patient Safety Reporting Portal	The transplant hospital becomes aware

Transplant hospitals must report if:	To the:	Within ~~24~~72 hours after:
~~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~~	~~Improving Patient Safety 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*	~~Improving~~ 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 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 donor is listed on the wait list within 2 years after organ donation	~~Improving~~ OPTN Patient Safety Reporting Portal	The hospital becomes aware
A living kidney donor 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

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 ~~24~~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	~~Improving Patient Safety Portal~~ 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	~~Improving Patient Safety Portal~~ OPTN Patient Safety Reporting Portal	The OPO becomes aware

~~**18.5.D Required Reporting by all OPTN Members**~~

~~OPTN members must report the following events to the OPTN according to *Table 18-6* below.~~

~~**Table 18-6: Required Reporting by all OPTN Members**~~

~~Members must report if:~~	~~To the:~~	~~Within 24 hours after:~~
~~Any sanction is taken by a state medical board or other professional body against a transplant professional working for an OPTN member~~	~~Improving Patient Safety Portal~~	~~The member becomes aware~~
~~Evidence is discovered of an attempt to deceive the OPTN or the Department of Health and Human Services (HHS)~~	~~Improving Patient Safety Portal~~	~~The member becomes aware~~