



CONFIDENTIAL MEDICAL PEER REVIEW

June 16, 2020

VIA SECURE EMAIL

████████████████████
Chief Executive Officer
Indiana Donor Network
████████████████
████████████████

Dear ██████████

The United Network for Organ Sharing (UNOS) serves as the Organ Procurement and Transplantation Network (OPTN) under contract with the Health Resources and Services Administration (HRSA) of the U.S. Department of Health and Human Services. Under that contract, UNOS staff review reported or identified patient safety and/or public health-related concerns associated with organ donation and transplantation occurring within the OPTN.

UNOS' Member Quality staff screen all reports to determine whether the matter suggests a risk or threat to patient safety or public health. Often additional information is needed from the involved OPTN member(s) to finalize the assessment of threat. If the matter is assessed as both time-sensitive and serious, this department will alert UNOS and/or OPTN Membership and Professional Standards Committee (MPSC) leadership and, under that direction, work with OPTN member(s) to alleviate the threat.

UNOS' Member Quality Department staff also screen all reports to determine if there is a possible violation of OPTN bylaws or policies associated with the matter. Again, additional information is typically needed from OPTN member(s) involved in order to complete the assessment.

We are currently reviewing the organ recovery by Indiana Donor Network (INOP) for donor ██████████. Our preliminary analysis indicates that hospital staff inadvertently discarded both kidneys when cleaning the donor operating room.

We are contacting you to obtain a complete understanding of what occurred. We appreciate as much detail as you can provide. Any information you provide that suggests a potential policy or bylaw violation, or which may pose a threat to transplant or donor patient health or public safety may be referred for review by UNOS leadership, including the MPSC, and in some cases the OPTN Board of Directors.

Please address the following issues related to the kidneys' discard:

- Provide a detailed summary with a timeline of this event, include the following:
 - Where OPO staff were located in relation to the kidney sterile table during the events leading up to the error, and which staff member was attending to the kidneys while in the operating room;
 - Describe any attempts to allocate the kidneys after the error;
 - Describe all information considered when INOP ceased kidney allocation efforts;
 - If the kidneys were able to be placed for research.
- Summarize any communication related to this event that occurred, or is planned, between INOP and others involved (i.e. OPO staff, recovering teams, donor hospital staff, donor hospital risk management team and/or leadership and the donor family).
- Provide your policies and/or Standard Operating Procedures for organ recovery, labeling and packaging. Did staff follow those procedures in this case?
- Provide a root cause analysis or findings of any post-case reviews, if available.
- What corrective actions, if any, have been implemented or are planned as a result of this event? If corrective actions include revisions to existing documents, please provide those documents with the changes easily identifiable (i.e., highlight changes, etc.).

The OPTN bylaws and policies guide the sequence of allocation and wait listing practices of OPTN members in an effort to assure equitable organ allocation for transplant. The bylaws and policies also guide safe and effective practice connected to organ transplantation and living donor care. UNOS is responsible for monitoring compliance by OPTN members with these OPTN obligations, as well as for processing reports of transplant-related patient safety and living donor safety.

The OPTN MPSC, and in certain cases, the OPTN Board of Directors, perform the peer review functions of the OPTN. Please be aware that this correspondence and all documents and information requested by UNOS staff, on behalf of the OPTN, are protected by applicable peer review statutes and will not be disclosed. For this reason, all associated reports, inquiries, deliberations, findings, recommendations, and actions must be kept confidential. This means we will not be able to provide you with the results of our investigation.

I look forward to hearing from you by June 30, 2020. Responses can be sent via mail, email and/or fax. I can be contacted at [REDACTED] Thank you in advance for providing the additional information requested.

Sincerely,

[REDACTED]

[REDACTED]

Safety Analyst
UNOS Member Quality

SFC OPTN Hearing
Exhibit M.127

[REDACTED]
Indiana Donor Network

June 16, 2020

Page 3

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cc: [REDACTED], OPTN Alternate Representative
[REDACTED] Director, UNOS Member Quality