

Brian M. Shepard
Executive Director & CEO



Matching organs. Saving lives.

CONFIDENTIAL MEDICAL PEER REVIEW

February 28, 2019

VIA SECURE EMAIL



Dear [REDACTED]:

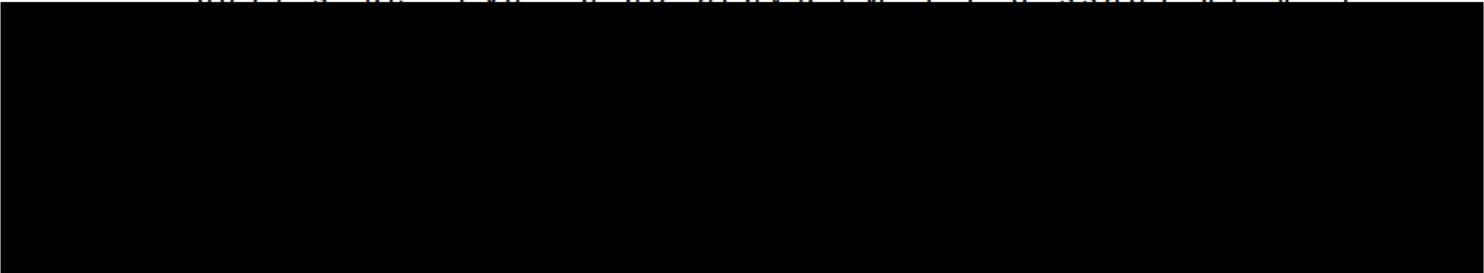
The United Network for Organ Sharing (UNOS) serves as the Organ Procurement and Transplantation Network (OPTN) under contract with the Health Resources and Services Administration (HRSA) of the U.S. Department of Health and Human Services. Under that contract, UNOS staff review reported or identified 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 OPTN 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/UNOS 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 reporting of carcinoma in donor [REDACTED]. Our preliminary analysis indicates that [REDACTED] received an autopsy report in June of 2018, which showed the donor had right testicular embryonal carcinoma. This information was not reported to UNOS or to the receiving transplant centers.

We are contacting you to obtain a complete understanding of what occurred. We appreciate as



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bylaw violation, or which may pose a threat to transplant or donor patient health or public safety may be referred for review by OPTN leadership, including the Membership and Professional Standards Committee (MPSC), and in some cases the OPTN Board of Directors.

Please address the following issues related to the reporting of carcinoma in this donor:

- Explain why the autopsy findings were not reported to UNOS and to the receiving centers upon receipt. Provide a root cause analysis, if available.
- What quality assurance measures are in place to ensure that post-procurement donor test results are reported to UNOS and to receiving centers in a timely manner? Include a copy of your policies and/or Standard Operating Procedures regarding reporting of post-procurement donor test results.
- What corrective actions have been implemented or are planned to prevent recurrence of this type of oversight? Include any documentation that supports these corrective actions, such as revised policy, staff re-training materials, 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 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 **March 14, 2019**. Responses can be sent via mail, email and/or fax. I can be contacted at [REDACTED] or [REDACTED] or [REDACTED]. Thank you in advance for providing the additional information requested.

Sincerely,

[REDACTED]
Safety Analyst
UNOS Member Quality

cc: [REDACTED] OPTN/UNOS Alternate Representative
[REDACTED] M.B.A., Director, UNOS Member Quality