



Matching organs. Saving lives.



CONFIDENTIAL MEDICAL PEER REVIEW

March 13, 2019

VIA SECURE EMAIL



CEO/President
OPTN/UNOS Representative
We Are Sharing Hope SC



Medical Director, Organ Division
We Are Sharing Hope SC



Dear [Redacted]

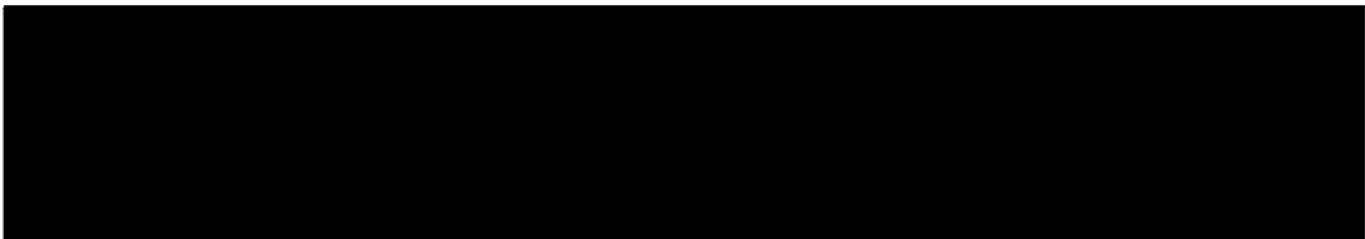
As you know, Membership and Professional Standards Committee (MPSC) leadership, including the Vice Chair, Chair of the Performance Analysis and Improvement Subcommittee (PAIS), and Chair of the Policy Compliance Subcommittee (PCSC), along with the OPTN President reviewed We are Sharing Hope's (SCOP) root cause analysis, containment plan and corrective actions regarding donor [Redacted]'s ABO determination that led to incompatible transplants. After this review, the leadership group requested additional specific information and requested that the program participate in an informal discussion to discuss this case.

SCOP participated in an informal discussion on January 28, 2019 with an MPSC subcommittee. The MPSC met on February 27, 2019, and reviewed submitted documentation and the subcommittee's recommendations.

Based on its review, the MPSC approved the following:

RESOLVED, that the Membership and Professional Standards Committee issues a Notice of Noncompliance to We are Sharing Hope for violation of Policy 2.6.A (Deceased Donor Blood Type Determination).

The Committee voted 29 For; 0 Against; and 1 Abstention.



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The MPSC also requests that SCOP submit the following documentation for MPSC review:

- A log of all cases escalated for Medical Director review identifying:
 - The trigger that escalates the case for review
 - Steps taken by the AOC and Medical Director to resolve the case
 - The case resolution

The MPSC also suggests that SCOP consider looking at additional cases of unexpected graft failure. SCOP may want to look at those cases, even if they did not meet their criteria for review, to determine whether they may also have blood type determination issues. Please submit the requested documentation to [REDACTED] Compliance Operations Analyst, no later than **May 23, 2019**.

Pursuant to the above resolution, the MPSC hereby issues this Notice of Noncompliance to SCOP.

Please note, a Notice of Noncompliance is included in Appendix L of the Bylaws, which is accessible at <http://optn.transplant.hrsa.gov>. A Notice of Noncompliance is not an adverse action under the Bylaws but is meant to inform the member of the need to ensure continuing compliance with policies monitored by UNOS. A Notice of Noncompliance does not need approval from the Board of Directors and is not made public. UNOS will include the letter in your member compliance history, and it may be considered by the MPSC should future compliance issues arise.

Please be aware that this correspondence and all related documents and information are protected by applicable peer review statutes. Members must keep all information provided in the medical peer review processes and settings confidential. Therefore, all inquiries, deliberations, recommendations, and actions of the MPSC, Board of Directors, other committees, and Organ Review Boards must be kept confidential by members during the review process and after the matter is closed. The Board of Directors may make public certain final adverse actions as outlined in the Bylaws.

If you have any questions or concerns, or need any additional information regarding this resolution, please contact [REDACTED]

Sincerely,

[REDACTED]
[REDACTED]
Vice Chair, OPTN/UNOS Membership and Professional Standards Committee
[REDACTED]