



Health Resources & Services Administration

Health Systems Bureau/Division of Transplantation

5600 Fishers Lane
Rockville, MD 20857



August 30, 2024

Richard N. Formica, Jr., MD
President, Board of Directors
Organ Procurement and Transplantation Network
c/o United Network for Organ Sharing
700 N. 4th Street
Richmond, VA 23219

Dr. Maureen McBride
OPTN Executive Director
United Network for Organ Sharing
700 North 4th Street
Richmond, VA 23219

Dear Dr. Formica and Dr. McBride:

The Health Resources and Services Administration (HRSA) received the attached letter from [REDACTED], concerning the activities related to “expedited” allocation of organs (see: Organ Procurement and Transplantation Network (OPTN) Policies 1.3, 5.4.B(2), 5.4.G, and 5.6.D). Dr. [REDACTED]’s communication included copies of letters sent to Dr. [REDACTED], dated January 29, 2024 and April 9, 2024.

The OPTN, OPTN Board of Directors, and OPTN members, which include transplant centers such as [REDACTED], and organ procurement organizations (OPOs) that allocate deceased donor organs, are subject to specific requirements under the National Organ Transplant Act (NOTA), the OPTN Final Rule, OPTN Bylaws¹, and OPTN Policies (see: OPTN Bylaw B.1, Article 1.1.E). OPOs have specific Bylaw requirements regarding compliance with OPTN Policies regarding organ allocation, stated at Appendix B.4.E *“Each OPO must have a plan to equitably allocate donated organs among transplant patients that is consistent with the obligations of the OPTN. An OPO must demonstrate it has policies and procedures that meet or exceed OPTN obligations. An OPO’s failure to comply with these requirements will be considered a noncompliance with OPTN Obligations that may result in an OPTN action according to Appendix L: Reviews and Actions.”*

OPTN Bylaw 1.1.G further requires that *“Any member who becomes aware of a potential noncompliance of OPTN Obligations must inform the OPTN as soon as the member becomes*

¹ For the purposes of this letter, HRSA has cited “OPTN Bylaws” as accessed at https://optn.transplant.hrsa.gov/media/lgbmahi/optn_bylaws.pdf. HRSA notes that the transition between bylaw and policy documents regarding INVEST is still underway.

aware of the issue, including potential noncompliance by the member itself. All incidences of potential noncompliance are referred for further review as outlined in these Bylaws. Any member who fails to comply with OPTN Obligations may be subject to actions as set forth in these Bylaws.”

The OPTN Board of Directors, under OPTN Bylaw XI, “*is responsible for approving and implementing policies that reflect the mission of the OPTN.*” The OPTN Final Rule sets forth “*terms and conditions for the operation of the OPTN*” (OPTN Bylaws Appendix M). Oversight of the implementation of policies includes activities described in Appendix L, which describes “*OPTN² review of potential noncompliance with OPTN Obligations, the process for other reviews as specified in OPTN Policies and Bylaws, and the actions the OPTN may take in response.*” The task of reviewing reports of noncompliance has been delegated by the Board of Directors to the MPSC. However, the OPTN Board of Directors, in its role and responsibilities, must ensure the compliance of OPTN policies with the OPTN Final Rule and NOTA in addition to the conditions defined in the OPTN Bylaws.³

After review, HRSA considers the April 15, 2024, letter from ██████████ to be a “critical comment” under NOTA and the Final Rule (42 U.S.C. 274(c); 42 CFR 121.4(d)). Under the OPTN Final Rule, “[t]he Secretary will seek, as appropriate, the comments of the OPTN on the issues raised in the critical comment related to OPTN policies or practices.” The Secretary will consider the critical comment in light of NOTA and the OPTN Final Rule. After this review, the Secretary may:

- (1) Reject the comment;
- (2) Direct the OPTN to revise the policies or practices consistent with the Secretary’s response to the comment; or
- (3) Take such other action as the Secretary determines appropriate.

To assist in the consideration of the critical comment, I am seeking a response from the OPTN on the issues raised in the April 15, 2024, ██████████ letter and attachments in relation to NOTA and the OPTN Final Rule. This response should include a complete description and timeline of all MPSC actions related to the ██████████ complaint, all committee discussions, and all data and documents collected in the evaluation, investigation, and/or adjudication of the complaint. Please also include all correspondence between the MPSC and ██████████ regarding the complaint. Please also include all correspondence among OPTN contractor staff, MPSC members, and ██████████ regarding this complaint.

Under 42 U.S.C. 274(c) and 42 CFR 121.4(d), OPTN policies relevant to the issues raised in the comment are included in the Secretary’s review. As such, HRSA seeks additional information regarding OPTN policies relevant to organ allocation, enforcement, and the compliance of members with organ allocation policies and membership requirements as set forth by the OPTN. HRSA understands from the OPTN contractor’s June 2024 public presentation of data regarding systemic allocation of organs out of sequence (AOOS) or “expedited placement” that the OPTN and OPTN contractor are both aware that the practice described in the critical comment is not limited to a single event,⁴ that AOOS is increasing as a share of all kidneys allocated since 2019,^{1,4} and that AOOS allows “vulnerable patients [to be] bypassed under current practice.”⁴

² OPTN Bylaw L.2.A clarifies that the OPTN Board of Directors is referenced using the term “OPTN” throughout Appendix L.

³ The OPTN Final Rule sets forth “*terms and conditions for the operation of the OPTN*” (OPTN Bylaws Appendix M).

⁴ Bradbrook, K. (2024, June). “Allocation Out of Sequence: A Kidney Perspective.” [PowerPoint Slides]. Research Department, United Network for Organ Sharing.

Therefore, HRSA requests that the OPTN also include in its response a detailed description of current OPTN procedures for the following:

1. The process that the OPTN uses to review and adjudicate reports made to the MPSC and/or to the OPTN regarding allocation out of sequence (AOOS), non-compliant, and/or “expedited” allocation events, including:
 - a. The OPTN committees that receive information about the nature and number of AOOS event reports.
 - b. Which OPTN committees and/or OPTN staff/teams that review reports of AOOS events
 - i. For each committee, please include the cadence at which the committee receives reports and any associated data analysis generated regarding AOOS events, individually or in aggregate.
 - ii. For each OPTN staff/teams, please include the cadence at which the staff/teams receive reports and any data analysis generated regarding AOOS events, individually or in aggregate.
2. All data reporting generated for the OPTN since 2019 that tracks or otherwise monitors the frequency, nature, or any other descriptive statistics regarding AOOS events at the OPTN member organization level.
3. All data reporting generated for the OPTN since 2019 that tracks or otherwise monitors the frequency, nature, or any other descriptive statistics regarding AOOS events at the OPTN system level.

HRSA is also aware that the OPTN has approved a policy variance supporting the testing of various proposals for AOOS/expedited placement (known as “rescue pathways”), and that the OPTN contract is about to implement the first proposal to be tested. Given that the issues of concern raised in this critical comment could be experienced by OPTN members not participating in the first or any subsequent rescue pathway, HRSA is directing the OPTN to delay implementation of any rescue pathway proposals until the Secretary issues a determination regarding this critical comment.

Please send your comments to me by September 9, 2024. Given that my role as HRSA’s Health Systems Bureau Associate Administrator is one of oversight, on behalf of the Secretary, I will review the OPTN’s response considering the requirements of NOTA and the OPTN Final Rule.

Sincerely,

Suma Nair, PhD, MS, RD
Associate Administrator

Enclosure:
Attachment A

Cc:



