HRSA
Health Resources & Services Administration

Health Systems Bureau
5600 Fishers Lane
Rockville, MD 20857

September 27, 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

Dear Dr. Formica:

The Health Resources and Services Administration (HRSA) received a letter on September 16, 2024, concerning activities related to potential violations of Organ Procurement and Transplantation Network (OPTN) Policies 2.2.5, 2.14.D, 2.15, 2.15.G, 2.15.H, and OPTN Bylaws[1] B.6.H, D.12.E. In the letter, the incident reporter cited the OPTN's lack of policy requirements and data collection for the procurement of organs using Normothermic Regional Perfusion (NRP); the OPTN is obligated to create standards regarding the acquisition of donated organs and to collect data regarding the procurement of organs under 42 U.S.C. 274.

Upon receipt of this information, HRSA directed the OPTN Membership and Professional Standards Committee (MPSC) to begin an investigation into the specific incidents. HRSA also provided the information to the Centers for Medicare and Medicaid Services (CMS).

The incident reporter's letter included the following:

> The OPTN has acknowledged ethical issues surrounding [Normothermic Regional Perfusion (NRP)] since at least August of 2022. There are debates about this process that include philosophical inquiries into the definition of death and the OPTN has carefully documented these discussions. What the OPTN has failed to do is regulate the procedure, or even to monitor how many of these cases are being done. To this date there is no data being collected, no requirements for documentation, and while individual transplant organizations may have written protocols the OPTN has ignored the issue. Any current protocol that states the circulation must be blocked is unenforceable because there are only two ways to confirm this has been done, either by a second surgeon or some form of monitoring of blood flow or brain activity**.** It is unthinkable that it did not occur to anyone in an organization that requires 2-party checks of every bit of documentation to ensure the safety of the transplant recipients, that it would be wise to confirm that we are

[1] For the purposes of this letter, HRSA has cited "OPTN Bylaws" as accessed at https://optn.transplant.hrsa.gov/media/lgbbmahi/optn_bylaws.pdf. HRSA notes that the transition between bylaw and policy documents regarding the legal entity INVEST, which comprises the OPTN Board of Directors, is still under way.

> not taking organs from people who have been resuscitated and may have sensation. I personally have been witness to three cases in which circulation to the brain has either definitely (2 cases) or possibly restored. I have reported each case, but this last time it has become apparent that I cannot trust this issue will be addressed appropriately without external pressure.

The incident reporter states that the OPTN has failed to establish policy requirements for the practice of Normothermic Regional Perfusion in the clinical setting of organ procurement. According to OPTN data, OPOs have seen significant growth in donation after circulatory death (DCD) organ donors,[2] for whom NRP may be used in the clinical procurement setting. In fact, DCD procurements in 2023 accounted for 36%, or more than 1 in 3 procured donor patients,[3] and year to date in 2024, account for nearly 1 in 2 procured donor patients.[4] In addition, HRSA notes that the DCD patient population is increasing in share among hospitals that did not yield a DCD donor prior to 2019, patients over age 65, patients at hospitals with fewer than 250 beds, and non-white patients.[5] It is clear that both the clinical settings and patient population for NRP use in DCD are growing.

The obligation for the OPTN to create policy requirements necessary for the operation of the OPTN is described under 42 U.S.C. 274(b)(2)(E), which requires that the OPTN shall "*adopt and use standards of quality for the acquisition and transportation of donated organs.*" Further, the incident reporter states that the OPTN has not moved to collect data regarding the procurement of organs using NRP. Data collection is also required of the OPTN at 42 U.S.C. 274(b)(2)(I) and (J), which provide that the OPTN shall:

> "*(I) collect, analyze, and publish data concerning organ donation and transplants,*
> *(J) carry out studies and demonstration projects for the purpose of improving procedures for organ procurement and allocation,*

The OPTN, OPTN Board of Directors, and OPTN members, which include transplant centers and organ procurement organizations (OPOs) that procure deceased donor organs, are subject to specific requirements under the National Organ Transplant Act (NOTA), the OPTN Final Rule, OPTN Bylaws, and OPTN Policies (see: OPTN Bylaw B.1, Article 1.1.E). Pursuant to OPTN Policy, stated at Appendix B.4.E, OPOs must have specific policies and procedures demonstrating compliance with OPTN Policies regarding organ procurement:

> *"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:

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[2] See: https://optn.transplant.hrsa.gov/news/continued-increase-in-organ-donation-drives-new-records-in-2023-new-milestones-exceeded/
[3] Ibid.
[4] Data accessed from: https://optn.transplant.hrsa.gov/data/
[5] Ibid.

> "*Any 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. 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 "*OPTN*[6] *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 Membership and Professional Standards Committee (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.[7]

After review, HRSA considers the incident reporter's letter 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. Policies or practices that are the subject of critical comments remain in effect during the Secretary's review, unless the Secretary directs otherwise based on possible risk to the health of patients or to public safety."* 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 incident reporter's letter in relation to NOTA and the OPTN Final Rule. This response should include:

1. A complete description and timeline of all MPSC and/or Operations and Safety Committee activities related to the potential adverse events communicated by the incident reporter occurring at OPO member [redacted], including the dates of complaint, all committee discussions, and all data and documents collected in the evaluation, investigation, and/or adjudication of the complaint. Please also include all

[6] OPTN Bylaw L.2.A clarifies that the OPTN Board of Directors is referenced using the term "OPTN" throughout Appendix L.
[7] The OPTN Final Rule sets forth "*terms and conditions for the operation of the OPTN*" (OPTN Bylaws Appendix M).

correspondence between the OPTN contractor, MPSC, and/or Operations and Safety Committees, and [redacted] regarding the complaint.

Please provide the response to (1) by October 8, 2024, 5 p.m. EDT.

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 procurement including NRP in the care of potential organ donor patients, enforcement, and the compliance of members with organ procurement policies and membership requirements as set forth by the OPTN.

HRSA requests that the OPTN also include in its response a detailed description of the following:

1. For each OPTN OPO member:
    a. The member's policy regarding the use of NRP within their Donation Service Area.
    b. The current list of third-party vendors with which the OPTN OPO member contracts or formerly contracted for NRP.
    c. The member's training requirements, licensure requirements, and/or procedures around the use of NRP in any of the following clinical settings: donor hospitals, privately held OPO surgical facilities, or OPO-operated, hospital-based surgical units.
2. All OPTN Bylaw and Policy requirements related to use, monitoring, data reporting, and clinical setting for NRP in the care of potential organ donor patients.
3. All OPTN Bylaw and Policy requirements related to the training for OPO procurement and surgical staff, including contracted transplant center-affiliated surgeons, third-party procurement contractors, and OPO surgical teams, using NRP in the care of potential organ donor patients.
4. The process that the OPTN uses to review and adjudicate reports made to the OPTN regarding both use of NRP and/or adverse events involving donor patients who were placed on NRP, including:
    a. The OPTN committees that receive information about the nature and number of patients placed on NRP and/or NRP adverse event reports.
    b. Which OPTN committees and/or OPTN staff/teams that review reports of patients placed on NRP and/or NRP adverse event reports
        i. For each committee, please include the cadence at which the committee receives reports and any associated data analysis generated regarding patients placed on NRP and/or NRP adverse event reports, 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 patients placed on NRP and/or NRP adverse event reports, individually or in aggregate.

Please provide the response to requests numbered (1) through (4) above by October 8, 2024, 5 p.m. EDT.

In addition, please provide the following:

5. All data collected by or reported to the OPTN since 2021 that tracks or otherwise monitors the frequency, nature, and/or any other descriptive statistics regarding patients placed on NRP and/or NRP adverse event reports by OPTN member organization.
6. All data reporting generated for the OPTN since 2021 that tracks or otherwise monitors the frequency, nature, and/or any other descriptive statistics regarding patients placed on NRP and/or NRP adverse event reports at the OPTN system level.

Given the additional time that may be required to access complete system-level data, please provide the response to items (5) and (6) before October 11, 2024, 5 p.m. EDT.

The incident reporter's letter requested an immediate OPTN moratorium on NRP practice. HRSA asks the OPTN to provide the requested information regarding NRP activity, data collection, and policy and proposed OPTN action to address this critical comment to HRSA. This information will help inform further action.

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/

Suma Nair, PhD, MS, RD
Associate Administrator

Cc : Maureen McBride, PhD
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