

November 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:

Thank you for the September 9, 2024, response from the Organ Procurement and Transplantation Network (OPTN) to the Health Resources and Services Administration (HRSA) communication regarding the critical comment about alleged organ allocations out of sequence (AOOS). After review of the OPTN response, HRSA has additional questions and clarifications for the OPTN.

(A) The OPTN response to HRSA provided additional information regarding AOOS as a practice. HRSA notes that the OPTN response included the following statement regarding AOOS:

There are times when, in order for the precious gift of an organ to be accepted and transplanted into a recipient, a transplant program or an organ procurement organization (OPO) may adopt these practices to avoid organ non-use and non-utilization. The OPTN Final Rule contemplates this practice as a failsafe to avoid non-use [footnote citation: 42 C.F.R. §121.7(f)].

1. HRSA believes this response is too generic to answer the question. Thus, HRSA requests that the OPTN explain more fully whether, and if so how, the AOOS practices that are either described in HRSA's initial communication or of which the OPTN is aware, comply with the National Organ Transplant Act (NOTA) (42 U.S.C. 273 et. seq), 42 CFR part 121, and OPTN policies, or are necessary to avoid organ wastage in every instance.
2. Of the AOOS cases provided to HRSA by the OPTN, HRSA requests that the OPTN identify those scenarios under which the OPTN believes AOOS practices did not comport with NOTA, 42 CFR part 121 regulatory requirements, and OPTN policies.

(B) The OPTN response to HRSA stated that AOOS “allows OPOs to quickly place organs they believe are at risk of not being used for transplantation.” In addition, the OPTN response states that:

“[The allocation analyst team] retrospectively reviews every deceased donor organ allocation that results in a transplant, and therefore reviews any potential AOOS cases that arise in a routine fashion. [...] When insufficient information is available, the team also reaches out to the OPTN member(s) involved to obtain a complete picture.”

HRSA seeks clarification regarding the process by which the OPTN assesses whether an OPO’s “belief” regarding a specific organ’s potential use is consistent with the transplant center’s assessment(s) of potential use of the organ for which the patient was matched, and the patient’s understanding of this process. Therefore, HRSA requests that the OPTN describe whether individual patients and/or transplant centers which, due to an identified AOOS action, are not provided an organ for which the patient was matched, are:

1. informed of the specific AOOS events,
2. provided general information regarding OPTN allocation policies and the practice of AOOS,
3. given an opportunity to inform the OPTN whether the transplant center and/or patient intends to accept or reject an organ that was not provided to them under the following conditions:
 - a. an organ offered to the patient with a provisional acceptance (or “provisional yes”)¹ entered by the transplant center but the organ was not provided to the patient, or
 - b. an organ offered to the patient with an organ offer acceptance entered by the transplant center but the organ was not provided to the patient
4. provided information regarding compliance or enforcement actions taken, if any, regarding the specific AOOS event.

If the OPTN is not aware of individual patients and/or transplant centers being provided with such information, please specify this in the OPTN’s response.

(C) Regarding information provided by the OPTN addressing the incidents reported by [REDACTED] [REDACTED]² please provide a record of all communications related to these

¹ See: OPTN Policy 1.2, Definitions “Provisional yes: When the transplant hospital notifies the OPTN or the host OPO that they have evaluated the offer and are interested in accepting the organ or receiving more information about the organ.”

² See: Enclosure Attachment A, HRSA letter to the OPTN dated August 30, 2024.

incidents between the incident reporter and the OPTN, including but not limited to communications between the incident reporter and any OPTN board and committee member(s), between the incident date and August 30, 2024.

(D) HRSA requests that the OPTN provide a detailed description of the following:

1. The process by which the OPTN assesses or otherwise monitors the rate of transplanted organs associated with an executed match run without a corresponding electronic offer.
2. The process by which the OPTN assesses or otherwise monitors the rate of organ offers for which the datetime of cross-clamp is entered late (i.e., greater than 60 minutes elapsed between time of cross-clamp and time of cross-clamp entry into UNet).
3. The process by which the OPTN assesses or otherwise monitors the timing of and rate of changes in renal biopsy results after an executed match run with electronic organ offers.
4. The process by which the OPTN assesses or otherwise monitors the frequency, nature, and/or any other descriptive statistics regarding the use of offers made outside of the UNet system by OPOs, including those conducted via phone call and/or text message.
5. The process by which the OPTN assesses or otherwise monitors the frequency, nature, and/or any other descriptive statistics regarding organs offered by batch. For the purpose of this inquiry, HRSA requests information from the OPTN regarding how frequently and under what circumstances OPOs provide offers by batch allocation to a group of transplant programs represented on the waitlist with the first responding program receiving the offer.³
6. The process by which the OPTN assesses or otherwise monitors the frequency, nature, and/or any other descriptive statistics regarding:
 - a. the use of the term “*family time constraints*” in “*Donor Highlights*” or other free text fields in UNet records for potential donor patients,
 - b. the use of the code 761, “*donor family time constraint*,”
 - c. the fraction of (a) and/or (b) in organs transplanted after allocation out of sequence.
 - d. the fraction of (a) and/or (b) in organs transplanted after allocation in sequence.
7. The process by which the OPTN assesses or otherwise monitors the frequency, nature, and/or any other descriptive statistics regarding previously declined organs re-offered to transplant centers by OPO and/or transplant center contractors, such as third-party procurement services and/or normothermic machine perfusion companies.

³ This practice, and similar practices, are described in: Formica R. N., Jr (2023). The National Organ Transplant Act Must Be Updated to Meet the Demands of Transplantation's Future. *Clinical Journal of the American Society of Nephrology : CJASN*, 18(5), 554–556. <https://doi.org/10.2215/CJN.0000000000000139>

Please send your response to me by December 13, 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 -S<sup>Digitally signed by Suma Nair -S
Date: 2024.11.27 09:55:19 -05'00'</sup>

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