

December 13, 2024

Dr. Suma Nair
Associate Administrator
Health Systems Bureau
Health Resources and Services Administration (HRSA)
5600 Fishers Lane
Rockville, MD 20857

VIA ELECTRONIC MAIL

Dear Associate Administrator Nair,

Thank you for the opportunity to provide additional information regarding alleged allocations out of sequence (AOOS). In this letter, the Organ Procurement and Transplantation Network (OPTN) provides responses to the questions posed by HRSA in its November 27, 2024 correspondence. This response contains PHI, and is therefore made in accordance with 45 C.F.R. § 164.512(d), which permits such disclosures without patient authorization for the purposes of facilitating government health oversight activities. Further, this disclosure contains documentation and/or information created for peer review purposes and subject to applicable legal protections. UNOS and OPTN produce this documentation subject to the understanding that HRSA is considered a party to OPTN peer review processes, and such disclosure will therefore not disrupt any applicable privilege. The OPTN requests that HRSA treat this information securely and confidentially.

For the purposes of this response, "Allocation out of sequence" or "AOOS" refers to any organ that has been offered, accepted, and transplanted into a transplant candidate or potential transplant recipient (PTR) that deviates from the match sequence and is not consistent with OPTN policy. To illustrate this point, a directed donation "deviates from the match sequence" but is permitted by OPTN Policy 5.4.E., which states "Acceptable reasons for allocation to the candidate may include, but are not limited to, directed donations..."

HRSA's questions are copied below in bold font, and the OPTN's responses follow each question.

(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 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.**

The OPTN retrospectively reviews all deceased donor match runs that result in a transplanted organ.¹ The analysis includes a review of the refusal reasons and bypass codes entered into the OPTN computer system for each, to determine which allocations may need additional explanations or information in order to determine whether that particular allocation was consistent with OPTN and other OPTN Obligations. For those allocations that cannot be immediately determined to be consistent with OPTN policy, requests for additional information are sent to the OPTN member.² The OPTN contractor then provides that packet of information to the MPSC, which determines whether the reasons provided for allocating the organ out of order of the match sequence is consistent with a permitted policy purpose. On a regular cadence, the MPSC also receives retrospective reports of all allocations investigated.³ Additionally, regardless of MPSC disposition, the MPSC also reports on all allocation reviews to the OPTN Board of Directors in its twice-yearly Board Reports.⁴

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.

Consistent with the description provided in the answer above, the following OPTN members were reviewed by the MPSC for AOOS over the last five years, and a list of actions taken against members based on their allocation practices.

- November 2019: [REDACTED] received a Notice of Non-compliance for a kidney offer for donor ID [REDACTED]
- February 2020: [REDACTED] Notice of Non-compliance for a heart offer for donor ID [REDACTED]; [REDACTED] Notice of Non-compliance for a lung and heart offer for donor ID [REDACTED]; heart offer for donor ID [REDACTED]; and heart offer for donor ID [REDACTED]
- October 2020: [REDACTED] Notice of Non-compliance for a kidney offer for donor ID [REDACTED]
- Feb 2022: [REDACTED] Notice of Non-Compliance for a kidney offer for donor ID [REDACTED]
- July 2023: [REDACTED] Notice of Non-Compliance for a kidney offer for donor ID [REDACTED]; [REDACTED] Notice of Non-Compliance for a liver offer for donor ID [REDACTED]; [REDACTED] Notice of Non-Compliance for a kidney offer for donor ID [REDACTED]

¹ See "Allocation Reviews," at Page 6 in OPTN Member Monitoring Processes, https://optn.transplant.hrsa.gov/media/gqrbxjba/optn_member_monitoring_processes.pdf (Version Date 8/1/2024) (Accessed on 12/11/2024)

² See OPTN Member Evaluation Plan, at Page 19-20, https://optn.transplant.hrsa.gov/media/5vebjkji/evaluation_plan.pdf (Version Date 8/3/2024)(Accessed on 12/12/2024).

³ See e.g. OPTN Membership and Professional Standards Committee Meeting Summary, July 23-25, 2024: https://optn.transplant.hrsa.gov/media/423fsumo/20240723_mpsc_meeting-summary_public.pdf (Accessed on 12/12/2024)

⁴ See e.g. OPTN Membership and Professional Standards Committee Report to the Board of Directors, December 2, 2024: https://optn.transplant.hrsa.gov/media/2qshp3rk/20241202_mpsc_report-to-the-board-final.pdf (Accessed on 12/12/2024).

ID [REDACTED] and [REDACTED]; [REDACTED] Notice of Non-Compliance for a heart offer for donor ID [REDACTED]

- November 2023: [REDACTED] Notice of Non-Compliance for a liver offer for donor ID [REDACTED] and other kidney allocations where [REDACTED] allocated according to their aggressive kidney PDSA.

(B) 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

The OPTN does not directly inform patients about AOOS events. However, transplant programs have access to tools that provide comprehensive visibility into match run responses for their candidates, including all bypasses. Specifically, the Verify Organ Offer Information tool in DonorNet allows programs to review all PTR responses entered by an OPO, including bypasses. Transplant programs have 45 days to verify or update refusal codes, ensuring accuracy in reporting. While OPTN policy does not require OPTN members to notify a patient if they were "not provided an organ for which the patient was matched," it is quite possible that this practice occurs according to OPTN members' institutional practices.

2. Provided general information regarding OPTN allocation policies and the practice of AOOS

The OPTN website offers information on allocation policies for both patients and transplant professionals. All OPTN Policies are available to the public. Additionally, the Evaluation Plan outlines the methods used to monitor organ allocation.

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") 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**

If the organ is still being offered on the match run through the OPTN Computer System, then each transplant program that receives an offer for at least one of their potential transplant recipients on that match run has an opportunity to enter a response to the offer. Transplant programs also provide acceptance criteria for all of their patients to the OPTN.

Additionally, OPTN Bylaws Appendix B.4.E: Organ Allocation Plans, requires OPOs to maintain a plan to equitably allocate organs in compliance with OPTN policies. Following allocations, it is common for OPOs and transplant programs to work together, to discuss recent allocations and identify opportunities for improvement.

Everyone, including OPTN members and patients, donor families and transplant professionals have access to multiple reporting mechanisms, including the patient safety portal, a dedicated reporting phone line, and email. These channels are available for addressing any OPTN concerns, including Allocation issues.

4. Provided information regarding compliance or enforcement actions taken, if any, regarding the specific AOOS event.

As required by the OPTN Final Rule⁵ and the compliance monitoring plans submitted to HRSA by the OPTN Contractor pursuant to the OPTN contract, the compliance monitoring activities performed by the OPTN are conducted under the auspices of confidential medical peer review. Therefore, the OPTN does not disclose information about compliance or enforcement actions related to specific AOOS events. However, as mentioned above, the public is informed of monitoring activities in an aggregate, retrospective manner through publicly available reports to the MPSC and the OPTN Board of Directors, as well as through an abundance of information posted on the OPTN website.⁶

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

All communication was previously submitted in the OPTN Critical Comment response provided on September 9, 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.

The OPTN systems are designed to support members in maintaining compliance with electronic offer processes. For every recipient removed from the waitlist due to receiving a transplant, a corresponding donor ID must be provided. Completed match runs that result in a transplant require a match acceptance to finalize the match run. Additionally, the donor ID is necessary to update the recipient's status and remove them from the waitlist.

When an OPO closes the Donor Disposition, they are required to document the outcome for each organ, specifying whether it was recovered and transplanted. This system of checks and balances between the OPO and transplant program helps to ensure that offers are being made within the system.⁷

⁵ 42 C.F.R. §121.10(b)(1)

⁶ <https://optn.transplant.hrsa.gov/policies-bylaws/compliance-and-evaluation/>

⁷ OPTN Policy 18, Table 18-1: Data Submission Requirements.

https://optn.transplant.hrsa.gov/media/eavh5bf3/optn_policies.pdf (Accessed on 12/12/24).

- 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).**

The OPTN can identify when the cross-clamp date and time are entered into the OPTN computer system and determine if the entry exceeds 60 minutes from the event. However, this is not actively monitored, as there is no OPTN policy requiring cross-clamp time to be entered into DonorNet within 60 minutes of the event.

- 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.**

The OPTN can identify the timing and rate of changes in the renal biopsy results. However, this is not actively monitored, as there is no OPTN policy addressing the timing of and rate of changes in renal biopsy results.

- 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.**

The OPTN systems are designed to support members in maintaining compliance with electronic offer processes. For every recipient removed from the waitlist due to receiving a transplant, a corresponding donor ID must be provided. Completed match runs that result in a transplant require a match acceptance to finalize the match run. Additionally, the donor ID is necessary to update the recipient's status and remove them from the waitlist. When an OPO closes the Donor Disposition, they are required to document the outcome for each organ, specifying whether it was recovered and transplanted. Initial offers made outside the system, such as via phone call or text, are difficult or impossible for the OPTN to track.

- 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.**

The OPTN identifies all AOOS that result in a transplant for review by the MPSC, including batch offers that lead to AOOS. Furthermore, the OPTN is aware that OPOs use various approaches to allocate hard-to-place organs.⁸

- 6. The process by which the OPTN assesses or otherwise monitors the frequency, nature, and/or any other descriptive statistics regarding:**

⁸ See Dolan, T., Bradbrook, K., and Martinez, C., Descriptive Data Request: Hard to Place Kidneys, Presented to OPTN Kidney Transplantation Committee on February 21, 2024.

- 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.

The use of the term “family time constraints” used in bypass text in DonorNet and/or used in the member’s response to inquiry is noted by contractor staff for the MPSC review of AOOS. The OPTN does not routinely assess or otherwise monitor the fraction of organs transplanted where family time constraint is mentioned.

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.

The OPTN contractor respectfully requests additional clarification or further details regarding HRSA's request regarding previously declined organs re-offered to transplant programs by OPO and/or transplant center contractors. Is HRSA referring to offers that have been declined by a transplant program and then re-offered to the same program?

To conclude, the type of data analysis questions posed by HRSA in Section D of this inquiry are the very types of questions the OPTN is eager to charge an OPTN governance group, whether it be an OPTN committee or the Expeditious Task Force (ETF), to review. The creation of the expedited placement variance⁹ is evidence of the OPTN’s good faith commitment to analyzing and solving these allocation challenges. The protocols developed thereunder will be monitored for effectiveness and may employ similar analyses to those posed by HRSA in Section D. Therefore, as the President of the OPTN, I implore HRSA to permit the OPTN to continue to explore innovative approaches to analyzing and solving the challenges leading to the use of AOOS by reversing HRSA’s prior directive to “delay implementation of any rescue pathway proposals until the Secretary issues a determination regarding this critical comment.”

Sincerely,

/Richard N. Formica, Jr., MD/

Richard N. Formica, Jr., MD
President, OPTN Board of Directors

⁹ OPTN Policy 5.4.G: Open Variance for Expedited Placement.

https://optn.transplant.hrsa.gov/media/eavh5bf3/optn_policies.pdf (Accessed on 12/12/2024).