

September 9, 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 information about the Organ Procurement and Transplantation Network's (OPTN) actions related to [REDACTED] concerns, which the Health Resources and Services Administration (HRSA) considers to be a "critical comment," related to "expedited" allocation of organs, as requested in your August 30, 2024 letter. This letter is also responsive to HRSA's request for additional information regarding OPTN procedures and policies relevant to organ allocation, enforcement, and the compliance of members with organ allocation policies and membership requirements as set forth by the OPTN. The requested data will be transmitted securely to HRSA by the current OPTN contractor. This disclosure 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 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 the data and files that we are transmitting pursuant to this request securely and confidentially, as they contain both personal health information and confidential medial peer review information.

HRSA correctly notes that the OPTN has been aware of the existence of allocation out of sequence (AOOS) and expedited placement. 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.¹ The National Academies of Sciences, Engineering, and Medicine (NASEM) observed in its expansive consensus study report that, "Expedited

¹ See 42 C.F.R. §121.7(f), stating "Nothing in this section shall prohibit a transplant program from transplanting an organ into any medically suitable candidate if to do otherwise would result in the organ not being used for transplantation. The transplant program shall notify the OPTN and the OPO which made the organ offer of the circumstances justifying each such action within such time as the OPTN may prescribe."

organ placement has been an important tool in organ allocation for many years as it allows OPOs to quickly place organs they believe are at risk of not being used for transplantation.”²

Although AOOS and expedited placement have been and will be a part of the deceased donor allocation process, the OPTN has observed a marked increase in AOOS. While AOOS and expedited placement achieve the goal of reducing organ non-use, doing so may come at the expense of equity: the pillar around which the deceased donor allocation sequences are built.³ This is why, building on the recommendations from the NASEM report, the OPTN Board of Directors created Expeditious: Organ Use through Placement Efficiency Task Force (ETF) in September 2023.^{4,5}

The ETF is driving opportunities for improvement in the transplant community at the system level through multiple methods. The OPTN at all times uses evidence-based, scientific approaches to policy-making and problem-solving. In fact, the National Organ Transplantation Act (NOTA) and the OPTN Final Rule require the OPTN to “carry out studies and demonstration projects for the purpose of improving procedures for organ procurement and allocation,”⁶ including developing “experimental policies that test methods of improving allocation,” so long as such “variances” are “accompanied by a research design and include data collection and analysis plans.”⁷

Specific to the issue of AOOS and expedited placement, the OPTN Board of Directors recently created a pathway for the testing of short-term, iterative variances to determine whether any new strategies could systemically improve the approach to expedited placement of organs and AOOS.⁸ The ETF refers to these strategies as “rescue pathways.” The rescue pathways protocols will test different criteria for determining which organs should be placed on an expedited basis and which candidates should be eligible to receive those offers. The first protocol for accelerated placement of hard-to-place kidneys due to be implemented is Protocol 1: Pre Cross Clamp Placement of KDPI 75-100 Kidneys.⁹ Both the variance and Protocol 1 were distributed for public comment and duly adopted by the OPTN. Pursuant to HRSA’s August 30, 2024, letter, the OPTN has delayed implementation of any rescue pathway proposals until HRSA provides notice to the OPTN that implementation may resume.

² See National Research Council. 2022. *Realizing the Promise of Equity in the Organ Transplantation System*. Washington, DC: The National Academies Press. <https://doi.org/10.17226/26364> (Accessed September 4, 2024).

³ See 42 C.F.R. §121.4(a)(1) and §121.8(a). See also OPTN Equity in Access Dashboard. <https://optn.transplant.hrsa.gov/data/dashboards-metrics/equity-in-access/> (Accessed on September 9, 2024).

⁴ See <https://optn.transplant.hrsa.gov/professionals/improvement/improving-organ-usage-and-placement-efficiency/> (Accessed on September 4, 2024). The ETF roster includes a representative from HRSA, who serves as an ex officio member.

⁵ The OPTN Ethics Committee is also examining the ethical implications of AOOS and plans to provide a white paper to the OPTN Board of Directors. Summaries of the Committee’s discussions of this topic can be found at <https://optn.transplant.hrsa.gov/about/committees/ethics-committee/> (Accessed September 9, 2024).

⁶ 42 U.S.C. §274(b)(2)(J) and (N)

⁷ 42 C.F.R. §121.8(g)

⁸ See Notice of OPTN Policy Changes: Expedited Placement Variance.

<https://optn.transplant.hrsa.gov/media/cxwnfwqc/policy-notice-expedited-placement-variance.pdf> (Accessed on September 4, 2024).

⁹ See <https://optn.transplant.hrsa.gov/professionals/improvement/improving-organ-usage-and-placement-efficiency/protocols-for-expedited-placement-variance/accelerated-placement-of-hard-to-place-kidneys/> (Accessed on September 4, 2024).

In the meantime, we will continue to monitor every single allocation of every single deceased donor organ according to the processes described in the OPTN Member Monitoring Process document¹⁰ and in Appendix A, below.

Sincerely,

/Richard N. Formica, Jr., MD/

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

¹⁰ See OPTN Member Monitoring Processes: Allocation Reviews at page 6-7.
https://optn.transplant.hrsa.gov/media/gqrbxjba/optn_member_monitoring_processes.pdf (Accessed on September 4, 2024).

Description and timeline of all MPSC actions related to the [REDACTED] complaint (see April 15, 2024, letter), all committee discussions, and all data and documents collected in the evaluation, investigation, and/or adjudication of the complaint.

Neither the OPTN Membership and Professional Standards Committee (MPSC) leadership nor OPTN contractor staff received the January and April 2024 correspondence from [REDACTED]. While we never received the formal complaints, we can confirm that the specific allocation cases referenced in the letters were reviewed (or will be reviewed) following standard AOOS processes, described in more detail below under the response to question 1.

All correspondence between the MPSC and [REDACTED] regarding the complaint (see April 15, 2024, letter).

There is no correspondence between MPSC and [REDACTED] regarding the complaint, because the complaint never reached MPSC leadership or OPTN contractor staff.

All correspondence among OPTN contractor staff, MPSC members, and [REDACTED] regarding this complaint (see April 15, 2024, letter).

There is no correspondence among OPTN contractor staff, MPSC members, and [REDACTED] regarding the complaint, because the complaint never reached MPSC leadership or Contractor staff.

1. OPTN process for review and adjudication of reports made to MPSC and/or the OPTN regarding AOOS, non-compliant, and/or expedited allocation events

General Process for AOOS Review and Adjudication

The MPSC is the only OPTN committee charged by the OPTN Board of Directors to monitor OPTN member compliance with OPTN Obligations, including member compliance following OPTN policies, bylaws, and the OPTN Final Rule.¹¹ The MPSC, on which HRSA representatives serve as ex officio members, employs a confidential, medical peer review process for assessing potential violations of OPTN Obligations. To allow the MPSC to focus on the most significant, impactful, and riskiest issues, the MPSC has approved “operational rules” for various case types, which are rules that OPTN Contractor staff follow when triaging cases that will eventually come before the MPSC.¹² It is important to note that the OPTN Contractor retrospectively reviews every single deceased donor organ that is allocated and results

¹¹ See <https://optn.transplant.hrsa.gov/about/committees/membership-professional-standards-committee-mpsc/> (Accessed on September 8, 2024)

¹² See OPTN Member Monitoring Processes: Allocation Reviews at page 14. https://optn.transplant.hrsa.gov/media/gqrbxjba/optn_member_monitoring_processes.pdf (Accessed on September 8, 2024). The MPSC reviews all operational rules on an annual basis and will be reviewing them again in November 2024.

in a transplant.¹³ This information and analysis is then packaged for MPSC review at various intervals, depending on the allocation scenario and the applicable operational rule:

- **Real-Time Review:** Individual cases that raise concerns for patient safety, equity of the transplant system, or based on historical MPSC decisions are immediately escalated to MPSC reviews for real-time review.
- **Standard Review:** All other AOOS cases, excluding those covered by specific operational rules, are reviewed during the MPSC's multiple-day meetings, which occur three times a year. Each meeting involves the review of one year's worth of allocation data from approximately one-third of the OPOs.
- **Trend Monitoring:** Trends of concern are monitored and shared with MPSC leadership as soon as they are identified, especially if they deviate from community patterns.

For example, when there was a notable increase in AOOS, the MPSC received a presentation outlining the trend in February 2022. Following that meeting, an update on the allocations out of sequence was provided to the MPSC at its July 2022 meeting. The MPSC Allocation Review Subcommittee was established following the July 2022 MPSC meeting and met in closed session six times from September 2022 through January 2024 with a goal to evaluate and develop a new process for review of allocations. The Subcommittee evaluated what the MPSC should review to adequately provide oversight of the allocation process, whether there are areas that are not currently monitored that should be and whether there are changes in process or data collection that would need to be made to adequately monitor allocation. The Subcommittee reviewed data on the:

- Number and percentage of allocations out of sequence overall and by organ
- Number of allocation cases reviewed by the MPSC
- Distribution of kidney allocation out of sequence by Kidney Donor Profile Index (KDPI) categories and by donation after brain death (BD) versus donation after circulatory death (DCD)
- Characteristics of hard-to-place kidneys and potential hard-to-place kidney definitions
- Characteristics of kidney late turndowns

The MPSC was provided updates on the Subcommittee work during its October 2022, February 2023, May 2023, June 2023, July 2023, November 2023, and January 19, 2024, meetings.¹⁴ Throughout this timeframe, the MPSC included extensive information on AOOS in its reports to the OPTN Board of Directors in December 2022, June 2023, December 2023, and June 2024, noting the recommendation for the OPTN to develop standardized allocation practices for hard-to-place organs to achieve equity while maximizing organ utilization.¹⁵ The OPTN Board of Directors heeded this advice, establishing the

¹³ *Id.* at page 6.

¹⁴ All OPTN MPSC meeting summaries are available at <https://optn.transplant.hrsa.gov/about/committees/membership-professional-standards-committee-mpsc/> (Accessed on September 8, 2024).

¹⁵ All recent OPTN MPSC reports provided to the OPTN Board of Directors are available at <https://optn.transplant.hrsa.gov/about/committees/membership-professional-standards-committee-mpsc/mpsc-resources/> (Accessed on September 9, 2024).

Expeditious Task Force (ETF) (described in the cover letter, above) and charging the OPO Committee to develop definition of “late declines.”

Currently, the Allocation Review Subcommittee work has been paused until work is completed on the development of late decline definitions and while the OPTN Expeditious Task Force is investigating effective rescue pathways for hard-to-place kidneys.

Review of Cases Listed in [REDACTED] Letter

The first three cases described in the [REDACTED] letter were reviewed by the OPTN contractor’s Allocation Analyst team in February 2024. An Allocation Analyst sent a standard inquiry letter to the OPO.¹⁶ The OPO responsible for these allocations provided the following reasons for allocating out of sequence:¹⁷

- **Case 1:** DCD status, age, donor medical history, elevated KDPI, and biopsy results
- **Case 2:** high amounts of cold ischemic time, as well as anatomy and biopsy findings
- **Case 3:** high amounts of cold ischemic time, biopsy findings, and pump numbers

Although these specific cases were not individually reviewed by the MPSC due to the operational rule that 50% of an OPO’s cases are randomly selected for individual monitoring unless exceptional concerns arise, similar cases from this OPO were assessed during the July 2024 multi-day MPSC meeting. The MPSC reviewed 40 AOOS cases from this OPO from March 1, 2023, to February 29, 2024, and subsequently closed the review with no further action. It was determined that the OPO had taken all necessary steps to prevent organ non-use for the organs in question.

The other two cases mentioned in the [REDACTED] letter were reviewed by the Allocation Analyst team in May 2024. The OPOs involved in these cases provided the following information for reasons for allocating out of sequence:¹⁸

- **Case 4:** the right kidney was accepted and transferred to a transplant hospital for sequence # on kidney match run #####¹⁹. Transplant hospital had initially performed a virtual crossmatch that came back negative. However, after 14.5 hours of cold ischemic time (CIT), the final crossmatch came back positive, rendering the intended recipient unsuitable for transplantation. After consultation with the administrator on call, an open offer was made to the original accepting center to avoid organ non-use. The right kidney was successfully transplanted to the recipient at ####, sequence ##. This case was self-reported by the OPO.
- **Case 5:** donor's age, DCD status, and past medical history.

¹⁶ See SFTP transmission, “Response to Q1 Folder,” document titled “CONFIDENTIAL MED PEER REVIEW March 2024 Allocations Inquiry.”

¹⁷ See SFTP transmission, “Response to Q1 Folder,” document titled “CONFIDENTIAL OPO Responses to Donor Inquiries.”

¹⁸ *Id.*

¹⁹ A “#” indicates where PHI was redacted

In line with the standard MPSC review process, cases from these OPOs for the period of March 2024 to February 2025 will be reviewed during the MPSC's July 2025 multi-day meeting.

- a. **OPTN committees that receive information about the nature and number of AOOS events**
- b. **Which OPTN committees and OPTN teams review reports of AOOS events.**
 - i. **For each committee, include cadence at which committee receives reports and associated data analysis generated regarding AOOS events, individually or in the aggregate.**
 - ii. **For each OPTN team, include the cadence at which the teams receive reports and any data analysis generated regarding AOOS events, individually or in the aggregate**

The MPSC is provided with yearly rolling average data for the OPO and national average, covering the years 2020-current. This includes data on non-use rates and total AOOS rates. Such data allows the MPSC to analyze trends over time and compare performance across different regions and OPOs, ensuring that the allocation processes remain fair and compliant with OPTN policies.²⁰

As described above, the MPSC is the primary OPTN committee that receives information about the nature and number of AOOS cases. However, other OPTN Committees and groups, such as the ETF, also receive presentations regarding AOOS as needed or requested.²¹ For example, the ETF has been reviewing AOOS cases at an aggregate level to inform their work on systemic improvements and policy recommendations.

There are various OPTN contractor teams involved with compiling and analyzing AOOS data as well:

- **Patient Safety:** This team investigates AOOS cases that involve human error or pose risks or ongoing threats to patient safety. They also review self-reports or referrals from the community, and when insufficient information is available within the OPTN Computer System, they reach out to the OPTN member(s) involved to obtain a complete picture. The information gathered is crucial for the MPSC's adjudication process. Due to the nature of their work, the cadence of reviews by the Patient Safety team is variable and dependent on the frequency of self-reports and referrals. In some instances, the patient safety team will refer cases to Allocation Analysts when issues initially reported as potential patient safety risks instead meet criteria for standard routine monitoring processes.
- **Allocation Analysts:** This 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. They receive monthly reports prepared by the OPTN contractor's Research team of all potential AOOS from across the community, and conduct thorough

²⁰ See SFTP transmission, "Response to Q1 Folder," Excel spreadsheet titled "CONFIDENTIAL - Allocations Data Jan 1 2019-March 31 2024."

²¹ An inventory of presentations to OPTN committees is provided in the SFTP transmission, "Response to Q1" Folder.

reviews of the data submitted to the OPTN for that allocation in the OPTN Computer System (such as through DonorNet, TIEDI, or Waitlist) to determine if any potential allocation policy violations occurred. When insufficient information is available, the team also reaches out to the OPTN member(s) involved to obtain a complete picture. All data collected during these reviews is included in a monthly monitoring spreadsheet.²²

- **Compliance Operations Analysts:** This team provides case information to MPSC members for both Patient Safety and Allocation Analysts. They receive cases as they are ready for MPSC review, assign MPSC reviewers, answer questions and compile MPSC reviewer recommendations. If requested, they present the allocation information to the MPSC for discussion. They also communicate the results of the MPSC's review to the OPTN member that allocated the organ out of sequence. Compliance case reviews typically occur at the MPSC's multi-day meetings, although they can be brought to an MPSC conference call if it is time-sensitive.²³

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**
 - a. See SFTP Transmission, Response to Q2 and 3 Folder.
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**
 - a. See SFTP Transmission, Response to Q2 and 3 Folder.

²² See SFTP transmission, "Response to Q1 Folder," Excel spreadsheet titled "CONFIDENTIAL – Allocations Cases_Monthly Monitoring Spreadsheet."

²³ See SFTP transmission, "Response to Q1 Folder," document titled "CONFIDENTIAL – MPSC Summary AA." This document is an exemplar of the summaries that the Compliance Operations Analysts prepare for MPSC review for allocations cases.