

Health Systems Bureau
5600 Fishers Lane
Rockville, MD 20857

May 13, 2025

Richard N. Formica, Jr., MD
President, Board of Directors
Organ Procurement and Transplantation Network
[REDACTED]

Rexanah Wyse Morrisette, Esq.
Interim Executive Director
Organ Procurement and Transplantation Network
[REDACTED]

Dear Dr. Formica and Ms. Morrisette,

Thank you for the March 31, 2025 response from the Organ Procurement and Transplantation Network (OPTN) to the Health Resources and Services Administration (HRSA) regarding the OPTN's proposed plan for addressing the Secretary's February 21, 2025, directive on allocations out of sequence (AOOS), or organs allocated in a way that deviates from the match sequence and is not compliant with OPTN policy requirements. HRSA is conducting a thorough review of the plan and will issue further guidance to the OPTN.

Directed Action: Development of an Analytic Definition for AOOS

In the interim, HRSA directs the OPTN to propose an analytic definition of AOOS, which can be used to quantitatively estimate AOOS practices, to HRSA by **May 27, 2025**, as well as an accompanying justification for why the proposed definition includes or excludes certain variables. The OPTN should include, at a minimum, members of the Data Advisory Committee (DAC) and Patient Affairs Committee (PAC) in the group that defines the analytic definition of AOOS.

The analytic definition of AOOS should derive from an operational definition¹ of AOOS, which the OPTN has previously characterized as occurring when an organ is “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.”²

¹ “An operational definition is a description of a concept in measurable terms” from Haggerty, J., Burge, F., Lévesque, J. F., Gass, D., Pineault, R., Beaulieu, M. D., & Santor, D. (2007). Operational definitions of attributes of primary health care: consensus among Canadian experts. *Annals of Family Medicine*, 5(4), 336–344. <https://doi.org/10.1370/afm.682>

² OPTN response to November 27, 2024 HRSA letter, dated December 13, 2024.

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HRSA views the development of an analytic definition of AOOS as a foundational first step to inform the parameters of future AOOS data analyses,³ policy changes, stakeholder communication, and oversight conducted in response to the Secretary's directive on AOOS. HRSA recognizes this integrated effort, in collaboration with appropriate stakeholders, might require off-cycle work, but notes that there is significant expertise and interest in the topic within DAC membership, with the current and past chairs having cumulatively published at least eight manuscripts on AOOS. Given the need to address AOOS in an urgent manner, HRSA is prepared to support the OPTN in this effort, including by joining meetings with the DAC, reviewing draft definitions, and/or providing clarification as needed.

HRSA will review the OPTN's proposed AOOS analytic definition upon receipt and either approve or request changes by **June 10, 2025**.

Parameters for AOOS Analytic Definition

At a minimum, the OPTN's proposed analytic definition of AOOS should take into account the parameters used in peer-reviewed research on this topic. For example, Tucker, et al.⁴ define "out-of-sequence" transplants as meeting the following conditions:

- 1) The match-run contains one of the following conventional out-of-sequence codes: 861, 862, or 863; OR the match-run contains the code 799 (other, specify) or 898 (other, specify), and the accompanying free-text field contains one of the following OOS-equivalent terms (or an alternative spelling of the same): "expedited", "aggressive", "open offer", and/or "out of sequence"
AND
- 2) The out-of-sequence code appears earlier in the match-run than the organ acceptance code.

The Final Rule requires that the transplant program document and provide the reasons for organ refusal to the OPTN (42 CFR 121.7(b)(4)). The proportion of organs skipped with an "Other, specify" code has increased substantially since 2021⁵. As such, the OPTN should also discuss the inclusion of "Other, specify" codes, including but not limited to 799, as well as other refusal and bypass codes, in the proposed definition.

³ HRSA recognizes that the OPTN's initial AOOS analytic definition developed in this 2025 effort may need to be revisited in subsequent evaluations as OPTN remediation actions to address AOOS evolve.

⁴ Tucker, Emma G., et al (2025). "Under recognition of deceased-donor kidney out-of-sequence allocation due to increasing use of free text coding." *American Journal of Transplantation* (Journal pre-proof). <https://www-sciencedirect-com.ezproxyhhs.nihlibrary.nih.gov/science/article/pii/S160061352500173X>.

⁵ The use of "Other, specify" bypass/refusal codes 898, 798, and 799 increased from ~10% of match runs at the beginning of 2021 to >30% in the beginning of 2022 (Source: OPTN data, 3/31/2025).

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Additional Analysis to Support Development of AOOS Analytic Definition

In addition to the Tucker, Yu, et al. article cited above, HRSA notes that recent OPTN contractor analysis and peer-reviewed research, including the following publications, provides additional information which the OPTN may use to support the development of an AOOS analytic definition:

- Cron, D. C., Husain, S.A, Kuk, A.E., Mohan, S., & Adler, J. T. (2024). Increasing Incidence of Out-of-Sequence Allocation of Deceased-Donor Kidneys. *Kidney360*. <https://doi.org/10.34067/kid.0000000640>.
- Mohan, S., & Pastan, S. (2023). Out-of-sequence placement of deceased donor kidneys is exacerbating inequities in the United States. *American Journal of Transplantation*. <https://www.medrxiv.org/content/10.1101/2025.02.27.25322934v1>.
- Liyanage, L. N., Daniyar Akizhanov, Patel, S. S., Segev, D. L., Massie, A. B., Stewart, D. E., & Gentry, S. E. (2024). Contemporary Prevalence and Practice Patterns of Out-of-Sequence Kidney Allocation. *American Journal of Transplantation*. <https://doi.org/10.1016/j.ajt.2024.08.016>.
- King, K. L., Husain, S. A., Perotte, A., Adler, J. T., Schold, J. D., & Mohan, S. (2022). Deceased donor kidneys allocated out of sequence by organ procurement organizations. *American Journal of Transplantation*. <https://pubmed.ncbi.nlm.nih.gov/35000284/>
- Adler, Joel T. et al. (2025). Out-of-sequence allocation: a necessary innovation or a new inequity in transplantation? *American Journal of Transplantation*. [https://www.amjtransplant.org/article/S1600-6135\(24\)00577-X/fulltext](https://www.amjtransplant.org/article/S1600-6135(24)00577-X/fulltext).

The OPTN should not be limited by these references, and HRSA encourages the OPTN to consider a broader range of refusal and bypass codes than are represented in these publications to strengthen policy compliance monitoring.

HRSA reiterates the importance of addressing in a timely, transparent, and patient-centered manner the issue of policy-noncompliant organ allocation. Please send your response to me by **May 27, 2025**. 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 the National Organ Transplant Act and the OPTN Final Rule.

Sincerely,
/Suma Nair/

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