

**Health Systems Bureau**

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Dear Dr. Formica and Ms. Wyse 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 organ allocation that is conducted out of compliance with the OPTN Final Rule and OPTN policy requirements.

Update on HRSA's Review of Analytic Definition of AOOS

Following HRSA's letter to the OPTN dated May 13, 2025, which directed the OPTN to develop an analytic definition of AOOS, HRSA has supported the OPTN through providing technical assistance, aligning contractor resources and support, and attending OPTN workgroup meetings to finalize an analytic definition of AOOS. This definition will inform the parameters of future¹ AOOS data analyses, policy changes, stakeholder communication, and oversight conducted in response to the Secretary's directive on AOOS. In addition, once the analytic definition of AOOS is finalized, HRSA will direct the Scientific Registry of Transplant Recipients (SRTR) contractor to align all public data dashboards, analysis, and reporting² to adopt the new definition.

Update on HRSA's Review of Proposed OPTN Plan to Address AOOS

HRSA has conducted a thorough review of the OPTN's proposed plan for addressing AOOS. HRSA will schedule a meeting with the OPTN Board of Directors and OPTN volunteers who are

¹ HRSA recognizes that the OPTN's AOOS analytic definition developed in this 2025 effort will likely need to be revisited in subsequent evaluations in order to evolve with OPTN remediation actions to address AOOS.

² For example, see the contractor's "SRTR Donation and Transplant System Explorer" accessible at <https://www.srtr.org/tools/donation-and-transplant-system-explorer/>, which will be updated to align with the analytic definition of AOOS.

engaged in AOOS remediation to discuss feedback on the proposed plan and as well as next steps. HRSA will share a redline version of the plan with suggested edits and recommendations following the meeting.

While we appreciate the complexity of OPTN member non-compliance with OPTN organ allocation policy, as well as the caveats and considerations outlined in the OPTN's proposed AOOS plan, we believe the timeline, processes, and organizational structures described in the OPTN's draft plan do not demonstrate the level of urgency, efficiency, and agility that AOOS requires.

We would like to discuss opportunities to better align the OPTN's proposed AOOS plan with the core tenets of OPTN Modernization, including *transparency*, *patient centrality*, and *efficiency*. HRSA concurs with the OPTN's assessment that HRSA feedback and input throughout the AOOS plan development and implementation process is critical, and HRSA remains committed to working collaboratively with the OPTN to address this issue.

Interim Next Steps: AOOS Website, MPSC Assessment of AOOS, and AOOS Member Education and Outreach

The OPTN Modernization Initiative allows for, and increasingly necessitates, a more streamlined and enterprise-level approach to policymaking than has been utilized in the past. While HRSA and the OPTN continue to work collaboratively to finalize an AOOS remediation plan, we direct the OPTN to undertake the following actions to increase the transparency, patient centrality, and efficiency of our collective remediation efforts.

1. AOOS Website

Ongoing AOOS continues to undermine public and patient trust in the fairness and transparency of the national organ procurement and transplantation system, as well as trust in the OPTN's ability to create, implement, and ensure compliance with organ allocation policy. At the same time, HRSA recognizes that historical OPTN policy processes and infrastructure were insufficiently rigorous to support timely monitoring and enforcement of OPTN policy to address the large volume of AOOS at the member and system levels.

Therefore, as an immediate next step to addressing AOOS, HRSA will separately direct the OPTN contractor to develop and administer a public-facing AOOS webpage that will include the following components:

- **AOOS Oversight Dashboard:** Using the finalized AOOS definition, in collaboration with the OPTN and HRSA, the contractor will develop a dashboard to monitor individual member and system-wide patterns of organ allocation noncompliance. HRSA has developed a similar monitoring tool for the purpose of federal oversight and will assist the OPTN and OPTN contractor with the development of a public-facing dashboard.

- **Information and Tools:** Links to existing AOOS materials (e.g., current policies, research, data, initiatives) sourced from across the OPTN website will promote more seamless information sharing across OPTN committees, members, and the public.
- **Updates and Engagement:** Regular updates on the OPTN’s progress towards remediating AOOS in collaboration with HRSA, including the final OPTN AOOS Plan, relevant definitions, policy changes, training materials, and public comment deadlines.

HRSA anticipates the initial AOOS webpage will be active within 30 days from issuance of this letter, with iterative improvements made over time, and will work closely with the OPTN, including the Patient Affairs Committee (PAC), to incorporate patient, family member, and community feedback throughout the development process.

2. *Membership and Professional Standards Committee (MPSC) Assessment of AOOS*

While the MPSC is charged with reviewing each individual case of AOOS, HRSA recognizes that the large volume of policy non-compliance through AOOS makes this process challenging at the current scale. Therefore, to assist the MPSC with managing its workload, until further notice, HRSA directs the OPTN MPSC to evaluate member compliance in the aggregate by OPTN member, communicate with members more regularly regarding patterns of policy non-compliance in allocation, and prioritize trends of non-compliance over routine reviews of individual allocations as currently flagged by the contractor. In addition to the current contractor practice of sending a notice of non-compliance for any AOOS instances, specific incidents that arise from the member complaint or safety reporting channels, such as when a transplant center alleges that their patient was skipped by an OPO through a policy non-compliant allocation action, should be paired with member-level AOOS data to trigger additional MPSC review.

3. *OPTN Member Education and MPSC Outreach*

HRSA is encouraged by early data³ suggesting that organ allocation practices among OPTN members have become increasingly more compliant since the Secretary’s February 21, 2025, directive on AOOS, as this implies that OPTN members, including front-line staff at organ procurement organizations (OPOs), are responsive to education on existing OPTN AOOS policies. Therefore, in the near term, we direct the OPTN to prioritize education initiatives that promote greater awareness of and compliance with existing OPTN allocation policy among all OPOs and transplant centers.

³ See, e.g., Adler, et al. (2025), “Reforming Out-Of-Sequence Allocation: A Turning Point For Organ Transplant Policy,” Health Affairs, <https://www.healthaffairs.org/content/forefront/reforming-out-sequence-allocation-turning-point-organ-transplant-policy-1747919779003>.

HRSA directs the OPTN, with support from the OPTN contractor, to identify members with patterns and/or large volumes of AOOS⁴ and send notices and/or requests to mitigate risks as described at OPTN Membership and Management Policy L.6⁵ that:

- describe the member's use of AOOS over the past 12 months,
- inform the member of applicable OPTN allocation policies and definitions, and
- reiterate the HHS determination⁶ that the wastage provision only applies to transplant centers and may not be exercised by OPOs.

HRSA and the OPTN should evaluate the efficacy of the outreach effort by measuring OPTN member compliance with organ allocation policy over time. Assessing the impact of these preliminary efforts should allow the OPTN to identify future policy changes and education initiatives to address remaining gaps in knowledge and associated potential noncompliance among OPTN members. HRSA is ready to assist the MPSC with overcoming any perceived barriers to issuing notices and/or requests to mitigate risks to OPTN members, if needed.

Conclusion

The OPTN's role in designing, implementing, and ensuring compliance with organ allocation policy is critical to the fairness, safety, and performance of the national organ procurement and transplant system. As the OPTN has acknowledged, remediating challenges to public trust, fairness, and transparency in the national system is of the highest priority. Through its response to HRSA's directives regarding AOOS, the OPTN will be more prepared to create stronger policies, and related education, implementation, and enforcement structures that will support patient safety and improved system performance.

HRSA will continue to help the OPTN refine the plan to address AOOS, and through this work, support a restoration of public and patient trust in the fairness and transparency of the national organ procurement and transplantation system.

Sincerely,

/ Suma Nair /

Suma Nair, PhD, MS, RD
Associate Administrator

⁴ As defined by the OPTN's analytic definition of AOOS.

⁵ OPTN Membership and Management Policies Appendix L.6 states (emphasis added): "If an OPTN review suggests a potentially urgent or severe risk exists to patient health or public safety, **the OPTN may ask that the member take appropriate actions to mitigate the urgency and severity of the risk.** A member's failure to sufficiently mitigate the risk in the period requested will be considered a separate potential noncompliance with OPTN Obligations."

⁶ See HRSA's letter to the OPTN dated February 21, 2025: "Section 121.7(f) of the OPTN Final Rule (Identification of Organ Recipient – Wastage) does not authorize out-of-sequence offers by OPOs. Transplant centers in receipt of an organ may find that the intended recipient is not able to utilize the organ. This provision creates a limited exception to transplant programs to transplant the organ into a different medically suitable candidate to avoid organ wastage other than in accordance with 42 CFR 121.7(b)(1) and OPTN policies and procedures, and does not provide this authority to OPOs."

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