



Health Systems Bureau

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Dear Dr. Formica and Ms. Wyse Morrisette,

Thank you for the June 3, 2025 communication from the Organ Procurement and Transplantation Network (OPTN) to the Health Resources and Services Administration (HRSA) proposing operational and analytic definitions of allocations out of sequence (AOOS), or organ allocation that is conducted out of compliance with the OPTN Final Rule and OPTN policy requirements.

We would like to recognize the Analytic Definition Work Group for moving quickly and thoughtfully to align on these definitions, particularly highlighting contributions from members of the Patient Affairs and Data Advisory Committees, who provided valuable structure and technical expertise. The Work Group's discussions and the OPTN's response demonstrate an appreciation of both the inherent challenges of this work and the importance of navigating those challenges to take effective action.

To continue the momentum generated by the Work Group's success, HRSA supports moving forward with the definitions proposed. We acknowledge the OPTN's assertion that "some proportion of AOOS is consistent with policy" and observe that this is not a concern for the OPTN's analytic definition, which is comprised of bypass codes entered by OPOs. As the OPTN is aware, HHS OGC has determined that "Section 121.7(f) of the OPTN Final Rule (Identification of Organ Recipient – Wastage) does not authorize out-of-sequence offers by OPOs."¹

¹ 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

HRSA understands that allocation practice is likely to shift in response to ongoing efforts to reduce AOOS, and it will be critical to continue monitoring practices to detect any increases in non-compliant organ allocation that do not meet this analytic definition. As allocation practice evolves, the OPTN should be prepared to evolve the analytic definition of AOOS accordingly.

Finally, HRSA is in agreement with the OPTN's recommendations for future work outlined in the June 3, 2025 communication. While these recommendations are largely already captured by the OPTN's proposed AOOS remediation plan², HRSA will work with the OPTN to ensure that they are fully incorporated moving forward.

We look forward to continued collaboration to improve the fairness, transparency, and patient centrality of organ allocation.

Sincerely,

/ Suma Nair /

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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.”

² See the OPTN's letter to HRSA dated March 31, 2025.