

Health Systems Bureau
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February 21, 2025

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Dear Dr. Formica and Ms. Wyse Morrissette:

The Health Resources and Services Administration (HRSA) has considered the Organ Procurement and Transplantation Network (OPTN) response to the critical comment regarding allocation out of sequence in light of the requirements of the National Organ Transplant Act (NOTA) of 1984, as amended, and the final rule governing the operation of the OPTN (OPTN Final Rule) as described in 42 U.S.C. 274(c); 42 CFR 121.4(d). The information provided by the OPTN, and independent assessment and analysis of OPTN data by HRSA, has demonstrated potentially widespread non-compliance with regulatory requirements of organ allocation. *See* 42 C.F.R. 121.7(b)(1), which provides that “*Organs shall be offered to potential recipients in accordance with policies developed under 121.8 and implemented under 121.4*”¹ and Section 121.7(f). Under the authority described in 42 CFR 121.4(d)(2) and (3), the Secretary of Health and Human Services may: “*Direct the OPTN to revise the policies or practices consistent with the Secretary’s response to the comments; or [t]ake such other action as the Secretary determines appropriate.*”(emphasis added)

Consistent with the Secretary’s authority and HRSA’s oversight role, this letter directs the OPTN to complete the following actions by March 31, 2025:

(A) *Provide a detailed remediation plan to improve OPTN allocation policy requirements and policy definitions.*

Notable deficiencies in OPTN policies, policy definitions, and quality assurance monitoring should be urgently remediated in order to improve compliance with OPTN organ allocation policy. In addition, the OPTN should leverage better, more granular data to comprehensively

¹ See: OPTN policies 5.4.B(2), 5.4.G, 5.6.A, 5.6.B, and 5.6.D

describe rates and drivers of Allocation Out of Sequence (AOOS) practices. The OPTN’s remediation plan should include the following:

1. Propose a plan to audit OPTN member usage of “other, specify” codes in cases where AOOS has occurred, including assessments of patterns of organ type, peri-procurement timing, sequence at final recipient, and centers. A high rate of “other, specify” usage and/or “other, specify” usage, concerning for evidence of organ diversion, should be immediately referred to the Membership and Professional Standards Committee (MPSC) and reported to HRSA.
2. Direct the OPTN Data Advisory Committee (DAC) to undertake an urgent review and revision of refusal codes for greater specificity and standardization. This action is among 19 priorities already identified by the OPTN DAC.² The OPTN has moved slowly to refine or otherwise improve organ refusal codes, with only two updates to codes in the past 25 years (in 2004 and 2021).³ The latest revision took the OPTN more than 2 years to develop and implement. HRSA will direct OPTN contractor resources to support the OPTN’s expedient efforts. The DAC should also include:
 - a. A proposed timeline to implement and train OPTN members on the use of updated organ refusal codes, once adopted into policy.
 - b. A proposed OPTN policy requirement for OPOs⁴ and transplant centers to attest that staff have been trained on OPTN data collection requirements, including updated refusal codes, and describe OPTN member-level accountability for inaccurate or insufficient coding.
3. Develop a proposed OPTN policy and associated definition to describe “batched organ offers” and specifically prohibit the practice to comply with requirements of NOTA and the OPTN Final Rule.⁵ Please note that under these legal authorities, organ offers must be made to individual transplant patients, and that organ offers cannot be made to transplant programs or transplant centers.
4. Develop a proposed OPTN policy and associated definition for the “offer” of an organ by an OPO to a transplant center.⁶ Current OPTN policies describe initial clinical data required for an organ offer. Improved minimum requirements that define an offer between an OPO and a transplant center should include what constitutes notification to a transplant center of an organ offer made to a transplant patient, and the timeliness and accuracy of information in an offer for the time of

² See: OPTN Data Advisory Committee meeting agenda and meeting materials describing OPTN DAC priorities shared on January 13, 2025, meeting (minutes have not yet been posted by OPTN contractor).

³ See: https://optn.transplant.hrsa.gov/media/4695/update_to_refusal_codes_june_2021_policy_notice.pdf

⁴ See: 42 CFR 121.7(b).

⁵ This practice, and similar practices, are described in: Formica R. N., Jr (2023). The National Organ Transplant Act Must Be Updated to Meet the Demands of Transplantation's Future. *Clinical Journal of the American Society of Nephrology: CJASN*, 18(5), 554–556. Available at: <https://doi.org/10.2215/CJN.000000000000139>.

⁶ Currently, OPTN policy 1.2 is silent on the definition of the term “offer.”

- consideration to start.⁷ In addition, late changes in clinical status that impact the potential acceptance of an organ should be further described and reported.
5. Develop a proposed OPTN policy and associated definition to describe acceptable modalities and associated content of an organ offer made by an OPO to a transplant patient at a transplant center. Current OPTN policy is silent regarding the modalities and content of organ offers as made by OPOs, and consequently, organs may be offered outside of UNet through channels that the OPTN cannot access nor audit.⁸ It is notable that personal cell phones and text messages appear to be in use in the clinical setting for extra-UNet offers of organs by organ procurement organizations, which is outside of the visibility of the OPTN and HRSA oversight.⁹ In addition, offers made outside of the UNet environment may compromise information covered by the OPTN System of Record Notice (SORN)¹⁰ under the Privacy Act.

(B) Propose a detailed, prospective OPTN compliance plan to ensure OPTN members come into compliance with the regulatory wastage provision and otherwise comply with statutory and regulatory requirements for the allocation of organs.

To assist the OPTN in developing the requested compliance plan, please note the following information regarding the operation of the wastage provision contained in the OPTN Final Rule. 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.

Regarding the authority of transplant centers to utilize this exception, transplant centers may only do so to the extent that an individual organ would otherwise go to waste, and not on the basis of a general assertion of avoiding organ wastage. *See* 42 CFR 121.7(f) (“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”(emphasis added)).

The OPTN’s proposed compliance plan, which will be reviewed and approved by HRSA, should specifically describe potential OPTN actions that will protect the ongoing utility and function of the organ allocation process, as well as technical enhancements and data

⁷ See: OPTN Policy 2.11 (Required Deceased Donor Information); Policy 5.4 (Organ Offers).

⁸ During a discussion on November 6, 2024, MPSC members opined that the amount of AOOS to a local center with whom an OPO CEO shares business ties was concerning for potential “*organ diversion*.”

⁹ See: OPTN letter to HRSA, dated December 13, 2024: “*Initial offers made outside the system, such as via phone call or text, are difficult or impossible for the OPTN to track.*”

¹⁰ See: System of Record Notice 09-15-0055 at [Federal Register : Privacy Act of 1974; System of Records](#).

reporting that support the implementation of the policies proposed by OPTN in response to the directions described at (A)2-5 above.

(C) Create transparency into the submission, approval, and performance of protocols under the OPTN expedited placement variance¹¹ to ensure government oversight, increase patient awareness and public transparency of variances, and increase patient access to transplants.

To ensure patient awareness of variances and to ensure effective oversight of these expedited placement protocols, including the potential to sunset any variances that meet stopping criteria, all proposed variances, approved protocols, associated effective dates, and monitoring metrics should be published on the OPTN website prior to implementation. The OPTN Final Rule at 42 CFR 121.8(c) states “*Each organ-specific allocation policy shall include performance indicators. These indicators must measure how well each policy is... [g]iving patients... accurate information to assess the performance of transplant programs.*” (emphasis added). Publicly accessible information on the OPTN website describing all variances proposed, approved, and in progress will ensure patient access to information about variances that may increase their access to transplants. The OPTN should also publish data and analysis describing the performance of each implemented variance, and the aggregate effects of all variances implemented under OPTN policy 5.4.G to inform patients and the public of the results of all activities under the open variance. In conjunction with this letter, HRSA is permitting the OPTN to restart exploring expedited placement protocols based on the parameters above.

(D) Propose a tool to provide public transparency into how frequently patients are excluded from access to organs for which they have been matched as a consequence of AOOS.

Pursuant to 42 CFR 121.11, the OPTN should maintain in UNet, the number of organs refused on behalf of each patient and how many of those refusals meet the definition of AOOS. Aggregate data for OPOs and transplant centers should be published in regular OPTN reports as required by 42 CFR 121.11(b)(1)(ii) and be made accessible to patients researching transplant centers through transmittal of these data to the Scientific Registry of Transplant Recipients for inclusion in program specific reports as specified at 42 CFR 121.11(b)(1)(iv).

Please send your response to me by March 31, 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. To ensure that the national organ procurement and transplant system continues to serve patients and families with transparency, efficiency, and effectiveness, HRSA stands ready to work with the OPTN and the community on addressing this important matter.

¹¹ See: OPTN policy 5.4.G, “*Open Variance for Expedited Placement.*”

Sincerely,

Suma Nair, PhD, MS, RD
Associate Administrator