

Health Systems Bureau

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To: Organ Procurement and Transplantation Network Board of Directors

From: Raymond J. Lynch, MD, MS
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Date: July 10, 2025

Subject: HRSA Feedback on the OPTN's Proposed AOOS Remediation Plan

Background

The Health Resources and Services Administration (HRSA) has conducted a thorough review of the Organ Procurement and Transplantation Network's (OPTN) proposed Allocation Out of Sequence (AOOS) Remediation Plan. HRSA appreciates the effort that went into developing the plan and notes the Definition Work Group's leadership in developing the foundational operational and analytic definitions of AOOS¹ to inform the plan's activities.

HRSA looks forward to discussing our feedback on the plan during our scheduled meeting on July 10, 2025 and to addressing any questions or concerns you may have. Please note that HRSA will hold separate meetings with OPTN contractors regarding how we expect them to support this plan and associated activities.

AOOS Remediation Plan Feedback

Guiding Principles

AOOS remediation work should be guided by the principles of fairness and transparency. The principle of fairness dictates that organs should be allocated according to the match sequence defined by OPTN policy; the principle of transparency allows the OPTN to prioritize patient safety by ensuring that allocation practice aligns with policy, and that any unintended consequences of the policy as implemented are described to the community and remediated as a matter of course.

¹ See: [OPTN June 3, 2025 Response to the Allocation out of Sequence \(AOOS\)](#)

Timeline of HRSA support for AOOS Remediation Plan

The OPTN's proposed AOOS Remediation Plan cites iterative HRSA review and approval as a potential delay to implementing AOOS remediation activities and states that "collaboration and feedback from HRSA throughout the process to limit the back-and-forth will help avoid a prolonged timeline."² HRSA concurs and remains fully committed to partnering with the OPTN throughout the implementation of the AOOS Remediation Plan. Moreover, HRSA is well-positioned to provide robust operational support through our Program Management professionals, Data and Analytics Team, and subject matter experts (SMEs). Following the model of HRSA's involvement in the development of the OPTN's analytic and operational definition of AOOS, HRSA plans to participate in AOOS-related meetings and, whenever possible, to resolve questions and concerns in real time.

Coordination with the Centers for Medicare and Medicaid Services (CMS)

In the proposed AOOS Remediation Plan, the OPTN expresses concerns regarding what is characterized as "competing priorities of [CMS] regulation for OPOs" and the perception that CMS will penalize OPOs that run out of time trying to place transplantable organs due to the constraints of the OPTN's organ allocation policies.³

HRSA acknowledges that the policies created, implemented, and enforced by the OPTN, as well as the regulatory framework enforced by CMS, simultaneously constrain organ allocation activity in the interest of patient safety and system fairness. However, HRSA does not view CMS and HRSA priorities as competitive,⁴ and notes for the OPTN that CMS requirements⁵ specify that organ procurement organizations must (emphasis added) "*become a member of, participate in, and abide by the rules and requirements of the OPTN established and operated in accordance with section 372 of the Public Health Service Act (42 U.S.C. 274).*" While the end goal of the organ procurement and transplant system is transplantation, organ allocation should occur within a framework for fairness, and under a system in which all OPTN members operate in compliance with the applicable laws, regulations and policies.

² OPTN's March 31, 2025 Response to Secretary's Directive on AOOS (Part A, Objectives 3-5). [OPTN Response to HRSA AOOS Directive](#)

³ Ibid.

⁴ For example, see the Center for Medicare and Medicaid Innovation's (CMMI) Increasing Organ Transplant Access (IOTA) model at 42 C.F.R 512.462(b)(2)(x), which calls for (emphasis added) "[m]onitoring out of sequence allocation of kidneys by— (A) Assessing the frequency at which IOTA waitlist patients, top-ranked on an IOTA participant's kidney transplant waitlist, receive the organ that was initially offered to them; and (B) Determining the reasons behind cases where IOTA waitlist patients identified in paragraph (b)(x)(A) of this section, did not receive the kidney offered to them."

⁵ 42 C.F.R. 486.320

Moreover, data do not support the hypothesis that OPOs allocating organs in ways that are compliant with OPTN policy requirements will result in increased organ non-use.^{6,7} Therefore, the goal of increasing the number of organ transplants should not be incongruous with the OPTN’s mandate to set and enforce transparent and fair organ allocation policies.⁸ HRSA and CMS are aligned with the OPTN in the understanding that minimizing non-use of transplantable organs is a top priority, and it will be critical to monitor and confirm in an ongoing manner that the remediation of AOOS does not drive negative, unintended consequences, including but not limited to a significant or sustained increase in organ non-use.

CMS and HRSA maintain a strong partnership and clear communication channels through the Organ Transplantation Affinity Group (OTAG)⁹ and other vehicles to ensure alignment of actions and priorities.

Proposed Activities to Remove, Pause, or Reassign

HRSA acknowledges that the OPTN operates in an environment with time and resource constraints and competing priorities. HRSA has identified a subset of activities that either do not immediately advance the goals of improving the fairness and transparency of the organ procurement and transplantation system, or that HRSA can take the lead on executing. Therefore, the OPTN should remove these activities from the AOOS Remediation Plan.

1. Ethics Committee AOOS White Paper (Part A)

HRSA affirms the role of the OPTN Ethics Committee in contributing to the advancement of the Secretary’s AOOS Directive. Nevertheless, as HRSA has already conveyed its feedback on the White Paper through an alternative channel, this activity should be excluded from the OPTN AOOS Remediation Plan.

2. Develop a public transparency tool to show how frequently patients are excluded from access to organs for which they have been matched as a consequence of AOOS (Part D)

HRSA developed an AOOS web page to inform the public about relevant definitions, policies and compliance information, and resources related to AOOS.¹⁰ In addition, HRSA is in the process of developing an AOOS dashboard that will be used to monitor individual member and system-wide patterns of organ allocation non-compliance using

⁶ “Organ procurement organizations (OPOs) are responsible for organ recovery and allocation using this sequence, but sometimes deviate by giving an organ “out of sequence” to a center with lower wait-list priority. The purpose is ostensibly to overcome allocation system inefficiencies, improving organ utilization rates by expediting the placement of kidneys at a high risk of nonuse. [...] There was no association between increase in OPO out-of-sequence allocation between 2020 and 2023 and change in organ discard over this time.” Available at: Mohan S., Yu M.E., Adler J.T., et al. Socioeconomic Disparities in Out-of-Sequence Placement of Deceased Donor Kidneys in the US. *JAMA Intern Med.* Published online July 07, 2025. <https://doi:10.1001/jamainternmed.2025.2783>

⁷ Adler, J. T., Kulkarni, S., & Ladin, K. (2025). Reforming out-of-sequence allocation: A turning point for Organ Transplant Policy. *Health Affairs Forefront.* <https://doi.org/10.1377/forefront.20250522.531268>

⁸ Ibid.

⁹ For more information, see: [The Organ Transplantation Affinity Group \(OTAG\) | HHS.gov](https://www.hhs.gov/otag/)

¹⁰ Available at: <https://optn.transplant.hrsa.gov/policies-by-laws/a-closer-look/allocation-out-of-sequence-aos/>

the OPTN’s analytic definition of AOOS. HRSA will work with the OPTN to make iterative improvements to the web page and dashboard, but the OPTN can remove the development of a public-facing tool from the OPTN AOOS remediation plan.

3. Create transparency into the submission, approval, and performance of protocols under the OPTN expedited placement variance (Part C).

As individual OPTN member variances under OPTN policy 5.4.G are paused by the OPTN under the valence of the critical comment, Part C of HRSA’s directive is moot. At the same time, the OPTN continues to advance a proposed national Kidney Expedited Placement policy. It is relevant to the AOOS remediation process that this policy was developed in an environment of widespread OPTN member non-compliance with organ allocation policies. The OPTN should refrain from further categorical policy changes related to expedited placement unless and until the OPTN can demonstrate how those policy changes interact with the current reality of widespread non-compliance, and how they will be impacted by a system-wide shift to policy-compliant allocation practice. In the meantime, the OPTN should focus on enforcing and educating members on *existing* policies related to organ allocation.

Threshold for Allocation Policy Non-Compliance

The proposed OPTN AOOS Remediation Plan references the establishment of a “threshold for high rate of bypass code 799 to warrant MPSC review.”¹¹ HRSA notes that the MPSC holds responsibility for monitoring and responding to all instances of allocation policy non-compliance, regardless of frequency or severity. Therefore, there should be no acceptable threshold for non-compliance.

As HRSA has acknowledged in previous communications with the OPTN, the large volume of OPTN member policy non-compliance through AOOS makes the process of reviewing each individual case of AOOS challenging at the current scale.¹² From that letter (emphasis added):

*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***

¹¹ OPTN’s March 31, 2025 Response to Secretary’s Directive on AOOS (Part A, Objective 1). [OPTN Response to HRSA AOOS Directive](#)

¹² May 30, 2025 letter from HRSA to OPTN Board. [Allocations Out Of Sequence Communication on Directive OPTN](#)

allocation action, should be paired with member-level AOOS data to trigger additional MPSC review.

[...]

HRSA directs the OPTN, with support from the OPTN contractor, to identify members with patterns and/or large volumes of AOOS and send notices and/or requests to mitigate risks as described at OPTN Membership and Management Policy L.6¹³ 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 determination¹⁴ that the wastage provision only applies to transplant centers and may not be exercised by OPOs.*

With the AOOS Workgroup, OPTN Board, and OPTN contractors, HRSA will coordinate the above actions to ensure the directive to the OPTN is implemented. For more details, see the “AOOS Remediation Plan implementation” section below.

AOOS Remediation Plan implementation

Project Management Approach

HRSA notes that the OPTN’s remediation plan was framed as an extended, sequential timeline in which siloed committees and contract support progress through periods of meetings and document creation that multiply both dependencies for subsequent actions and the need for significant waiting periods between actions. Considering that observation, HRSA elected to support the OPTN using an agile-informed^{15,16,17} “sprint” to create an analytic definition of

¹³ 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.*”

¹⁴ 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.”

¹⁵ Desai, M., Tardif-Douglin, M., Miller, I., Blitzer, S., Gardner, D. L., Thompson, T., Edmondson, L., & Levine, D. M. (2024). Implementation of Agile in healthcare: methodology for a multisite home hospital accelerator. *BMJ Open Quality*, 13(2), e002764. <https://doi.org/10.1136/bmjopen-2024-002764>.

¹⁶ Boustani, M., Alder, C. A., & Solid, C. A. (2018). Agile Implementation: A Blueprint for Implementing Evidence-Based Healthcare Solutions. *Journal of the American Geriatrics Society*, 66(7), 1372–1376. <https://doi.org/10.1111/jgs.15283>

¹⁷ A metareview of Agile principles applied to healthcare and healthcare facilities which identified the following characteristics which the OPTN may find useful to contemplate in this and future work to improve or remediate OPTN policy-related suboptimal outcomes for patients and providers (emphasis added): “(1) *Transparent and*

AOOS. The OPTN achieved a valid, workable definition in a relatively short timeframe, and this successful action should be the model for subsequent sprints moving forward.

HRSA has leveraged Project Management expertise to reconfigure the plan's proposed implementation timeline into a phased, iterative approach. Separating the work into manageable, time-bound phases with parallel execution of multiple workstreams will allow for early wins, continuous stakeholder feedback, and course correction as needed. This approach will also help ensure that progress is both measurable and responsive to emerging insights. HRSA understands that estimates are subject to change, and expects the AOOS Workgroup to communicate on a regular cadence how plans and expectations for future work are refined as work proceeds, as described below.

To more rapidly address OPTN policy design, implementation, and compliance issues, HRSA strongly recommends that the OPTN consider:

- **Introducing short, concurrent sprints** into AOOS remediation work, decreasing burden on OPTN volunteers and decreasing time¹⁸ to delivery of necessary knowledge products, such as definitions, reports, and letters to OPTN members.
- **Breaking down silos** between OPTN committees through engaging cross-functional groups.
- **Leveraging asynchronous¹⁹ strategies** for collaboration and meetings related to delivery of knowledge products.
- Using the OPTN Board of Directors' ability to approve and **involve new OPTN volunteers** on pre-defined project sprints.

HRSA will support this shift in framework from the previous OPTN paradigm to an agile-informed approach.

Action Items

Here we provide suggestions and support for practical implementation of the OPTN's remediation plan, including two immediate action items:

- 1) creation of an AOOS Workgroup; and
- 2) establishment of an execution plan for the next 90 days.

transient inter-organizational links at all levels. (2) Market sensitivity and customer focus. (3) Management by support for self-organizing employees. (4) Organic structures that are elastic and responsive. (5) Flexible human and resource capacity for timely delivery" Available at: Tolf, S., Nyström, M. E., Tishelman, C., Brommels, M., & Hansson, J. (2015). Agile, a guiding principle for health care improvement?. *International Journal of Health Care Quality Assurance*, 28(5), 468–493. <https://doi.org/10.1108/IJHCQA-04-2014-0044>

¹⁸ Ibid.

¹⁹ "One of the benefits of asynchronous communication is that it is not inherently interruptive, and if a communication is not urgent, asynchronous channels may be a preferred way of communicating with otherwise busy individuals." Available at: Coiera E. (2006). Communication systems in healthcare. *The Clinical Biochemist. Reviews*, 27(2), 89–98.

Creation of an AOOS Workgroup

On June 25th, 2025, HRSA met with the OPTN Board to preview the formation of an AOOS Workgroup, in alignment with the project management feedback above. This AOOS Workgroup will be comprised of representatives from, at a minimum, the following OPTN committees: Patient Affairs Committee (PAC), Data Advisory Committee (DAC), Ethics Committee, and Membership and Professional Standards Committee (MPSC). In addition, the Workgroup should include a Veteran's Health Administration transplant center surgeon or transplant coordinator. HRSA can assist the OPTN with identifying representatives as needed.

The AOOS Workgroup should be composed within an explicit responsibility assignment framework.²⁰ For example, the Workgroup should designate at least two individuals responsible for coordinating Workgroup activities; tracking progress towards completing AOOS remediation activities; and rapidly escalating questions, challenges, or concerns to HRSA, with HRSA-directed contractor support. The Workgroup should engage in collaborative work, including regular synchronous or asynchronous meetings, to ensure efficient use of volunteer time and OPTN resources. HRSA will further direct the OPTN contractors to provide options to the OPTN for maximizing currently available tools and strategies to reduce meeting burden, while retaining the ability for the Workgroup to collaborate and communicate on knowledge products.

The Workgroup should provide biweekly status updates to HRSA, which will be posted publicly, to coordinate activities, inform the community, and demonstrate progress toward goals. If the OPTN wishes to create sub-workgroups to more efficiently implement specific activities and/or leverage specific expertise, they should provide HRSA with the cadence and process by which these sub-workgroups will coordinate with the larger AOOS Workgroup. To ensure the transparency of the AOOS remediation process, HRSA will publish how the Workgroup and sub-workgroup(s) are selected, what activities are assigned to Workgroup and sub-workgroup(s), and accurate membership information.

ACTION ITEM: In collaboration with the Board Support contractor, please provide HRSA with the AOOS Workgroup membership (by **July 18**) and associated RACI roles (by **July 25**), as well as membership and RACI roles for any sub-workgroups deemed necessary by the OPTN at this time. HRSA will provide feedback and/or approval within one week of receiving these proposals and is happy to review early drafts to expedite the process.

Establishment of a 90-Day Execution Plan

The table below outlines an example task list for an initial 90-day project phase, which the AOOS Workgroup can adjust and finalize as they deem appropriate. At the start of each time-bound phase, the AOOS Workgroup should provide HRSA with a list of tasks to be completed

²⁰ See [Responsibility assignment matrix - Wikipedia](#).

during the phase, anchored in the overall goals of fairness and transparency. At the end of each phase, the AOOS Workgroup should provide:

- a review of the work completed during that phase,
- a new task list for the upcoming phase, and
- a check-in on what is or is not working with this project management approach, to motivate adjustments as needed.

ACTION ITEM: By **August 1**, please provide HRSA with a finalized task list for the first 90-day project phase. HRSA will provide feedback within one week of receiving these proposals and is happy to review early drafts to expedite the process.

Draft 90-day phase task list

<i>Phase 1 Tasks</i>			
<i>Plan Section</i>	<i>Task</i>	<i>Owner</i>	<i>Notes</i>
Part D	Create AOOS dashboard.	HRSA	
Part D	Embed AOOS dashboard into AOOS web page.	OPTN contractor	
Part B	Evaluate member compliance in the aggregate by OPTN member and identify members with patterns and/or large volumes of AOOS.	OPTN MPSC with support from HRSA	
Part B	Send notices and/or direction to members to mitigate non-compliance.	OPTN MPSC	
Part B	Send a notice to OPTN members highlighting applicable OPTN policies and definitions, including appropriate application of the wastage provision.	OPTN	
Part A, Objective 4	Develop an administrative definition for the "offer" of an organ by an OPO to a transplant center, including minimum requirements for notification and information accuracy.	AOOS Workgroup or Sub-Workgroup	This activity is critical to the AOOS Remediation Plan. HRSA suggests following the highly effective Analytic Definition Workgroup sprint process.
Part A, Objective 4	Review OPTN policies for possible updates to the term "offer" and its related policies.	AOOS Workgroup	

<i>Evergreen Tasks</i>			
Part D	Monitor feedback from users or prospective users of the AOOS web page. Update web page content in response to project progress and stakeholder feedback.	AOOS Workgroup, OPTN contractor	
Part B	Educate OPTN members on existing applicable OPTN policies and definitions, including any policy changes.	OPTN	
<i>Backlog (to be implemented as tasks in future phases)</i>			
Part A, Objective 5	Conduct a policy development sprint to describe acceptable modalities and content of organ offers made by OPOs to transplant patients in compliance with requirements of NOTA and the OPTN Final Rule.	AOOS Workgroup or Sub-Workgroup	HRSA considers this a high priority. This activity should be analogous to the AOOS definition sprint, with a goal of completing a policy proposal for the next OPTN public comment cycle.
Part B	Routinely audit member compliance and identify patterns of non-compliance. Undertake compliance actions for OPTN members with patterns of non-compliance and/or in response to specific incidents reported by members.	OPTN MPSC	
Part A, Objective 3	Develop an administrative definition of “batched organ offers.”	AOOS Workgroup or Sub-Workgroup	
Part A, Objective 3	Create a policy constraining or prohibiting batched organ offers in compliance with requirements of NOTA and the final rule.	OPTN POC	

Conclusion

HRSA looks forward to continued collaboration with the OPTN to improve the fairness, transparency, and patient centricity of organ allocation.