HRSA
Health Resources & Services Administration
Health Systems Bureau
5600 Fishers Lane
Rockville, MD 20857

July 30, 2025

John Magee, MD
President, Board of Directors
Organ Procurement and Transplantation Network
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Dear Dr. Magee:

With over 100,000 patients awaiting life-saving transplants, the Health Resources and Services Administration (HRSA) is committed to ensuring an organ procurement and transplantation system that is safe, fair, and effective. This includes developing transparent, effective organ allocation policy[1] that prioritizes accountability to patients.[2] In reviewing the Organ Procurement and Transplantation Network's (OPTN) Kidney Committee's[3] recent efforts to develop the proposed Expedited Placement Kidney Policy (EPP), the OPTN Data Advisory Committee (DAC), the OPTN Kidney Committee, and HRSA identified several concerns related to implementation and effectiveness that require the OPTN's immediate attention.

In summer 2024, the Kidney Committee's proposed development of the EPP was described in a "Committee Update" on continuous distribution that was posted for public comment.[4] The stated purpose of the proposal, which has been drafted and preliminarily tracked for public comment in August 2025, is to establish a standardized, national expedited allocation policy for kidneys at risk of non-use.[5] According to the Kidney Committee, the goal of the proposal is to improve efficiency in the allocation of 'hard-to-place' kidneys and increase the likelihood of offer, acceptance, and transplant, thereby reducing kidney non-use.[6]

[1] Organ allocation, under federal statutory, regulatory, and associated OPTN policy requirements, should be fair (42 U.S.C. 274(b)(2)(D) and 42 CFR 121.4(a)(1), OPTN Bylaw B.4.E), via the offer of organs not to transplant centers but instead to potential recipients (42 CFR 121.7(a), OPTN policy 5.4.A and 5.4.B), be ranked by priority (42 CFR 121.7(a)(2), OPTN policy 5.4.B), and be sequentially offered to potential recipients (OPTN policy 5.4.B.3).
[2] See: OPTN Modernization July 2025 Update, *Modernization in Action: Advancing Oversight and Policy Reform*: https://www.hrsa.gov/optn-modernization/updates
[3] The OPTN Kidney Expedited Placement Workgroup, sponsored by the OPTN Kidney Committee, also helped develop the proposed policy.
[4] See: https://optn.transplant.hrsa.gov/policies-bylaws/public-comment/continuous-distribution-of-kidneys-update-summer-2024/
[5] See: OPTN Kidney Committee minutes, 5/19/2025: https://optn.transplant.hrsa.gov/media/rzsjomda/20250519_kidney-committee-meeting-summary-1.pdf
[6] Ibid.

During a June 9, 2025 meeting of the DAC, members voted to endorse the EPP data collection effort, despite expressing significant concerns, described below, which remain unaddressed.[7] **HRSA shares the concerns raised by committees and notes that the proposed EPP, as written, may present challenges to implementation, compliance, and fairness in organ allocation.**

(A) Concerns raised by the OPTN DAC

- **The cold ischemic time (CIT) of an offer is not knowable in the current system, so the proposed policy would not be auditable.** Currently, technical limitations make it impossible to know definitively what an organ's CIT was when it was first offered out of sequence. According to a DAC member, allocation timestamps "*are a moving target because they get overwritten all the time.*"[8] During the June 9th meeting, several DAC members expressed substantial discomfort with this unresolved issue, calling it "*a gap*,"[9] emphasizing that "*there's no way to hold anyone accountable for [this] variable*,"[10] and specifically requesting that the Kidney Committee develop a solution before bringing the policy back before the DAC. The unreliability of this variable is especially concerning given that the CIT over 6 hours at the time of organ acceptance is sufficient to establish any kidney, regardless of other aspects, as 'hard to place.' HRSA has previously drawn the OPTN's attention to this known and ongoing deficiency in data collection and integrity that inhibits the OPTN's visibility into potential mis-assessment, misreporting, or artificially inflated CIT.[11]

- **The hard-to-place criteria are too general and will include kidneys that do not require expedited placement**. According to one DAC member, "*hypertension of more than 5 years and a [donation after circulatory death]... is too broad. I think you're going to pull a lot of kidneys that aren't going to fit here into that classification.*"[12]

- **The proposal does not address challenges in the practical implementation of notifications that may cause a substantial burden or present significant inefficiencies**

[7] Note that during the June 9, 2025 meeting, the Kidney Committee presentation to the DAC asked whether the DAC endorsed the EPP proposed data collection effort. The OPTN contractor facilitated a voice vote that was in the inverse, where members were presumed to endorse the EPP unless they explicitly indicated they did not.
[8] See: June 9, 2025 OPTN Data Advisory Committee meeting recording. A summary of the meeting, written by the OPTN contractor, is available here: https://optn.transplant.hrsa.gov/media/d1snvsd2/20250609_dac_committee-meeting-summary-final.pdf
[9] See: June 9, 2025 OPTN Data Advisory Committee meeting recording.
[10] See: June 9, 2025 OPTN Data Advisory Committee meeting recording.
[11] See: HRSA letter to the OPTN dated November 27, 2024, section (D).
[12] See: June 9, 2025 OPTN Data Advisory Committee meeting recording.

for transplant centers. A DAC member estimated that EPP "*would be providing several thousand more notifications than what we're getting... which will add to the confusion*."[13] HRSA is particularly concerned about this consideration in the context of continuous distribution on the horizon, where the number of patients per match run is expected to increase substantially.[14] This impact should be quantified, assessed, and mitigation strategies considered before moving the policy forward.

- **There is a lack of clarity regarding which patients may safely receive from EPP kidneys, which raises concerns about centers' ability to apply EPP filters effectively.** One DAC member requested further guidance on who should be eligible for EPP kidneys, asking "*have you… heard of any data that describes the optimal recipient for these types of kidneys?*"[15] and later noting that "*[OPTN policies] focus on non-use… [and] taking away penalties to programs for aggressive use, but they never say anything about the recipients that get a kidney that doesn't work.*"[16] HRSA believes that clarification on which patients would benefit from these hard-to-place kidneys is necessary to increase transparency, support healthcare providers, and prioritize patient outcomes. This transparency is crucial for the success of the policy and the well-being of the patients.

- **There is a significant risk that this proposal (and any expedited placement proposal) prioritizes maximizing transplants and minimizing non-use at the expense of medium- and long-term patient outcomes.** DAC members emphasized the need to center longer-term patient outcomes as a measure of success instead of just non-use rates. One member noted that they hadn't "*seen a paper or a presentation that talked about the most hard-to-place kidneys... with an adequate definition of what [patient success] means... we're not focusing on putting these kidneys in the right recipients*."[17]

(B) Concern raised by the OPTN Kidney Committee

- **Centers could respond to this policy by listing every patient as eligible for EPP.** According to one member, "*given the clinical criteria, what's to prevent every*

[13] See: June 9, 2025 OPTN Data Advisory Committee meeting recording.
[14] A 2023 study on allocation strategy for lung transplantation recorded a 59% increase in lung donor offers after continuous distribution was introduced. See: Banga, A., Hartley, C., Tulu, Z., MacArthur, J. W., & Dhillon, G. (2025). Impact of continuous distribution as the allocation strategy on lung transplantation. *American journal of transplantation: official journal of the American Society of Transplantation and the American Society of Transplant Surgeons*, *25*(6), 1218–1225. https://doi.org/10.1016/j.ajt.2025.02.001
[15] See: June 9, 2025 OPTN Data Advisory Committee meeting recording.
[16] See: June 9, 2025 OPTN Data Advisory Committee meeting recording.
[17] See: June 9, 2025 OPTN Data Advisory Committee meeting recording.

center from putting every candidate as eligible?"[18] The committee deferred this concern to a future post-policy review. HRSA disagrees that the appropriate response to this identified risk is to proceed with policymaking and implementation and instead would recommend, at a minimum, an assessment of the extent to which this pathway may be used.

(C) Concerns raised by HRSA

- **The EPP, as written, relies heavily on two pieces of functionality that do not currently exist in UNet:**
    - **Patient-level filters based on a combination of CIT and distance** – While there are program-level filters and patient-level acceptance criteria, there is not a unified tool for this at the patient level. HRSA believes that if this functionality were available, it might address a key problem EPP intends to target without additional policy development. In particular, patient-level filters would relieve the unnecessary burden on surgeons who must review and decline offers to their highest-urgency patients for organs that all potential recipients in the local donor service area have rejected. In the words of one Kidney Committee member, "*out in Los Angeles… routinely we'll get a kidney offer from somewhere like Minnesota. But then it will be for the top of our list… if [the kidney] is not being accepted locally, why would I consider it for anyone at the top of my list?*"[19] To respond to these offers, the member currently must "*go through all the declines for the top of my list…[to] identify someone who would benefit from this type of donor… This proposal at least would allow [me to]… opt out of expedited offers for my younger recipients who are at the top of the list who have a lot of wait time.*"[20]
    - **Batch offers that go to the highest-ranking accepting patient** – This practice is not specific to kidneys, nor organs at high risk of discard. If the OPTN is interested in assessing this approach to allocation, it may be able to develop a more robust, generalizable understanding of its effectiveness through a variance applied (ideally in a randomized, controlled context) to a broad range of organs rather than only higher-risk kidneys.

- **HRSA is concerned that DAC members may feel pressured during meetings to**

[18] See: June 9, 2025 OPTN Data Advisory Committee meeting recording.
[19] See: June 9, 2025 OPTN Data Advisory Committee meeting recording.
[20] See: June 9, 2025 OPTN Data Advisory Committee meeting recording.

approve items despite valid concerns. During the June 9th meeting, the contractor used an opt-out voting system where members, if silent, were presumed to endorse the EPP. No members verbally endorsed the policy when asked to vote. Additionally, despite DAC members expressing discomfort over the lack of reliable CIT data after being called to vote, the contractor postponed the issue to an unspecified future meeting, stating that the committee could "*separate [CIT] from [the EPP]… after the public comment*."[21] HRSA notes that CIT is a critical part of EPP enforceability and cannot be "*separated*" from the EPP. Significant time, resources, and budgetary constraints exist within the OPTN. Advancing a policy that has known risks and tremendous challenges to practical implementation is costly in time, effort, and budget not only to the OPTN, but all impacted providers, patients, and families.

HRSA acknowledges that the EPP could replace the non-policy compliant OPO practice of "open offers" with an approach where offers are (as required by policy) received by and responded to on a patient level, rather than a center level. However, if the issues listed above are not resolved before the policy is once again advanced in the policymaking process, **the EPP risks exacerbating ongoing AOOS noncompliance by providing a non-auditable pathway to allocate critically needed organs out of the OPTN-defined sequence**. Further action is required to avoid unnecessarily burdensome and expensive policymaking and technical implementation, only to discover afterwards whether the policy can be implemented and monitored as intended.

HRSA would be supportive of off-cycle consideration of this policy, once revised, given the urgency of the concerns outlined above and the pace at which the proposed policy is moving forward. In the meantime, to address these concerns, HRSA directs the OPTN to take the following actions by September 30th:

- Please provide responses, via written communication to HRSA, to (A) – (C) above. HRSA will review the OPTN's responses in light of the requirements of the National Organ Transplant Act (NOTA), the OPTN Final Rule, and OPTN policies. This additional step to address known concerns is intended to increase the effectiveness of the OPTN public comment and policymaking process. Significant potential issues should be addressed now so that public comments can provide feedback on the strongest possible version of the proposed policy.

- Perform user research with transplant coordinators and surgeons to inform expectations of how they would be most likely to utilize (or not utilize) the EPP pathway. Please provide the output from this user research to HRSA, the DAC, and the Kidney

[21] See: June 9, 2025 OPTN Data Advisory Committee meeting recording.

committee. HRSA will direct the OPTN operations contractor to support the OPTN in this effort.

Given our shared interest in effective, data-driven policymaking and system oversight, HRSA invites the OPTN Board (and its relevant committees) to provide feedback or suggest additional actions to resolve the concerns outlined above. If you have any questions, please contact the HRSA Data and Analytics Team at HSBDAT@hrsa.gov.

Sincerely,

Suma Nair, PhD, MS, RD
Associate Administrator

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