



February 4, 2024

**OPTN Special Comment Period: Expedited Placement Variance**

The National Kidney Foundation (NKF) submits the following to the Organ Procurement and Transplantation Network (OPTN) in response to the policy proposal, *Expedited Placement Variance*.

Before commenting on the proposal's substance, NKF would like to express our concerns about the process surrounding this initiative. The OPTN Executive Committee presented the proposal on December 21, 2023 – days before a major holiday – as a special comment period rather than as part of the traditional OPTN Winter Comments, which were scheduled to be released only a month later. Further, the review period for this proposal was only 30 days, rather than the traditional 60-day review period. Finally, there was little public notice about the proposal or the comment period.

Regarding the proposal's merits, NKF supports strategies that increase the number of transplants by improving efficiency in the OPTN. We agree that iterative Plan, Do, Study, Act pilot projects can help identify methods to reduce the underutilization of recovered kidneys and improve the transplantation process. To ensure patient-centricity and accountability, however, pilot projects must operate under strict guidelines, demonstrate how they achieve the pilot's objectives, and be tested transparently and equitably. Unfortunately, we believe procedural and equity issues could arise from the current proposal that requires modification before implementation.

**Overview**

Patients on the transplant waitlist - and the American taxpayer who underwrites much of the transplant system - expect that the allocation system is rooted in fairness and predictability. Unfortunately, we know this is not always the case. While the matching algorithm might predict that an organ - even a poorly defined "hard to place" organ — is a suitable biological match for a candidate, the system doesn't account for the risk tolerance of the transplant center (or even the surgeon) who will be making the final decision about that "hard to place" organ's utility. Instead, the current process blindly works down the list, offering organs to each center. Maybe that "hard to place" will ultimately be presented to a more aggressive center that will transplant it, but as has been the case more than 8,000 times this past year, that organ is not transplanted and is ultimately discarded. This is a dishonor to people who become organ donors and their loved ones but also a life-threatening disservice to patients needing a kidney transplant.

Frustrated by the inefficiency and inaccuracy of the current system, some Organ Procurement Organizations (OPOs) and Transplant Centers undertake the process of "list-diving," where they bypass the existing system and deploy a random self-created process for matching "hard to place" organs with the centers or surgeons who are most likely to accept them. While this deviatory

process may result in more organs being utilized, it lacks transparency. It is fundamentally unfair to patients who are unknowingly passed over and spend additional months and years on the waitlist.

NKF appreciates the focus and effort of the Executive Committee in creating the Expedient Task Force to place organs rapidly. We understand that reducing organ waste is urgent and acknowledge that a solution is necessary to address the rising number of out-of-sequence organ-offers.

As drafted, however, the *Expedited Placement Variance* does not address the lack of transparency and inequity incumbent in current list-diving practices. If anything, the proposal seems to endorse this secondary market – which is more of a workaround of the flaws in the existing system rather than an effort to address the problems that are at the root of underutilization – without providing any systems for ensuring transparency, equity, or accountability.

If this policy moves forward as drafted, we are concerned that it will only perpetuate or solidify this secondary, arbitrary system without offering meaningful alternatives that could be adopted to drive performance improvement and transparency across the system.

## Recommendations

Before allowing variances to be tested, we strongly encourage OPTN to examine the existing protocols, eliminate those that do not meet clinical benefits or violate OPTN procedures, and study the root cause of increased organ matching deviations. As we explain below, we recommend that OPTN modify the Expedited Placement Variance to incorporate plans to address concerns about equity, create more standardization and transparency, articulate its plans to evaluate pilots and consider alternative approaches that will protect and promote public confidence in the transplant system.

- **Equitable Distribution of Kidneys for Transplant:** NKF is concerned about the effect of out-of-sequence offers on equitable organ allocation. We understand that OPOs are responsible for ensuring that recovered kidneys become transplanted. Still, we urge the OPTN to create protocols that reduce and not exacerbate inequities in organ matching and allocation.

In February 2022, the National Academies of Sciences, Engineering, and Medicines (NASEM) published a consensus study report, *Realizing the Promise of Equity in the Organ Transplantation System*. The report highlights the critical need for the U.S. transplant to operate ethically, with transparency, to maintain public trust, and it concludes that the “principle of justice is central for the system’s success and that one essential measure of justice is the measure of the system’s processes and patient outcomes.”<sup>1</sup> The NASEM report further

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<sup>1</sup> National Research Council. 2022. *Realizing the Promise of Equity in the Organ Transplantation System*. Washington, DC: The National Academies Press. <https://doi.org/10.17226/26364>.



concludes that the OPTN is not accountable to all patients needing a transplant and that there must be policies that engender that accountability. It is well-documented that disparities exist in transplant access, including geographic inequities. OPOs that employ “list diving” to ensure the highest probability of kidney transplantation—perhaps in good faith— are unfairly skipping patients who are likely unaware of this practice, decreasing kidney failure patients’ likelihood of receiving a life-saving transplant. OPTN policies must ensure that utility does not outweigh equity in the organ distribution process.

- **Definitions and Operational Guidelines:** We recommend that the OPTN create a standardized definition for “hard-to-place” organs so that the organ donation and transplant community operate from the same understanding. Further, more clarity and specificity are needed to fully understand the implementation of this policy proposal. For example, each pilot should have varying goal-driven time limits and a plan to determine if a pilot program should become a national policy. As currently stated, it seems there is a fixed 18-month period for each variance. Still, we propose an interim analysis of the pilots to evaluate the impact on clinical and equity outcomes, as we would need to stop early pilots that increase inequity or cause clinical harm. Similar to all clinical trials, “stopping rules” should be defined to minimize damage and maximize benefits.
- **Best Practices and Geographic Congruency:** The sharing of expedited organ placement best practices between OPOs and transplant centers makes the most sense among those with geographic congruency. Procedures that may work in population-dense parts of the country with many kidney transplant programs in a 250-nautical mile area may not produce the same results in rural locations.
- **Variance Tracking and Data Collection:** The OPTN plans to track multiple variances simultaneously. We implore OPTN to transparently communicate its processes for measurement and oversight to ensure organs are shared judiciously and do not contribute to increasing rates of organ waste and disparity. If OPTN moves forward with this policy, it should be required for OPTN to collect comprehensive data to demonstrate the efficacy of the variance.
- **HRSA OPTN Modernization Initiative:** Lastly, with the imminent release of the contract proposal by the Health Resources and Services Administration (HRSA), we are concerned that the timing of this proposal will hinder the appropriate oversight of any changes made to allocation policy, including through a variance process, during any potential transition phases.

The National Kidney Foundation supports efforts to transplant more kidney failure patients through increased organ utilization. There must be a balance for allocating kidneys efficiently and equitably, with accountability. We appreciate OPTN’s desire to explore pathways to reduce non-utilization and are eager to work with you to develop more refined proposals to help achieve this objective.



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Please contact Morgan Reid, Director of Transplant Policy and Strategy, at [Morgan.Reid@kidney.org](mailto:Morgan.Reid@kidney.org) with any questions.

Sincerely,

A handwritten signature in black ink, appearing to read "K Longino".

Kevin Longino  
CEO and Transplant Patient

A handwritten signature in black ink, appearing to read "S Rosas".

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