ASTS
American Society of Transplant Surgeons

Expedited Placement Variance

While ASTS strongly supports efforts to reduce the number of organs that are procured but not transplanted, we regretfully cannot support the proposal as written. We strongly believe that the proposal has the potential to substantially disadvantage our waitlisted patients and undermine the fragile public trust in the organ allocation system that the OPTN and the transplant community as a whole have established over decades through a process that, while painstaking, has been comprehensive, evidence-based, and publicly vetted.

We have three major concerns: (1) the rushed nature of the approach and the timing of this proposal in the midst of significant uncertainty in the transplant field associated with the OPTN Modernization Initiative; (2) that the policy as proposed would authorize the OPTN Executive Committee to approve variance proposals without public input and without guardrails; and (3) the lack of sufficient rigor in the scientific approach (insufficient details and requirements for variance proposal application and reporting) for evaluation of variance protocols and the lack of substantive, quantitative, and holistic post-implementation monitoring plans for variance protocols.

We support efforts to decrease the number of organs procured but ultimately not transplanted and efforts to increase the number of transplants performed. We recognize that the current allocation system is imperfect, and we are cognizant of the dynamic tension between utility and justice. The OPTN has done a reasonably good job of balancing those competing interests over the years, particularly considering the often apparently irreconcilable differences in opinion of some of the key transplant ecosystem stakeholders. One of the key strengths of the OPTN is its deliberate policy development cycle, with robust public comment and reliance on data-driven decision making. We believe that an open-ended variance policy, as embodied in the current proposal, circumvents the advantages of the OPTN's historic, highly deliberative organ allocation policy-making process and does a disservice to our patients, whose lives depend on the equity of the system.

The proposal would give the OPTN Executive Committee (EC) virtually unlimited authority to authorize any variance from approved allocation methodologies, for any organ, including organs not at increased risk of non-utilization. Such variances would essentially place an OPTN imprimatur on widespread out-of-sequence organ placement without establishing guardrails to protect the interests of waitlisted patients to whom such an organ otherwise might be offered pursuant to established allocation criteria. While we certainly understand the pressing need to reduce the number of organs that are procured but not transplanted, we strongly oppose doing so at the potential cost of undermining public trust in the Nation's allocation system. Our waitlisted patients deservedly expect that out-of-sequence organ allocation will be minimized—that is, that others will not be able to "jump the line" based on criteria that are not subject to public vetting and that are disclosed only after they are approved.

Nor do we believe that adoption of the proposal as written is likely to serve its stated purpose. The stated purpose of this proposal is to "develop and test new approaches on a smaller scale than national policy, as well as a framework to study the effects of such approaches for additional potential action." Yet, no provision of the proposed policy ensures that approved protocols will share consistency in key variables, including, for example, the criteria that organs will need to meet in order to be eligible for out-

of-sequence allocation. The range of variables is so large that authorizing variances in a manner that is not systematic and public undermines an organized approach to allocation, is unlikely to prove helpful in establishing a national variance policy or in informing adjustments to the current allocation methodologies; and is likely to obscure the harm of approved variance(s) on bypassed waitlisted patients. In fact, the proposal appears to suggest that waivers may be granted to different types of entities (transplant programs and OPOs), for different periods of time, in areas with very different local transplant dynamics, and with no uniformly defined criteria to measure success. Under these circumstances, we do not believe that this proposal will result in any clear insight into the kind of national changes to allocation policies that may be necessary to reduce non-utilization. For those reasons, and because the proposal mandates virtually no coherent post-implementation monitoring of approved variance protocols, we believe it likely that this approach will not yield data that is sufficiently reliable or generalizable to inform efforts to formulate national variance criteria moving forward.

We are also extremely concerned about the timing of this proposal. The Health Resources and Services Administration (HRSA) announced a comprehensive OPTN Modernization Initiative last year and has made it clear that two of the objectives of the Modernization Initiative are to increase transparency and to update and strengthen the IT resources and systems used for allocation. This proposal is clearly inconsistent with the public interest in transparency in organ allocation. Approval of this proposal will give the EC wide latitude to alter organ allocation processes and will grant that power to the EC without any attendant public comment period for variance protocols or modeling of the impact of any individual proposal. Rather than increasing transparency, this proposal would authorize the OPTN to approve waivers of otherwise applicable organ sequencing without public notice, without modeling the potential impact of the variance on those to whom the organ might otherwise be offered pursuant to established allocation methodologies and without a clear and effective means to ensure that an approved waiver does not inadvertently impact allocation of organs that are not in fact at risk of non-utilization or disadvantage those candidates bypassed by the expedited allocation variances.

In addition, we are concerned that adoption of this proposal, as written, will disrupt the allocation system concurrently with major upheavals in the OPTN itself. According to HRSA's public issuances, transition contractors will be operating the OPTN by the end of 2024, and this year they will need to begin to operate the organ matching IT. The transplant community was previously told by the OPTN that IT programming could not accommodate any allocation variances, yet this proposal would entail running multiple variances at a time and introducing and potentially phasing them out on a rolling basis. We are extremely concerned that introducing significant variances to otherwise applicable organ allocation policies has the potential to create chaos in the organ allocation system precisely when new contractors may be trying to learn the intricacies of operating it.

We also believe that the proposal is inconsistent with broader organ sharing across geographic regions. Over the past several years, significant resources and hard work have gone into eliminating geography as a basis for allocation in attempts to decrease inequity and increase access. Under the proposal, variance protocols, which would be unilaterally approved by the EC without public comment, may be limited to specific geographic areas. Under these circumstances, we believe that those adversely impacted by a waiver may credibly allege that the approval of a waiver is inconsistent with the Final Rule, which states

that candidate access to organs is "*not based on the candidate's place of residence of place of listing*." Any waiver that advantages waitlisted recipients in one geographic area over another has the potential to spur legal challenge and, even more importantly, to undermine the geographic equity that long has been a major objective of OPTN (and federal) policy.

While we oppose the current proposal, we believe that policy changes can and should be made to reduce the number of deceased donor kidneys that are procured and not transplanted. We are cognizant that 2024 is the OPO "Performance Year" under new Medicare OPO conditions of participation and that many OPOs are under extraordinary pressure to increase the proportion of organs that are procured and transplanted. Nonetheless, we are concerned at the skyrocketing number of out of sequence organ placements being reported at the current round of OPTN Regional Meetings:

Individual Organ Allocations Reviewed by MPSC

MPSC Review Period	Allocation Deviations
2017 (average for three review cycles)	125
2018 (average for three review cycles)	150
2019 (average for three review cycles)	125
February 2020 Meeting	166
July 2022 Meeting	500
October 2022 Meeting	820
February 2023 Meeting	758
July 2023 Meeting	795
November 2023 Meeting	**1528**

Under these circumstances, the current proposal may be viewed most accurately as an effort to provide an OPTN imprimatur via policy to OPO practices that already have been widely instituted with respect to out-of-sequence placement of organs at risk of non-utilization. In fact, we believe that the current proposal is likely to dramatically increase out-of-sequence organ placement. That so many organs are being offered out of sequence certainly suggests that flaws exist in current allocation policies; however, we do not believe that the answer is for the OPTN to formally endorse out-of-sequence organ placement through variances that circumvent public comment. If the new operative philosophy for organ placement is to essentially ignore the match run and the equity for candidates inherent in the concept of a wait-list and instead produce a system that places a huge fraction of organs outside the match run sequences, then it is beholden on the OPTN to advance that concept in public forums, and receive approval for that paradigm shift from the transplant community, prior to such a dramatic upending of the paradigm that has informed allocation policy since its inception.

For these reasons, we believe that the current proposal should not be adopted in its current form. Rather, we urge the OPTN to delay consideration of this variance proposal for three months, and in the interim, to take the following steps:

- **Conduct a root cause analysis of the reasons for organ non-utilization**, focused primarily on the area of most pressing concern—the non-utilization of deceased donor kidneys. To date, there has been no root cause analysis of the non-utilization of the thousands of unused organs in the US. Performing such an analysis has been discussed at Board meetings and endorsed by OPTN leadership, yet no action appears to have been taken. Absent this difficult but critical investigation, we believe that it will be extremely difficult, if not impossible for the Executive Committee or any other entity to engage in well-informed policy development on allocation through the proposed variance process or otherwise.
- It is our understanding from discussions with the Expeditious Task Force that the Expeditious Task Force has already begun to consider the criteria to be used in evaluating variance proposals. While the root cause analysis described above is being performed, the Expeditious Task Force should be charged with developing comprehensive variance approval criteria that:
    - Limit variances to deceased donor kidneys at risk of non-utilization.
    - Establish a uniform definition of deceased donor kidneys at risk of non-utilization to be used in all variance protocols eligible for approval. [1]
    - Establish a limited timeframe during which the variance(s) would remain in effect. In this regard, ASTS believes that the 18-month timeframe referenced in the proposal is too long, and that a shorter timeframe, in the range of 6-12 months, would be more appropriate.
    - Establish standard criteria for reporting pre- and post-variance data,[2]
    - Define quantitative (not just qualitative) metrics to evaluate the success (or unintended harm) of the variance(s), including the impact on both transplanted and bypassed patients.
    - Refine transparency requirements (manner of disclosure of the details of the variance)
    - Determine an appropriate and finite limit on the number of variances to be approved, and criteria to determine whether, and under what circumstances, the geographic

[1] For this purpose, ASTS believes that consideration should be given to the following criteria:

- Kidneys that reach 6-hours CIT not on pump or 8-hours on pump without acceptance for standard adult candidates.
- KDPI ≥90%.
- Any kidney with **DCD** donor status and donor **age greater than 60 years**.
- Biopsy: Severe arterial disease, interstitial fibrosis, or GS>10% on biopsy.
- Procurement gross anatomic criteria: Hard renal arterial plaque.

[2] Data elements might include, for example, reasons for expedited placement; outcome of expedited placement process (Accepted, Transplanted, Not utilized and reasons for non-utilization); CIT (at the time of expedited placement, at the time of allocation; and at the time of transplant); impact on the recipient (short term (Initial DGF or not) and long term (time to dialysis free, one year outcomes)); number of waitlisted patients bypassed by the variance and modeling of the estimated impact on bypassed candidates); pre/post efficiency; pre/post organ utilization.

regions affected by the variance(s) should be permitted to overlap. (ASTS believes that the number of concomitantly running variances should be limited to four or fewer.)

- We are concerned that the proposal delegates the responsibility of approval variance(s) to the OPTN Executive Committee, which currently includes little transplant program or transplant surgeon representation. This responsibility should be exercised by a representative body that includes significant transplant program and transplant surgeon representation.
- ASTS urges the OPTN to utilize an independent third party to monitor compliance with the conditions of variance(s) that are approved and to conduct the necessary modeling and analysis. In this regard, we are aware that recent errors made by the SRTR in modeling the continuous distribution allocation system for lungs has adversely impacted organ offers made to over 100 patients on the lung waitlist, and we believe that third party monitoring should be utilized until it is clear what steps are being taken to ensure that such errors do not recur.

We appreciate the opportunity to comment on this policy proposal and look forward to working with the OPTN to ensure that all organs appropriate for transplantation are utilized, while maintaining the public's hard-won trust in OPTN allocation methodologies.

ASTS Position: Strongly Oppose