February 4, 2024

Dianne LaPointe Rudow, DNP
Chair
Organ Procurement and Transplantation Network
Executive Committee
Mt. Sinai Medical Center
1425 Madison Ave
New York, NY 10029

RE: Proposed Expedited Placement Variance

Dear Dr. Rudow:

On behalf of the more than 37,000,000 Americans living with kidney diseases and the 21,000 nephrologists, scientists, and other kidney health care professionals who comprise the American Society of Nephrology (ASN), thank you for the opportunity to respond to provide comment regarding the Organ Procurement and Transplantation Network (OPTN) Executive Committee's request for feedback on the proposal "Expedited Placement Variance."

Maximizing patients' access to kidney transplant—and ensuring that access is equitably available to all patients—is of utmost priority for ASN. The society stands ready to work with OPTN, including the OPTN Executive Committee and the *Expeditious* task force, to achieve this goal. Transplantation is the optimal therapy for most people with kidney failure and the growing body of evidence pointing to inefficiencies in the system, as noted in the proposal, is of deep concern to ASN. In particular, the increasing organ nonuse rate is a troubling trend the society agrees should be urgently addressed through policy change. In this context, the society is particularly appreciative of the chance to weigh in on the December 2023 proposal developed by the *Expeditious* task force and sponsored by the OPTN Executive Committee.

ASN is strongly supportive of policy changes to decrease organ nonuse rates and increase both patient access and system efficiency—and believes testing an approach to "expedited placement" is a reasonable endeavor—however, the society has several concerns and recommendations regarding the proposed approach, particularly:

- As OPTN pursues increasing efficiency and decreasing nonuse, the values of utility, equity and transparency can and should be advanced simultaneously in a balanced fashion.
- The current match run allocation process is flawed: OPTN should prioritize improving this process over expanding and making permanent workarounds (expedited placement practices) that attempt to compensate for the current allocation algorithm's apparent shortcomings.

- Should expedited placement pilots proceed under a variance[1] as proposed, an increasing number of patients at transplant centers that do not participate may not get a fair opportunity in terms of access to transplant, and these changes in access may not be evident to patients, referring nephrologists, and researchers: ensuring transparency about these changes is essential if this variance moves ahead.
- Any pilots or protocols that are approved should be rigorously designed, including controls, clear monitoring strategies, and predefined end points (including to assess effects on equity in access), and be programmed by OPTN in order to obtain data that will yield meaningful lessons and inferences from the expedited placement variance.
- The OPTN, the Centers for Medicare and Medicaid Services (CMS), and the Health Resources and Services Administration (HRSA), must to work together collaboratively as they craft expectations and metrics for organ procurement organizations (OPOs) and transplant centers (as well as other stakeholders, such as nephrologists and dialysis organizations) so that all stakeholders are aligned towards the same end—increased, equitable patient access to transplant.

General Observations and Concerns

ASN recognizes that, particularly following the December 2020 CMS Final Rule "Organ Procurement Organizations (OPO) Conditions for Coverage: Revisions to the Outcome Measure Requirements for Organ Procurement Organizations," OPOs have faced increasing pressure to place kidneys.[i] At the same time, the implementation of the Kidney Allocation System (KAS) 250 in March 2021 made allocation more logistically complex, increasing the time it takes for an OPO to progress through the match run to place a kidney.[ii] Recently, there has been an increase in out-of-sequence offers, "open offers,"[2] and similar workarounds to the allocation system to facilitate placement of kidneys that might otherwise go unused.[iii] Yet at the same time, organ nonuse—formerly referred to as organ discards—is also on the rise, with more than 1 in 4 kidneys going unused—even though data suggest many patients would have benefitted from transplantation with many of those non-used organs.[iv]

The growth in these types of workarounds (system violations, at present) strongly suggests that the current allocation system is not optimized to efficiently match organs with a patient and a program that is likely to accept and to use them in a timely fashion. If the match run were optimized, OPOs and transplant programs would not feel compelled to engage in systems violations that allow them efficiently make kidney offers (to programs and to patients, respectively) with confidence that there will be a high likelihood of success (acceptance and use).

ASN is concerned that should these 'workaround' practices expand, as is envisioned under the proposal, an increasing number of patients at transplant centers that are not participating in pilot

[1] Because the terms "variance," "pilot," and "protocol" at times appeared to be used interchangeably in the proposal, ASN clarifies that these comments from the society use the following lexicon: Variance = the single umbrella change to existing rules that would allow for testing different expedited placement approaches. Protocol = the specific deviation(s) from the match run that would be green-lighted for a set of participating OPOs and transplant centers. Pilot = the small-scale study in which a given protocol is tested by a group of OPOs and transplant centers.

[2] ASN notes that the term "open offers" refers to offers that an OPO makes to one center exclusively, allowing that center to select the patient it would like to offer the kidney to (irrespective of where they would have been in the match run) once the kidney is offered to the center out of sequence (functionally, more of a "closed" offer than an "open" offer).

programs will not be getting a fair opportunity in terms of access to transplant. Further, based on the proposal in its current form, these changes in access likely will not be clear to patients, referring nephrologists, and researchers, further exacerbating the issue of lack of transparency. As currently described, it is uncertain whether sufficient data will be collected to meaningfully and rigorously evaluate these efforts and ascribe outcomes to the pilots. Potentially, as various pilots are made permanent in various regions, a patchwork of opaque organ allocation practices that are not transparent to patients or the community at large could arise, exacerbating existing concerns about the system being difficult to navigate, effectively nullifying the match run, and deepening inequities.

In sum, the society is concerned that this proposal may be prioritizing utility over equity and transparency, which ASN believes is a false choice: **all three goals—utility, equity and transparency—can and should be advanced simultaneously**.

The proposal notes that at present "without a consistent approach to expedited placement," it is difficult to analyze the impacts or "share effective practices," with respect to expedited placement. ASN observes that the foundational reason there is not a consistent approach to expedited placement is in because the current match run process is flawed, and because expedited placement practices are system violations. This reality is worth bearing in mind as we consider expanding expedited placement practices. The current match-run algorithm, in apparently a growing number of cases, does not make match suggestions that the dedicated professionals at OPOs or transplant centers have confidence in.

Furthermore, ASN is not aware of available evidence that out-of-sequence offers actually improve the organ nonuse rate. Indeed, a recent study found that OPOs that more frequently used an expedited placement approach (invoked a discretionary allocation exception) did not have lower discard rates than other OPOs.[v] Nonuse rates have recently gotten *worse* despite a seven-fold increase in the proportion of kidneys being out of sequence, raising questions about the effectiveness of this approach in actually preventing nonuse.[vi] ASN suggests that before advancing a variance to expand expedited placement practice, the task force and the Committee should provide evidence that these practices achieve the intended goal of decreasing organ nonuse.

In addition to strengthening plans to rigorously assess expedited placement pilot(s), the shortcomings of the existing system should be acknowledged, and consideration be given to addressing the root cause(s) of the problems. In addition to rigorously assessing expedited placement pilot(s), approaches that deserve serious consideration to decrease nonuse and increase system efficiency include:

- Optimizing the match run algorithm, including by leveraging AI and predictive analytics
- "Increasing equity in organ allocation algorithms," along the lines recommended by the 2022 National Academies of Science, Engineering, and Medicine (NASEM) report *Realizing the Promise of Equity in the Organ Transplantation System*, including requiring the OPTN to update its prediction models (e.g., Kidney Donor Profile Index, Expected Post-Transplant Survival score…) with the most recent data no less than every five years[vii]
- Aligning goals and incentives for OPOs with those of the transplant centers to facilitate timely, fair and transparent matching of organs to recipients

- Changing transplant center performance evaluation and public reporting practices that create more latitude for programs to accept marginal kidneys, in consultation and agreement with the potential transplant recipient.
- Increasing shared decision-making with patients, including routinely and systematically sharing with wait-listed patients information about organ offers declined on their behalf.
- Ensuring peri-operative care for kidney transplant recipients is adequately reimbursed by Medicare, Medicaid, Medicare Advantage plans, and other payors, alleviating concerns related to prolonged delayed graft function that may impact the decision by centers to use an organ and thus facilitating more consideration of more "marginal" kidneys.
- Ensuring longer-term post-transplant care for kidney recipients is adequately reimbursed by Medicare, Medicaid, Medicare Advantage plans, and other payors, to ensure patients have access to long-term chronic post-transplant care that maximizes the duration of transplant graft survival and minimizes the risk of late graft failure and return to dialysis (and the growing waiting list)
- Surfacing strategies to help transplant centers build internal leadership support to invest in growing their kidney transplant programs to accommodate more transplants
- Fostering innovative approaches by transplant centers to increasing organ utilization, rather than creating disincentives as a result of risk aversion
- Providing feedback to programs that declined organs regarding whether or not those organs were successfully transplanted elsewhere.
- Developing clinical decision support tools for transplant professionals who make organ offer decisions.

ASN believes that it is critically important for CMS, HRSA, and the OPTN to work together collaboratively as they craft expectations and metrics for OPOs and transplant centers (as well as other stakeholders, such as nephrologists and dialysis organizations) so that all stakeholders are aligned towards the same end—increased, equitable patient access to transplant—and are increasingly operating in a regulatory environment that intentionally fosters more "yes" responses to organ offers, in consultation with patient input.

The need for inter-agency coordination is underscored, at this moment in time, by multiple known forthcoming policy proposals and efforts: the Improving Organ Transplant Access (IOTA) model, an OPO proposed rule, and the OPTN Modernization Initiative. While the shift to continuous distribution for kidneys is on pause, the advancement of mandatory organ offer filters is another moving part.[viii] The kidney and transplant community need the U.S. Department of Health and Human Services (HHS) to ensure these and other policy changes (including this proposal) evolve in an aligned and harmonious fashion to maximize patient access without interruptions, and to ensure that access is equitable and transparent to patients, their care teams, and the research community.

The society notes that this vision for equity in the transplant ecosystem is shared by the NASEM report, which emphasized that HHS should align reimbursement and other programs and "incentivize all providers—from primary and specialty care of patients with organ failure to referral for transplant, from care while awaiting a transplant to long-term posttransplant care — to improve equity in access to care and outcomes for patients."[ix]

Timeline

ASN appreciates the OPTN's sense of urgency to address the growing nonuse rate but does not concur this proposal warrants such an expedited consideration process: this timeline for consideration is too rushed for a potentially extremely impactful policy change. For example, allowing the proposal to be considered for a full standard public comment cycle and discussed while still open for public comment at UNOS regional meetings, would increase the likelihood of broad stakeholder awareness and opportunity for meaningful input. As discussed elsewhere in this letter, ASN maintains similar concerns about overly limited opportunities for community input on proposed pilots and other aspects of this effort over the course of the variance's lifetime, should the variance[3] move ahead.

Transparency and Equity

Efficiency in the organ allocation process is a critically important goal, but it is vital to consider which stakeholders will benefit from efficiencies, and whether the establishment of such efficiencies will come at the expense of specific functions or stakeholders within the transplant ecosystem. The current proposal could be strengthened by more directly addressing these first-order questions.

ASN is concerned that, as proposed, this variance will unintentionally exacerbate existing inequities in the transplant system in ways that are not transparent to researchers or patients and their families and care teams. This outcome would be in direct violation of the principles outlined in the recent NASEM report.[x]

ASN also points out that part of the rationale for KAS 250 in the first place was to reduce inequities in transplant access by eliminating all pre-existing variances other than two that were specifically retained or added for purposes of greater equity (increased access for blood type B and including pre-registration dialysis time in candidates' waiting time calculation). As recognized by OPTN at that time, variances within a single system increase the risk of worsening disparities.

ASN appreciates that the proposal states that "successful variances will show acceptable deviations from policy that do not violate the Final Rule and/or result in decreased equity in access to transplant or undue harm to patients awaiting transplant," and concurs that this is a crucial part of any efforts to test or expand expedited placement. The society requests more information regarding how the Committee anticipates equity will be evaluated and monitored at both the proposal stage and over the course of the pilot – as well as how findings would be used to inform any iterative changes over the 18 months. (ASN notes that at the present time, out-of-sequence placements appear to be exacerbating inequities.)[xi]

In particular, how will equity be defined, and how will the population that is impacted by an OPO decision be defined? Will the effects of the pilot on equity be examined exclusively on the population of only those at the center(s) or OPO(s) participating in the study, or will a broader examination be undertaken (such as the effects on patients served by adjacent OPOs or centers)? ASN encourages a broader, rather than a narrower, assessment on the effects on equity, and recommends a rigorous evaluation plan also stratify by important population subgroups to examine impact of the variance overall as well as by subgroups of the population (e.g., race, ethnicity, age, sex, income, geographic region, center, OPO, etc). Aligned with these

observations and concerns, in discussing variation in practices across OPOs and transplant centers, the NASEM report noted that "each source of significant variation decreases the reliability and functionality of the system and directly affects equity in patient care."[xii]

Based on the proposal, it seems quite plausible that pilots could adversely impact access to transplant at certain non-participating centers because the local OPO has entered into a pilot to expedite placement with a (different) given transplant center. Currently, where OPOs are already using expedited placement approaches, centers report discovering after the fact that they (and their patients) have been skipped over for organs that they would have otherwise accepted.

ASN appreciates that the proposal states that the Committee does not expect impacts on the Final Rule **"**based on the candidate's place of residence or place of listing" but wonders how a pilot program that directs organs from an OPO to transplant center A (participating in the pilot) that may have previously been offered to transplant center B (not participating in the pilot) does not affect the candidates who reside closer to center B? To promote equitable access for patients, ASN encourages the Committee to ensure rigorous study design to assess equity in access in any pilots, and to consider the potential impacts on equitable access from a holistic standpoint that includes both patients inside and outside of pilot programs.

Over time, if multiple pilots are pursued (and especially if they are made permanent) the net effect could become a patchwork of allocation practices that are difficult to understand and navigate, making it even harder for patients to identify the center that is the best fit to meet their individual needs and preferences, a key ask of the transplant community from the 2022 SRTR conference.[xiii] More than one pilot could be conducted in the same area under the current proposed variance, making it impossible to tease apart the impact of any one pilot or protocol. Given that the OPTN is not going to program any of the variances into the allocation algorithm, it is unclear what the source of the data will be to determine if the variance is successful (recognizing the challenges in defining successful).

As currently proposed, data are not going to be available to study the impact of the variances, no interim analyses are planned to assess the impact of variance, and the OPOs will have the ability to "iterate" during the 18-month cycle with no clear process for oversight or rigorous evaluation. This framework essentially allows for the creation of multiple parallel allocation processes that are determined by OPO preferences—all of which are, based on the current proposal, likely to be opaque to the patients that the system exists to serve.

Even if the variation were easily understood, because many patients do not have the ability to select amongst multiple transplant centers, they may be hampered in their access to transplant through being listed at a center that is not in a pilot program compared to other patients at transplant centers participating in a pilot, exacerbating local or regional disparities – or that they are at a transplant center that is not favored as an aggressive center worthy of being offered certain organs by the participating OPO. While aspects of this inequitable dynamic exist in our current system, they are challenges we should be moving away from through policy change (e.g. aligning goals, re-examining imposed penalties), not further entrenching them with additional non-transparent variation.

Aligning with a growing emphasis on patient engagement and shared decision-making as outlined in the NASEM report, the society suggests the next iteration of the proposal include more detail regarding how the pilots and the impact on access to a transplant would be explained to patients, allowing them to make informed decisions about where and how they

receive their care. The development of a process for notifying patients that a local OPO or center is participating in a pilot, and an explanation of what it might mean for them, as well as an explanation of what it might mean for patients if their local OPO or center are *not* participating in a pilot, is essential and demanded by ethical principles. This information should be included in proposed protocols and documented to the extent possible during the pilot programs, particularly with an eye to equity (including socioeconomic status information).

Patients should also be informed if the pilot protocols create changes that they may wish to take advantage of. For example, if consideration of certain types of marginal kidneys that might not have previously been considered by the program is an aspect of the protocol, patients should be informed about this change and given an opportunity to state their preferences.

Pilot/protocol development and initial pilot/protocol approval questions

At the level of detail provided in this proposal, ASN has many questions regarding how pilots and protocols will be proposed, reviewed and approved for testing, how participation will work, and how success and failure will be defined prospectively. The society recognizes that not all of these answers would *necessarily* have to be defined at this stage; however, it is not clear to what extent there will be additional public opportunities to weigh in. ASN encourages the Committee to balance the desire for speed with ample public input, particularly emphasizing input from patients and patient organizations.

ASN urges the Committee to provide a publicly transparent rubric for how any pilots/protocols will be developed, evaluated, and approved given the potential impact of such pilots/protocols and to retain public trust in the transplant network. Equally important would be the need to understand how these will be monitored, and outcomes measured. Similar considerations also exist for how iterative changes will be handled. Given the absence of any operational data reporting requirements, the absence of a plan for programming by the OPTN in the proposal, and the fact that it is not clear to what extent allocation violations are reviewed by MPSC members at present, or if any OPO (or transplant center) has been held accountable for any violation beyond a single letter of noncompliance, it is quite unclear what the monitoring plan would look like. ASN believes monitoring plan details are essential to define at the proposal stage.[xiv]

On page 6, the proposal states “therefore, this variance proposes that one committee (the Executive Committee) solicit and approve the protocols while multiple committees can submit protocols and review the results of the variance before a policy proposal for expedited placement is proposed.” Are OPTN committees developing and proposing the protocols, or are OPTN members (such as OPOs or transplant centers) developing and submitting the protocols to the Executive Committee? (Additionally, does this sentence suggest that success would be defined at the level of the entire variance itself, or at the level of each pilot/protocol, as is discussed elsewhere? How can the results of the variance be reviewed prior to the proposal [and testing] of a protocol under the variance?)

The proposal notes that an alternative option would be to write the specific protocols into the variance itself, allowing the community to review each protocol before members use it. “While this would allow more public participation in developing each protocol, it would also add time to the policy development process. Instead, the Executive Committee proposes a more iterative approach.” ASN is unclear regarding what is meant by “iterative approach”: what iterative opportunities to participate in protocol development are envisioned, as the current proposal appears to provide the Executive Committee unilateral authority to review and approve

protocols? The concept of writing the specific protocols into the variance itself, and allowing the community to review each protocol before members use it, holds significant appeal to ASN as it would allow the broadest input to ensure the protocols are optimized to yield the most useful results for participants and patients.

Particularly, given that transplant centers may feel the need to join the variance and participate in pilots/protocols to gain a chance of receiving expedited placement organs, it seems appropriate that they (as well as other stakeholders, such as patients) have an opportunity to help shape the pilots/protocols. Given the limited information available regarding what the pilots/protocols might contain at this stage, ASN encourages the Committee to allow for broader input on the proposals rather than just review and approval by the Executive Committee.

It appears that the Committee is still determining whether participation in pilots/protocols will be optional. While the decision to join the variance appears solidified as voluntary ("no member will be required to join this variance,") the proposal notes that "the OPTN could dictate to the OPO which protocol they use," and also that "an OPO in one area of the country could decide to test one protocol, while another OPO can decide to try a different protocol." ASN encourages OPTN to offer opportunity for public comment on whether the nature of participation in specific pilots and protocols will be optional or not, in context with additional information on study design and definitions of success for those pilots/protocols. Aspects of mandatory participation could make a lot of sense in the context of a well-defined, rigorous pilot(s) study, but more detail would be needed for the society to weigh in at this time.

ASN also encourages the Committee to detail an appeal process for transplant centers (either participating in a pilot or not) that are concerned their patients are at an unfair disadvantage in accessing a transplant due to a pilot. This process should also enunciate how patients should be informed if a pilot is perceived as adversely impacting their access to a transplant.

The proposal notes that while community conversation has focused on high KDPI kidneys, this variance would permit the Executive Committee to explore additional options. Particularly until results from the first pilots/protocols have been well-understood, ASN urges the Committee to draw tight boundaries around the clinical criteria and conditions for organs to be considered for expedited placement, in order to limit deviations from the match run to the most strictly necessary circumstances, and allow for a clear assessment of the effects of the protocol(s).

Definition of success questions and research-and-evaluation-related questions

ASN appreciates that the proposal makes several references to data collection, evaluation, and definitions of success, but the society believes additional details about these crucial aspects should be defined with more specificity before the variance moves forward. In particular, ASN is concerned that, if multiple intersecting pilots/protocols are tested, ascribing meaning to any one—particularly without an adequate control or comparison group to rigorously evaluate impact—could be a challenging, if not impossible, task. One appealing path forward could be to propose for public comment a set number (two to four?) of specific pilots to test different protocols across the country, including controls, and have clear monitoring strategies and predefined end points. The need to ensure rigor in pilots conducted under the proposed variance is underscored by the fact that prior efforts to study expedited placement practices have not successfully increased utilization of hard-to-place kidneys, so our understanding of which specific approaches may be effective remains scant.[xv,xvi]

Below, ASN poses questions and reactions to specific aspects of the proposal related to evaluation of success and next steps for pilots/protocols under the variance.

- **"Using standard evaluation criteria, the OPTN will be able to compare the effectiveness of the various protocols."** ASN requests more detail regarding the "standard evaluation criteria" envisioned for this variance. How will the success of pilots/protocols be gauged individually, and how will the success of different pilots/protocols across different OPOs and hospitals be gauged against one another? Will there be any controls?

  ASN urges the Committee to design protocols focused on understanding the reasons why a given pilot/protocol was successful (in its own right, and relative to other pilots/protocols) so that those insights could potentially be scaled and replicated (or not), rather than whether or not a given pilot/protocol increased transplants or decreased discards.

- **"The OPTN does not plan to program initial protocols tested in this variance. So OPOs will need to identify qualifying candidates according to the approved protocols." "This proposal will not require any significant IT programming by the OPTN."** ASN is deeply concerned that, without programming initial protocols, there may be no way to subsequently identify these variances/pilots/protocols in the underlying data. This omission will eliminate the ability gather any data on these pilots and thus preclude the ability to glean meaningful lessons and inferences from the expedited placement variance. In the absence of meaningful operational data related to a variance, the suggested "standard evaluation criteria" is harder to envision. The society strongly suggests that all protocols tested under this variance be programmed to ensure their ability to be identified and studied in the future.

- **"How will participating members monitor themselves for compliance with the expedited placement protocols?"** This question is posed in the proposal, and ASN strongly recommends that rather than relying solely on self-monitoring (a resource-intensive and challenging task), with considerable concerns about incomplete or inaccurate data particularly in the year where OPOs are being evaluated by the new CMS metrics, an independent oversight review entity be established to track compliance with the protocols (as well as monitor the effects of the protocols) in as close to real-time as possible and with rigorous data analyses.

- **"MPSC will continue to review deceased donor match runs to ensure that allocation is carried out according to OPTN Policy, which may include these variances."** ASN appreciates that the match runs will be reviewed to ensure compliance with OPTN policy and the variance but is concerned that no plans for formal interim monitoring of the effects of the variance/pilots/protocols are yet detailed. As noted earlier, given the absence of any operational data reporting requirements, the absence of a plan for programming by the OPTN in the proposal, and the fact that it is not clear to what extent allocation violations are reviewed by the MPSC at present, or if any OPO (or transplant center) has been held accountable for any violation beyond a single letter of noncompliance, ASN has concerns about how these reviews will be conducted and evaluated.[xvii]

With an 18-month time horizon, it could be quite some time before the effects of pilots/protocols are evaluated or understood. The society strongly recommends that the Committee develop more detailed plans (and share them for public comment) to conduct ongoing monitoring during the course of these pilots/protocols. Ideally, an independent oversight review entity would be established to track compliance with the protocols (as well as monitor the effects of the protocols) in as close to real-time as possible. In addition, protocols to pause or end a pilot early should be developed to evaluate for unintended consequences.

- **"The organ specific, MPSC, Operations and Safety, and OPO Committees and the Expeditious Taskforce each could bring valuable insights to evaluating the results of this proposed variance."** ASN concurs that these committees would bring valuable insights to evaluating results and suggests that a detailed plan for evaluation—both in terms of criteria and in terms of process—be pre-specified and made available for public comment. Further, ASN encourages the expertise of other stakeholders within and external to OPTN, including but not limited to the OPTN Data Advisory Committee (DAC), HRSA, and others, be engaged in evaluation efforts.

- **"If one or more of the expedited protocols are deemed successful [they could be converted] into permanent policy. Any subsequent policy proposal would require public comment."** ASN appreciates and agrees with making any expedited protocols that would be converted to permanent policy available for public comment. Does the Committee envision that if a pilot/protocol is made permanent, will it be made permanent only for the members who participated in its testing, or for others? ASN suggests this would be an important distinction to clarify before pilot/protocol testing is initiated.

- **"Additionally, the Board could transition this variance into permanent policy prior to or after the expiration of the variance."** As ASN understands it, as proposed, the variance would last for up to 18 months (during which time various pilots/protocols could be proposed, approved, launched, evaluated, and potentially made permanent). If the Board transitions the variance into permanent policy, various pilots/protocols could be proposed, approved, launched, evaluated, and potentially made permanent, in perpetuity. While there are likely existing OPTN rules concerning the transition of variances from temporary to permanent policy, ASN suggests that, at minimum, before this proposed variance could be transitioned into permanent policy there be a robust public comment period that includes the complete findings from the initial pilots/protocols. Also, is there a process whereby the executive committee could deem a pilot as a failure before 18 months and end it early?

Conclusions

ASN recommends that the Committee issue another round of public comment building on this initial proposal, such as during the 2024 summer comment period. Ideally, it would provide more detail related to plans for patient engagement and transparency, equity, and study design and evaluation and monitoring methods. Again, ASN also strongly urges the Committee to consider tackling the root cause drivers of the growth in expedited placement practices by optimizing the current match run allocation algorithm, as well as advancing complementary approaches to increasing system efficiency and decreasing organ nonuse in ways that balance utility, equity, and transparency and enhance collaborative growth amongst all stakeholders in the transplant ecosystem.

ASN appreciates OPTN's and the Committee's interest in reducing organ nonuse ad increasing system efficiency and is grateful for the opportunity to provide input on this proposal. The society stands ready to work with OPTN and the Committee to address the recommendations and concerns included in this letter. Please contact ASN Strategic Policy Advisor Rachel Meyer at rmeyer@asn-online.org with any questions or to discuss this letter in more detail.

Sincerely,

Deidra C. Crews, MD, MS, FASN
President

CC: Xavier Becerra, JD
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Carole Johnson
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[i] https://www.govinfo.gov/content/pkg/FR-2020-12-02/pdf/2020-26329.pdf
[ii] Deviating from the Match Run to Save a Kidney. SRTR poster presentation, ATC 2023. https://www.asn-online.org/policy/webdocs/23.3.15ASNOPTNPublicCommentProp.pdf
[iii] Deceased donor kidneys allocated out of sequence by organ procurement organizations. Am J Transplant. 2022;22:1372–1381.
[iv] Mohan S et al. "Increasing Discards as an Unintended Consequence of Recent Changes in United States Kidney Allocation Policy." Kidney International Reports. February 2023. Vol. 8 Issue 5.
[v] Deceased donor kidneys allocated out of sequence by organ procurement organizations. Am J Transplant. 2022;22:1372–1381.
[vi] Deviating from the Match Run to Save a Kidney. SRTR poster presentation, ATC 2023. https://www.asn-online.org/policy/webdocs/23.3.15ASNOPTNPublicCommentProp.pdf
[vii] 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.
[viii] Deviating from the Match Run to Save a Kidney. SRTR poster presentation, ATC 2023. https://www.asn-online.org/policy/webdocs/23.3.15ASNOPTNPublicCommentProp.pdf
[ix] 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.
[x] Ibid.
[xi] Deceased donor kidneys allocated out of sequence by organ procurement organizations. Am J Transplant. 2022;22:1372–1381.
[xii] 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..
[xiii] https://www.srtr.org/media/1683/snyder-ajt-2023-stakeholders-perspectives-on-transplant-metrics_the-2022-srtr-consensus-conference.pdf
[xiv] OPTN Membership and Professional Standards Committee Report to the Board of Directors. December 2022. https://optn.transplant.hrsa.gov/media/ojenbrcm/20221205_mpsc_report-to-the-board.pdf. Pages 16-17.
[xv] Kidney accelerated placement project: Outcomes and lessons learned. Am J Transplant. 2021 https://doi.org/10.1111/ajt.16859

[xvi] Accelerating deceased donor kidney utilization requires more than accelerating placement. Am J Transplant. 2021.https://doi.org/10.1111/ajt.16866

[xvii] OPTN Membership and Professional Standards Committee Report to the Board of Directors. December 2022. https://optn.transplant.hrsa.gov/media/ojenbrcm/20221205_mpsc_report-to-the-board.pdf. Pages 16-17.