

Briefing Paper

Expedited Placement Variance

OPTN Executive Committee

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Expedited Placement Variance

<i>Affected Policies:</i>	<i>1.3: Variances</i> <i>5.4.G Open Variance for Expedited Placement</i>
<i>Sponsoring Committee:</i>	<i>Executive Committee</i>
<i>Public Comment Period:</i>	<i>December 22, 2023– February 5, 2024</i>
<i>Board Meeting:</i>	<i>March 26, 2024</i>

Executive Summary

In response to requests from the transplant community, the OPTN formed the Expeditious Task Force to improve efficiency in the organ transplant system. The task force has endorsed using quick, iterative PDSAs (Plan, Do, Study, Act), pilots, and other process improvement initiatives to improve the system rapidly. Initiatives related specifically to organ allocation align with the OPTN's variance process. This proposal 1) proposes a new variance related to expedited organ placement and 2) modifies the OPTN's governance of variances to facilitate more rapid studies of potential improvement.

Key Terms

- **Variance:** This is an experimental policy approved by the OPTN. Any variance must comply with the requirements in the OPTN Final Rule and Policy 1.3 *Variances*. The variance in this specific proposal requires the Executive Committee to approve specific *protocols*.
- **Protocol:** This proposed variance calls for specific *protocols*. Each of these protocols will contain instructions to study a particular change in allocation. All of these protocols must meet the requirements dictated by the proposed variance.
- **Expedited Organ Placement:** A method of organ allocation to quickly place organs that are at risk of not being used for transplant.

Purpose

This proposal 1) creates a variance to pilot and assess different expedited organ placement protocols and 2) makes minor adjustments to the OPTN's governance of variances. This will allow the OPTN to pilot expedited placement protocols in a rapid, iterative manner and improve the efficiency of the organ placement system.

Background

In August 2023, the Executive Committee authorized a task force focused on improving efficiency in the organ transplantation system.¹ In the Executive Committee's initial conversation about the task force, the Committee identified an "alternative allocation process for hard-to-place kidney" as a topic of concern from the community. The Board of Directors affirmed this as a topic of interest in September 2023 when they charged the Kidney Transplantation Committee to consider an expedited placement pathway for kidneys at high risk of non-use.² This topic was again raised as an area of interest at the October 2023 Expeditious Taskforce meeting. This is consistent with feedback from the community received during the summer 2023 regional meetings. This interest also reflects the interest raised in numerous articles written about the potential for expedited placement or rescue allocation to increase the utilization of deceased donor organs.^{3,4,5,6,7,8,9,10}

OPTN policy does not contain standardized protocols for expedited placement of organs, except for limited liver¹¹ and pancreata¹² protocols. Instead, these allocations are considered "allocation out of sequence" and are reviewed by OPTN staff and the OPTN Membership & Professional Standards Committee (MPSC). The number and percentage of organs allocated out of sequence has grown in the last several years.^{13, 14} Without a consistent approach to expedited placement, it is difficult to 1) analyze

¹ Minutes of OPTN Executive Committee, Aug 14, 2023.

² OPTN Board of Directors Meeting Summary, September 5, 2023.

³ Giorgakis, E., & Mathur, A. K. (2020). "Expedited placement to maximize utilization of marginal organs." *Current Opinion in Organ Transplantation*, 25(6), 640–646. DOI: 10.1097/MOT.0000000000000827.

⁴ Kilambi, V., Bui, K., Hazen, G. B., Friedewald, J. J., Ladner, D. P., Kaplan, B., & Mehrotra, S. (2019). "Evaluation of Accepting Kidneys of Varying Quality for Transplantation or Expedited Placement With Decision Trees." *Transplantation*, 103(5), 980–989. DOI: 10.1097/TP.0000000000002585.

⁵ Foley, David. "Expedited / Batch Allocation for Liver Transplantation" (Conference Presentation, Cutting Edge Of Transplantation, Phoenix, AZ, February 2019). Available at:

https://www.myast.org/sites/default/files/ceot19/Friday_0815_Salon%20EF_David%20Foley_Expedited%20v2.pdf.

⁶ Whitrock, J., A. Delman, A. Price, K. Wima, R. Quillin, K. Lemon, A. Chang, et al. "It's a New World: Safety and Use of Expedited Donor Liver Allografts to Increase Rate of Transplant." HPB 25 (2023): S4. DOI: 10.1016/j.hpb.2023.05.015.

⁷ Kinkhabwala M, Lindower J, Reinus JF, Principe AL, Gaglio PJ. "Expedited Liver Allocations in the United States: A Critical Analysis." *Liver Transplantation* 2013; 19: 1159-1165.

⁸ Mohan, Sumit, and Jesse D. Schold. "Accelerating Deceased Donor Kidney Utilization Requires More than Accelerating Placement." *American Journal of Transplantation* 22, no. 1 (January 2022): 7–8. DOI: 10.1111/ajt.16866.

⁹ National Academies, "Realizing the Promise of Equity in the Organ Transplantation System Recommendations for Transplant Centers," (August 2022). Available at: https://nap.nationalacademies.org/resource/26364/Policy_Brief_Transplant_Centers.pdf.

¹⁰ Kilambi, Vikram, Barah, Masoud, Formica, Richard N. Friedewald, John J., Mehrotra, Sanjay. "Evaluation of Opening Offers Early for Deceased Donor Kidneys at Risk of Nonutilization." *Clinical Journal of the American Society of Nephrology*. November 09, 2023. DOI: 10.2215/CJN.0000000000000346.

¹¹ OPTN Policy 11.6 *Facilitated Pancreas Allocation*.

¹² OPTN Policy 9.10 *Expedited Placement of Livers*.

¹³ Wood, Nicholas, Lyden, Grace, and Snyder, Jon. "Deviating from the Match Run to Save A Kidney." (Conference Poster, American Transplant Conference. San Diego, CA, June, 2023.) Available at: https://www.str.org/media/1677/wood_atc_2023_match_run_deviation.pdf.

¹⁴ Gauntt, Katrina. "What is Contributing to the Rise in out of Sequence Kidney Transplants?" (Conference Presentation, Association of Organ Procurement Organizations Conference, Orlando, FL, June, 2023).

the utility and equity impacts of expedited placement and 2) share effective practices regarding expedited placement.

Proposal for Board Consideration

The task force intends to conduct multiple iterative pilots or PDSAs with the community to identify effective practices to improve the efficiency of the organ allocation process. (Not all pilots or PDSAs will require a policy variance.) This proposal 1) creates a variance to govern the expedited placement pilots and 2) adjusts the OPTN's governance of all variances. Additional variances or process improvement projects will focus on other topics to improve the efficiency of the organ allocation process.

Creation of a New Variance Related to the Expeditious: Organ Usage through Placement Efficiency Taskforce

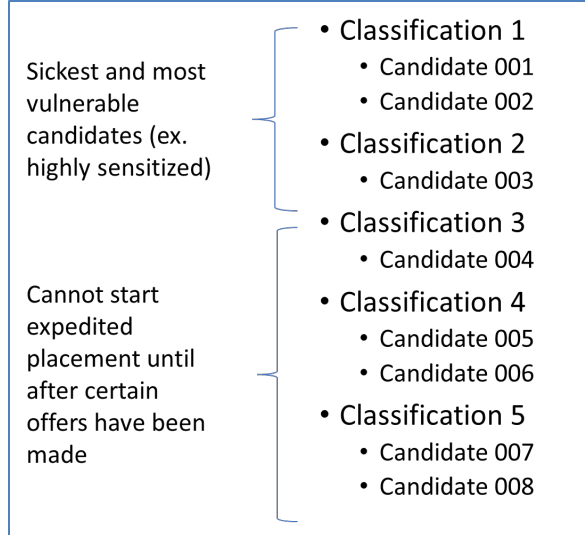
This variance works by charging the Executive Committee to approve protocols for expedited placement. This approach will allow the OPTN to review multiple protocols simultaneously. For example, an OPO in one area of the country could decide to test one protocol, while another OPO can decide to try a different protocol. Using standard evaluation criteria, the OPTN will be able to compare the effectiveness of the various protocols.

Per the proposed variance, the committee may only approve protocols that include the following information:

- 1) **Explicit clinical criteria for organs eligible for expedited placement.** For example, which organs are included in this protocol? Kidneys, livers, etc. Is the protocol for all kidneys or just high KDPI kidneys? Most community conversation has focused on high KDPI kidneys; but, this variance would permit the Executive Committee to explore additional options.
- 2) **Explicit criteria for candidates eligible to receive expedited placement offers.** For example, is any candidate eligible, only those candidates at hospitals with a history of accepting high KDPI kidneys, or only those candidates close to the donor hospital? Can hospitals choose any of their candidates or only certain candidates? Should the protocol be limited to a specific geographic area to understand environmental factors in allocation?
- 3) **Explicit conditions for the use of expedited placement.** Initial discussions have identified at least three different types of expedited placement protocols: 1) hard-to-place organs where expedited or alternative placement is sought at the beginning of the match run; 2) the OPO attempted to place the organ using the standard process but new information now requires the OPO to enter an expedited process to increase its chance of utilization; or 3) there is a late turn down or reallocation and a need to utilize a backup offer. This third condition could include, for

example, whether expedited placement can only be employed after a certain number of offers have been sent, once there is a certain amount of cold ischemic time on the organ, or within a certain amount of time relative to the scheduled procurement time in the operating room?

During public comment, some respondents questioned whether this variance should focus only on hard-to-place organs (ex. high KDPI kidneys or DCD livers). The Executive Committee discussed this and agreed that the variance could apply to any organ. This would allow two styles of expedited placement. The first style would include organs known to be hard-to-place based on donor information (ex. high KDPI kidneys). The other style would consist of organs that become difficult to place due to a trigger in the allocation process (ex. a certain amount of cold time or late turndowns).¹⁵



During public comment, some respondents were concerned that expedited placement would begin too soon in the match run and not protect the careful prioritization of the sickest and most vulnerable candidates at the top of the match run. The Executive Committee discussed setting thresholds to protect the top of the match run. Instead of setting thresholds for all protocols, the Executive Committee agreed that protocols must contain a threshold, which could vary between protocols. The task force and Executive Committee could then consider the threshold while reviewing the protocols.¹⁶

- 4) **Any OPO and transplant hospital responsibilities.** For example, do hospitals have to respond to the OPO within a specific time? Do OPOs need to submit specific bypass codes for the specific expedited placement protocol? Also, how will participating members monitor themselves for compliance with the expedited placement protocols?

Example of A Protocol

Using the above criteria, below is an example of a potential expedited placement protocol.

- 1) **Explicit clinical criteria for organs eligible for expedited placement.**
Kidneys with a KDPI greater than 85%.
- 2) **Explicit criteria for candidates eligible to receive expedited placement offers.**
Candidates registered at hospitals with a demonstrated history of accepting high KDPI kidneys. Evidence for this can be found by reviewing the RUM (Recovery and Usage Map) report and identifying hospitals that have transplanted at least ten high KDPI kidneys in the last year.
This protocol will apply to kidneys offered by the following OPOs: [Each approved protocol will contain the specific members involved.]

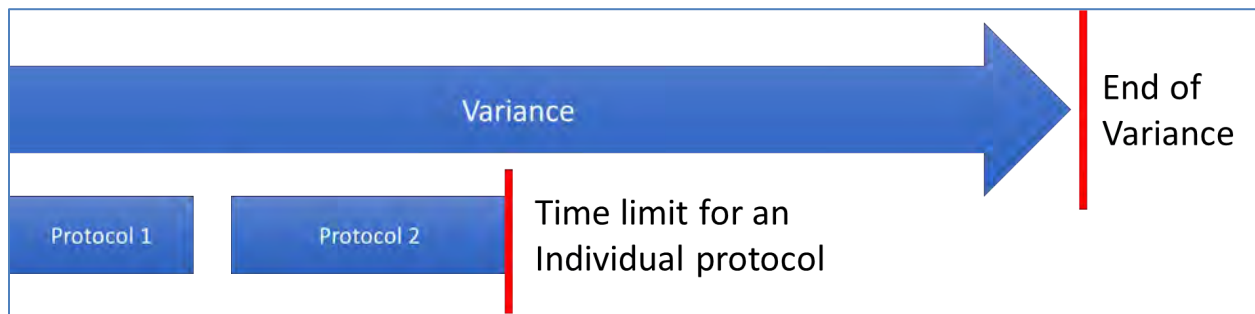
¹⁵ Minutes of OPTN Executive Committee, March 5, 2024.

¹⁶ Id.

- 3) **Explicit conditions for the use of expedited placement.**
Before starting expedited placement, the OPO must offer the organ through the first 19 sequences of the kidney match run. This threshold includes high CPRA, medically urgent, O-ABDR, and safety net candidates.
- 4) **Any OPO and transplant hospital responsibilities.**
The OPO will send offers to candidates as mentioned above. The candidate with the highest sequence number to accept the offer will receive the organ. OPOs will report candidates bypassed using a specific bypass code for this protocol.

Time Limit

During public comment, some respondents were concerned that this variance could permit long-term exceptions to allocation without following the normal policy development process for allocation proposals. The Executive Committee agreed that this is not the proposal's intent, and therefore, any variance is limited to six months. If the protocol is successful, the Executive Committee will refer it to a committee for policy development. The Executive Committee could also amend a protocol to study its impact in alternative situations.¹⁷

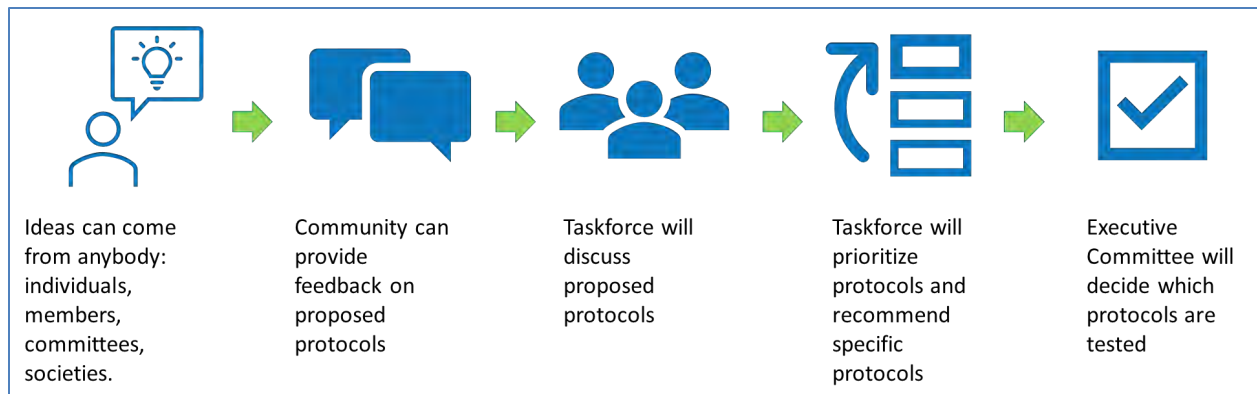


Approval Process

During public comment, some respondents requested clarification regarding how protocols would be submitted and approved. The task force and Executive Committee discussed this and agreed upon the following process:

1. Ideas can come from anybody. This includes individuals, OPTN members, OPTN committees, societies, researchers, etc. The OPTN will provide instructions on the OPTN website on submitting proposed protocols.
2. The OPTN will share proposed protocols on the OPTN website and allow the community to provide feedback on any proposed protocols. This will also enable the organ-specific committees to provide input on proposed protocols.
3. The Expeditious task force will discuss proposed protocols and any online feedback on the protocols.
4. The task force will prioritize the protocols and recommend which protocols should be tested to the Executive Committee.
5. The Executive Committee will review the recommendations from the task force and decide which protocols to test.

¹⁷ Minutes of OPTN Executive Committee, March 19, 2024.



Review Process

During public comment, several respondents asked for more information about how the OPTN would review the overall variance and individual protocols. Several respondents also voiced concern about how the OPTN would identify and respond to potential unintended consequences of this variance.

The variance and individual protocols review process contains three groups in addition to automatic safeguards. The three groups are the community, variance participants, and the expeditious task force. The OPTN will post the variance and individual protocol results on the OPTN website. Similar to how the community can review and provide feedback on proposed protocols, the community will also be able to review and provide feedback on the results of protocols. Next, the variance participants will convene monthly to discuss the variance results. This step helps collect qualitative information from participants. Finally, a subgroup of the Expeditious task force will meet regularly to review reports regarding the protocols. The Executive Committee considered whether the Executive Committee should do this analysis, the Policy Oversight Committee, the organ-specific committees, or the task force. The Executive Committee selected the task force because they will prioritize the protocols but not write any policy proposals; therefore, they would have sufficient knowledge of the project but be independent of the participation in the variance and the eventual decisions on national policy.¹⁸

¹⁸ Id.



Community

Results will be posted online for anybody to review.

Website will allow anybody to provide feedback on results.



Participants

Variance participants will meet to discuss results share lessons learned

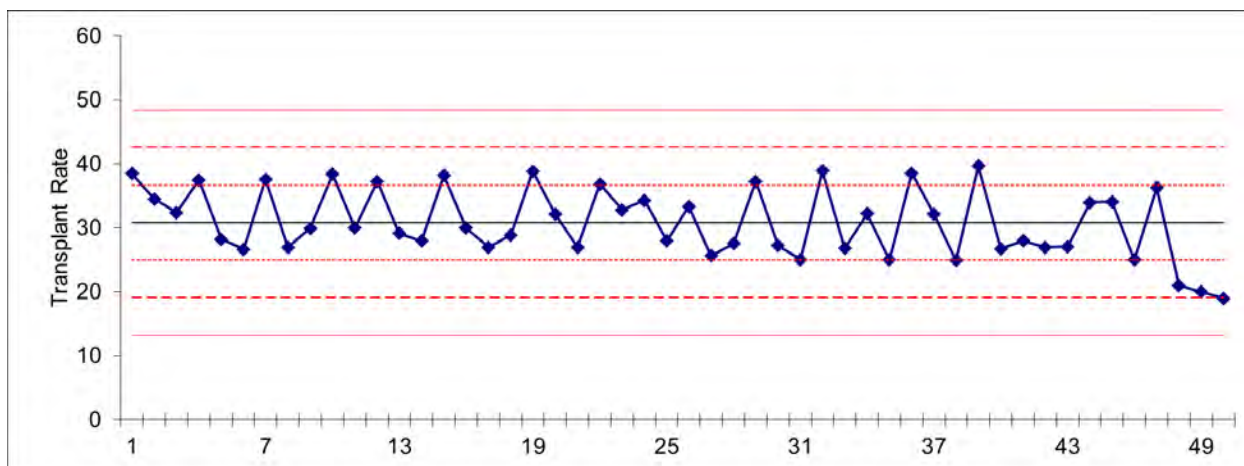


Taskforce

Subgroup of Taskforce will discuss results

As mentioned above, this variance will also contain built-in safeguards. Several respondents voiced concern about potential negative consequences and the OPTN's ability to respond rapidly. The Executive Committee discussed this and agreed to add automatic safeguards.¹⁹

Figure 1: Example of a Control Chart



These safeguards will use control charts, a standard method for tracking process changes over time.²⁰

Figure 1 shows an example of a control chart. Control charts help distinguish between natural variations in the process (like the number of transplants) and unusual changes that might indicate problems.

Control charts are a standard method for measuring change in processes over time. Walter Shewhart first proposed these in 1924.²¹ A control chart distinguishes between natural variation and unusual changes. Processes have normal variation; for example, the number of transplants varies weekly. When process changes are introduced, one can expect changes in that variation. Shewhart's process is

¹⁹ Id.

²⁰ Western Electric, *Statistical Quality Control Handbook*, Western Electric Corporation, Indianapolis, Ind., (1956). NIST, *e-Handbook of Statistical Models*, Sec. 6.3.2 What are Variable Control Charts?, (2012). DOI: 10.18434/M32189. Anhoj, *qicharts2: Quality Improvement Charts* (2023), available at: <https://cran.r-project.org/web/packages/qicharts2/>.

²¹ Best, M., & Neuhauser, D., Walter A Shewhart, 1924, and the Hawthorne factory. *Quality & safety in health care*, 15(2), 142–143. (2006). DOI: 10.1136/qshc.2006.018093.

supplemented by the Western Electric (WECO) rules for testing non-random variation rules. These consist of four simple tests that can be applied to control charts by visual inspection and are based on the identification of unusual patterns in the distribution of data points relative to the control and center lines.

1. One or more points below the 3-sigma limits (Shewhart's original 3-sigma rule).
2. Two out of three successive points below the 2-sigma limit
3. Four out of five successive points below the 1-sigma limit.
4. A run of eight successive points below the center line.

The Executive Committee agreed to automatic safeguards for pediatrics, racial minorities, and gender.²² The OPTN will measure these weekly for each organ and compare it to the median for the past six months. The OPTN selected six months because WECO rules are most effective with control charts between 20 and 30 data points. If unintended consequences are identified, then active protocols for that organ will stop. If multiple protocols are active for an organ, then all active protocols will stop. This approach allows rapid response to unintended consequences instead of waiting for a review and identifying which protocol is causing the unintended consequences.

The control charts in the automatic safeguards will include the participating members for all protocols by organ instead of national metrics. (The task force and others may still review national trends.) This focus is because an individual protocol could have a significant impact on the members and candidates impacted by the protocol; but, the number of participants in the protocol might not have a noticeable impact on national metrics. For example, the kidney control chart would include *all OPOs* participating in *any* kidney protocol, and if the WECO safeguards are triggered, the OPTN would require all kidney protocols to cease. The task force could then look individually at protocols to determine which can restart.

On March 25, the Executive Committee agreed to modify the WECO rules for small sample sizes. With small populations, the 3-sigma and 2-sigma rules can frequently be negative or zero. Therefore, the 3-sigma rule regarding pediatrics will only apply to kidney and liver. Additionally, the 3-sigma and 2-sigma rules will not apply when the average sample size over a six month period is less than ten.

Interaction Between Variance and Other OPTN Policies

In some ways, variances are an exception to a general policy requirement. This proposed variance supersedes Policies 5.4.B *Order of Allocation*, 5.6.B *Time Limit for Review and Acceptance of Organ Offers*, and 5.9 *Released Organs*. Specifically, Policy 5.4.B requires "3. OPOs must first offer organs to potential transplant recipients (PTRs) in the order that the PTRs appear on a match run." With this variance, participating OPOs may offer organs according to the expedited placement protocol approved by the Executive Committee. Relatedly, Policy 5.6.B *Time Limit for Review and Acceptance of Organ Offers* sets requirements for transplant hospitals to respond to organ offers. With this variance, transplant hospitals will follow the acceptance requirements according to the expedited placement protocols approved by the Executive Committee. Finally, this proposed variance would supersede the requirements for allocating released organs in Policy 5.9. Released organs are at a higher risk of under-utilization; therefore, making these organs a potential area to explore in this variance.

²² Minutes of OPTN Executive Committee, March 19, 2024.

OPTN Variance Requirements

OPTN policy requires that new variances must address the following:

1. **The purpose for the proposed variance and how the variance will further this purpose.** The Board created the Expeditious task force to improve efficiency in the organ placement system and to increase the utilization of organs. This variance analyzes expedited placement protocols to increase utilization and the efficiency of the organ placement process.
2. **If a member's application to create, amend, or join a variance will require other members to join the variance, the applicant must solicit their support.** No member is required to join this variance. That said, feedback at regional meetings in 2023 and at the October 2023 task force webinar indicated community support for pilot programs related to expedited placement. Additional support will be gathered following approval of this variance.
3. **A defined expiration date or period of time when the variance will end, the participating members will report results, and the sponsoring Committee will evaluate the impact of the variance.** The proposed variance will run for approximately 18 months from Board approval. To iterate on the expedited placement protocols, individual protocols will run for less time than the full variance. After that time, the Board could extend, modify, or terminate this variance. Additionally, the Board could transition this variance into permanent policy prior to or after the expiration of the variance.

The expiration date was changed from July 1, 2025 to December 31, 2025 post public comment. This allows for some additional time for the variance to operate since public comment was extended and the variance did not start as early as originally anticipated.

4. **An evaluation plan with objective criteria to measure the variance's success achieving the variance's stated purpose.** The success of this variance will primarily be evaluated by the degree to which approved variances for expedited placement decrease the non-use rate and/or increase utilization of deceased donor organs. Successful variances will demonstrate an increase in the utilization rate and/or decrease in non-use rate. Further, 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.

To assist in this evaluation, participating members must submit the following to the OPTN: the date, time, and match run when they initiate an expedited placement protocol. This will be collected through new bypass codes instead of new data collection.

5. **Any anticipated difficulties in demonstrating whether the variance is achieving its stated purpose.** Variances are inherently challenging to analyze due to their limited sample size. This particular variance contains a few specific analytical difficulties.

First, rapid iteration on this variance will allow the OPTN to explore alternative solutions quicker but will limit the ability to understand the impact of the outside factors and could limit the sample size. (More information about the sample size is below.)

Next, numerous committees are interested in the results of this variance. Having multiple committees review and approve potential protocols could take significant time and dampen the ability for rapid iteration. Therefore, this variance proposes that one committee (the Executive

Committee) 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. The Executive Committee will rely upon recommendations from the Expeditious task force regarding the specific protocols used in this variance.

Finally, evaluation of this variance will contain several unique complications, and known limitations will be reported with the analysis.

- This variance will allow multiple, simultaneous expedited protocols. In an experimental trial, OPOs would be randomly assigned the protocol; this condition is important in comparing the impact of treatments across groups. Without the randomness, there will be a greater possibility of unintentional bias introduced into the data that could impact the results we see. Options to overcome this bias include: 1) The OPTN could dictate to the OPO which protocol they use. This option could remove some of the unintentional bias. 2) The OPTN could schedule the protocols so that all participating members use one protocol at a time and then test another protocol for a period of time. This option could lengthen the time to study different protocols.
- Some OPOs already have existing expedited placement protocols. Comparing a member's utilization before and during this variance will require the OPTN to know whether the member was previously utilizing an expedited placement protocol and how that protocol compares against the protocols in this variance. Because the OPTN does not know which OPOs are using protocols right now, it will be challenging to establish a proper control group for this analysis. This is a known limitation, and the OPTN will need to account for this in the analysis of this variance. One option is to require participating members to submit their existing expedited placement protocols as a condition of participation in this variance. This will allow the OPTN to understand when a member is changing their expedited placement protocols due to this variance. Another option is to randomly use the expedited placement protocol for one kidney and regular allocation for the other kidney and compare the results.
- Organ utilization is different depending on donor organ characteristics, such as KDPI.²³ Therefore, when comparing the results of different expedited placement protocols, the OPTN will need to control for differences in organ utilization based on donor organ characteristics. Some have suggested that preliminary protocols focus on high KDPI kidneys, which could help control this issue.

- 6. Whether this is an open variance or closed variance and, if this is an open variance, any additional conditions for members to join this variance.** This is an open variance. Any member can join this variance by notifying the OPTN, agreeing to follow the approved protocol(s) for expedited placement, and submitting the above-mentioned evaluation information. As mentioned above, the specific protocols can include specific criteria for members or candidates eligible for each protocol – thus potentially limiting access to each protocol.

Other Options Considered

In developing any proposal, the OPTN always considers multiple options. This proposal considered the following five options:

1. Inclusion of specific protocols

²³ Crannell, W. C., Perkins, J. D., Leca, N., & Kling, C. E. (2022). "Deceased donor kidneys are discarded at higher rates when labeled as high kidney donor profile index." *American Journal of Transplantation*, 22(12), 3087–3092. DOI: 10.1111/ajt.17197.

2. Selection of committee to develop protocols
3. Which member actions are changed
4. Reporting timelines
5. Sample size and number of protocols

1. Inclusion of Specific Protocols

This proposed variance does not contain the specific expedited placement protocols; instead, it provides a framework within which the Executive Committee is to approve protocols for assessment. Another option would be to write the specific protocols into this variance. This alternative approach would allow 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.

The proposed variance also sets requirements for each protocol and that the protocols be publicly available. The OPTN will post these protocols online so the community can comment on proposed protocols under consideration and those approved by the Executive Committee. This approach will allow real-time feedback from the community to the OPTN throughout this variance.

2. Selection of Committee to Develop Protocols

Multiple OPTN groups are discussing improving efficiency in the organ placement system. Therefore, multiple committees could be charged with developing the expedited placement protocols for this variance. At its December 2023 meeting, the Executive Committee discussed this proposal and agreed it would be the proper committee to approve any expedited placement protocols. The Executive Committee will seek recommendations from the Expeditious task force regarding which protocols to test.

Due to the significant interest in this topic, the OPTN will have a robust collaboration and communication plan to include relevant stakeholders. For example, similar to other proposals, multiple committees can submit ideas for potential protocols and be included in the review of the proposal once implemented. The organ specific, MPSC, Operations and Safety, and OPO Committees and the Expeditious task force each could bring valuable insights to evaluating the results of this proposed variance.

3. Which Member Actions are Changed

Expedited placement impacts both OPOs and transplant hospitals, and this variance could be written such that one or the other is the main actor in this variance. For example, this variance is written such that OPOs would have an alternative mechanism to offer organs under Policy 5.4 *Organ Offers*. Additionally, this variance is also written such that hospitals have an alternative mechanism to how they accept organ offers under Policy 5.6 *Receiving and Accepting Organ Offers*. (For example, some transplant hospitals have suggested a protocol that allows them to accept an organ offer for one of their candidates lower on the match run.) Instead of choosing one or the other, the variance allows both types of expedited placement protocols.

4. Reporting Timelines

The OPTN Final Rule requires that variances have a "research design and include data collection and analysis plans." Some of the key information relevant to this variance is included in Deceased Donor

Registration (DDR) and Potential Transplant Recipient (PTR) forms. To analyze the data and iterate more rapidly, this variance could require that this information be submitted earlier than the timelines in Policy 18 *Data Submission Requirements*. Because the analysis is most useful compared to similar match runs, it would be better to analyze match runs from the same time periods. Therefore, it would not be helpful to require data submission earlier than the timelines in Policy 18 *Data Submission Requirements*.

5. Sample Size and Number of Protocols

During public comment, the OPTN asked whether they should run multiple, concurrent expedited placement protocols or to test one protocol at a time. Evaluating multiple protocols concurrently can add complexity due to interactions and differences between OPOs. Conversely, testing one protocol at a time could add time to the length of this variance and time to build consensus on national, effective practices for expedited placement. After considering public comment, the Executive Committee agreed they would permit concurrent protocols. They also decided they would evaluate protocols for any potential interactions between them.

Related to this issue is the sample size necessary to analyze this variance. There were 26,310 kidney transplants in 2022, or 2,192 kidney transplants per month. Since 2021, over 10% of kidney transplants have been allocated out of sequence.²⁴ If all those transplants were allocated according to this variance, this would provide hundreds of monthly allocations to review. The more protocols that are concurrently run, the longer it will take to collect sufficient information about each protocol. Therefore, the OPTN might decide to limit the number of concurrent protocols in order to better analyze each protocol.

Changes to the Governance of Variance Process

Variances allow the OPTN to collect evidence regarding potential changes to policy for which the member actions are not allowed under current policy and they cannot be sufficiently analyzed through simulation modeling. The OPTN Final Rule allows the OPTN to create variances:

Variances. The OPTN may develop, in accordance with § 121.4, experimental policies that test methods of improving allocation. All such experimental policies shall be accompanied by a research design and include data collection and analysis plans. Such variances shall be time limited. Entities or individuals objecting to variances may appeal to the Secretary under the procedures of § 121.4.²⁵

OPTN Policy 1.3 sets further requirements for variances. These requirements were created considering variances that would take months or years to complete and analyze. The task force intends to use a more rapid, iterative approach that does not fit within the parameters of these policy requirements, and, therefore, the Executive Committee proposes the following changes to the OPTN requirements regarding variances.

Current OPTN Requirement	Proposed OPTN Requirement	Rationale
1.3.B Application for a Variance Members	1.3.B Application for Creation of a Variance	Prior to overhauling the variance policies in 2012, OPTN policy permitted Committee

²⁴ OPTN Data as of November 20, 2023.

²⁵ 42 CFR 121.8(g).

Current OPTN Requirement	Proposed OPTN Requirement	Rationale
<p>wishing to create or amend a variance must submit an application to the OPTN.</p>	<p>Members wishing to create or amend a variance must submit an application to the OPTN. <u>OPTN Committees may also propose new variances without a member application.</u></p> <p><u>Proposed new variances</u> The application must address all of the following:</p>	<p>Sponsored Variances.²⁶ This concept was incorporated into current policy by requiring variances to follow the policy development process in the OPTN Bylaws – where committees sponsor policy proposals.</p> <p>This approach has confused committees that wish to create a variance without a member sponsor. This change would allow committees to propose a variance but would still require the variance to follow the policy development process in the OPTN Bylaws.</p>
<p>1.3.B Application for a Variance (2) If a member's application to create, amend, or join a variance will require other members to join the variance, the applicant must solicit their support. Committees will not review a member's variance application unless the applicant receives affirmative support from at least 75% of the members required to join the proposed variance.</p>	<p>1.3.B Application for a Variance (2) If a member's application to create, amend, or join a variance will require other members to join the variance, the applicant must solicit their support. Committees will not review a member's variance application unless the applicant receives affirmative support from at least 75% of the members required to join the proposed variance.</p>	<p>This concept originates from alternative allocation units or alternative allocation systems when the OPO or region primarily drove allocation. With broader distribution and more national allocation, any allocation change has the potential to impact any transplant hospital. Therefore, a strict reading of this requirement would require 75% of all transplant hospitals to agree to any proposed allocation variance.</p> <p>This concept also originated when the Board and Committees discussed variances without public comment. New variances have been released for public comment for several years, allowing impacted stakeholders to comment on proposed variances.</p> <p>Neither NOTA nor the OPTN Final Rule require this specific requirement. Therefore, the Committee suggests striking this requirement because the transplant community can comment during the public comment period.</p>

²⁶ OPTN, "Briefing Paper: Proposal to Clarify and Improve Variance Policies," June 2012.

Current OPTN Requirement	Proposed OPTN Requirement	Rationale
<p>1.3.C Joining an Open Variance</p> <p>Members wishing to join an existing open variance must submit an application as dictated by the specific variance. When an open variance is created, it may set conditions for the OPTN Contractor to approve certain applications. However, if the application to join an existing open variance does not receive affirmative support from all of the members required to join by the application, the OPTN Contractor may not approve the application and only the sponsoring Committee may approve the application.</p>	<p>1.3.C Joining an Open Variance</p> <p>Members wishing to join an existing open variance must submit an application as dictated by the specific variance. When an open variance is created, it may set conditions for the OPTN Contractor to approve certain applications. However, if the application to join an existing open variance does not receive affirmative support from all of the members required to join by the application, the OPTN Contractor may not approve the application and only the sponsoring Committee may approve the application.</p>	<p>The last sentence is struck to mimic the change to Policy 1.3.B(2).</p>

Current OPTN Requirement	Proposed OPTN Requirement	Rationale
<p>1.3.D Reporting Requirements for Variances</p> <p>Members participating in a variance must submit data and status reports to the sponsoring Committee at least annually that does all of the following:</p>	<p>1.3.D Reporting Requirements for Variances</p> <p>Members participating in a variance must submit data and status reports to the sponsoring Committee at <u>the frequency defined in the variance, and at least annually,</u> that does all of the following:</p>	<p>Members in variances are already required to submit information according to the specifics of the variance. This change clarifies that the information must be submitted according to the frequency defined in the variance.</p>
<p>1.3.D Reporting Requirements for Variances</p> <p>...</p> <p>Participating members must also provide a final report to the sponsoring Committee at least six months before the variance's expiration date.</p>	<p>1.3.D Reporting Requirements for Variances</p> <p>...</p> <p>Participating members must also provide a final report to the sponsoring Committee at least six months before the variance's expiration date.</p>	<p>This concept originates from variances that lasted multiple years and when the Board only met in-person, twice a year instead of more frequent, virtual meetings. This requirement is not functional for variances with rapid iteration that last only a few months.</p> <p>This sentence also overlaps with the first sentence of Policy 1.3.D. To alleviate confusion, it is recommended to strike this sentence.</p>

Overall Sentiment from Public Comment

Overall sentiment for this proposal showed support for the broad concept but questions for more clarity regarding the specifics of the proposal. Sentiment is collected on public comment proposals and is measured on a 5-point Likert scale from strongly opposing to strongly supporting (1-5). These reports are helpful in spotting high-level trends; however, they are not meant to be used as public opinion polls or to replace the substantive analysis below. Generally, public comment sentiment has supported this proposal, as indicated by the total sentiment score of 3.6 by member type, with some pockets of concern. Below are graphics that illustrate the sentiment received through public comment.

Figure 2 shows the sentiment by region of all respondents (committee meetings, online, and email) by their stated region. (Not every respondent submits a sentiment score, so the volume of responses in the sentiment charts is lower than the total volume of respondents.) These are not sentiments from regional meetings since special public comment proposals are not usually presented at regional meetings. The average response of 3.6 from the eleven regions indicates general support for the proposal but the number of responses that opposed the proposal was higher than normal for a public comment proposal.

Figure 2: Sentiment by Region

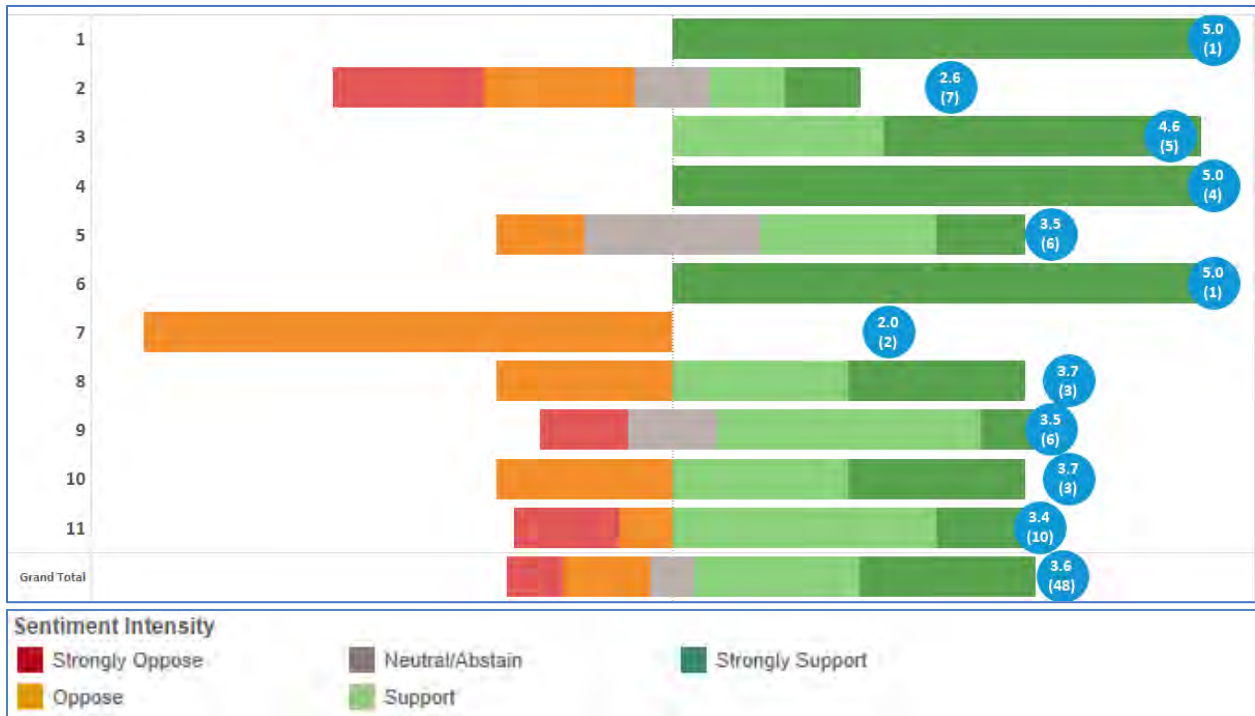
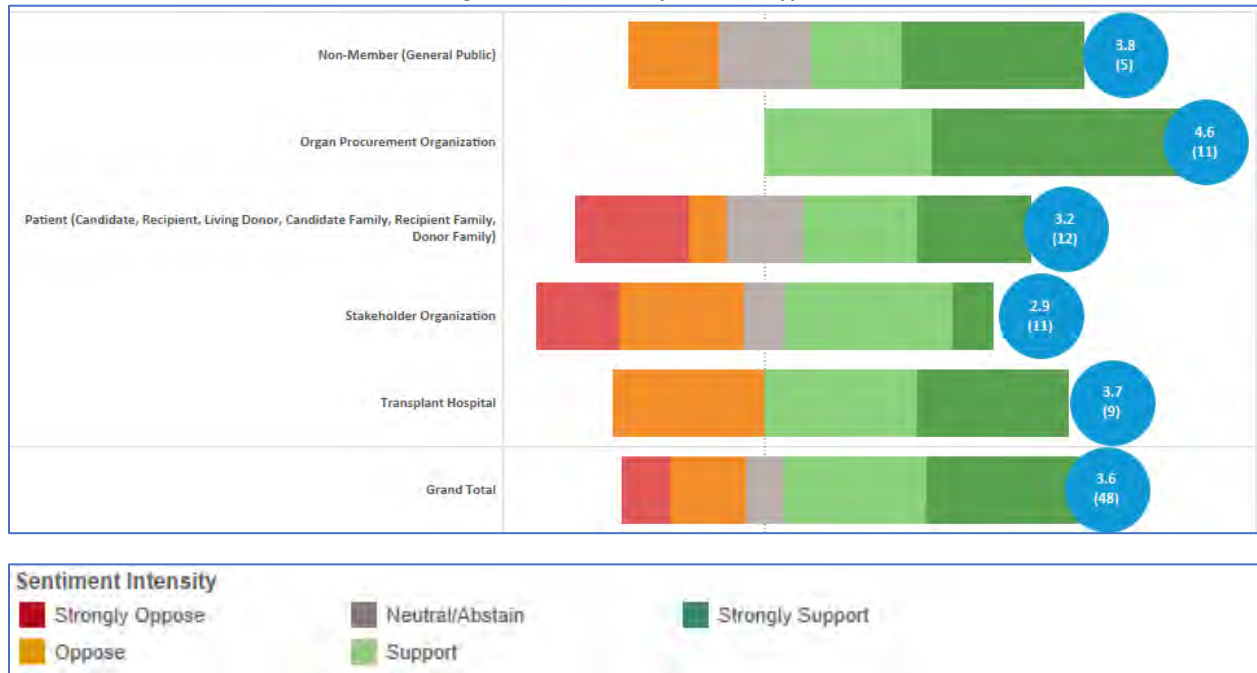


Figure 3 shows the sentiment by member type. Most member types supported the proposal, though stakeholder organizations and patients had mixed sentiments, demonstrated by 2.9 and 3.2 for their respective sentiment scores.

Figure 3: Sentiment by Member Type



Themes in Public Comment

In addition to the sentiment score, items out for public comment also provide the opportunity for respondents to submit a substantive written comment. Commenters covered many different topics, including the following themes.²⁷ A complete analysis of these themes was provided to and discussed by the Executive Committee on March 5, 2024.²⁸

- 1) Review Process of individual protocols
- 2) Request for More Details
- 3) Concerns About Equity
- 4) Public Comment Period
- 5) Concurrent or Sequential Study of Protocols
- 6) Understanding the Drivers of Utilization
- 7) Eligible Organs
- 8) Geographic Differences
- 9) Member Compliance
- 10) Data and the Design of Study
- 11) Timing with OPTN Modernization

²⁷ Comments were reviewed and coded using NVivo 14.

²⁸ Minutes of OPTN Executive Committee, March 5, 2024.

Compliance Analysis

NOTA and Final Rule Analysis

The Committee submits this proposal for consideration under the authority of the National Organ Transplant Act of 1984 (NOTA) and the OPTN Final Rule. NOTA requires the OPTN to "establish...medical criteria for allocating organs and provide to members of the public an opportunity to comment with respect to such criteria."²⁹ The OPTN Final Rule states the OPTN "shall be responsible for developing...policies for the equitable allocation for cadaveric organs."³⁰ The Final Rule requires that when developing policies for the equitable allocation of cadaveric organs, such policies must be developed "in accordance with §121.8," which requires that allocation policies "(1) Shall be based on sound medical judgment; (2) Shall seek to achieve the best use of donated organs; (3) Shall preserve the ability of a transplant program to decline an offer of an organ or not to use the organ for the potential recipient in accordance with §121.7(b)(4)(d) and (e); (4) Shall be specific for each organ type or combination of organ types to be transplanted into a transplant candidate; (5) Shall be designed to avoid wasting organs, to avoid futile transplants, to promote patient access to transplantation, and to promote the efficient management of organ placement; ... (8) Shall not be based on the candidate's place of residence or place of listing, except to the extent required by paragraphs (a)(1)-(5) of this section."³¹

This policy proposal aligns with 42 CFR 121.8(g) which sets standards for OPTN variances. As explained above, this variance includes a research and analysis plan, includes relevant data collection, and is time limited. Additionally, this proposal:

- **Is based on sound medical judgement³²** because each expedited placement protocol must include information about donor organ and candidate qualifications and will rely upon the medical judgment of the Executive Committee.
- **Seeks to achieve the best use of donated organs³³ and is designed to avoid wasting organs³⁴** by seeking to increase the utilization of organs at high risk of non-utilization.
- **Promotes the efficient management of organ placement³⁵** by seeking to offer organs at a high risk of non-utilization to programs and candidates more likely to benefit from those offers.

This proposal also preserves the ability of a transplant program to decline an offer or not use the organ for a potential recipient,³⁶ and each protocol will state the specific organ type impacted.³⁷

Although the proposal outlined in this briefing paper addresses certain aspects of the Final Rule listed above, the Committee does not expect impacts on the following aspects of the Final Rule:

- Is designed to avoid futile transplants³⁸
- Is designed to ... promote patient access to transplantation³⁹

²⁹ 42 U.S.C. § 274(b)(2)(B).

³⁰ 42 C.F.R. § 121.4(a)(1).

³¹ 42 C.F.R. § 121.8(a)

³² 42 C.F.R. § 121.8(a)(1).

³³ 42 C.F.R. § 121.8(a)(2)

³⁴ 42 C.F.R. § 121.8(a)(5).

³⁵ Id.

³⁶ 42 C.F.R. § 121.8(a)(3).

³⁷ 42 C.F.R. § 121.8(a)(4).

³⁸ Id.

³⁹ Id.

- Is not based on the candidate's place of residence or place of listing⁴⁰

The Final Rule also requires the OPTN to set "priority rankings expressed, to the extent possible, through objective and measurable medical criteria, for patients or categories of patients who are medically suitable candidates for transplantation to receive transplants."⁴¹ Medical criteria, such as qualifying time, sensitization, and medical urgency, are included in current allocation policy. This clause requires that any expedited placement protocol consider medical criteria to the extent possible. This clause would likely prohibit one form of expedited placement whereby organ offers are sent to multiple candidates, and whoever responds first, without any consideration of the sequence number, would receive the organ.

OPTN Strategic Plan

This project aligns with the OPTN's strategic goal to increase the number of transplants. This variance will allow the OPTN to study different expedited placement protocols with the intent to improve the efficiency of this process and utilize more organs. Expediting offers of difficult to place organs is a specific initiative mentioned in goal one of the OPTN strategic plan.

Implementation Considerations

Member and OPTN Operations

Operations affecting Histocompatibility Laboratories

None expected.

Operations affecting Organ Procurement Organizations

OPOs are eligible, but not required, to join this variance. If they join, they will be able to utilize approved expedited placement protocols. 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.

Operations affecting Transplant Hospitals

Transplant hospitals are eligible, but not required, to join this variance. If they join, they will be able to utilize approved expedited placement protocols.

Operations affecting the OPTN

If this variance is approved,

- The Executive Committee will solicit potential expedited placement protocols from the community, including, at a minimum, the above mentioned OPTN committees.
- Interested members may join the variance by agreeing to follow the approved protocol(s) for expedited placement and submitting the above-mentioned evaluation information. See **Attachment 1**.
- The OPTN will publicize any approved expedited placement protocols.
- Participating members will convene monthly to discuss the results of this variance. The OPTN will conduct qualitative interviews with participants to assess their results with this variance.

⁴⁰ 42 C.F.R. § 121.8(a)(8).

⁴¹ 42 CFR 121.8(b)(2).

Results of the variance will be provided to the community and, at a minimum, the Executive, MPSC, Operations and Safety, and OPO Committees, as well as the Expedious task force.

- If one or more of the expedited protocols are successful, the variance could be extended long enough to convert the protocols into permanent policy. Any subsequent policy proposal would require public comment.
- This proposal will not require any significant IT programming by the OPTN. It will require the creation of new bypass codes for each approved protocol.

Potential Impact on Select Patient Populations

This variance intends to increase organ utilization rate, thereby increasing candidates' overall transplant rate. The Committee will want to ensure that any utilization increases do not result from decreased patient equity.

Projected Fiscal Impact

Because this is a variance that no members are required to join, this proposal is not anticipated to have any fiscal impact on any OPTN members. This variance is intended to improve the efficiency of the organ placement system.

If approved, the OPTN will utilize the following resources to implement this variance: 1) This proposal will include new bypass codes used to track the use of the expedited placement protocols. 2) Research staff will analyze the information described in the policy evaluation section of this document. 3) OPTN staff will conduct qualitative interviews and discussions with participating members to solicit additional information regarding this variance.

Post-implementation Monitoring

Member Compliance

The proposed language may change the current routine monitoring of OPTN members. Any data submitted to the OPTN Contractor may be subject to review, and the Membership and Professional Standards Committee (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. Members are required to provide documentation as requested.

Policy Evaluation

The goal of this variance is to increase the utilization of organs. To assess this, the Committee will review the following based on the expedited pathway utilized and compare results across different expedited pathways protocols as well as to the standard pathway of allocation:

- The count of organs where expedited placement was attempted
- The count of organs where expedited placement resulted in a final acceptance
 - The count of organs where expedited placement resulted in a transplant
 - Successful protocols will increase the number of organs with a final acceptor and/or transplanted among those that qualify for expedited placement.
- Count of the number of programs notified (overall and prior to final acceptance). Successful protocols will decrease the number of programs needing to be contacted.

- Count of allocations out of sequence where expedited placement was not attempted. Successful protocols will decrease allocations out of sequence not related to the approved expedited placement pathway.
- The organ utilization rate and non-use rate over time for donors recovered by participating members (overall and for donors that meet the criteria of the pathway). Successful protocols will show an increase in the utilization rate and/or decrease in the non-use rate depending on the stated objectives.
- The characteristics of recipients that receive an organ from the protocol in comparison to those allocated through the standard process. Successful protocols will show acceptable deviation between protocol recipients and other recipient groups.

Conclusion

The OPTN recently formed a task force to improve the efficiency of the organ transplant system. Many community segments are interested in pilot projects to assess the impact of expedited placement on organ utilization and placement efficiency. This proposal 1) creates a variance to govern pilots related to expedited placement and 2) updates portions of the OPTN's governance regarding variances.

Post public comment changes include:

- Addition of automatic safeguards for vulnerable populations.
- Time limit of six months for individual protocols.
- Extension of variance from July 1 to December 31, 2025.

Policy Language

Proposed new language is underlined (example) and language that is proposed for removal is struck through (~~example~~). Heading numbers, table and figure captions, and cross-references affected by the numbering of these policies will be updated as necessary.

1 **1.3.B ~~Application for~~ Creation of a Variance**

2 Members wishing to create or amend a variance must submit an application to the OPTN. Completed
3 applications will be considered through the policy development process described in Article XI: Adoption
4 of Policies of the OPTN Bylaws. OPTN Committees may also propose new variances without a member
5 application.

6 Proposed new variances ~~The application~~ must address all of the following:

7 1. The purpose for the proposed variance and how the variance will further this purpose.

8 ~~2. If a member's application to create, amend, or join a variance will require other members to join the~~
9 ~~variance, the applicant must solicit their support. Committees will not review a member's variance~~
10 ~~application unless the applicant receives affirmative support from at least 75% of the members required~~
11 ~~to join the proposed variance.~~

12 ~~2. 3.~~ A defined expiration date or period of time when the variance will end, the participating members
13 will report results, and the sponsoring Committee will evaluate the impact of the variance.

14 ~~3. 4.~~ An evaluation plan with objective criteria to measure the variance's success achieving the
15 variance's stated purpose.

16 ~~4. 5.~~ Any anticipated difficulties in demonstrating whether the variance is achieving its stated purpose.

17 ~~5. 6.~~ Whether this is an open variance or closed variance and, if this is an open variance, any additional
18 conditions for members to join this variance.

19 **1.3.C Joining an Open Variance**

20 Members wishing to join an existing open variance must submit an application as dictated by the
21 specific variance. When an open variance is created, it may set conditions for the OPTN Contractor to
22 approve certain applications. ~~However, if the application to join an existing open variance does not~~
23 ~~receive affirmative support from all of the members required to join by the application, the OPTN~~
24 ~~Contractor may not approve the application and only the sponsoring Committee may approve the~~
25 ~~application.~~

26 **1.3.D Reporting Requirements for Variances**

27 Members participating in a variance must submit data and status reports to the sponsoring Committee
28 at the frequency defined in the variance, at least annually, that does all of the following:

- 29 1. Evaluate whether the variance is achieving its stated purpose
- 30 2. Provide data for the performance measures in the variance application
- 31 3. Address any organ allocation problems caused by the variance

32 ~~Participating members must also provide a final report to the sponsoring Committee at least six~~
33 ~~months before the variance's expiration date.~~ The sponsoring Committee must actively monitor
34 and evaluate these reports to determine if the variance achieved of its stated purpose.

35 **5.4.G Open Variance for Expedited Placement**

36 This variance allows participating members to allocate organs in a manner consistent with any
37 expedited placement protocol approved by the Executive Committee. This variance supersedes
38 Policies 5.4.B Order of Allocation, 5.6.B Time Limit for Review and Acceptance of Organ Offers
39 for all participating members, and 5.9 Released Organs.

40 The Executive Committee will approve protocols for expedited placement of
41 organs. Each protocol must include 1) criteria for organs eligible for expedited placement; 2)
42 criteria for candidates eligible to receive expedited placement offers; 3) conditions for the use of
43 expedited placement; and 4) OPO and transplant hospital responsibilities.

44 Approved expedited placement protocols will be made available to the public. Protocols can last
45 no longer than six months unless amended by the Executive Committee.

46 This variance will be monitored for the following metrics:

- 47 • For kidney and liver transplants, Percent of weekly transplants that went to pediatric
48 candidates among the participating members compared to the median percent of
49 weekly transplants that went to pediatric candidates among the participating members
50 for the last six months.
- 51 • Percent of weekly transplants that went to female candidates among the participating
52 members compared to the median percent of weekly transplants that went to female
53 candidates among the participating members for the last six months.
- 54 • Percent of weekly transplants that went to non-white ethnicity candidates among the
55 participating members compared to the median percent of weekly transplants that
56 went to non-white ethnicity candidates among the participating members for the last six
57 months.

58 Expedited placement protocols for a given organ will expire if any of the below respective
59 organ specific conditions occur for any of the above monitoring metrics:

- 60 • One or more points equal to or below the 3-sigma limits; however, if the average
61 sample size over a six month period is less than ten this rule will not apply.
- 62 • Two out of three successive points equal to or below a 2-sigma limit; however, if the
63 average sample size over a six month period is less than ten this rule will not apply.
- 64 • Four out of five successive points equal to or below a 1-sigma limit.
- 65 • A run of eight successive points equal to or below the center line.

OPTN

66 Each participating member must report to the OPTN expedited placements with the the date,
67 time, and match run when they initiate an expedited placement protocol. Participating
68 members must meet monthly to review the results of this variance.

69 This variance will expire on December 31, 2025.

70 #

Attachment 1: Template to Submit Proposed Protocols

Name of submitting organization/individual: _____

- 1) **Explicit clinical criteria for organs eligible for expedited placement.**

- 2) **Explicit criteria for candidates eligible to receive expedited placement offers.**

- 3) **Explicit conditions for the use of expedited placement.**

- 4) **Any OPO and transplant hospital responsibilities.**

Has this protocol been used? Yes/No

If yes, please include any additional results regarding its usage.