

## *Public Comment Proposal*

# 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–January 21, 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.

## 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.<sup>1</sup> 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.<sup>2</sup> 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.<sup>3,4,5,6,7,8,9,10</sup>

OPTN policy does not contain standardized protocols for expedited placement of organs, except for limited liver<sup>11</sup> and pancreata<sup>12</sup> 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.<sup>13, 14</sup> Without a consistent approach to expedited placement, it is difficult to 1) analyze

<sup>1</sup> Minutes of OPTN Executive Committee, Aug 14, 2023.

<sup>2</sup> OPTN Board of Directors Meeting Summary, September 5, 2023.

<sup>3</sup> 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.

<sup>4</sup> 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.

<sup>5</sup> 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](https://www.myast.org/sites/default/files/ceot19/Friday_0815_Salon%20EF_David%20Foley_Expedited%20v2.pdf).

<sup>6</sup> 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.

<sup>7</sup> 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.

<sup>8</sup> 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.

<sup>9</sup> 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](https://nap.nationalacademies.org/resource/26364/Policy_Brief_Transplant_Centers.pdf).

<sup>10</sup> 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.

<sup>11</sup> OPTN Policy 11.6 *Facilitated Pancreas Allocation*.

<sup>12</sup> OPTN Policy 9.10 *Expedited Placement of Livers*.

<sup>13</sup> 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.sstr.org/media/1677/wood\\_atc\\_2023\\_match\\_run\\_deviation.pdf](https://www.sstr.org/media/1677/wood_atc_2023_match_run_deviation.pdf).

<sup>14</sup> 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.

## Overview of Proposal

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.

The Committee is issuing this proposal for a thirty-day public comment period, which is shorter than the usual public comment period. This is to allow the variance to take effect sooner than the end of regular public comment but allow the community time to comment on the proposed variance. It also is in line with the public comment periods for emergency and expedited policy changes.<sup>15</sup>

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

This variance works by charging the Executive Committee to develop 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 to 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

<sup>15</sup> OPTN Bylaw 11.1.A: The Public Comment Period. While proposals are "usually" distributed for at least a 45 day public comment period, NOTA, the OPTN Final Rule, and the OPTN Bylaws do not specify a minimum time period for public comment. This proposal does not meet the criteria for "Emergency Action" under OPTN Bylaw 11.7, nor "Expedited Action" under OPTN Bylaw 11.8.

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?

- 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?

In some ways, variances are an exception to a general policy requirement. This proposed variance supersedes Policies 5.4.B *Order of Allocation* and 5.6.B *Time Limit for Review and Acceptance of Organ Offers*. 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.

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 Taskforce 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 during the public comment period for this proposed 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 18 months from Board approval. To iterate on the expedited placement protocols, individual protocols could 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.
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 likely 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) 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. The Executive Committee will rely upon recommendations from the Expeditious Taskforce 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.<sup>16</sup> 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 three options:

1. Inclusion of specific protocols
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 that the community can comment on proposed protocols under consideration and protocols approved by the Executive Committee. This 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 Taskforce regarding which protocols to test.

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<sup>16</sup> 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.

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 Expedient Taskforce 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. 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.

### *5. Sample Size and Number of Protocols*

One outstanding issue for the OPTN to decide is whether to 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.

Related to this issue is the sample size necessary to analyze this variance. There were currently 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.<sup>17</sup> 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.

**Therefore, the committee requests feedback on this topic during public comment.**

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<sup>17</sup> OPTN Data as of November 20, 2023.



## Changes to the Governance of Variance Process

Variations 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 variations:

**Variations.** 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 variations shall be time limited. Entities or individuals objecting to variations may appeal to the Secretary under the procedures of § 121.4.<sup>18</sup>

OPTN Policy 1.3 sets further requirements for variations. These requirements were created considering variations 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 variations.

Current OPTN Requirement	Proposed OPTN Requirement	Rationale
<p><b>1.3.B Application for a Variance</b> Members wishing to create or amend a variance must submit an application to the OPTN.</p>	<p><b>1.3.B Application for Creation of a Variance</b> Members wishing to create or amend a variance must submit an application to the OPTN. <u>OPTN Committees may also propose new variations without a member application.</u></p> <p><u>Proposed new variations</u> The application must address all of the following:</p>	<p>Prior to overhauling the variance policies in 2012, OPTN policy permitted Committee Sponsored Variations.<sup>19</sup> This concept was incorporated into current policy by requiring variations 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><b>1.3.B Application for a Variance</b> (2) If a member’s application to create, amend, or join a variance will require other members to join the variance, the applicant</p>	<p><b>1.3.B Application for a Variance</b> (2) If a member’s application to create, amend, or join a variance will require other members to join the variance, the applicant</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</p>

<sup>18</sup> 42 CFR 121.8(g).

<sup>19</sup> OPTN, “Briefing Paper: Proposal to Clarify and Improve Variance Policies,” June 2012.

Current OPTN Requirement	Proposed OPTN Requirement	Rationale
<p>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><del>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.</del></p>	<p>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>

Current OPTN Requirement	Proposed OPTN Requirement	Rationale
<p><b>1.3.C Joining an Open Variance</b></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><b>1.3.C Joining an Open Variance</b></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. <del>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.</del></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><b>1.3.D Reporting Requirements for Variances</b></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><b>1.3.D Reporting Requirements for Variances</b></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><b>1.3.D Reporting Requirements for Variances</b></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><b>1.3.D Reporting Requirements for Variances</b></p> <p>...</p> <p><del>Participating members must also provide a final report to the sponsoring Committee at least six months before the variance’s expiration date.</del></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>

## 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.”<sup>20</sup> The OPTN Final Rule states the OPTN “shall be responsible for developing...policies for the equitable allocation for cadaveric organs.”<sup>21</sup> The Final Rule requires that when developing policies for the equitable allocation of cadaveric organs, such policies must be

<sup>20</sup> 42 U.S.C. § 274(b)(2)(B).

<sup>21</sup> 42 C.F.R. § 121.4(a)(1).

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.”<sup>22</sup> This proposal:

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 judgement**<sup>23</sup> 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 organs**<sup>24</sup> and **is designed to avoid wasting organs**<sup>25</sup> by seeking to increase the utilization of organs at high risk of non-utilization.
- **Promotes the efficient management of organ placement**<sup>26</sup> 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,<sup>27</sup> and each protocol will state the specific organ type impacted.<sup>28</sup>

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 transplants<sup>29</sup>
- Is designed to ... promote patient access to transplantation<sup>30</sup>
- Is not based on the candidate’s place of residence or place of listing<sup>31</sup>

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.”<sup>32</sup> 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

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<sup>22</sup> 42 C.F.R. § 121.8(a)

<sup>23</sup> 42 C.F.R. § 121.8(a)(1).

<sup>24</sup> 42 C.F.R. § 121.8(a)(2)

<sup>25</sup> 42 C.F.R. § 121.8(a)(5).

<sup>26</sup> Id.

<sup>27</sup> 42 C.F.R. § 121.8(a)(3).

<sup>28</sup> 42 C.F.R. § 121.8(a)(4).

<sup>29</sup> Id.

<sup>30</sup> Id.

<sup>31</sup> 42 C.F.R. § 121.8(a)(8).

<sup>32</sup> 42 CFR 121.8(b)(2).

candidates, and whoever responds first, without any consideration of the sequence number, would receive the organ.

## 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. 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 Expeditious Taskforce.
- 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.

### 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 might 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.

## Considerations for the Community

- If you have a specific expedited placement protocol for the committee to consider, please include that in your public comment.
- Should the OPTN run multiple, concurrent expedited placement protocols or sequentially run different expedited placement protocols?



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

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

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

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

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

## 36 **5.4.G Open Variance for Expedited Placement**

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

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

45 Approved expedited placement protocols will be made available to the public.

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

49 This variance will expire on July 1, 2025.

50

## 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.