

Notice of OPTN Policy Changes

Expedited Placement Variance

Affected Policies:	1.3: Variances 5.4.G Open Variance for Expedited Placement
Sponsoring Committee:	Committee Name
Public Comment Period:	December 22, 2023– February 5, 2024
Board Meeting:	March 26, 2024
Effective Date:	April 2, 2024

Purpose of Policy Changes

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.

Proposal History

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 was released for special public comment from December until February. Following public comment, the Executive Committee met to discuss comments (both operational issues and policy changes), then these revisions were presented to the community at a town hall in March. The Executive Committee then revised the policy language consistent with the public comment and townhall feedback and on March 25th approved the policy proposal for Board consideration.

Summary of Changes

- Creates a new variance to test different expedited placement variances.
- Updates OPTN governance rules of variances to account for recent changes in policy development process and short term, iterative variances.

Implementation

- Interested individuals should view information on the OPTN website about proposed and approved expedited placement variances.
- Interested OPTN members should sign up for the variance.
- Interested individuals may submit proposed expedited placement protocols according to the instructions on the OPTN website.

The OPTN will update the OPTN website with information about proposed protocols and the results of approved protocols. The website will also allow interested individuals to provide feedback on both of those and additionally submit proposed protocols. The OPTN website will also contain information for

members interested in joining the variance. Finally, the OPTN will create new bypass codes to track the usage of each protocol.

Affected Policy Language

Proposed new language is underlined (example) and language that is proposed for removal is struck through (~~example~~).

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 to~~
11 ~~join the proposed variance.~~

12 ~~2. 3.~~ A defined expiration date or period of time when the variance will end, the participating members will
13 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 variance's
15 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 specific
21 variance. When an open variance is created, it may set conditions for the OPTN Contractor to approve
22 certain applications. ~~However, if the application to join an existing open variance does not receive~~
23 ~~affirmative support from all of the members required to join by the application, the OPTN Contractor may~~
24 ~~not approve the application and only the sponsoring Committee may approve the application.~~

25 1.3.D Reporting Requirements for Variances

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

28 1. Evaluate whether the variance is achieving its stated purpose

29 2. Provide data for the performance measures in the variance application

30 3. Address any organ allocation problems caused by the variance

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

34 5.4.G Open Variance for Expedited Placement

35 This variance allows participating members to allocate organs in a manner consistent with any
36 expedited placement protocol approved by the Executive Committee. This variance supersedes

37 Policies 5.4.B Order of Allocation, 5.6.B Time Limit for Review and Acceptance of Organ Offers
38 for all participating members, and 5.9 Released Organs.

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

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

45 This variance will be monitored for the following metrics:

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

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

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

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

68 This variance will expire on December 31, 2025.

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.