

within the context of a points-based allocation system.²⁴ Upon further discussion, the Committee agreed that it would be more efficient to extend and align the end dates of all four variances, which would allow the Committee to focus on incorporating aspects of the variances into OPTN policy within a continuous distribution framework.

The Committee began work on developing a points-based framework, or continuous distribution, in December 2021. The purpose of the new allocation system is to remove the hard boundaries that exist in current organ allocation and to create a more flexible, equitable, and transparent allocation system.²⁵ The Committee is working towards developing a proposal for community input in 2024 with an implementation date tentatively slated for 2025.

The current liver variances utilize a classification-based structure, which aligns with the current allocation system. However, these classifications will be eliminated with the implementation of continuous distribution. During the Committee's development of continuous distribution, they will review the liver variances and incorporate aspects of each variance as appropriate, and convert these aspects from their current classification-based structure to a points-based framework. For example, current liver allocation policy factors in blood type of both the transplant candidate and the deceased donor.²⁶ As the Committee considers candidate biology in a points-based allocation system, they may include aspects of the ABO Blood Type Variance into the attribute for candidate blood type. This means that through the development of continuous distribution, the Committee will have the ability to address appropriate access to transplant for candidates registered in HI and PR by giving specific consideration and weight to these populations.

Similarly, the Committee has discussed how they could incorporate aspects of the split liver variances into continuous distribution to increase the number of split liver transplants in the upcoming points-based framework.²⁷

Proposal for Board Consideration

The Committee proposes the four variances in OPTN liver allocation policy expire upon implementation of continuous distribution and allocation of livers and intestines. The Committee will continue to monitor each of the four variances annually. If the data reveals the need to modify the variances prior to the implementation of continuous distribution, the Committee may sponsor a proposal to address any identified problem.

This proposal does not change the content of any of the four variances. This proposal extends and aligns the expiration dates of the four variances so that the Committee can focus on the development of continuous distribution rather than extending and amending variances throughout the process. The proposed project has no expected changes for transplant programs, but terminating the variances prior to the implementation of continuous distribution would affect transplant program split liver procurement practices and access to transplant for candidates registered at transplant programs in HI and PR.

²⁴ OPTN Liver and Intestinal Organ Transplantation Committee, *Meeting Summary*, May 6, 2022.

https://optn.transplant.hrsa.gov/media/1rchv1yc/20220506_liver_summary_final.pdf

²⁵ OPTN, *Continuous Distribution*. Available at <https://optn.transplant.hrsa.gov/policies-bylaws/a-closer-look/continuous-distribution/>.

²⁶ OPTN Policy: 9.8.C: Allocation of Livers by Blood Type

²⁷ OPTN Liver and Intestinal Organ Transplantation Committee, *Meeting Summary*, April 4, 2022.

Overall Sentiment from Public Comment

This proposal was released for public comment from August 3, 2022 to September 28, 2022. The proposal was on the non-discussion agenda during regional meetings. Feedback on the proposal was received via the OPTN website and sentiment polling during regional meetings.²⁸ Most public comment expressed support for the proposed alignment and extension of expiration dates for the four variances. As seen in **Figure 1**, most of the regions indicated sentiment of support for the Committee’s *Review of Liver and Intestine Variances* proposal.²⁹

Figure 1: Sentiment by Region

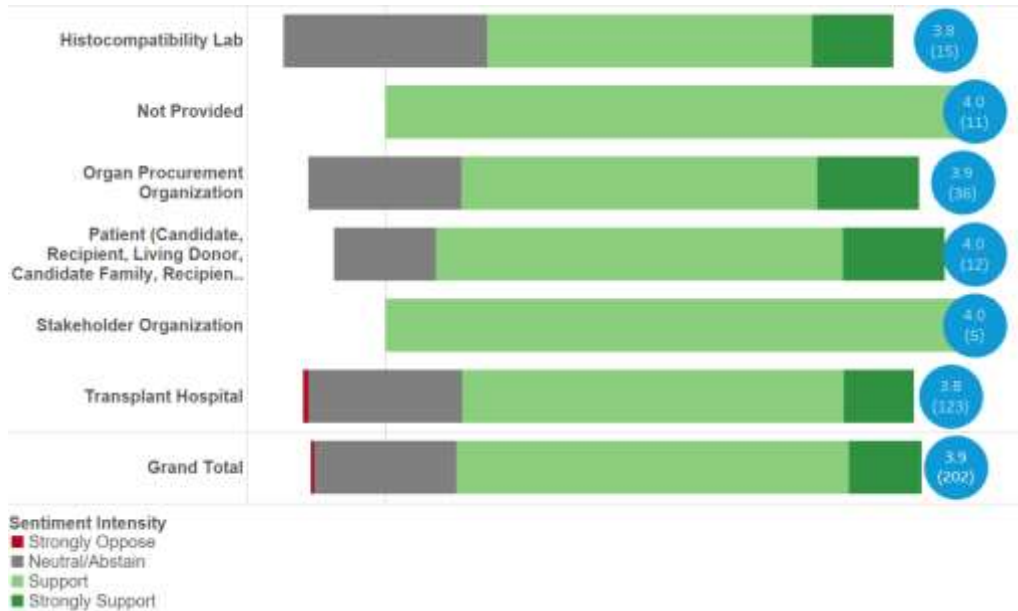


²⁸ All public comments submitted on the proposal are available at <https://optn.transplant.hrsa.gov/>.

²⁹ This chart shows the sentiment for the public comment proposal. Sentiment is reported by the participant using a 5-point Likert scale (1-5 representing Strongly Oppose to Strongly Support). Sentiment for regional meetings only includes attendees at that regional meeting. Region 6 uses the average score for each institution. The circles after each bar indicate the average sentiment score and the number of participants is in the parentheses

Public comment by member type is below in **Figure 2**.³⁰

Figure 2: Sentiment by Member Type



The transplant community recognized that the proposed extension and alignment of the four variance expiration dates will allow the Committee to incorporate aspects of the variances into the continuous distribution of livers and intestines. American Society of Transplant Surgeons (ASTS), American Society of Transplantation (AST), and NATCO all submitted supportive sentiment for the proposal during public comment. ASTS noted a caveat that they are supportive as long as the implementation of continuous distribution occurs in a reasonable period of time.

Sentiment from regional meetings was also supportive. Regional members recommended that split liver allocation should be promoted. Another regional member was opposed to the proposal and commented that ineffective variances should be discontinued. There was an additional anonymous public comment submitted that was out of scope for this project.

Compliance Analysis

NOTA and OPTN Final Rule

This project is authorized by the NOTA which states that the OPTN shall, "carry out studies and demonstration projects for the purpose of improving procedures for organ donation procurement and allocation, including but not limited to projects to examine and attempt to increase transplantation

³⁰ This chart shows the sentiment for the public comment proposal. Sentiment is reported by the participant using a 5-point Likert scale (1-5 representing Strongly Oppose to Strongly Support). Sentiment by member type includes all comments. The circles after each bar indicate the average sentiment score and the number of participants is in the parentheses.

liver transplants, thereby increasing access to transplant for pediatric candidates and small-statured adults.

The Committee discussed if any populations would be disadvantaged by this proposal and did not identify any such populations. As such, the Committee agreed that no transition procedures are required for this proposal.³⁸

Implementation Considerations

Histocompatibility Laboratories

Operational Considerations

No anticipated impact affecting histocompatibility laboratories.

Fiscal Impact

There is no expected fiscal impact for histocompatibility laboratories.

Organ Procurement Organizations

Operational Considerations

Organ procurement organizations will need to be familiar with the variances and continue to work with transplant programs who are participating in the variances to allocate livers and intestines accordingly.

Fiscal Impact

There is no expected fiscal impact for organ procurement organizations.

Transplant Programs

Operational Considerations

Extending the variances will keep the current allocation system in place until the implementation of continuous distribution.

Fiscal Impact

There is no expected impact for transplant hospitals.

OPTN

Resource Estimates

The OPTN contractor estimates 17 hours for implementation. Implementation will involve standard communication efforts to inform the transplant community of the extension to liver variance end dates.

³⁸ OPTN Liver and Intestinal Organ Transplantation Committee, *Meeting Summary*, October 11, 2022.

The OPTN contractor estimates 245 hours for ongoing support. Ongoing support will involve answering member questions and ongoing, annual monitoring of the four variances, using pre vs. post comparisons, until the implementation of continuous distribution and allocation of livers and intestines.

Post-implementation Monitoring

Member Compliance

This proposal will not change current routine monitoring of OPTN members. The OPTN may review any data entered in the OPTN Computer System, and members must provide documentation as requested.

Policy Evaluation

Using pre vs. post comparisons, the four variances will continue to be monitored annually until the implementation of continuous distribution and allocation of livers and intestines using the following metrics:

Open Variance for Segmental Liver Transplantation

Metrics will be evaluated for participating OPOs and OPTN Regions and performed in comparison to the nation. Metrics to be evaluated include:

- The number (and percent) of split liver transplants overall, and by both recipient and donor demographics, including but not limited to:
 - Recipient age, allocation MELD/PELD or status at transplant
- Descriptive statistics on primary and secondary recipient of split liver, including but not limited to:
 - Recipient age, allocation MELD/PELD or status at transplant, gender, OPTN Region
- Geography of secondary recipient of liver segment as it relates to primary recipient

Closed Variance for Allocation of Blood Type O Deceased Donor Livers

Metrics for Hawaii and Puerto Rico will be performed in comparison to the nation and stratified by blood type where feasible and appropriate. Metrics to be evaluated include:

- Number of deceased donor liver transplants
- Size and composition of the waiting list
- Discard rates (Number of livers recovered for transplant and not transplanted)
- Number and percent of organs distributed to and from Hawaii
- Number and percent of organs distributed to and from Puerto Rico

Closed Variance for Any Segment Liver Transplantation

Metrics for OPTN Region 8 will be performed in comparison to the nation and include:

- The number (and percent) of liver transplants (whole vs. segment) overall, and by both recipient and donor demographics, including but not limited to:
 - Recipient age, allocation MELD or PELD or status at transplant, primary recipient liver segment (left lobe or left-lateral segment vs. right lobe or right tri-segment)
- Descriptive statistics on primary and secondary recipient of split liver, including but not limited to:
 - Allocation MELD or PELD or status at transplant, gender, OPTN Region

- Geography of secondary recipient of liver segment as it relates to primary recipient
- The number (and percent) of deceased donor liver transplant programs performing split liver transplants

Closed Variance for Liver Transplantation in Hawaii and Puerto Rico

Metrics will be performed for transplant programs in Hawaii and Puerto Rico and include:

- Number of liver candidates ever waiting at Status 1A, Status 1B, or MELD or PELD 37 or higher
- Number of liver match runs with a liver acceptance that contain at least one Status 1A, Status 1B, or MELD or PELD 37 or higher potential liver candidate
 - Distribution of distance (NM) from donor hospital to liver transplant program for these match runs
- Number of deceased donor liver transplants for Status 1A, Status 1B, or MELD or PELD 37 or higher
 - Distribution of distance (NM) from donor hospital to liver transplant program for deceased liver donor recipients
- Number of liver candidates removed from the waiting list due to death or too sick to transplant while listed at Status 1A, Status 1B, or MELD or PELD 37 or higher
- Distribution of time in Status 1A, Status 1B, or MELD or PELD 37 or higher before waitlist removal

Conclusion

The Committee proposes to align the expiration dates of the four variances in OPTN liver policy to expire upon implementation of continuous distribution and allocation of livers and intestines. Alignment of the expiration dates will allow for more consistent evaluation and administration, as the Committee develops a points-based allocation system for liver and intestinal organs. While the Committee develops the continuous distribution framework, they can comprehensively address whether, and how, to include the variances into permanent OPTN policy.

Policy Language

1 **RESOLVED, the following variances are hereby extended to expire upon the implementation**
2 **of the continuous distribution of livers and intestines.**

3 4 **9.12 Variances**

5 6 **9.12.A Open Variance for Segmental Liver Transplantation**

7
8 This variance only applies when a transplant program transplants a right lobe or right trisegment
9 of the liver.

10
11 Under this variance, a transplant program may offer the remaining left lobe or left-lateral
12 segment into a different, medically suitable, potential recipient registered at the same
13 transplant hospital or an affiliated pediatric institution instead of offering the remaining
14 segment to potential recipients at other transplant programs. The transplant program must
15 determine potential recipient for the second segment by using the same match run used to
16 allocate the right lobe or tri-segment. Additionally, the transplant program must document all
17 refusals of potential transplant recipients that are prioritized ahead of the potential transplant
18 recipient that received the second segment.

19
20 Each participating region or DSA must meet to review the results of the first ten segmental liver
21 transplants performed as a result of this variance, and each ten thereafter. If the re-transplant
22 rate for segmental liver transplant recipients at any liver transplant program participating in the
23 variance exceeds three within any sequential twenty transplants, the variance at that transplant
24 program will be put on hold until the transplant program can review results and surgical
25 practices.

26 27 **9.12.B Closed Variance for Allocation of Blood Type O Deceased Donor Livers**

28
29 This is a closed variance that applies only to liver and liver-intestine organs allocated by the
30 OPOs in Hawaii and Puerto Rico to potential transplant recipients registered at transplant
31 programs in Hawaii and Puerto Rico, respectively due to geographic location. This variance
32 supersedes the treatment of blood type O donors according to 9.8.C Allocation of Livers by
33 Blood Type, and instead the OPO will allocate these blood type O organs to potential transplant
34 recipients with any blood type within the same classification.

35 36 **9.12.C Closed Variance for Any Segment Liver Transplantation**

37
38 This is a closed variance. The OPTN maintains a list of participating transplant programs.
39 If a participating transplant program chooses to split an accepted liver, the program will decide
40 which segment of the liver to transplant into the intended recipient. The transplant program
41 must notify the host OPO of the remaining segment prior to transplanting the remaining
42 segment. The OPO must then offer the remaining segment to the following potential transplant
43 recipients, using the same match run used to allocate the liver:

44

- 45 • Lower-ranked status 1A and 1B potential transplant recipients registered at any
 46 transplant hospital within 500 nautical miles of the donor hospital
 47 • Lower-ranked potential transplant recipients with a MELD or PELD of 33 or higher that
 48 are registered at any transplant hospital within 500 nautical miles of the donor hospital
 49

50 If the remaining segment is not accepted for any of the potential transplant recipients in the
 51 bulleted classifications listed above, the OPO must notify the participating transplant program
 52 that accepted the liver. The participating transplant program may then transplant the remaining
 53 segment into a different, medically suitable, candidate registered at the same transplant
 54 hospital or an affiliated transplant program with an active pediatric liver component. If the first
 55 segment is accepted for a pediatric potential transplant recipient, the participating transplant
 56 program may transplant the remaining segment into a different, medically suitable, candidate at
 57 the same transplant hospital or an affiliated transplant program. For purposes of this variance,
 58 participating transplant programs may only have one affiliated transplant program, and must
 59 identify the program they are affiliated with in their application for the variance.
 60

61 If the participating transplant program declines the remaining segment, the OPO may offer the
 62 remaining segment to any lower ranked potential transplant recipients off the same match run
 63 used to allocate the liver to the recipient of the first segment.
 64

65 **9.12.D Closed Variance for Liver Transplantation in Hawaii and Puerto Rico**

66
 67 This is a closed variance that applies only to liver and liver-intestine candidates registered at
 68 transplant programs in Hawaii or Puerto Rico, due to geographic location. This variance provides
 69 for additional classifications in the allocation sequences in Policies 9.8.E-9.8.J. The additional
 70 classifications apply to the following:
 71

- 72 • Candidates registered at transplant programs in Hawaii when the transplant hospital is
 73 at or within 2,400 NM of the donor hospital.
 74 • Candidates registered at transplant programs in Puerto Rico when the transplant
 75 hospital is at or within 1,100 NM of the donor hospital.
 76

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