

*Briefing to the OPTN Board of Directors on*

# **Review of Liver and Intestine Variances in OPTN Policy**

*OPTN Liver and Intestinal Organ Transplantation Committee*

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# Review of Liver and Intestine Variances in OPTN Policy

<i>Affected Policies:</i>	<p><i>9.12.A: Open Variance for Segmental Liver Transplantation</i></p> <p><i>9.12.B: Closed Variance for Allocation of Blood Type O Deceased Donor Liver</i></p> <p><i>9.12.C: Closed Variance for Any Segment Liver Transplantation</i></p> <p><i>9.12.D: Closed Variance for Liver Transplantation in Hawaii and Puerto Rico</i></p>
<i>Sponsoring Committee:</i>	<i>Liver and Intestinal Organ Transplantation</i>
<i>Public Comment Period:</i>	<i>August 3, 2022 - September 28, 2022</i>
<i>Executive Committee Meeting:</i>	<i>October 26, 2022</i>

## Executive Summary

There are four different variances, policies which test potential changes to OPTN policy on a smaller scale, related to the allocation of livers and intestines in OPTN policy. Two variances provide increased access to transplant for candidates registered in Hawaii (HI) and Puerto Rico (PR) due to their geographic isolation.<sup>1,2</sup> The other two variances relate to the allocation of split liver segments, with the intent of increasing the number of split liver transplants.<sup>3,4</sup> Each of these variances has a different expiration date. The OPTN Liver and Intestinal Organ Transplantation Committee (the Committee) is proposing to align the expiration dates of the four variances in OPTN policy to expire upon implementation of continuous distribution of livers and intestines.

Alignment of the expiration dates will allow for more consistent evaluation and administration, while simplifying the Committee's project portfolio as they focus on continuous distribution. As the Committee develops a points-based system for liver and intestine allocation, they will comprehensively address whether, and how, to include the variances in the new allocation framework.

Public comment received on this proposal was supportive of aligning and extending the expiration dates of the four variances.

<sup>1</sup> OPTN Policy: 9.12.B: Closed Variance for Allocation of Blood Type O Deceased Donor Livers, as of June 2022

<sup>2</sup> OPTN Policy 9.12.A: Open Variance for Segmental Liver Transplantation, as of June 2022

<sup>3</sup> OPTN Policy 9.12.C: Closed Variance for Any Segment Liver Transplantation, as of June 2022

<sup>4</sup> OPTN Policy 9.12.D: Closed Variance for Liver Transplantation in Hawaii and Puerto Rico, as of June 2022

## Purpose

The purpose is to align the expiration dates of the four variances in OPTN policy to expire upon the implementation of continuous distribution of liver and intestines. Aligning the variances’ expiration dates with the implementation of continuous distribution will allow the OPTN Liver and Intestinal Organ Transplantation Committee (the Committee) to holistically consider which aspects of the four variances require incorporation into permanent OPTN policy, as they develop the new points-based allocation framework.

## Background

Through the authority of the National Organ Transplant Act (NOTA) and the OPTN Final Rule, the OPTN sponsors policy variances to test potential changes to OPTN policy on a smaller scale.<sup>5</sup> Variances may be considered experimental policies, and are accompanied by specific research designs, monitoring, and analysis plans.<sup>6</sup> OPTN policy highlights acceptable variances, such as, but not limited to, those that address alternative allocation systems, alternative local units, sharing arrangements, or alternative point assignment systems.<sup>7</sup>

This proposal is to extend the following variances in OPTN liver allocation policy to expire upon the implementation of continuous distribution of liver and intestinal organs. There are four variances in current OPTN liver allocation policy (**Table 1**) which trial alternative allocation systems. Two variances provide increased access to transplant for liver transplant candidates registered in Hawaii (HI) and Puerto Rico (PR) due to the geographic isolation of the islands.<sup>8,9</sup> The other two variances relate to the allocation of split liver segments, with the intent of increasing the number of available grafts.<sup>10,11</sup>

**Table 1: Description of Policy 9.12: Variances**

Variance	Description
<i>Policy 9.12.A: Open Variance for Segmental Liver Transplantation</i>	Allows transplant programs that transplant a right lobe or right tri-segment into an index candidate to transplant the left lobe or left lateral segment into another liver transplant candidate on the same match run at the same transplant program
<i>Policy 9.12.B: Closed Variance for Allocation of Blood Type O Deceased Donor Livers</i>	Removes priority for O and B liver transplant candidates so that potential liver transplant recipients with any blood type within the same classifications for blood type O deceased donors in HI and PR

<sup>5</sup> 42 USC §274(b)(2)(N); 42 CFR §121.8(g)

<sup>6</sup> 42 CFR §121.8(g)

<sup>7</sup> OPTN Policy 1.3.A: Acceptable Variances, as of June 2022

<sup>8</sup> OPTN Policy: 9.12.B: Closed Variance for Allocation of Blood Type O Deceased Donor Livers, as of June 2022

<sup>9</sup> OPTN Policy 9.12.A: Open Variance for Segmental Liver Transplantation, as of June 2022

<sup>10</sup> OPTN Policy 9.12.C: Closed Variance for Any Segment Liver Transplantation, as of June 2022

<sup>11</sup> OPTN Policy 9.12.D: Closed Variance for Liver Transplantation in Hawaii and Puerto Rico, as of June 2022

Variance	Description
<i>Policy 9.12.C: Closed Variance for Any Segment Liver Transplantation</i>	Permits transplant programs in Region 8 to offer the second segment of a split liver for transplant into a liver transplant candidate at same transplant program after being offered to potential transplant recipients with a MELD or PELD 33+ and Status 1A or Status 1B within 500 NM of the donor hospital
<i>Policy 9.12.D: Closed Variance for Liver Transplantation in Hawaii and Puerto Rico</i>	Provides additional access to deceased donor livers for Status 1A or Status 1B or MELD or PELD 37+ liver transplant candidates in HI and PR due to geographic isolation

Public comments submitted for this proposal were supportive of aligning and extending the expiration dates for each of the four variances described below.

### *Open Variance for Segmental Liver Transplantation*

The first split liver variance, *Policy 9.12.A: Open Variance for Segmental Liver Transplantation*, is commonly referred to as the "Open Split Liver Variance." This open variance<sup>12</sup>, which was approved by the OPTN Board of Directors (the Board) in 2011, allows participating transplant programs to offer a left lateral segment or left lobe to another potential transplant recipient at the same program or an affiliated pediatric program if the right tri-segment or right lobe is transplanted into the index candidate<sup>13</sup> at that program.<sup>14,15</sup> To determine the potential liver recipient for the second segment, the transplant program must use the same match run that was used to allocate the first segment. This variance does not currently have an expiration date.

### *Closed Variance for Allocation of Blood Type O Deceased Donor Livers*

*Policy 9.12.B: Closed Variance for Allocation of Blood Type O Deceased Donor Livers*, commonly referred to as the "ABO Blood Type Variance," was implemented in HI in 1994 and extended to include PR as part of the Acuity Circles (AC) policy in 2020.<sup>16</sup> The closed variance<sup>17</sup> allows for the allocation of deceased donor livers with blood type O that are recovered in HI or PR to liver transplant candidates with blood type A or AB in HI and PR, respectively, before national offers to O and B candidates.<sup>18</sup> In effect, the purpose of the variance is to keep more blood type O deceased donor livers on the islands, rather than allocating to liver transplant candidates within the contiguous US. This variance is set to expire on February 6, 2024.

During public comment, Region 3 noted that LifeLink of Puerto Rico needs this variance to continue to ensure appropriate access to transplant.

<sup>12</sup> An open variance allows members, other than the members that applied for the variance, to join it.

<sup>13</sup> An index candidate is the candidate at the top of the allocation match run.

<sup>14</sup> OPTN Liver and Intestinal Organ Transplantation Committee, *Report to the OPTN Board of Directors* November 14, 2011 – November 15, 2011.

<sup>15</sup> OPTN Policy 9.12.A

<sup>16</sup> OPTN Liver and Intestinal Organ Transplantation Committee, *Mini-Brief*, Extending Hawaii and Puerto Rico Blood Type Variance. Public Comment Period October 8, 2018 – November 1, 2018.

<sup>17</sup> A closed variance is not open for other members to join it.

<sup>18</sup> OPTN Policy 9.12.B

### *Closed Variance for Any Segment Liver Transplantation*

The second split liver variance is the "Region 8 Variance," as outlined in *Policy 9.12.C: Closed Variance for Any Segment Liver Transplantation*. This closed variance applies solely to members in Region 8 (Colorado, Iowa, Kansas, Nebraska, Missouri, and Wyoming). It allows participating transplant programs to accept a liver offer, transplant either segment into the index candidate, and transplant the remaining segment into another, medically suitable potential transplant recipient at the same transplant program. Whereas the Open Split Liver variance requires the right tri-segment or right lobe to be transplanted into the index candidate, under the Region 8 variance, the participating transplant program can transplant either segment or lobe into the index candidate. In addition, in the Region 8 variance, the remaining segment must first be allocated to a potential liver recipient listed as Status 1A or Status 1B within 500 nautical miles (NM) of the donor hospital and those with a MELD or PELD 33 or higher within 500 NM of the donor hospital.<sup>19</sup> If the remaining segment is not accepted for any potential transplant recipient, then the participating transplant program may transplant the remaining segment into a different, medically suitable potential liver recipient registered at the same transplant program, or an affiliated transplant program with an active pediatric liver program. The variance was implemented on December 3, 2019 and is set to expire on December 3, 2022.<sup>20</sup>

During public comment, it was suggested by Region 11 that the Region 8 variance should be extended across the country.

### *Closed Variance for Liver Transplantation in Hawaii and Puerto Rico*

The second HI/PR variance, typically referred to as the "Access for Medically Urgent Candidates Variance," provides additional access, by way of additional classifications in specific allocation sequences, to deceased donor livers in the contiguous US.<sup>21</sup> These additional classifications are for candidates listed as Status 1A or Status 1B or with a MELD or PELD score 37 or higher in HI and PR. The variance helps to ensure highly urgent liver transplant candidates in HI and PR are able to access transplant due to fewer deceased donor organs available on the islands.<sup>22</sup> This variance was implemented on February 18, 2020 and is set to expire on February 18, 2025.

During public comment, Region 3 noted that LifeLink of Puerto Rico needs this variance to continue to allow for equitable access to transplant for the most medically urgent candidates.

### *Variance Considerations*

As detailed above, the expiration dates of the four variances in current OPTN liver allocation policy vary. Since the Region 8 variance will expire on December 3, 2022, the Committee began to discuss whether the variance should be terminated, incorporated into OPTN policy, or if the end date should be extended to allow for more data collection.<sup>23</sup> The Committee discussed several modifications to the Region 8 variance but ultimately decided that extending the end date of the Region 8 variance would allow for more time to develop a larger, more comprehensive solution to increase split liver transplant

<sup>19</sup> OPTN Policy 9.12.C

<sup>20</sup> OPTN Liver and Intestinal Organ Transplantation Committee, *Briefing Paper*, Split Liver Variance. Public Comment Period January 22, 2019 – March 22, 2019. [https://optn.transplant.hrsa.gov/media/2992/liver\\_boardreport\\_201906.pdf](https://optn.transplant.hrsa.gov/media/2992/liver_boardreport_201906.pdf)

<sup>21</sup> OPTN Policy 9.12.D

<sup>22</sup> *Ibid.*

<sup>23</sup> OPTN Liver and Intestinal Organ Transplantation Committee, *Meeting Summary*, April 4, 2022. [https://optn.transplant.hrsa.gov/media/rgcloilq/20220404\\_liver\\_summary.pdf](https://optn.transplant.hrsa.gov/media/rgcloilq/20220404_liver_summary.pdf)

within the context of a points-based allocation system.<sup>24</sup> 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.<sup>25</sup> 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.<sup>26</sup> 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.<sup>27</sup>

## 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.

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

[https://optn.transplant.hrsa.gov/media/1rchv1yc/20220506\\_liver\\_summary\\_final.pdf](https://optn.transplant.hrsa.gov/media/1rchv1yc/20220506_liver_summary_final.pdf)

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

<sup>26</sup> OPTN Policy: 9.8.C: Allocation of Livers by Blood Type

<sup>27</sup> 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.<sup>28</sup> 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.<sup>29</sup>

**Figure 1: Sentiment by Region**

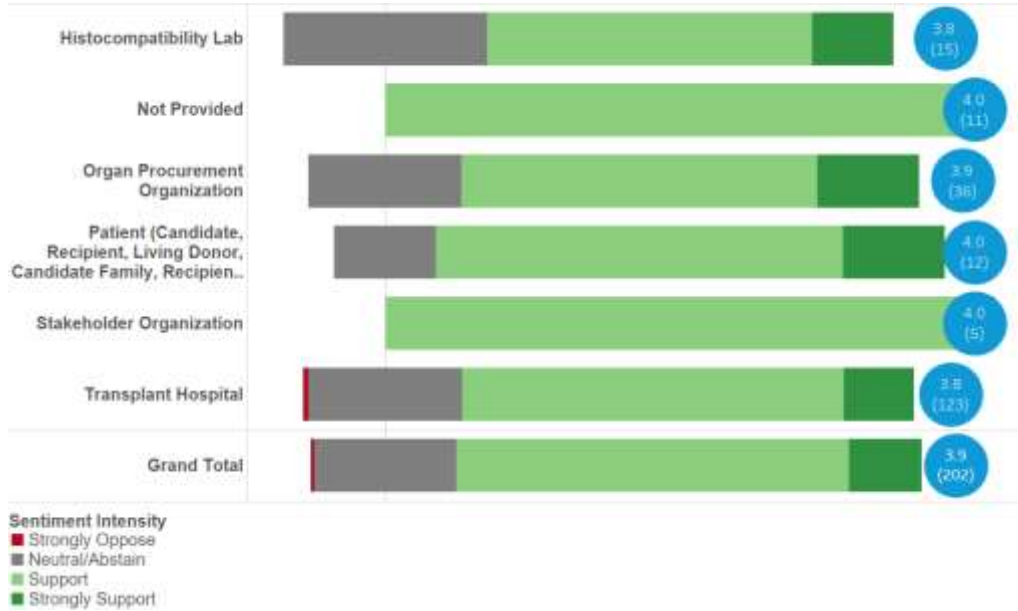


<sup>28</sup> All public comments submitted on the proposal are available at <https://optn.transplant.hrsa.gov/>.

<sup>29</sup> 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**.<sup>30</sup>

**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

<sup>30</sup> 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.



among populations with special needs, including children and individuals who are members of racial or ethnic minority groups, and among populations with limited access to transportation."<sup>31</sup>

Additionally, the OPTN Final Rule states, "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."<sup>32</sup> As stated, this project complies with the Final Rule by addressing the time limitations of the four variances in OPTN liver allocation policy.

## OPTN Strategic Plan

Per alignment with the OPTN Strategic Plan, this proposal seeks to increase the number of transplant and improve equity in access to transplants.

## Potential Impact on Select Patient Populations

The HI and PR variances ensure liver transplant candidates on the two islands are able to access transplant in a timely and equitable manner. The Access for Medically Urgent Candidates Variance allows highly urgent liver candidates on the islands increased access to deceased donor livers.<sup>33</sup> Similarly, the ABO Blood Type Variance creates an opportunity for organs to remain on the islands before being offered more broadly and accounts for the distinct blood type prevalence in the population.<sup>34</sup>

The two variances specific to split liver transplantation are important because it is a particularly beneficial procedure for pediatric and small-stature candidates who are able to receive a smaller liver graft, while the larger section of the liver can be transplanted into larger adult candidates.<sup>35</sup> Research has shown that smaller stature adults, particularly females, are disadvantaged in the current liver allocation system.<sup>36,37</sup> Increasing the number of split liver transplants could help this population of candidates access transplant in a more timely manner. While both split liver variances are intended to increase available grafts for transplant and increase access to transplant for individuals of small stature, the Region 8 variance specifically affects those individuals in the area of Region 8.

Extending the variances until the implementation of continuous distribution will ensure that candidates in HI and PR continue to have appropriate access to transplant. It may also increase the number of split

<sup>31</sup> 42 U.S.C. §274(b)(2)(N)

<sup>32</sup> 42 CFR Part 121.8(g) prior to implementation

<sup>33</sup> OPTN Liver and Intestinal Organ Transplantation Committee, *Briefing Paper, Access for Urgent Liver Candidates in Hawaii and Puerto Rico*. Public Comment Period December 5, 2019 – January 9, 2020.

<sup>34</sup> OPTN Liver and Intestinal Organ Transplantation Committee, *Notification of OPTN Variance Extension, Extending Hawaii and Puerto Rico Closed Blood Type Variance*. Public Comment Period October 8, 2018 – November 1, 2018. [https://optn.transplant.hrsa.gov/media/k3smcapv/policy-notice\\_liver\\_hi\\_pr\\_variance.pdf](https://optn.transplant.hrsa.gov/media/k3smcapv/policy-notice_liver_hi_pr_variance.pdf)

<sup>35</sup> Ge J, Perito ER, Bucuvalas J, Gilroy R, Hsu EK, Roberts JP, Lai JC. Split liver transplantation is utilized infrequently and concentrated at few transplant centers in the United States. *Am J Transplant*. 2020 Apr;20(4):1116-1124. doi: 10.1111/ajt.15696.

<sup>36</sup> Jin Ge and Jennifer C. Lai, "Identifying a Clinically Relevant Cutoff for Height That Is Associated with a Higher Risk of Waitlist Mortality in Liver Transplant Candidates," *American Journal of Transplantation* 20, no. 3 (April 2019): pp. 852-854, <https://doi.org/10.1111/ajt.15644>.

<sup>37</sup> Jayme E. Locke et al., "Quantifying Sex-Based Disparities in Liver Allocation," *JAMA Surgery* 155, no. 7 (2020), <https://doi.org/10.1001/jamasurg.2020.1129>.

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.<sup>38</sup>

## 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.

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<sup>38</sup> 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

77 #