Briefing Paper

Enhancing Liver Distribution

OPTN/UNOS Liver and Intestinal Organ Transplantation Committee

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Enhancing Liver Distribution

Affected Policies:	*Policies 1.2: Definitions, 5.4.B: Order of Allocation, 9.1.D: MELD Score, 9.8: Liver Allocation, Classifications, and Rankings, and 9.11: Variances*
Sponsoring Committee:	*Liver and Intestinal Organ*
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Board of Director's Date:	*December 4-5, 2017*

Executive Summary

Over a 5-year period during the 1990's, the OPTN tried and failed to reach consensus on liver allocation policy revisions aimed at broader sharing for liver allografts, particularly for the most urgent patients. The Secretary of Health and Human Services became involved and one result was implementation of federal transplant regulations, the OPTN Final Rule in March 2000. The Rule stipulates that OPTN allocation policies must, among other factors, be based on sound medical judgment, seek to achieve the best use of donated organs, and shall not be based on the candidate's place of residence or place of listing except to the extent needed to satisfy other regulatory requirements.[1]

During the years immediately following Final Rule implementation, the MELD and PELD disease severity scoring systems were developed, seen as the first necessary step before readdressing broader liver sharing.[2] On November 13th, 2012, the OPTN/UNOS Board of Directors directed all organ-specific committees to identify allocation equity metrics appropriate to their organ types.[3] The Liver and Intestinal Organ Transplantation Committee (hereafter called "the Committee") selected variance in median MELD at time of transplant (for exception and non-exception candidates), among other metrics, and observed continued and significant variance in this metric across regions. The Board instructed the Committee to develop evidence-based policy proposals aimed at reducing this variance in accordance with the Final Rule.

The OPTN recognizes that there are not enough organs for patients in need of lifesaving transplants and is invested in increasing the number of transplants each year by increasing donation, reducing organ discards, and improving OPO performance. However, these efforts will not change the fact that current regional boundaries often physically separate urgent candidates from donors in close proximity.

In progress for the last 5 years, the current proposal strives to balance equity in access while limiting the impact on travel and logistics. The Committee proposes a solution that implements a 150 nautical mile radius sharing circle around the donor hospital and increased sharing within the region. The 150 mile circle may include candidates outside of the region. Candidates at transplant hospitals within the circle will receive 3 additional MELD or PELD points. The Committee proposes sharing in the initial broader classification to be limited to candidates with a calculated MELD of at least 32 (candidate age greater than 18 at time of registration) and allocation MELD or PELD of at least 32 (candidate age less than 18). The Committee also proposes a separate allocation classification for DCD donors or donors at least 70 years old. The new allocation for these donors is expected to increase utilization and address concerns with the broader sharing of specific donor livers.

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[1] 42 C.F.R. § 121.8, available at Electronic Code of Federal Regulations

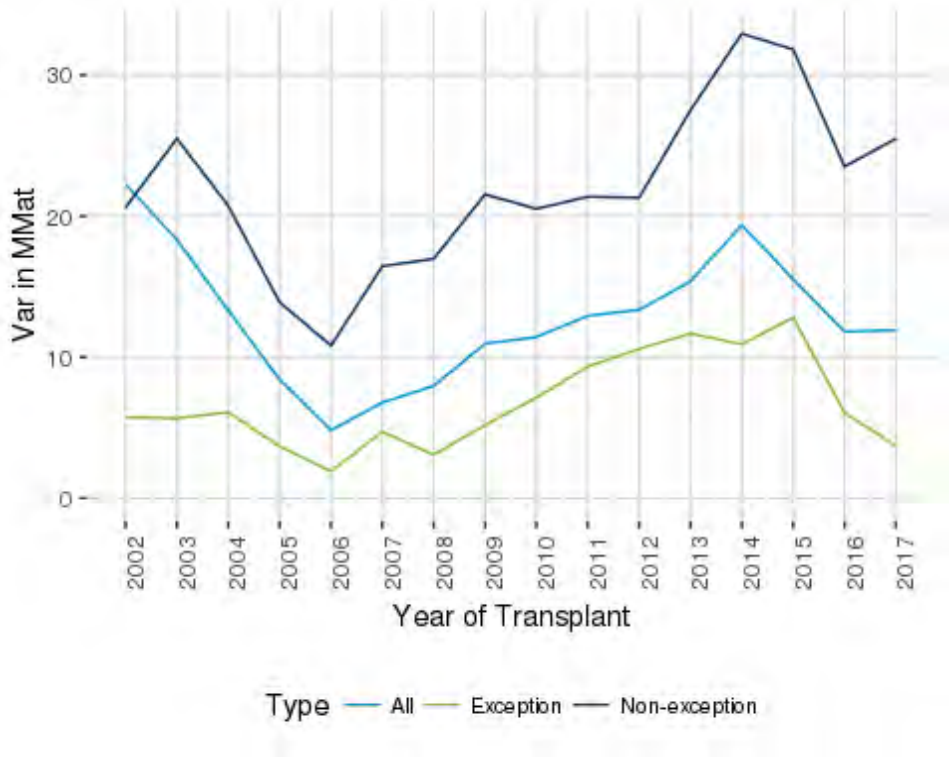
[2] A liver candidate receives a Model for End-Stage Liver Disease (MELD) score or, if less than 12 years old, a Pediatric End Stage Liver Disease (PELD) score that is used for liver allocation. This calculated score is intended to reflect the candidate's disease severity, or the risk of 3-month mortality without access to liver transplant. Some candidates receive an "exception" MELD or PELD score when the urgency of their need for liver transplant is not reflected by the calculate "lab" MELD/PELD score.

[3] OPTN Board resolution "the existing geographic disparity in allocation of organs for transplant is unacceptably high, and directing the organ-specific committees to define the measurement of fairness and any constraints for each organ system by June 30, 2013"

What problem will this proposal address?

This proposal aims to address geographical variation in access to liver transplants. The United States is currently divided into 11 regions and 58 donation service areas (DSAs). Adult deceased donor livers are first allocated to the most urgent candidates within a region (Status 1), followed by DSA and regional sharing for candidates by descending order of MELD score, through MELD 35. While the regions provide an effective mechanism for participation in the OPTN, neither the regional boundaries nor the DSA boundaries were designed to optimally distribute organs.[4] **Figure 1** shows the variance and range in the median allocation MELD or PELD score at transplant across the DSAs.

Figure 1. Variance and range in the median allocation MELD/PELD score (MMat) at transplant across DSAs, by year for deceased donor liver transplants (non-Status 1) 2/27/2002 – 5/31/2017



It is important to note that the magnitude of variation is even greater among candidates whose MELD scores do not reflect assignment of exception points (hereafter referred to as “non-exception candidates”). For the purposes of this proposal, the “calculated MELD” refers to the MELD value based on a candidate’s laboratory test results. “Allocation MELD” refers to the MELD score that is used in the allocation of livers, this score could be based on the candidate’s calculated MELD or their MELD score that includes points based on a MELD exception, because calculated MELD doesn’t reflect degree of urgency for all diagnoses.

Since the enactment of the Final Rule, the OPTN/UNOS has approved and implemented several policies to broaden geographic sharing of deceased donor livers. In June 2009, the OPTN/UNOS Board of Directors (hereafter, “the Board”) approved regional sharing for Status 1A and 1B candidates to increase access to livers for patients with acute liver failure. Later that year, the Committee distributed a Request

[4] The regional system provides an effective mechanism for communication among UNOS staff, the OPTN/UNOS Board of Directors and the transplant community. It facilitates the identification of geographically diverse transplant professionals to populate both the Board of Directors and Committees. The regions also provide a forum for consensus building and transparency of work throughout the OPTN/UNOS policy development process through regional meetings that are held twice a year during the public comment periods.

for Information (RFI) to solicit feedback from the transplant community and public regarding current liver distribution and allocation policy and opportunities for improvement. In April 2010, the OPTN/UNOS hosted a public forum that explored ways to improve organ allocation and distribution and to reduce geographic disparity in access to liver transplant. In June 2012, the Board passed "Share 35," a policy that sought to improve access to transplant for the sickest patients with chronic liver disease through:

- National sharing for candidates with MELD/PELD scores greater than 15
- Regional sharing for candidates with MELD/PELD scores of at least 35
- National sharing for liver-intestine candidates

The two year post-implementation outcome analysis suggest that, for patients with a MELD or PELD of at least 35, Share 35 increased the percentage of transplants from 19% to 27% and increased sharing within each region from 19% to 50%.[5]

Despite several efforts to expand liver sharing to regional candidates with the greatest medical urgency, the geographic disparity in disease severity at transplant persists.

Why should you support this proposal?

This proposal seeks to modify liver distribution to better match organs with urgent candidates, increasing access for those in need of liver transplant. This proposal strives to enhance equity in access while limiting the impact on travel and logistics. The Committee has relied on the collaborative approach to policy development facilitated by the OPTN/UNOS committee structure, extensive data analysis by UNOS staff, simulation modeling provided by The Scientific Registry of Transplant Recipients (SRTR) and input from the transplant community in the development of this proposal.

How was this proposal developed?

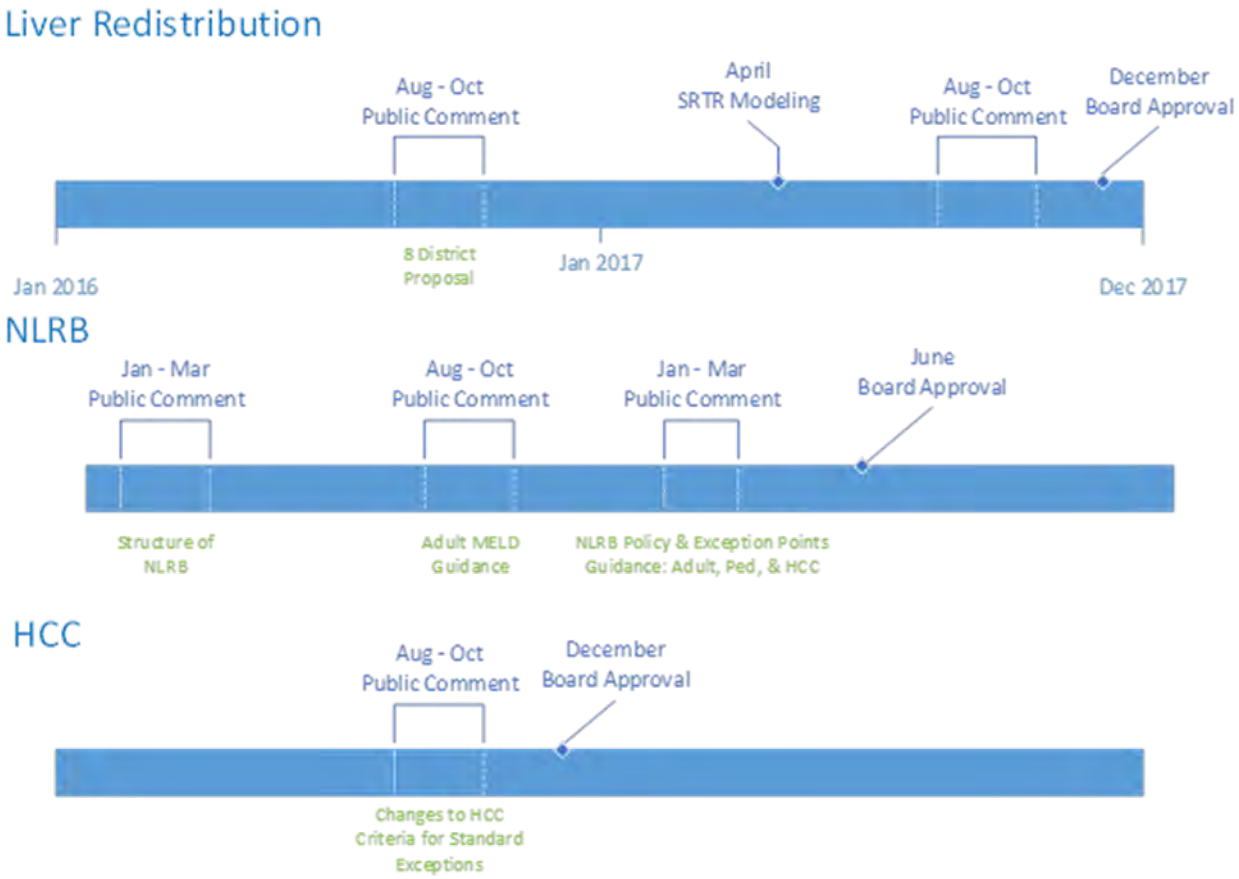
In June 2014, the Committee released the concept paper, "Redesigning Liver Distribution to Reduce Variation in Access to Liver Transplantation".[6] This paper, which included a survey to solicit feedback, provided the initial direction for the Committee. The Committee hosted two public forums in September 2014 and June 2015 to engage the community in a discussion of alternatives to the current system of distribution. In the interim, the Committee convened four Ad Hoc Subcommittees, which included non-Committee members, to develop recommendations for the development and implementation of solutions to reduce geographic disparity.

Based on feedback received from the forums and Committee discussions, the Committee adopted a comprehensive work plan to address geographic disparity in access to liver transplant. This included three projects:

1) Changes to the criteria for hepatocellular carcinoma (HCC) MELD exceptions
2) The establishment of a National Liver Review Board (NLRB)
3) Changes to liver distribution.

[5] Edwards, E. B., A. M. Harper, R. Hirose, "The impact of broader regional sharing of livers: 2-year results of 'Share 35.'" Liver Transplantation. 22(2016), 399-409.
[6] Concept paper available on the OPTN Website

Figure 2. OPTN/UNOS Liver and Intestinal Organ Transplantation Committee Work Plan, 2016-2017



The NLRB and HCC proposals were developed to address concern that geographic disparity in access to liver transplant was due to variable regional exception practices. The OPTN/UNOS Board of Directors approved the HCC proposal in December 2016 and the NLRB proposal in June 2017.[7]

The Committee submitted a policy proposal for public comment in August 2016.[8] This proposal included an eight-district concept that changed the current 11 regions into eight mathematically-optimized districts. To address concerns for increased flying for procurement, the proposal included policy that provided three MELD proximity points to candidates within the district and within a 150-mile radius proximity circle of the donor hospital. Additionally, the initial broader sharing was restricted to a subset of the waiting list, candidates with a MELD or PELD of at least 29. The proposal was met with extensive public comment, both in support and opposition.[9] During the fall 2016 regional meetings, eight of 11 regions opposed the proposal with three regions in support. At the December 2016 Board of Directors meeting, Committee leadership acknowledged the community's response and outlined a plan to respond to public comment, engage stakeholders, and build consensus for a proposal to be submitted for public comment in July 2017.

Recent Development

In January 2017, a gathering of liver surgeons, physicians, and stakeholders (hereafter the "Liver Panel"), was arranged during the American Society of Transplant Surgeons (ASTS) Winter Symposium. The goal was to build consensus on the topic of liver redistribution and develop recommendations for the

[7] Policy Notices available on the OPTN website for *Changes to HCC Criteria for Auto Approval* and *Proposal to Establish a National Liver Review Board*
[8] Proposal available on the OPTN website
[9] Public comment available on the OPTN website

Committee in their development of a proposal. The Liver Panel developed several recommendations that guided the Committee's efforts in 2017. Those recommendations and the Committee's response are outlined below.

Supply and Demand

In response to public comment regarding the supply and demand metrics used to construct and evaluate the eight-district concept, the panel recommended the Committee pursue supply and demand metrics that are independent of Donor Service Area (DSA) procurement performance and transplant center listing practices. The Committee had already begun addressing this concern by submitting a revised SRTR Liver Simulated Allocation Model (LSAM) request in December. This request included *concentric circle* and *neighborhoods* concepts, in addition to an eight-district concept. Both concentric circles and neighborhoods do not rely on supply and demand metrics in the construction of geographic areas of distribution.

In addition to modeling distribution concepts that are independent of supply and demand, UNOS staff requested data and created new "heat maps" that demonstrate alternative metrics of supply and demand. These maps were presented to the Committee and provided a different perspective on the current supply and demand for liver transplant, as well as the overall burden of liver disease in the country. Ultimately, the Committee voted in May 2017, not to pursue an eight-district proposal, alleviating concern on the use of supply and demand metrics in the development of a distribution concept.

Metrics to Assess Efficacy

The Liver Panel recommended that the metrics used to assess efficacy of proposed solutions should not be limited to MELD at transplant. The Committee has always prioritized three metrics to assess efficacy: the distribution and variance in MELD at transplant, transplant rate, and waitlist mortality. Additionally, the Committee has always assessed travel metrics including median transport distance and percentage of organs flying. MELD at transplant is certainly an important metric because livers are allocated by MELD score. However, the Committee embraced the recommendation of the Liver Panel and emphasized other metrics in its 2017 deliberations.

Effects on Medically Underserved Areas

In response to public comment that raised concern for the effect of broader sharing on certain vulnerable populations, the Liver Panel recommended the Committee investigate the potential effects on Medically Underserved Areas (MUAs). MUA is a designation by the Health Resources and Services Administration (HRSA) for areas of the country with a lack of access to primary care services.[10] UNOS staff investigated the MUA designation and provided analyses that correlated MUAs with OPTN data. Unfortunately, because candidate residence information is limited by zip code entered in the Transplant Candidate Registration (TCR) forms and MUAs are assigned to a variety of geographic divisions ranging from census tracts to groups of counties, determining with certainty whether a candidate resides in an MUA is not possible. For these reasons, the Committee is no longer investigating the effect of broader sharing on MUAs.

The Committee continues to discuss the effect of any proposal on vulnerable populations. This is an active area of research in the community and Committee members have discussed the topic with researchers focused on this issue. The Committee's goal is to better distribute livers to candidates on the waiting list. Issues with access to the waiting list are complex and cannot be solved with this proposal. However, the Committee has investigated, and will continue to investigate whether a proposal will *further disadvantage* any specific population. Any proposal brought forward to the Board will include an analysis of potential impact on vulnerable populations.

Logistical challenges

The Liver Panel echoed public comment with their concern for logistical issues with sharing livers more broadly. This is a priority to the Committee, but also an effort by the Organ Procurement Organization (OPO) Committee. The *System Optimizations Work Group* has been developing a proposal for July 2017

[10] Available at https://bhw.hrsa.gov/shortage-designation/muap

public comment that will address several of the concerns raised during public comment for the eight-district concept.

The Committee is also working to address logistical concerns by developing policy that prevents the flying of organs for small differences in MELD scores, and providing priority to candidates that are close to the donor hospital. The Committee's logistical considerations, as well as the OPO Committee's work, will be reviewed by the Board of Directors and incorporated into the implementation plan for this proposal in a manner that addresses concerns and facilitates the transition to broader sharing.

Phased Implementation Strategies

The Liver Panel acknowledged the benefit of a phased implementation strategy to broader sharing to prevent unintended consequences. These include potential financial, logistical, and contractual consequences that are better mitigated with a phased approach. The Committee agrees with this approach and has accepted that the ultimate goal may be better accomplished through a series of changes in contrast to what some may consider a drastic change to current liver transplantation. This approach has influenced the Committee's July 2017 proposal and will influence the timeline of the implementation plan if this proposal is approved by the Board.

July Public Comment Proposal

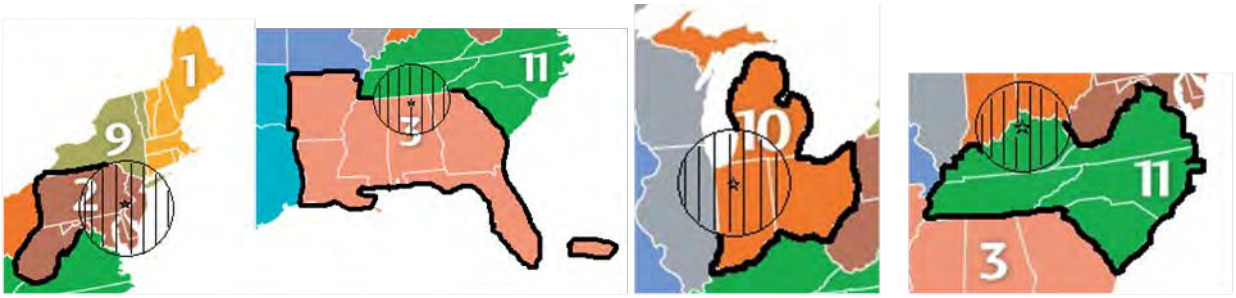
The proposal has four significant parts:

1. Increased sharing within the region + 150-nautical mile radius circle
2. Proximity points
3. Broader sharing to adult candidates based on calculated MELD and pediatric candidates based on allocation MELD or PELD
4. Separate allocation for DCD or donors at least 70 years old

Increased sharing within the region + 150-nautical mile radius circle

The proposal broadens the geographic areas in the initial sharing classifications from regional sharing to include out-of-region sharing within 150 miles of the donor hospital. The Committee proposes a broader sharing concept that includes a 150-nautical mile radius circle around the donor hospital. This circle may extend outside of the regional boundaries, (**Figure 3**).

Figure 3. Examples of 150-nautical mile radius circles around a donor hospital that include liver programs outside of the region. Note, circles are not exactly drawn to scale.



The 150-nautical mile radius circles around a donor hospital achieves the goal of expanding distribution beyond the regional boundaries, while being conscious of the logistical and financial challenges of broader sharing. The concept of circular distribution units around the donor hospital is utilized in thoracic allocation currently and serves as a unit of distribution that is well-matched with current organ offer and acceptance practices.

Note: The information below represents the current proposal with a MELD/PELD threshold of 32. The public comment proposal included a threshold of 29 and was subsequently changed for this final board proposal. There is more information on the change in "Was this proposal changed in response to public comment?"

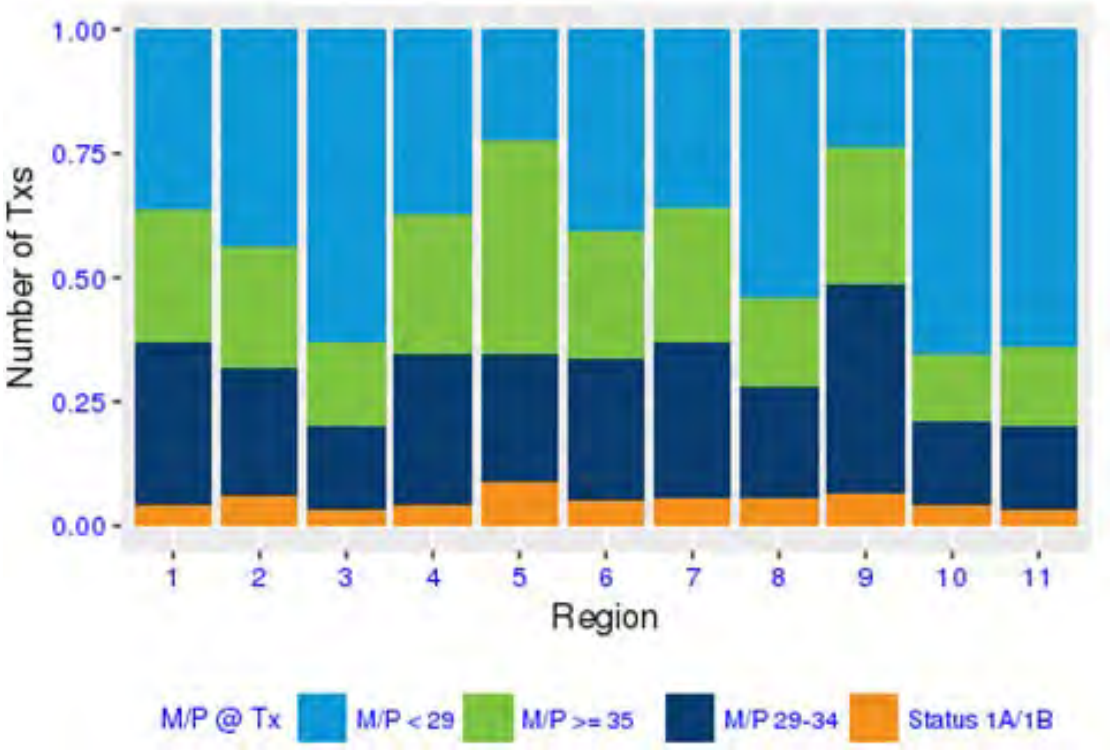
These initial broader sharing classifications are changed from all candidates with a MELD/PELD of at least 35, commonly referred to Share35, to include all candidates at least 18 years old at time of registration with a calculated MELD of at least 32, and candidates less than 18 at time of registration with an allocation MELD or PELD of 32 before introducing local (DSA) priority. The first eight classifications for adult deceased donor livers are provided in **Table 1**.

Table 1. Proposed allocation of livers from non-DCD deceased donors at least 18 years old and less than 70 years old, candidates with a MELD or PELD of at least 15

Classification	Candidates that are within the OPO's:	And are:
1	Region or Circle	Adult or pediatric status 1A
2	Region or Circle	Pediatric status 1B
3	Region or Circle	Any of the following: • At least 18 years old at time of registration and calculated MELD of at least 32 including proximity points • At least 18 years old at time of registration and has an approved HAT exception • Less than 18 years old at time of registration and allocation MELD or PELD of at least 32 including proximity points
4	DSA	MELD or PELD of at least 15
5	Region or Circle	MELD or PELD of at least 15
6	Nation	Adult or pediatric status 1A
7	Nation	Pediatric status 1B
8	Nation	MELD or PELD of at least 15

The Committee discussed the appropriate sharing threshold to use in the initial broader sharing allocation classification. The sharing threshold is used to expose a specific subset of the waiting list to the initial broader sharing, both to prioritize candidates with the greatest medical urgency due to their MELD or PELD score, and to constrain the amount of travel that would be expected if the entire waitlist was exposed in the initial broader sharing classification (no sharing threshold). The Committee analyzed data on the breakdown of deceased donor transplants by allocation MELD or PELD score and region (**Figure 4**).

Figure 4. Deceased donor transplants in 2016, by allocation MELD or PELD score and region



In the original public comment proposal, the Committee decided that a MELD or PELD sharing threshold of 29 would expose the most urgent candidates to broader sharing while limiting the impact on transportation logistics that could result from opening the initial broader sharing to the entire waitlist. This final board proposal includes a sharing threshold of 32. There is more information on the change in *"Was this proposal changed in response to public comment?"*

The specifics of the sharing threshold are discussed in *Priority for calculated MELD candidates* below. For all pediatric liver donors less than 18 years old, the Committee proposes sharing within the region or circle for all candidates. Due to their acute medical urgency, Status 1A and 1B candidates in the circle do not receive additional priority over other Status 1A and 1B candidates in the region based on proximity to the donor hospital.

Proximity points

Note: The information below represents the current proposal with three proximity points provided to candidates in the circle or OPO's DSA. The public comment proposal included five points restricted to candidates in the circle. This was subsequently changed for this final board proposal. There is more information on the change in "Was this proposal changed in response to public comment?"

Liver candidates within the circle will receive 3 MELD or PELD priority points. The specifics of the priority points are detailed below in **Table 2:**

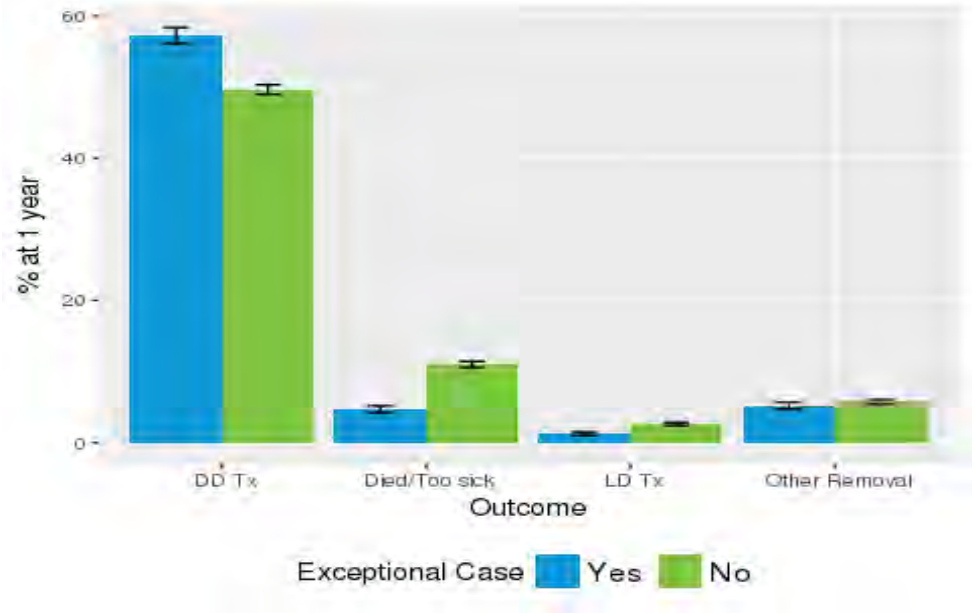
Table 2: Proximity points to candidates in the 150-nautical mile circle around the donor hospital, or candidates in the OPO's DSA, by candidate age

Candidates that are:	And have :	Will receive:
At least 18 years old at the time of registration on the waiting list	A calculated MELD score of at least 15	Three proximity points to their calculated MELD score
At least 18 years old at the time of registration on the waiting list	An approved HAT exception	Three proximity points to their allocation MELD score
12 to 17 years old at the time of registration on the waiting list	An allocation MELD score of at least 15	Three proximity points to their allocation MELD score
Less than 12 years old at the time of registration on the waiting list	An allocation PELD score of at least 15	Three proximity points to their allocation PELD score

Candidates within the 150-nautical mile radius circle around the donor hospital, or the OPO's DSA, will receive the additional points. Similar to the use of the circle as a unit of distribution, proximity points will be provided to candidates inside the circle regardless of whether they are in another region. These points are added prior to the match run so that their MELD or PELD reflects the additional points at time of allocation. The Committee discussed the distinction for the points to be added to the calculated MELD (versus allocation MELD) for adults is to prioritize urgent candidates with elevated calculated MELD scores.

A competing risks analysis was used to determine waiting list outcomes (deceased donor transplant, living donor transplant, removed for death/too sick, removed for other reason) (**Figure 5**). The analysis shows that a greater percentage of exception candidates received a deceased donor transplant and fewer exception candidates were removed from the waiting list due to death or too sick for transplant**.** This data supported the Committee's intention to provide additional priority to non-exception candidates by providing the proximity points to the calculated MELD of adult candidates.

Figure 5. Competing risks outcomes by exceptional case, candidates added to the OPTN liver waiting list, 2014-2016



For candidates less than 18 years old, the proximity points will be added to their allocation MELD or PELD scores. A significant percentage of pediatric liver have an allocation MELD or PELD score that reflects exception points, (**Table 3**).

Table 3. Pediatric Deceased Donor Liver Transplants, 2016

Recipient Age	Status 1A	Status 1B	Standard M/P	Exc Case	Total	% Exception
0-11	62	110	96	149	417	35.7
12-17	17	13	13	51	94	54.3

The Committee believes that adding proximity points to a pediatric candidate's calculated MELD or PELD and basing their allocation on their calculated MELD or PELD, would potentially disadvantage them in the allocation of livers from donors greater than 18 years old. The percentage of pediatric candidates transplanted under exception demonstrates the limitations of using the calculated MELD or PELD to show medical urgency for transplant. Therefore, the Committee proposes that the proximity points are added to the allocation MELD or PELD of pediatric candidates.

Providing priority to candidates within the 150-mile circle addresses concerns for flying livers for negligible differences in MELD or PELD score, both within the regional sharing and out-of-region sharing in the proximity circle. The Committee requested feedback on the concept of providing proximity points to the donor hospital DSA in addition to the proximity circle during public comment. This is discussed further in "*Was this proposal changed in response to public comment?*".

Broader sharing to adult candidates based on calculated MELD and pediatric candidates based on allocation MELD or PELD

For the allocation of non-DCD donors at least 18 years old and less than 70 years old at time of registration, this proposal provides priority for adult (>18 years old) candidates with a calculated MELD score above a MELD sharing threshold of 32 in the initial broader sharing classification. The Committee discussed that these candidates have the greatest medical urgency and should be prioritized in the initial broader sharing classification. As mentioned previously, the geographical disparity is greatest in non-exception candidates. Additionally, these candidates experience worse waiting list outcomes compared with exception candidates (**Figure 5**).

After the initial broader sharing classification, the sharing threshold no longer applies and candidates are allocated based on their allocation MELD or PELD. The distinction between calculated and allocation MELD only applies to the initial broader sharing classification for non-DCD donors at least 18 years old and less than 70 years old in liver, and liver-intestine donor allocation.

Separate allocation for DCD or donors at least 70 years old

The Committee discussed the potential logistical and clinical obstacles of offering certain donors with broader sharing. The Committee has identified a small subset of donors (age ≥70 years and donor after cardiac death (DCD) donors) that will be allocated differently from other donors. The Committee expects this change to better allocate this small subset of livers and requested feedback from the community on this topic. **Table 4** describes the share type and status/score at transplant for DCD liver transplants between 2014-2016.

Table 4. Share type and status/score at transplant for DCD liver transplants, 2014-2016

Status/Score at Transplant	# Local	% Local	# Regional	% Regional	# National	% National	Total
Status 1A	9	60.0	5	33.3	1	6.7	15
Status 1B	1	50.0	1	50.0	0	0	2
MELD or PELD <29	564	67.4	210	25.1	63	7.5	837

Status/Score at Transplant	# Local	% Local	# Regional	% Regional	# National	% National	Total
MELD or PELD 29-34	189	75.0	53	21.0	10	4.0	252
MELD or PELD 35+	59	57.3	43	41.7	1	1.0	103
Total	822	68.0	312	25.8	75	6.2	1209

The data in Table 4 reveals that 68% of DCD liver transplants in 2014-2016 occurred locally (within the DSA that the organ is recovered). This data reinforced the Committee's intentions to develop a separate allocation classification for DCD livers that prioritized allocation within the DSA (**Table 5**).

Table 5. Proposed allocation of livers from DCD Donors or donors at least 70 years old, first ten classifications

Classification	Candidates that are within the OPO's:	And are:
1	Region or Circle	Adult or Pediatric status 1A
2	Region or Circle	Pediatric status 1B
3	DSA	MELD or PELD of at least 15
4	Region or Circle	MELD or PELD of at least 15
5	Nation	Adult or Pediatric status 1A
6	Nation	Pediatric status 1B
7	Nation	MELD or PELD of at least 15
8	DSA	MELD or PELD less than 15
9	Region or Circle	MELD or PELD less than 15
10	Nation	MELD or PELD less than 15

In 2014-2016, 17% of livers recovered from donors at least 70 years old were discarded, compared to 9% for donors less than 70 years old.[11]The Committee proposes including donors at least 70 years old in the same allocation as DCD donors. The Committee believes the inclusion of DCD donors and donors at least 70 years old in a separate allocation classification will better allocate this subset of donor livers by prioritizing local allocation and limiting the logistical concerns for allocating these donor livers over broader geographical areas.

How well does this proposal address the problem statement?

This proposal appropriately balances the Final Rule requirements that "OPTN allocation policies must, among other factors, be based on sound medical judgment, seek to achieve the best use of donated organs, and shall not be based on the candidate's place of residence or place of listing except to the extent needed to satisfy other regulatory requirements.."

The public comment proposal included SRTR modeling of a similar concept in 2015. This concept included regional sharing to the full waitlist (no sharing threshold) and 150-nautical mile out-of-region circles around the donor hospital. The 2015 modeling showed that the concept of full sharing with the 11 regions, plus a 150-nautical mile out-of-region proximity circle with 5 points provided to candidates within the circle, was a concept that has a substantial effect on variation in median MELD at transplant (for all

[11] Based on OPTN data retrieved July 7, 2017

candidates and non-exception candidates) in addition to a predicted decrease in flying and transport distance compared to the current system.

Key Metrics

While the SRTR modeled this similar concept in 2015, the public comment proposal with a sharing threshold of MELD or PELD 29 had not been modeled. Subsequently, the Committee requested new modeling of the current proposal including all of the key metrics of disparity (median MELD at transplant, waitlist mortality, etc.) and an analysis of the potential impact of this proposal on vulnerable populations, including the effect on rural populations and candidate insurance status. The initial results of the modeling were provided on August 11th, prior to the first regional meetings. The initial results included the majority of the modeling request, except for the analyses on level of education, type of insurance, and by candidate place of residence. **Figures 6 and 7** below summarize the modeling data of the key metrics requested by the Committee. When reviewing, the concept on the left represents the sharing threshold and whether the proximity points are provided to candidates in the 150 nautical mile proximity circle alone, or to candidates in the circle and the OPO's. For example, "M29 150m" represents the public comment proposal, a MELD/PELD sharing threshold of 29 and points provided only to candidates in the circle.

Figure 6. Overview of main metrics

	variance in median allocation M/P at transplant	median allocation MELD/PELD at transplant	median transport time (hours)	median transport distance (miles)	% of organs flown
Current	10 (8.7,11.9)	29 (29,29)	1.7 (1.69,1.72)	88.5 (86.9,90)	50.7 (50.2,51.1)
M29 150m	6 (5.3,7.6)	29 (29,29)	1.74 (1.73,1.75)	100.7 (98.7,103.4)	55.2 (54.5,55.9)
M29 150m DSA	5.8 (5.2,7.4)	29 (29,29)	1.74 (1.74,1.75)	102.1 (99.8,103.7)	55.6 (55,56.1)
M22 150m	4.1 (3.4,4.6)	29 (29,29)	1.77 (1.76,1.77)	112.5 (110.2,115.4)	59.5 (58.8,60.1)
M22 150m DSA	4.3 (3.5,4.9)	29 (29,29)	1.77 (1.77,1.78)	113.8 (111.7,115.1)	59.9 (59.5,60.2)
150m	4.4 (3.9,4.8)	29.2 (29,30)	1.79 (1.78,1.79)	118.4 (117.2,119.3)	61.1 (60.8,61.7)
150m DSA	4.3 (3.9,5.3)	29.2 (29,30)	1.79 (1.78,1.79)	119.9 (118.5,122.3)	61.4 (61,62.1)

All metrics reported as *mean (min, max)* across the 10 simulation iterations.

Figure 7. Overview of additional metrics

	transplant rate	transplant count	waitlist mortality rate	waitlist mortality count	post-tx mortality rate	post-tx mortality count
Current	0.444 (0.436,0.452)	6651 (6575,6727)	0.097 (0.095,0.1)	1455 (1425,1504)	0.077 (0.075,0.08)	686 (666,721)
M29 150m	0.437 (0.429,0.446)	6651 (6586,6728)	0.09 (0.088,0.092)	1366 (1335,1404)	0.077 (0.075,0.08)	682 (659,717)
M29 150m DSA	0.437 (0.431,0.445)	6644 (6563,6724)	0.09 (0.089,0.092)	1369 (1343,1408)	0.078 (0.074,0.08)	688 (662,712)
M22 150m	0.434 (0.428,0.445)	6644 (6558,6746)	0.087 (0.085,0.088)	1337 (1302,1358)	0.077 (0.076,0.078)	681 (670,702)
M22 150m DSA	0.434 (0.429,0.443)	6647 (6562,6725)	0.087 (0.087,0.089)	1339 (1319,1366)	0.078 (0.076,0.08)	691 (669,718)
150m	0.436 (0.429,0.445)	6623 (6537,6709)	0.091 (0.09,0.093)	1390 (1368,1421)	0.078 (0.076,0.08)	687 (667,718)
150m DSA	0.435 (0.427,0.445)	6617 (6547,6713)	0.091 (0.089,0.093)	1387 (1349,1414)	0.078 (0.075,0.082)	686 (663,734)

All metrics reported as *mean (min, max)* across the 10 simulation iterations. All rates are per patient-year.

In reviewing the modeling results, the Committee was pleased to see no decrease in overall transplant count with the concept in the public comment proposal (M29 150m). Overall, the public comment proposal concept provided results in line with the Committee's expectations. A decrease in variance in Median MELD at Transplant and small increases in transport distance and percentage of organs flown. The decrease in waitlist mortality rate and count was not necessarily expected but can be explained by the concept of broadly distributing livers to candidates with higher MELD or PELD scores. These candidates exhibit the greatest waitlist mortality and an increase in access for this population can be expected to correlate with a decrease in waitlist mortality.

Median MELD/PELD at Transplant

Figure 8. Maps of Median Calculated MELD/PELD at Transplant by DSA – No exception candidates

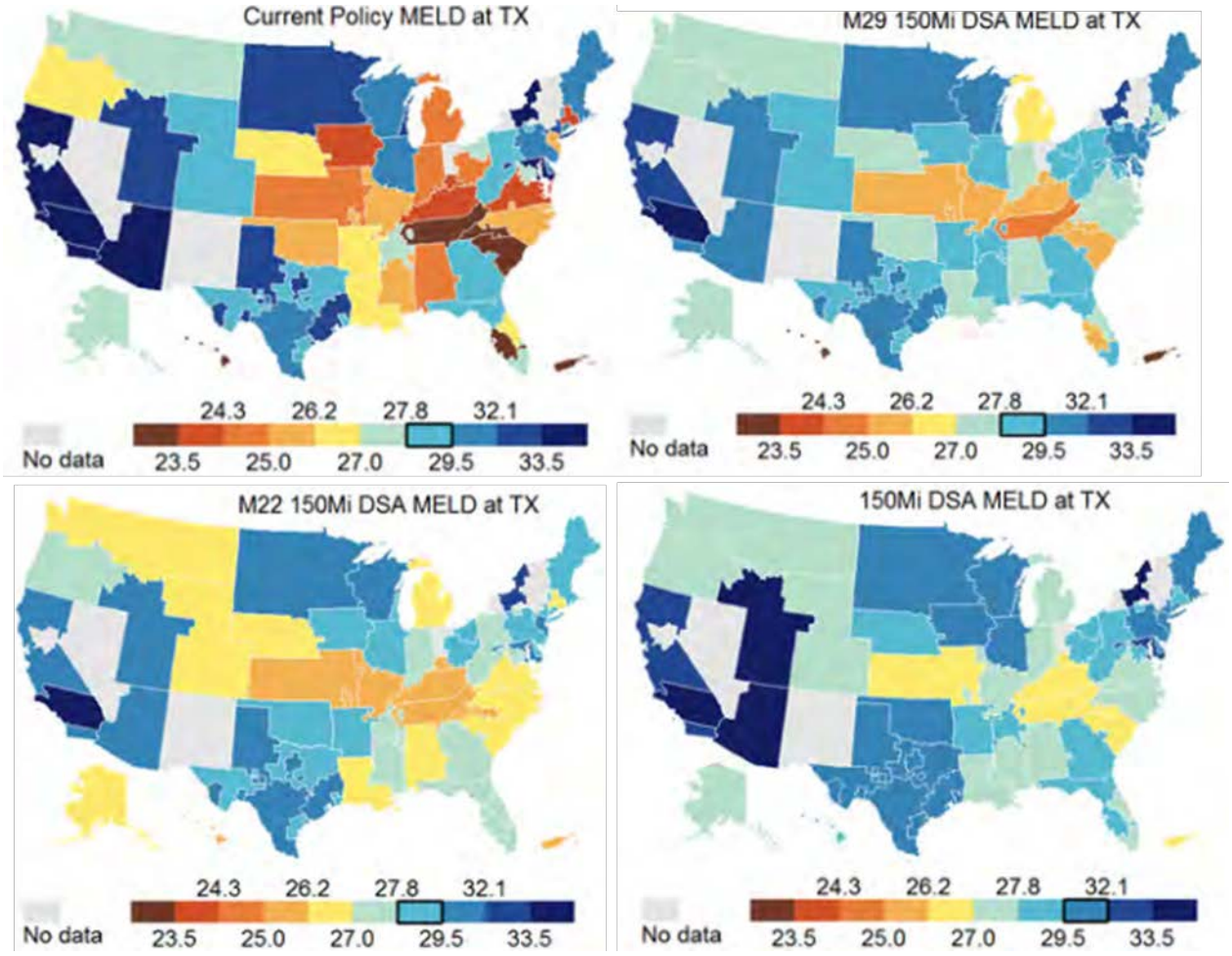
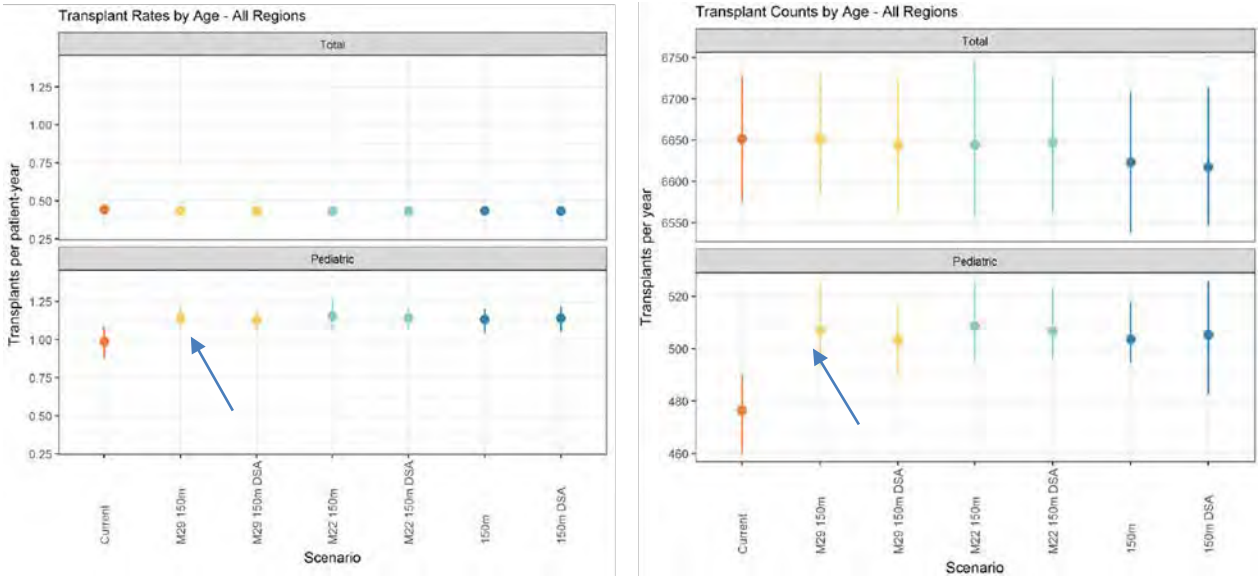


Figure 8 above shows how the differences between DSAs in Median MELD at Transplant changes with different sharing thresholds. The final map "150Mi DSA MELD at Tx" describes sharing within the regions and circles with no sharing threshold. A candidate's MELD or PELD score is used in liver allocation. Therefore, an overall decrease in the amount of variation among the DSAs is in line with the goal of increasing equity in access to a liver transplant.

Pediatrics

In the subgroup analyses performed in the modeling, most metrics (sex, race/ethnicity, education level, insurance type, and urban/rural subgroups) were affected similarly to the overall population. However the effect on pediatric candidates differed from overall results. Transplant counts and rates increased for the pediatric population **(Figure 9)**. In the current system, travel distance and percentage of organs flown is greater in the pediatric population compared to the overall population. However, the modeling predicts that transport time and distance decrease in the modeled scenarios for pediatric candidates.

Figure 9. Transplant rates and counts by age. Pediatric candidates compared to total population. Arrow identifies the public comment proposal concept “M29 150m”



This results showed that the public comment proposal reduces the extent of geographic sharing in the previous 8-district proposal but it addresses the concerns for increased flying of organs and potential unintended consequences resulting from an immediate shift to significantly broader sharing. The Committee acknowledges that this solution may not *solve* disparity in access to transplant. However it is expected to improve current distribution and the overall structure provides a foundation for future modifications based on the post-implementation monitoring data. The effect of changing the sharing threshold and number of proximity points is discussed below in *“Was this proposal changed in response to public comment?”*

The Committee plans to employ a robust post-implementation analysis to monitor the efficacy of the proposal and promptly address any unintended effects, see *“How will the sponsoring Committee evaluate whether this proposal was successful post implementation?”* below.

Was this proposal changed in response to public comment?

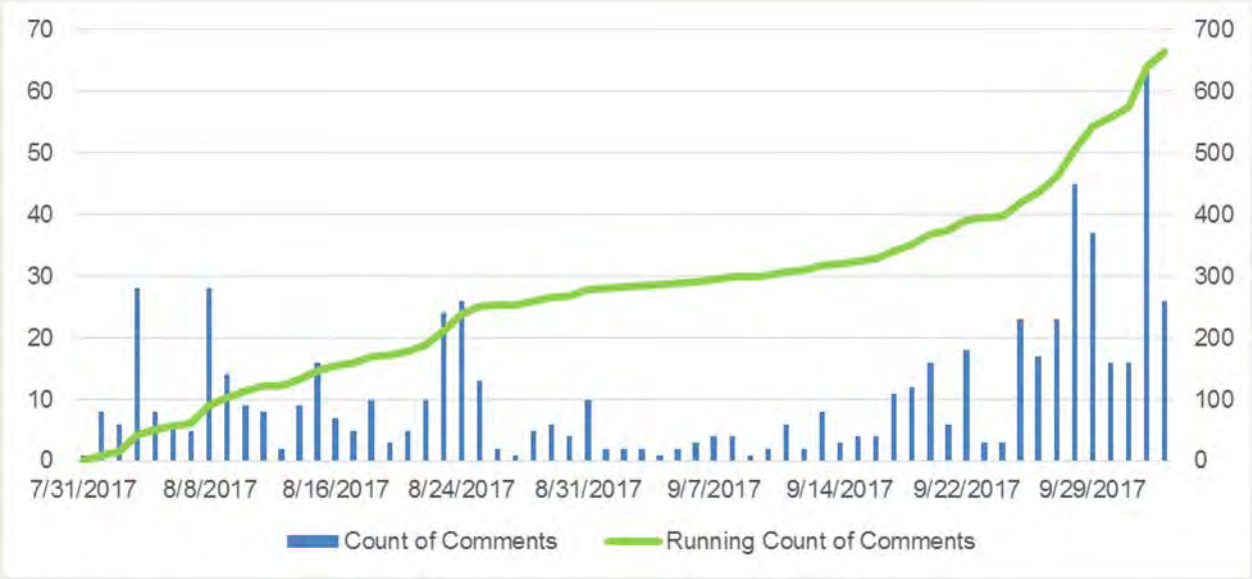
Yes, in response to public comment feedback, the Committee made changes to the original policy proposal and voted to send the modified proposal to the OPTN/UNOS Board of Directors for consideration during its December 2017 meeting. While the Administrative Procedure Act (APA) isn’t applicable to the OPTN, the post public comment changes are a logical outgrowth of the proposal that was released for public comment. The background materials circulated with the proposal gave notice regarding the possible issues that could be changed in the final proposal. This allowed all interested parties to have an opportunity to comment on any of these issues. This is evidenced by the comments received on all sides of these different issues. (Ex. the number of proximity points or the sharing threshold.) Any of the other changes (ex. the new definitions) are clarifying additions to the concepts released in the public comment proposal.

Overview of Public Comment

The proposal was released from July 31, 2017 to October 2, 2017. During that time, it received 665 comments. For comparison, the August 2016 liver redistribution proposal received 1,064 comments **(Figure 10)**. The most comments ever received for an OPTN/UNOS public comment proposal was 6,430

comments for the March 2014 proposal for adolescent classification exception for pediatric lung candidates.[12]

Figure 10. Total Comments received

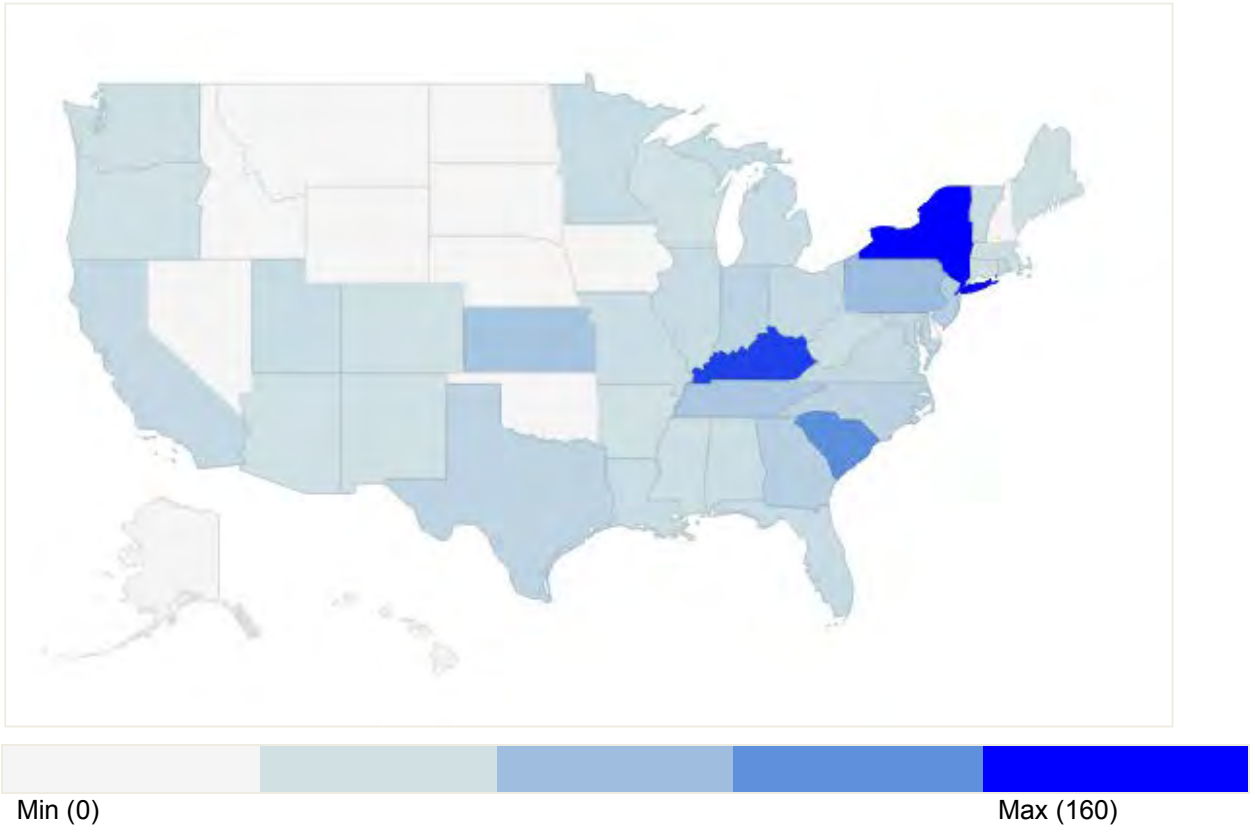


Most commenters only submitted one comment (n=502). However, some commenters submitted multiple comments (range 2-33). In total, 545 individuals or organizations submitted 665 comments.

The comments were submitted from at least 38 states across the country. A disproportionate number of the comment originated from New York, Kentucky, and South Carolina (n = 338, 51%), (**Figure 11)**. For this reason, it is important to evaluate the merits of each comment instead of utilizing the volume of individual comments as a national, public opinion survey.

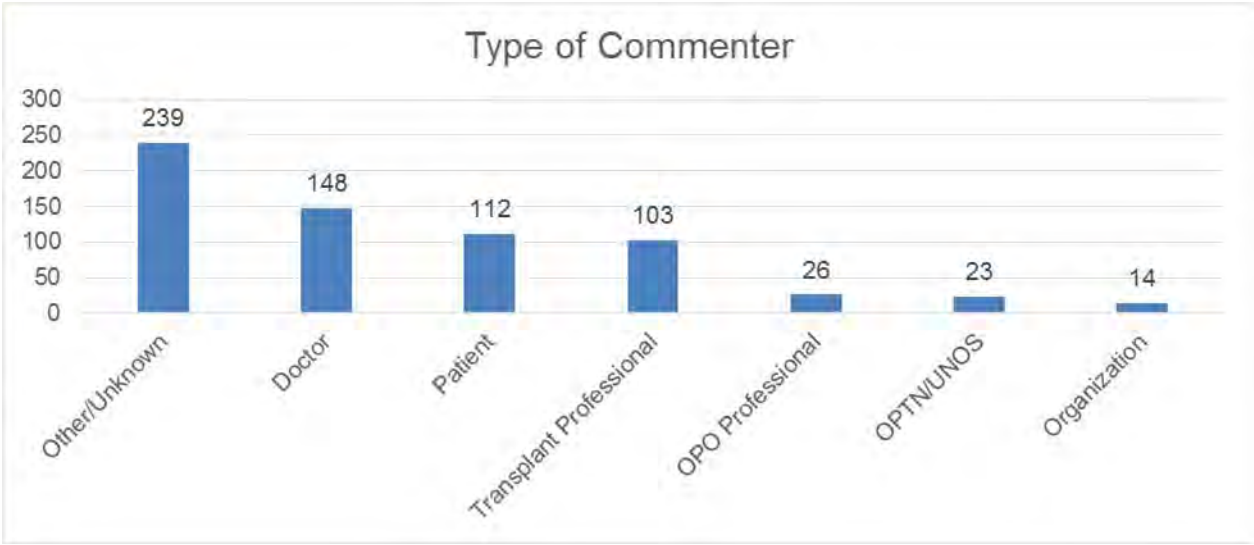
[12] Some comments were received by email prior to the close of public comment on October 2nd but were not posted online until the following morning on October 3rd.

Figure 11. Geographical distribution of comments



The comments were submitted by multiple different types of commenters. Commenters are not required to identify themselves or their professions but many give enough information to identify their background. Notably, 112 patients (recipients, candidates, living donors, and family and friends of patients) submitted comments on the proposal, **(Figure 12)**. OPTN/UNOS comments include those submitted by the 11 regions, 12 committees, and 2 comments from Board leadership.

Figure 12: Types of Commenters



Commenters covered many different topics. The committee focused on the following seven themes:

1. MELD or PELD Sharing Threshold
2. Proximity Circle
3. Proximity Points
4. Proximity Points Added to Candidates with a MELD/PELD of at least 15
5. Allowing MELD Scores to go Above 40 to Candidates in the Circle
6. Allocating to Adult Hepatic Artery Thrombosis (HAT) Candidates Based on their Allocation MELD
7. DSA Performance
8. Effect on Vulnerable Populations
9. Variances

1. MELD or PELD Sharing Threshold

The Committee had two goals with the implementation of a sharing threshold. First, to prioritize broader sharing to candidates with the greatest medical urgency on the waiting list. Second, to restrict the amount of the waiting list exposed to broader distribution, thus constraining the amount of broader distribution to address logistical concerns of moving to a new system. The public comment proposal included a sharing threshold within the initial broader sharing classification for the allocation of non-DCD donors at least 18 years old and less than 70 years old. After allocating to Status 1A and 1B candidates within the Region or Circle, the initial broader sharing classification in the public comment proposal was restricted to candidates at least 18 years old with a calculated MELD of at least 29, and candidates less than 18 years old (pediatrics) with an allocation MELD or PELD of at least 29.

There were at least 37 public comments regarding the inclusion of a sharing threshold of 29 within the initial broader sharing classification of donors at least 18 years old and less than 70 years old (donors >70 are allocated in the new DCD/Age>70 allocation). The community was split between individuals wanting a lower sharing threshold, supporting the threshold at 29, and wanting a higher sharing threshold.

A higher sharing threshold was supported in public comment for a few reasons. A higher sharing threshold will reduce the amount of the waiting list exposed to broader distribution, thus minimizing the overall effect of this proposal with regards to the current system. There was discussion that in areas which do not see increased 'out-of-region' livers into the Region (Region 5), that a lower threshold may increase sharing within the region but not have much of an effect on MELD at transplant, or waitlist mortality. Finally, there was public comment around the idea that a threshold of 29 may minimize the prioritization to candidates with a 35 or above in the current system.

A lower sharing threshold was supported in regions that would like to expand distribution beyond what is anticipated by this proposal. The exception to this is Region 5, which certainly wants to broaden liver distribution, however a larger circle (or other distribution area) and a corresponding influx of out-of-region livers is necessary to make a significant impact for Region 5. A lower sharing threshold would expose more of the waiting list to the proposed changes, and would increase the amount of sharing within the region and proximity circle. However, the modeling and public comment supports the sentiment that a lower sharing threshold would de-prioritize higher MELD candidates.

During the committee's meeting in Chicago on October 10th, they responded to the feedback received during public comment. The Committee's discussion on the appropriate sharing threshold focused on two significant themes:

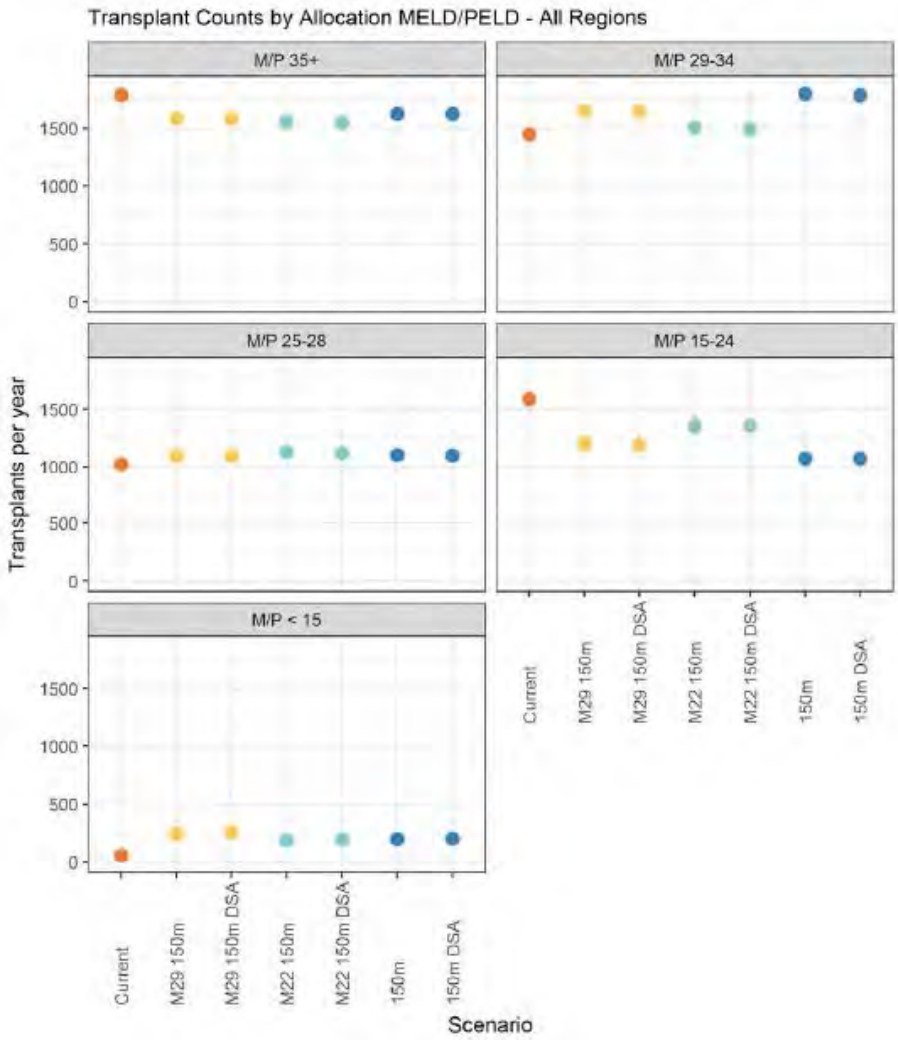
1) The effect of the threshold on geographic disparity and the amount of travel
2) The effect of the threshold on prioritizing medically urgent candidates

As discussed above, the sharing threshold is used to identify a subset of candidates to be exposed to the initial broader sharing classification based on their MELD or PELD score. The Committee discussed the effect of the sharing threshold on the key metrics identified by the Committee in the SRTR modeling results. The Committee requested modeling of a sharing threshold of 29, 22, and no threshold. Previously, the Committee has requested modeling of 35, 29, and 25 in relation to the 8-district model. The recent modeling showed a small decrease in variance in median MELD/PELD at transplant in the 22 threshold, compared to the 29 threshold (5.8 to 4.3) and a small decrease in waitlist mortality rate in the 22 threshold, compared to the 29 threshold (0.09 to 0.087).

Median transport distance (102.1 to 113.8 miles) and percent of organs flown (55.6 to 59.9) also see similar changes when comparing a sharing threshold of 29 to 22. For a full overview of metrics see **Figures 5 and 6** above. The Committee expects that a sharing threshold between 22 and 29 (for example a 27) would fall in the middle of these results. Additionally, a threshold above 29 (for example a 32) would see a comparatively reduced impact on these same metrics compared to a threshold of 29. Those members on the Committee in support of a higher sharing threshold (32) view it as a positive increase in distribution to current Share35 policy, while having a smaller impact on travel and logistics compared to 29.

The Committee discussed the concern with lowering the sharing threshold and the corresponding effect on the most medically urgent candidates (MELD 35+) who currently receive priority through the Share 35 policy. **Figure 13** below shows transplant counts by MELD/PELD group.

Figure 13. Transplant counts by allocation MELD/PELD – all regions



Transplant counts for the MELD/PELD 35+ group decrease with the 22 and 29 sharing threshold scenarios. This could suggest that a lowered threshold will deprioritize higher MELD candidates. In many ways this is intentional, due to the goal of broadening distribution to candidates before they reach higher MELD/PELD scores which correlate with higher predicted waitlist mortality. However, it is still a concern the Committee considered in identifying a final sharing threshold.

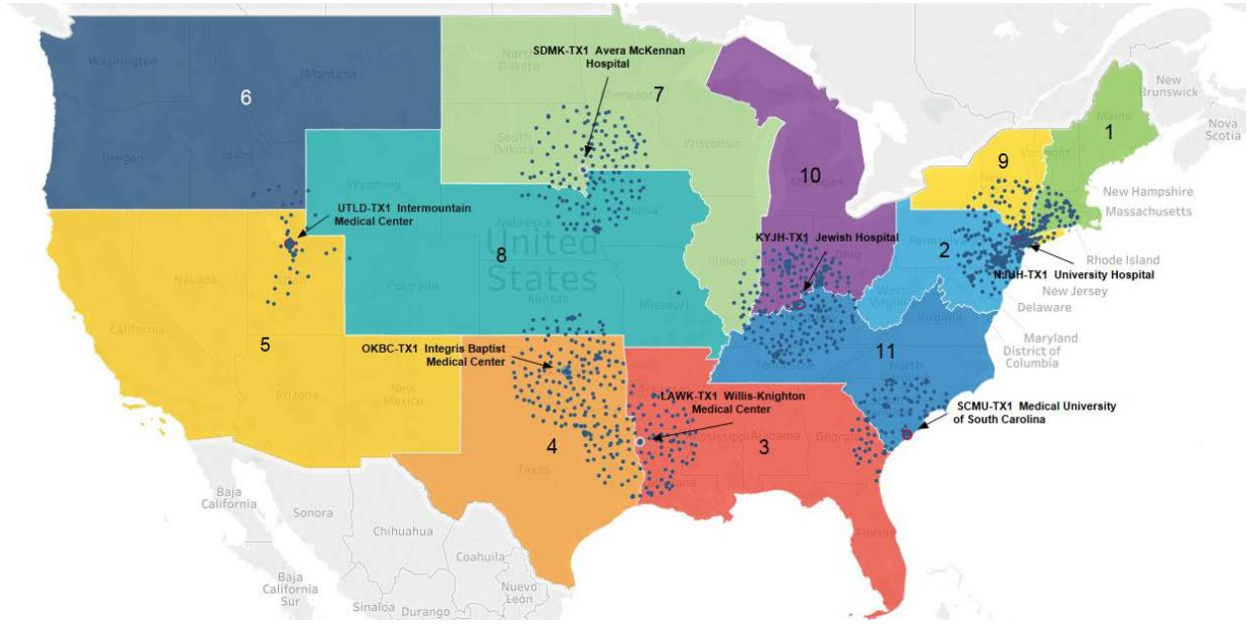
After discussing the entirety of public comment on the appropriate sharing threshold and reviewing the data and concepts above, the Committee decided on a sharing threshold of 32. A sharing threshold of 32

is a compromise to address concerns on the effect of the 29 sharing threshold proposed in public comment. Additionally, it alleviates the potential negative effect on candidates with the greatest medical urgency (MELD/PELD 35+). Finally, it serves as a gradual increase in regional distribution and identifies a subset of the waiting list exposed to the initial broader distribution classification. Both of these changes are expected to reduce the effect of geography on access to transplant and increase access to transplant for candidates with the greatest waitlist mortality.

2. Proximity Circle

There were at least 84 public comments regarding the concept of a 150-nautical mile radius circle around the donor hospital. The Committee's intention behind the current proposed circle was to expand distribution beyond the regional boundaries to candidates listed at a program within close proximity of an out-of-region donor hospital. The size of the circle, 150-nautical miles, was chosen based on the perceived distance to reduce the amount of flying. Additionally, compared to the size of circles looked at previously (250 and 500 miles), the 150 mile size was chosen to be conscious of the logistical and financial concerns of broader sharing.

Figure 14. Sampling of programs that will have increased access to donors outside their current region. The blue dots represent donor hospitals.



Regional feedback and public comment included discussion that the size of the proximity circle should be larger. This perspective is supported by previous modeling of large distribution areas (Districts and larger circles) that show an increased effect on geographical disparity and lower waitlist mortality. Additionally, there was sentiment that areas of the greatest disparity in access to transplant (Region 5) are not sufficiently improved by the current proposal. Finally, in support of a larger circle, there was sentiment in public comment that the current proposal is too incremental and the problem requires a more substantial solution.

Regional feedback and public comment on the proximity circle included feedback in opposition to the current circle or proposed the idea of a population based circle. The current proposal does not account for variations in population density or other form of geographical variation, such as being near the coastline or being in extremely isolated areas (Hawaii, Puerto Rico, etc.). The modeling predicts that there will be DSAs and Regions that experience comparatively greater effect from this proposal compared to others based on the density of liver programs within, and outside their respective region.

During the committee's meeting in Chicago on October 10th, they responded to the feedback received during public comment. Based on previous modeling, the Committee understands that a larger circle (250 mile, 500 mile, etc.) would further decrease the disparity in access to a liver transplant, however, this

would correspond with an increase in travel (distance and flying) that has been met with concern by the community. The 150 nautical mile radius distribution circle has been shown with recent modeling to broaden distribution and importantly, decrease the variance in access to transplant by allowing donor livers to travel across regional boundaries to candidates within close proximity of the donor hospital. Based on the positive modeling results, and in light of the concerns for larger distribution areas by the community, the Committee decided to move forward with the currently proposed 150 nautical mile radius proximity circle.

3. Proximity Points

There were at least 36 public comments regarding the geographic area (DSA or circle, or combined) that candidates listed within will receive proximity points. There was also a variety of perspectives on the number of proximity points that should be provided. The committee's intention of providing proximity points was to expand distribution beyond the regional boundaries, while being conscious of the logistical and financial challenges of broader sharing and provide some priority for candidates within close proximity of the donor hospital. The committee discussed four different options regarding proximity points, **(Table 6)**.

Table 6. Committee Options for Proximity Points

	Points go to patients in the Circle	Points go to patients in the Circle & DSA
5 points	Option 1 (Public comment proposal)	Option 2
3 points	Option 3	Option 4 (Board proposal)

Those in support of proximity points viewed them as a means to constrain travel, provide an advantage to local candidates, and ease the transition to broader liver distribution. Furthermore, the sentiment to provide proximity points to candidates within the circle and to candidates within the DSA is due to maintaining existing relationships between OPOs and their local programs. In some parts of the country, the proximity circle may exclude certain programs within a DSA due to the large size of the DSA. By providing proximity points to the DSA and circle, the potential to prioritize certain candidates within the DSA is eliminated.

During the committee's meeting in Chicago on October 10th, they responded to the feedback received during public comment. Pertaining to the geographic unit for candidates to receive proximity points, the Committee discussed providing proximity points to candidates within the proximity circle (proposed in public comment) or providing points to candidates within the OPO's DSA in addition to candidates in the proximity circle. To address relationships between OPO's and programs in their DSA, as well as the previously mentioned concerns of large DSAs where the circle may exclude certain programs within the DSA, the Committee decided to provide proximity points to candidates in the OPO's DSA and within the 150 nautical mile proximity circle.

Those in opposition of the number of proximity points (five in the public comment proposal) or the concept of proximity points as a whole, have provided several reasons for this sentiment. It is perceived that proximity points were a concept originating with the 8-district proposal as a means to reduce travel over large geographic areas. However, the public comment proposal had comparatively less travel by only broadening distribution within the region (to candidates with a MELD/PELD of 29) and outside the region through the use of the proximity circle. Therefore, those in opposition of proximity points argue that they may not be necessary (or be much less than five) under the proposal's comparatively narrower distribution. There was also public comment regarding the idea that five proximity points may reduce the current regional sharing under Share 35. Five proximity points has been perceived as a large advantage to local candidates, and may limit the amount of sharing outside the circle. In large geographic regions,

there was comment that proximity points may have an unintended consequence to reduce the amount of regional sharing within the current system of Share 35.

During the committee's meeting in Chicago on October 10th, they responded to the feedback received during public comment. The Committee discussed the importance of proximity points to prevent livers from traveling within the region, or outside the region, for small differences in MELD or PELD scores. The Committee discussed the number of points necessary to achieve the goal of mitigating small differences in MELD or PELD scores, while also not affecting the clinical implications of a candidates' score. 5 MELD or PELD points was viewed as a significant clinical advantage to a candidate that may be within close proximity of the donor hospital, over a candidate outside the circle in the region.

An example to illustrate this situation is a candidate within the region (but outside the circle) with a MELD of 35 versus a candidate within the circle with a MELD of 31. In this scenario, the candidate in the circle would be provided 5 MELD proximity points and at the time of the match run, be a MELD 36, thus being prioritized over the candidate with a MELD 35 in the region. The Committee noted that 5 MELD or PELD proximity points represents a significant clinical difference and the comparatively smaller increase in distribution of this proposal does not necessitate such a clinically significant advantage for candidates within close proximity of a donor hospital. **Table 7** below shows examples of how the relationship of proximity points (3) and the sharing threshold (32) relates to a candidate being in the initial broader sharing classification. The Committee decided to move forward with 3 MELD or PELD proximity points.

Table 7. Examples of candidates included in initial broader sharing classification (region or circle) for non-DCD donors at least 18 years old and less than 70 years old

Candidate Age	Calculated MELD or PELD	Allocation MELD or PELD (including potential exception points)	In the proximity circle or DSA?	In the Region?	Match MELD or PELD including 3 proximity points	Included in initial broader sharing?
10	17	29 with exception	Yes	-	32	Yes
13	20	24	Yes	-	27	No
17	20	30 with exception	No	Yes	30	No
25	32	32	No	Yes	32	Yes
30	32	32	Yes	-	35	Yes
40	18	30 with exception	Yes	-	21	No
45	29	34 with exception	Yes	-	32	Yes
35	39	39	Yes	-	42	Yes

4. Proximity Points Added to Candidates with a MELD/PELD of at least 15

Shortly after public comment began, the Committee identified a concern that the current proposal provided proximity points to all MELD/PELD candidates in the 150-nautical mile circle around the donor hospital. This would include candidates with a MELD or PELD score less than 15, and could potentially provide a MELD or PELD score of 15 to candidates with a score as low as 10 (with 5 proximity points). The Committee expressed concern on the idea of allowing low (less than 15) MELD or PELD candidates to have increased priority for a transplant. The committee solicited feedback during the regional meetings

and the vast majority of comment agreed that the proximity points should be provided to candidates with a MELD or PELD score of at least 15.

During the Committee's in-person meeting following public comment, the Committee reviewed the feedback from the regions and decided to only provide three proximity points to candidates with a MELD or PELD of at least 15. Specifically, candidates at least 18 years old at time of registration will receive three proximity points to their calculated MELD score of at least 15, and candidates less than 18 years old at time of registration will receive three proximity points to their allocation MELD or PELD of at least 15.

5. Allowing MELD Scores to go Above 40 to Candidates in the Circle

The public comment proposal put forth the idea of 5 proximity MELD or PELD points to candidates in the 150 mile circle. With this proposed policy change, candidates in the MELD 35-40 subset will all be capped at 40. For example, two adult candidates within the proximity circle, one with a calculated MELD of 35 and another with a calculated MELD of 39 would both have a 40 within the proximity circle. The tiebreaker would be waiting time, and the differentiation based on MELD would be lost. The Committee solicited feedback from the regions on the idea of uncapping MELD 40 for candidates in the circle to maintain MELD differentiation in the MELD 35-40 population. The majority of comments agreed that the score should be allowed to go above 40 with the inclusion of proximity points.

During the Committee's in-person meeting following public comment, the Committee reviewed feedback from the regions and decided to allow a candidate's score to go above 40 at the time of the match run with the introduction of proximity points. With the corresponding change to three proximity points to candidates in the circle and DSA, uncapping MELD for candidates within the circle or DSA would allow continued differentiation between the MELD 37-40 population. For example, two adult candidates within the DSA or circle, one with a calculated MELD of 38 and another with a calculated MELD of 40, would maintain differentiation. The MELD 38 candidate would be a MELD 41, and the MELD 40 candidate would be a 43 at the time of the match run.

6. Allocating to Adult Hepatic Artery Thrombosis (HAT) Candidates Based on their Allocation MELD

The Committee has recently discussed allowing adult candidates with an approved HAT exception, to be allocated based on their allocation MELD. Currently, an adult HAT candidate with a calculated MELD below the sharing threshold would not be included in Classification 3 for adult donor liver allocation. HAT candidates currently receive an exception score of MELD 40 due to their medical urgency. The Committee has discussed this concept and agree that adult candidates with an approved HAT exception should be included in classification 3, and be allocated to based on their allocation score. They are the only group of adult exception candidates who are allocated to based on their exception score in classification 3 of *Tables 9-4: Allocation of Livers from Non-DCD Deceased Donors at Least 18 Years Old and Less than 70 Years Old* and *9-8: Allocation of Liver-Intestines from Non-DCD Deceased Donors at Least 18 Years Old.*

7. DSA Performance

There was discussion during public comment regarding the relationship of this proposal with the concept of DSA performance. The overall discussion focused on the idea that this proposal would shift organs from "high performing DSAs" to "low performing DSAs" and would discourage the efforts of OPOs and their local transplant centers to increase donation and awareness of transplantation. The Committee responds to these concerns with the following points.

First, the goal of this proposal has always been to increase equity in access to transplant for candidates on the waiting list. A candidate has no control over the performance of their transplant hospital, other transplant hospitals in the DSA, or their local OPO. Therefore, candidates listed in a low-performing DSA should not be expected to have reduced access to transplant for reasons beyond their control, nor should they be expected to travel to other areas of the country for increased access to a transplant.

Second, the Committee is committed to identifying solutions that improve organ offer and acceptance practices that increase acceptance rates and the overall number of liver transplants. An example of such an initiative can be seen within this proposal in the separate liver allocation policy for DCD donors or donors at least 70 years old. The Committee reviewed data, collaborated with OPO partners, and built

consensus within the Committee on a subset of the donor population that would be allocated alternatively to increase utilization and address concerns with broader distribution of these organs. The Committee continues to remain engaged with the OPO Committee's efforts to improve the efficiency of organ allocation with the goal of increasing the number of transplants.

Finally, the topic of DSA performance is not specific, nor limited to the discussion of liver allocation and distribution. It is a topic related to all organs and one that will require effort outside the scope of this proposal. Of note, the President's Roundtable, a partnership among the presidents and chief staff officers of the American Society for Histocompatibility and Immunogenetics (ASHI), Association of Organ Procurement Organizations (AOPO), American Society of Transplantation (AST), American Society of Transplant Surgeons (ASTS), NATCO, The Organization for Transplant Professionals, The Organ Donation and Transplantation Alliance (The Alliance), and the United Network for Organ Sharing (UNOS) met on October 5th to promote collaboration and advance the transplant community. They released the following statement:

> *"The Presidents' Roundtable convened on October 5 in Washington, D.C. to address contemporary issues and explore opportunities to work together to solve them. The group supports the OPTN/UNOS process for policy development and the partnership for developing metrics for Donor Service Area (DSA) success. We also fully support the ongoing efforts of AOPO in the development of standard performance metrics to better identify a donation rate based on potential donor deaths and review the elements of successful donor registries. We are committed to work together to develop policies for review of DSA performance."*

The topic of DSA performance will remain a priority for the OPTN.

8. Effect on Vulnerable Populations

As discussed in "How was this proposal developed?", the effect of this proposal on vulnerable populations remains a priority for the Committee. In addition to the normal subgroup analyses including pediatrics (age younger than 18 years), sex (female), race/ethnicity (African American, Asian/Pacific Islander, Hispanic, white), gender, and race/ethnicity, the Committee requested modeling to determine the effects of the proposal on education level (high school or less, more than high school), insurance type (private, public), and urban/rural (Metropolitan, Micropolitan, Small Town, Rural). The modeling showed that the new subgroups were affected similarly to the overall population. A specific concern was the effect of the proposal on what would be considered as rural or non-metropolitan populations**. Figures 15 and 16** shows the breakdown by place of residence on transplant counts.

Figure 15. Transplant counts by candidate place of residence. Non-metropolitan includes micropolitan, small town, and rural groups.

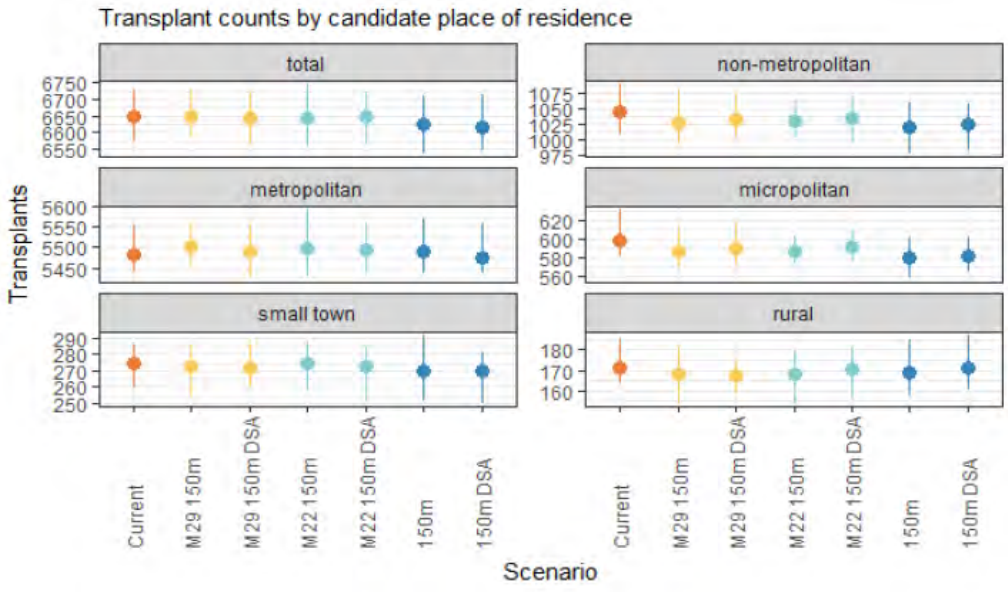
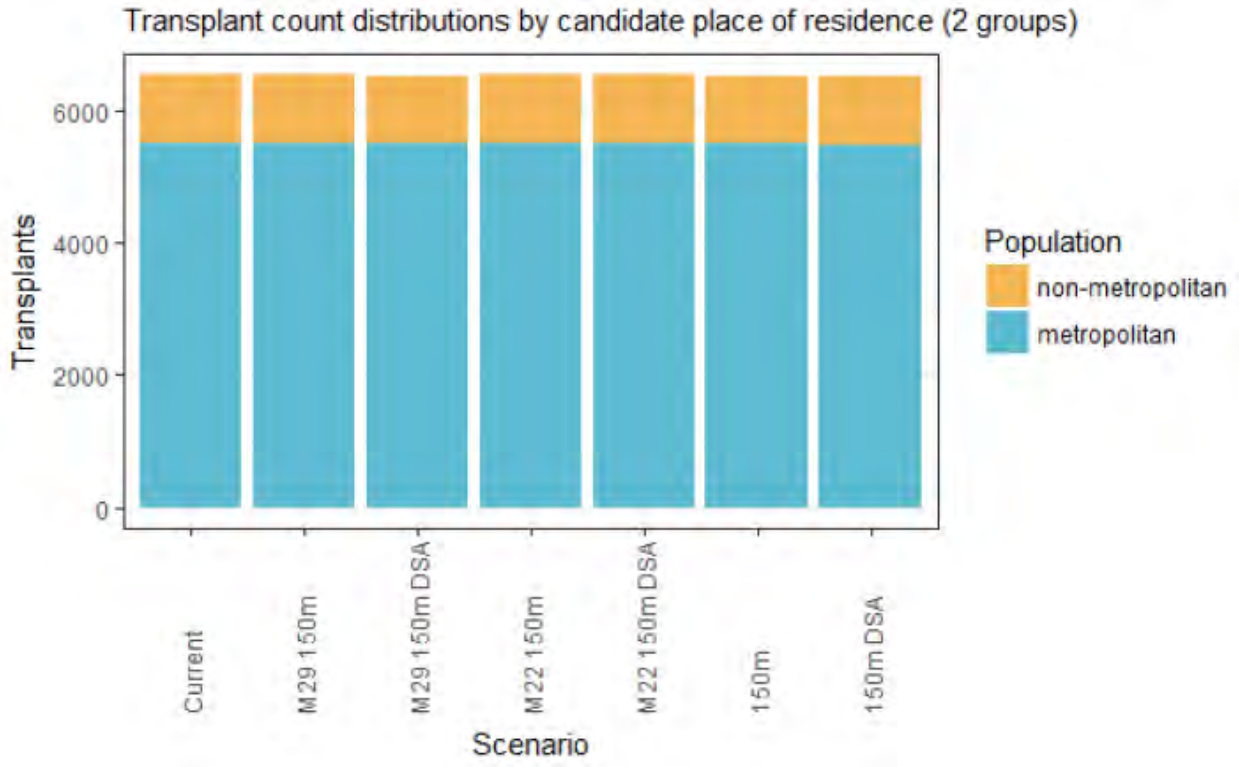


Figure 16. Transplant count distributions by candidate place of residence. Non-metropolitan includes micropolitan, small town, and rural groups.



The modeling shows little evidence of a disproportionate effect on any of the candidate place of residence subgroups. The monitoring plan for this proposal includes an analysis of the effects on socioeconomic factors. Pending Board approval and implementation, the Committee will monitor the effect of the proposal on vulnerable and disadvantaged populations to ensure that the change does not disproportionately affect these groups.

9. Variances

Following the decision on a final board proposal, the Committee addressed the current variances in place. There are four existing variances to current policy. The Committee made a recommendation to the OPTN/UNOS Board of Directors on the four existing liver variances.

Region 1 and 10

Region 1 and 10 use the standard distribution and allocation system with the following exception. The regions share for Status 1 patients on a common regional list. Pediatric donor livers are offered first to Status 1 patients within Region 1 and 10. Current policy has separate classifications for the DSA and Region with regards to allocation to Status 1A candidates for this subset of donor livers. The current proposal allocates regionally for Status 1A candidates for pediatric donors, therefore this variance is encompassed in the current proposal. Due to no longer serving its purpose as a variance to the national system, the Committee voted to terminate the Region 1 and 10 variances pending board approval and implementation of the current proposal.

HIOP

The Hawaii DSA in Region 6 uses the standard distribution and allocation system with the following exception. Liver candidates with compatible blood types are included with identical blood types for blood type O donors. The Hawaii agreement is a unique situation due to its geographical location. Due to its unique application and the variance's concurrence with the current proposal, the Committee voted to

extend the HIOP variance pending board approval and implementation of the current proposal. Policy language has been added to include this variance with other variances in Policy.[13]

Region 9

The region utilizes the standard distribution and allocation system for allocating livers with the following exception. As New York composes most of Region 9, the BOD approved an alternative local unit where "Statewide" classifications replace the DSA and Regional classifications. New York essentially shares all livers throughout Region 9. Vermont is the only state outside of New York in Region 9 and they do not currently have a liver program. The Committee discussed this variance at length. In its current state, the variance does not include references to the proximity circle and does not take into consideration the concept of proximity points. The Committee recognizes that Region 9, and specifically New York have shared broadly across their DSAs for several years. With the goal of this proposal being to distribute livers more broadly, the Committee sought a way for Region 9 to maintain the sentiment of their current variance, while also being applicable to the current proposal. The Committee voted to amend the current Region 9 variance pending board approval and implementation of the current proposal. The amended variance replaces DSA" with "region" throughout *Policy 9.8: Liver Allocation, Classifications, and Rankings*. This variance will have two implications:

1) For liver and liver-intestine allocation, all references to the DSA are replaced with "region". Livers and liver-intestines will be allocated to candidates in the region for all instances in the current proposal that policy would allocate to the DSA.
2) At the time of the match run, a liver or liver-intestine candidate with a MELD or PELD score registered at a transplant hospital within the circle or OPO's region will receive proximity points. As discussed throughout this proposal, the proposed policy includes proximity points to candidates in the circle or OPO's DSA.

Policy language has been added to include this variance with other variances in Policy.

Table 8. Summary of final board proposal

Topic	Summary	Post Public Comment Change?
1. MELD or PELD Sharing Threshold	Adult candidates who have a calculated MELD score of 32 or higher, as well as pediatric candidates younger than age 18 with a MELD or PELD score of 32 or higher, would be prioritized for organ offers within the region plus the circle.	The sharing threshold changed from 29 to 32
2. Proximity Circle	Liver distribution will be broadened to include candidates within a 150 nautical mile radius of a donor hospital. This circle may include candidates outside of the region.	No change

[13] In the interest of transparency, the OPTN began publishing variances as policy language starting with the Split Liver variance in 2011.

Topic	Summary	Post Public Comment Change?
3. Proximity Points	Additional transplant priority (equivalent to 3 MELD or PELD points) would be awarded to candidates with a MELD or PELD of at least 15, and who are either within the same donor service area (DSA) as a donor or are within 150 nautical miles of the donor hospital but in a different DSA or region.	Points changed from 5 to 3 and the policy of a MELD or PELD of at least 15 was added
4. DCD or Age $\geq$ 70 Donors	Livers from deceased donors who are age 70 or older, or who are DCD donors, have a separate allocation that prioritizes the DSA before broader distribution to the region or circle.	No change
5. Allowing MELD Scores to go Above 40 to Candidates in the Circle	For the purpose of calculating proximity points, MELD would not be capped at 40. For example, an adult candidate with a calculated (lab) MELD of 38 would receive a score of 41 if they are within the DSA or circle; an adult candidate with a calculated MELD of 40 would receive a score of 43 if they are within the DSA or circle.	This was not included in the original public comment proposal
6. Allocating to Adult Hepatic Artery Thrombosis (HAT) Candidates Based on their Allocation MELD	Adult candidates with early hepatic artery thrombosis currently receive a standard MELD exception score of 40, unless they meet specific additional criteria that make them eligible for status 1A. Under the current proposal, these candidates are the only ones who would receive immediate prioritization within the region and circle based on an exception score as opposed to a calculated score. They will retain their exception score of 40 for this purpose.	This was not included in the original public comment proposal
7. DSA Performance	This proposal does not address DSA performance, however current and future OPTN initiatives will address this	N/A
8. Effect on Vulnerable Populations	The modeling did not show a disproportionate impact on vulnerable populations. The Committee will continue to monitor this pending implementation.	N/A

Topic	Summary	Post Public Comment Change?
9. Variances	The Committee voted on a recommendation for the four existing liver variances. The Committee recommends that the Region 1 and 10 variances are terminated, HIOP variance is extended, and the Region 9 variance is amended.	This was not included in the original public comment proposal

Which populations are impacted by this proposal?

The goal of this project is to reduce the geographic disparity in access to transplant among the estimated 14,500 candidates waiting for a liver transplant each day. Candidates on the waiting list above the sharing threshold will have increased access to transplant within their region. Additionally, these candidates will have increased access to organs that may be outside their region, but within 150 nautical miles of their transplant program.

How does this proposal impact the OPTN Strategic Plan?

1. *Increase the number of transplants*: There is no expected impact to this goal
2. *Improve equity in access to transplants*: The primary goal of this proposal is to improve geographic disparity in access to liver transplant. Based on extensive previous modeling, this proposal is expected to decrease the variation in median MELD at transplant for all liver candidates.
3. *Improve waitlisted patient, living donor, and transplant recipient outcomes:* Overall pre- and post-transplant deaths are not predicted to increase over the current system.
4. *Promote living donor and transplant recipient safety*: No expected impact on this goal.
5. *Promote the efficient management of the OPTN*: No expected impact on this goal.

How will the OPTN implement this proposal?

If the Board approves this proposal, the OPTN plans to coordinate implementation such that the NLRB and revisions to standardized eligibility criteria for HCC exceptions are in place upon the implementation of this proposal.

This proposal will require programming in UNet^{SM}. The OPTN/UNOS will follow established protocols to inform members and educate them on any policy changes through Policy Notices. Due to the significant impact of these policy changes, the OPTN/UNOS will offer learning opportunities to specific audiences to promote knowledge, awareness, and compliance related to policy and system changes in advance of implementation. The OPTN/UNOS will deliver communications to the membership when instructional offerings are available. Members should take advantage of relevant educational opportunities offered.

UNOS IT provides cost estimates for each public comment proposal that will require programming to implement. The estimates can be small (108-419 hours), medium (420-749 hours), large (750-1,649 hours), very large (1,650-3,999 hours), or enterprise (4,000-8,000 hours). The IT estimate for this proposal is enterprise.

How will members implement this proposal?

OPOs and transplant hospitals may need to devote significant effort in developing new working relationships for organ offers that travel outside of current boundaries. Any broader sharing policy may pose logistical and financial challenges. The OPO Committee is currently addressing some of these challenges with their proposal, *Improving the Efficiency of Organ Allocation*.

OPOs

OPOs will need to prepare for any additional cost and coordination of transportation. OPOs may be interacting with transplant programs outside of their region more frequently than with the current system.

Fiscal Impact:

Additional staff or hours may be required for coordination if the number of imported livers increases in a substantial way. Additional fees for imported organs from outside of the local region may be collected, as well. Additional costs incurred by the OPO are typically included as a part of the acquisition fee, so are shifted to hospitals to claim as reimbursement.

Transplant Hospitals

Transplant hospitals may also need to prepare for the additional cost and coordination of transportation. Transplant programs may be interacting with OPOs and donor hospitals outside of their region more frequently than with the current system.

Fiscal Impact:

Implementation requires clinical and administrative staff time to revise protocol, educate other team members, and to establish logistics with additional partners. The timeframe to implement is almost immediate to a few months, depending on the hospital. Additional staff time to implement is estimated to total up to $3,000.

If liver recovery volume increases substantially, hiring additional staff may be needed. On call administrative and clinical (surgeons) staff can increase costs. Increased volume may require additional procurement personnel and/or on call surgeon availability. If OPO import offers increase substantially, some coordination may be shifted to hospitals, further impacting staffing. Lab fees to conduct crossmatching may increase, as well, although most livers are not crossmatched.

If additional flights are required for livers (with or without increased procurement volume), the cost per transplant case can rise substantially. Cost of transportation differs across regions, potentially causing the cost per liver transport to vary. Depending on the payer agreement, hospitals are reimbursed an average/standard acquisition cost per case. The standard acquisition cost may remain stable despite the occurrence of more flights. The hospitals must pay the cost of transportation and recovery team even if reimbursement of expense cannot be claimed. It will also require transplant centers' time to evaluate potential increase in organ acquisition and impact on existing commercial and managed care contracts.

Procurement costs, including flights, must often be paid up front by the importing hospital if the liver is from outside of the local region. OPOs outside of the local region may also charge different fees, causing uncertainly about overall cost impact. Increase in volume will create additional revenue overall. It is uncertain whether or not additional revenue can offset additional costs that hospitals may incur.

It is possible that smaller liver programs will see a decrease in volume and greater competition with larger regional programs, especially in dense areas. This may cause a decreased need for staff or surgeons, and a loss in revenue. Smaller programs may have marginal ability to absorb an increased cost per case, especially if courier fees for a number of cases increase. This could result in some smaller programs eventually closing, potentially impacting patient access to services. Overall, fiscal impact will differ among all programs. Change in cost is highly dependent on change in liver volume, change in length of stay per case, regulatory and private payer mix, additional supplier contracts, and competition from peers.

Will this proposal require members to submit additional data?

No, this proposal does not require additional data collection.

How will members be evaluated for compliance with this proposal?

The proposed language will not change the current monitoring of OPTN members. Organ allocation according to the match run will still be subject to OPTN review, and members are required to provide documentation as requested.

How will the sponsoring Committee evaluate whether this proposal was successful post implementation?

Using pre vs. post comparisons, analyses will be performed post-implementation at approximate 3-month intervals (as appropriate, up to 2 years) to identify trends and potentially unanticipated consequences of the policy. Analysis of post-transplant outcomes will be performed after sufficient follow-up data has accrued, which is dependent on submission of 6-month follow-up forms.

Metrics to be evaluated include:

- Number of deceased donor liver transplants
- Size and composition of the waiting list
- Variance in the median MELD/PELD at transplant by DSA and Region
- Waiting list mortality rates, transplant rates
- Transplant recipient demographics (age, gender, diagnosis, ethnicity, socioeconomic factors as available for analysis)
- Transplants by exception (ex. HCC, non-HCC)
- Post-transplant survival rates, overall and stratified by MELD/PELD category
- Post-transplant length of stay
- Liver discard rates (of livers recovered)
- Livers not recovered
- Organ travel distance, cold ischemia time, donor risk index
- Changes in transplant center or DSA-level transplant outcomes

Policy or Bylaws Language

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

RESOLVED, that changes to Policies 1.2 (Definitions), 5.4.B (Order of Allocation), 9.1.D (MELD Score), 9.8 (Liver Allocation, Classifications, and Rankings), and 9.11 (Variances), as set forth below, are hereby approved, effective pending implementation and notice to OPTN members.

1.2 Definitions

Allocation MELD or PELD Score

The highest exception or calculated MELD or PELD score available to the candidate according to Policy.

Calculated MELD or PELD Score

The highest non-exception MELD or PELD score available to the candidate according to Policy.

Circle

A geographic area used in the allocation of certain organs. For the allocation of deceased donor livers or liver-intestines, a circle is a 150 nautical mile radius around the donor hospital.

Match MELD or PELD Score

The MELD or PELD score available to the candidate at the time of the match for a deceased donor liver or liver-intestine.

Geographical Area

A physical area used to group potential transplant recipients in a classification. OPTN Policy uses the following geographical areas for organ allocation: *circle, DSA, region, nation, and zones*.

5.4.B Order of Allocation

The process to allocate deceased donor organs occurs with these steps:

1. The match system eliminates candidates who cannot accept the deceased donor based on size or blood type.
2. The match system ranks candidates according to the allocation sequences in the organ allocation policies.
3. OPOs must first offer organs to potential recipients in the order that the potential recipients appear on a match run.
4. If no transplant program on the initial match run accepts the organ, the host OPO may give transplant programs the opportunity to update their candidates' data with the OPTN Contractor. The host OPO must re-execute the match run to allocate the organ.
5. If no transplant program within the DSA or through an approved regional sharing arrangement accepts the organ, the Organ Center will allocate ~~an abdominal organ first regionally and then nationally, according to allocation Policies. The Organ Center will allocate thoracic organs according to *Policy 6: Allocation of Hearts and Heart-Lungs* and *Policy 10: Allocation of Lungs*~~ the organ according to Policy.
6. Members may export deceased donor organs to hospitals in foreign countries only after offering these organs to all potential recipients on the match run. Members must submit the *Organ Export Verification Form* to the OPTN Contractor prior to exporting deceased donor organs.

This policy does not apply to VCA transplants; instead, members must allocate VCAs according to *Policy 12.2: VCA Allocation*.

9.1.D MELD Score

Candidates who are at least 12 years old receive an initial $MELD_{(i)}$ score equal to: *0.957 x Loge(creatinine mg/dL) + 0. 378 x Log_e(bilirubin mg/dL) + 1.120 x Loge (INR) + 0.643*

Laboratory values less than 1.0 will be set to 1.0 when calculating a candidate's MELD score.

The following candidates will receive a creatinine value of 4.0 mg/dL:

- Candidates with a creatinine value greater than 4.0 mg/dL
- Candidates who received two or more dialysis treatments within the prior 7 days
- Candidates who received 24 hours of continuous veno-venous hemodialysis (CVVHD) within the prior 7 days

The maximum MELD score is 40. The MELD score derived from this calculation will be rounded to the tenth decimal place and then multiplied by 10. At the time of allocation, the MELD score may go above 40 with the inclusion of proximity points to a candidate within the circle or OPO's DSA.

For candidates with an initial MELD score greater than 11, the MELD score is then re-calculated as follows:

$$MELD = MELD_{(i)} + 1.32*(137-Na) – [0.033*MELD_{(i)}*(137-Na)]$$

Sodium values less than 125 mmol/L will be set to 125, and values greater than 137 mmol/L will be set to 137.

If a candidate's recalculated MELD score requires recertification within 7 days of implementation based on *Table 9-1: Liver Status Update Schedule*, the transplant hospital will have 7 days to update laboratory values. If after 7 days the laboratory values are not updated, the candidate will be re-assigned to the previous lower MELD score.

9.8 Liver Allocation, Classifications, and Rankings

~~Livers from pediatric deceased donors are first allocated to pediatric potential transplant recipients with respect to geographical proximity to donor and medical urgency, according to *Tables 9-7* and *9-8.*~~ Unless otherwise stated, all mentions of MELD or PELD in this section reference a candidate's match MELD or PELD score.

9.8.B Allocation of Livers for Other Methods of Hepatic Support

A liver must be offered first for transplantation according to the match run before it is offered for use in other methods of hepatic support. If the liver is not accepted for transplant within 6 hours of attempted allocation by the OPTN Contractor, the OPTN Contractor will offer the liver for other methods of hepatic support, according to *Tables 9-4, 9-5, 9-6, 9-7, 9-8,* and *9-9* below ~~to status 1A and 1B candidates, followed by all candidates in order of their MELD or PELD scores. Livers allocated for other methods of hepatic support will be offered first locally, then regionally, and then nationally in descending point order~~.

9.8.C Allocation of Livers by Blood Type

Livers from blood type O deceased donors may be offered to *any* of the following:

- Status 1A and 1B candidates.

- Blood type O candidates.
- Blood type B candidates with a MELD or PELD score ≧ greater than or equal to 30.
- Any remaining blood type compatible candidates once the blood type O and B candidates on the match run have been exhausted at the regiona~~l~~ plus circle, and national level.

For status 1A or 1B candidates or candidates with an allocation MELD or PELD score ≧ greater than or equal to 30, transplant hospitals may specify on the waiting list if those candidates will accept a liver from a deceased donor of any blood type. Candidates are given points depending on their blood type according to *Policy 9.7.B: Points Assigned by Blood Type*.

9.8.D MELD or PELD Points for Geographic Proximity to the Donor Hospital

At the time of the match run, a liver or liver-intestine candidate with a MELD or PELD score registered at a transplant hospital within the circle or OPO's DSA receives proximity points according to Table 9-3 below.

Table 9-3: Proximity Points

Candidates that are:	And have :	Will receive:
At least 18 years old at the time of registration on the waiting list	A calculated MELD score of at least 15	Three proximity points to their calculated MELD score
At least 18 years old at the time of registration on the waiting list	An approved HAT exception	Three proximity points to their allocation MELD score
12 to 17 years old at the time of registration on the waiting list	An allocation MELD score of at least 15	Three proximity points to their allocation MELD score
Less than 12 years old at the time of registration on the waiting list	An allocation PELD score of at least 15	Three proximity points to their allocation PELD score

9.8.~~D~~E Sorting Within Each Classification

Within each status 1A allocation classification, candidates are sorted in the following order:

1. ~~Total points, highest to lowest (waiting time points, plus blood type compatibility points)~~ Total waiting time and blood type compatibility points (highest to lowest), according to *Policy 9.7: Liver Allocation Points*
2. Total waiting time at status 1A (highest to lowest)

Within each status 1B allocation classification, candidates are sorted in the following order:

1. ~~Total points (highest to lowest)~~ Total waiting time and blood type compatibility points (highest to lowest), according to *Policy 9.7: Liver Allocation Points*
2. Total waiting time at status 1B (highest to lowest)

Within each ~~allocation~~ MELD or PELD score allocation classification, candidates with ~~a score ≤ six~~ a MELD or PELD less than or equal to 6 are sorted in the following order:

~~1. Identical blood types, compatible blood types, then incompatible blood types~~

~~2. Total waiting time (highest to lowest)~~
~~3. Then those waiting list positions assigned to candidates with a MELD or PELD score ≤ are redistributed between the pediatric candidates, according to their PELD or MELD score (highest to lowest).~~

1. First, all candidates are sorted in the following order:
   a. Identical blood types, compatible blood types, then incompatible blood types
   b. Waiting time at the current or higher allocation MELD or allocation PELD score (highest to lowest)
   c. Total waiting time (highest to lowest)
2. Then those waiting list positions assigned to candidates with a MELD or PELD score less than or equal to six are redistributed between the pediatric candidates, according to their PELD or MELD score (highest to lowest).

Within each allocation classification, all other candidates are sorted in the following order:

1. MELD or ~~/~~PELD score (highest to lowest)
2. Identical blood types, compatible blood types, then incompatible blood types
3. Waiting time at the current or higher MELD or PELD score, excluding proximity points (highest to lowest)
4. Total waiting time (highest to lowest)~~.~~

9.8.~~E~~F Allocation of Livers from Non-DCD Deceased Donors at Least 18 Years Old and Less than 70 years old

Livers from non-DCD deceased donors at least 18 years old and less than 70 years old are allocated to candidates according to *Table 9-~~3~~4* below.

Table 9-~~3~~4: Allocation of Livers from Non-DCD Deceased Donors at Least 18 Years Old and Less than 70 Years Old

~~Classification~~	~~Candidates that are within the:~~	~~And are:~~
~~1~~	~~OPO's region~~	~~Adult or pediatric status 1A~~
~~2~~	~~OPO's region~~	~~Pediatric status 1B~~
~~3~~	~~OPO's DSA~~	~~MELD/PELD of 40~~
~~4~~	~~OPO's region~~	~~MELD/PELD of 40~~
~~5~~	~~OPO's DSA~~	~~MELD/PELD of 39~~
~~6~~	~~OPO's region~~	~~MELD/PELD of 39~~
~~7~~	~~OPO's DSA~~	~~MELD/PELD of 38~~
~~8~~	~~OPO's region~~	~~MELD/PELD of 38~~
~~9~~	~~OPO's DSA~~	~~MELD/PELD of 37~~
~~10~~	~~OPO's region~~	~~MELD/PELD of 37~~
~~11~~	~~OPO's DSA~~	~~MELD/PELD of 36~~
~~12~~	~~OPO's region~~	~~MELD/PELD of 36~~
~~13~~	~~OPO's DSA~~	~~MELD/PELD of 35~~
~~14~~	~~OPO's region~~	~~MELD/PELD of 35~~
~~15~~	~~OPO's DSA~~	~~MELD/PELD of at least 15~~

Classification	Candidates that are within the:	And are:
16	OPO's region	MELD/PELD of at least 15
17	Nation	Adult or Pediatric status 1A
18	Nation	Pediatric status 1B
19	Nation	MELD/PELD of at least 15
20	OPO's DSA	MELD/PELD less than 15
21	OPO's region	MELD/PELD less than 15
22	Nation	MELD/PELD less than 15
23	OPO's DSA	MELD/PELD at least 40 and compatible blood type
24	OPO's region	MELD/PELD at least 40 and compatible blood type
25	OPO's DSA	MELD/PELD of 39 and compatible blood type
26	OPO's region	MELD/PELD of 39 and compatible blood type
27	OPO's DSA	MELD/PELD of 38 and compatible blood type
28	OPO's region	MELD/PELD of 38 and compatible blood type
29	OPO's DSA	MELD/PELD of 37 and compatible blood type
30	OPO's region	MELD/PELD of 37 and compatible blood type
31	OPO's DSA	MELD/PELD of 36 and compatible blood type
32	OPO's region	MELD/PELD of 36 and compatible blood type
33	OPO's DSA	MELD/PELD of 35 and compatible blood type
34	OPO's region	MELD/PELD of 35 and compatible blood type
35	OPO's DSA	MELD/PELD of at least 15 and compatible blood type
36	OPO's region	MELD/PELD of at least 15 and compatible blood type
37	Nation	MELD/PELD of at least 15 and compatible blood type
38	OPO's DSA	MELD/PELD less than 15 and compatible blood type
39	OPO's region	MELD/PELD less than 15 and compatible blood type
40	Nation	MELD/PELD less than 15 and compatible blood type
41	OPO's DSA	Adult or pediatric status 1A and in need of other method of hepatic support
42	OPO's DSA	Pediatric status 1B and in need of other method of hepatic support
43	OPO's DSA	Any MELD/PELD and in need of other method of hepatic support
44	OPO's region	Adult or pediatric status 1A and in need of other method of hepatic support

~~Classification~~	~~Candidates that are within the:~~	~~And are:~~
~~45~~	~~OPO's region~~	~~Pediatric status 1B and in need of other method of hepatic support~~
~~46~~	~~OPO's region~~	~~Any MELD/PELD and in need of other method of hepatic support~~
~~47~~	~~Nation~~	~~Adult or pediatric status 1A and in need of other method of hepatic support~~
~~48~~	~~Nation~~	~~Pediatric status 1B and in need of other method of hepatic support~~
~~49~~	~~Nation~~	~~Any MELD/PELD and in need of other method of hepatic support~~
~~50~~	~~OPO's DSA~~	~~Any MELD/PELD in need of other method of hepatic support, and a blood type compatible with the donor~~
~~51~~	~~OPO's region~~	~~Any MELD/PELD in need of other method of hepatic support, and blood type compatible with the donor~~
~~52~~	~~Nation~~	~~Any MELD/PELD in need of other method of hepatic support, and blood type compatible with the donor~~

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Classification	Candidates that are within the OPO's:	And are:
1	Region or Circle	Adult or pediatric status 1A
2	Region or Circle	Pediatric status 1B
3	Region or Circle	Any of the following: •At least 18 years old at time of registration and calculated MELD of at least 32 including proximity points •At least 18 years old at time of registration and has an approved HAT exception •Less than 18 years old at time of registration and allocation MELD or PELD of at least 32 including proximity points
4	DSA	MELD or PELD of at least 15
5	Region or Circle	MELD or PELD of at least 15
6	Nation	Adult or pediatric status 1A
7	Nation	Pediatric status 1B
8	Nation	MELD or PELD of at least 15
9	DSA	MELD or PELD less than 15
10	Region or Circle	MELD or PELD less than 15
11	Nation	MELD or PELD less than 15
12	Region or Circle	MELD or PELD of at least 32, blood type compatible

Classification	Candidates that are within the OPO's:	And are:
13	DSA	MELD or PELD of at least 15, blood type compatible
14	Region or Circle	MELD or PELD of at least 15, blood type compatible
15	Nation	MELD or PELD of at least 15, blood type compatible
16	DSA	MELD or PELD less than 15, blood type compatible
17	Region or Circle	MELD or PELD less than 15, blood type compatible
18	Nation	MELD or PELD less than 15, blood type compatible
19	DSA	Adult or pediatric status 1A, and in need of other method of hepatic support
20	DSA	Pediatric status 1B and in need of other method of hepatic support
21	DSA	Any MELD or PELD, and in need of other method of hepatic support
22	Region or Circle	Adult or pediatric status 1A, and in need of other method of hepatic support
23	Region or Circle	Pediatric status 1B and in need of other method of hepatic support
24	Region or Circle	Any MELD or PELD, and in need of other method of hepatic support
25	Nation	Adult or pediatric status 1A, and in need of other method of hepatic support
26	Nation	Pediatric status 1B and in need of other method of hepatic support
27	Nation	Any MELD or PELD, and in need of other method of hepatic support
28	DSA	Any MELD or PELD, and in need of other method of hepatic support, blood type compatible
29	Region or Circle	Any MELD or PELD, and in need of other method of hepatic support, blood type compatible
30	Nation	Any MELD or PELD, and in need of other method of hepatic support, blood type compatible

9.8.~~F~~G Allocation of Livers from Non-DCD Deceased Donors 11 to 17 Years Old

Livers from non-DCD deceased donors 11 to 17 years old are allocated to candidates according to *Table 9-~~4~~5* below.

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~~Classification~~	~~Candidates that are within the:~~	~~And are:~~
~~1~~	~~OPO's DSA~~	~~Pediatric status 1A~~
~~2~~	~~OPO's region~~	~~Pediatric status 1A~~
~~3~~	~~OPO's DSA~~	~~Adult status 1A~~
~~4~~	~~OPO's region~~	~~Adult status 1A~~
~~5~~	~~OPO's DSA~~	~~Pediatric status 1B~~
~~6~~	~~OPO's region~~	~~Pediatric status 1B~~
~~7~~	~~OPO's DSA or region~~	~~Any PELD~~
~~8~~	~~OPO's DSA~~	~~MELD of at least 15 and 12 to 17 years old~~
~~9~~	~~OPO's DSA~~	~~MELD of at least 15 and at least 18 years old~~
~~10~~	~~OPO's region~~	~~MELD of at least 15 and 12 to 17 years old~~
~~11~~	~~OPO's region~~	~~MELD of at least 15 and at least 18 years old~~
~~12~~	~~OPO's DSA~~	~~MELD less than 15 and 12 to 17 years old~~
~~13~~	~~OPO's DSA~~	~~MELD less than 15 and at least 18 years old~~
~~14~~	~~OPO's region~~	~~MELD less than 15 and 12 to 17 years old~~
~~15~~	~~OPO's region~~	~~MELD less than 15 and at least 18 years old~~
~~16~~	~~Nation~~	~~Pediatric status 1A~~
~~17~~	~~Nation~~	~~Adult status 1A~~
~~18~~	~~Nation~~	~~Pediatric status 1B~~
~~19~~	~~Nation~~	~~Any PELD~~
~~20~~	~~Nation~~	~~Any MELD and 12 to 17 years old~~
~~21~~	~~Nation~~	~~Any MELD and at least 18 years old~~
~~22~~	~~OPO's region~~	~~Any PELD, and compatible blood type~~
~~23~~	~~OPO's DSA~~	~~MELD at least 15, 12 to 17 years old, and Compatible blood type~~
~~24~~	~~OPO's DSA~~	~~MELD at least 15, at least 18 years old, and compatible blood type~~
~~25~~	~~OPO's region~~	~~MELD at least 15, 12 to 17 years old, and compatible blood type~~
~~26~~	~~OPO's region~~	~~MELD at least 15, at least 18 years old, and compatible blood type~~
~~27~~	~~OPO's DSA~~	~~MELD less than 15, 12 to 17 years old, and compatible blood type~~
~~28~~	~~OPO's DSA~~	~~MELD less than 15, at least 18 years old, and compatible blood type~~
~~29~~	~~OPO's region~~	~~MELD less than 15, 12 to 17 years old, and compatible blood type~~
~~30~~	~~OPO's region~~	~~MELD less than 15, at least 18 years old, and compatible blood type~~
~~31~~	~~Nation~~	~~0 to 11 years old and compatible blood type~~

~~Classification~~	~~Candidates that are within the:~~	~~And are:~~
~~32~~	~~Nation~~	~~12 to 17 years old and compatible blood type~~
~~33~~	~~Nation~~	~~Any MELD, at least 18 years old, and compatible blood type~~
~~34~~	~~OPO's DSA~~	~~Adult or pediatric status 1A and in need of other method of hepatic support~~
~~35~~	~~OPO's DSA~~	~~Pediatric status 1B and in need of other method of hepatic support~~
~~36~~	~~OPO's DSA~~	~~Any MELD/PELD and in need of other method of hepatic support~~
~~37~~	~~OPO's region~~	~~Adult or pediatric status 1A and in need of other method of hepatic support~~
~~38~~	~~OPO's region~~	~~Pediatric status 1B and in need of other method of hepatic support~~
~~39~~	~~OPO's region~~	~~Any MELD/PELD and in need of other method of hepatic support~~
~~40~~	~~Nation~~	~~Adult or pediatric status 1A and in need of other method of hepatic support~~
~~41~~	~~Nation~~	~~Pediatric status 1B and in need of other method of hepatic support~~
~~42~~	~~Nation~~	~~Any MELD/PELD and in need of other method of hepatic support~~
~~43~~	~~OPO's DSA~~	~~Any MELD/PELD in need of other method of hepatic support, and compatible blood type~~
~~44~~	~~OPO's region~~	~~Any MELD/PELD in need of other method of hepatic support, and compatible blood type~~
~~45~~	~~Nation~~	~~Any MELD/PELD in need of other method of hepatic support, and compatible blood type~~

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Classification	Candidates that are within the OPO's:	And are:
1	Region or Circle	Pediatric status 1A
2	Region or Circle	Adult status 1A
3	Region or Circle	Pediatric status 1B
4	Region or Circle	Any PELD
5	Region or Circle	MELD of at least 15 and 12 to 17 years old
6	Region or Circle	MELD of at least 15 and at least 18 years old
7	Region or Circle	MELD less than 15 and 12 to 17 years old
8	Region or Circle	MELD less than 15 and at least 18 years old
9	Nation	Pediatric status 1A
10	Nation	Adult status 1A
11	Nation	Pediatric status 1B

Classification	Candidates that are within the OPO's:	And are:
12	Nation	Any PELD
13	Nation	Any MELD and 12 to 17 years old
14	Nation	Any MELD and at least 18 years old
15	Region or Circle	Any PELD and blood type compatible
16	Region or Circle	MELD at least 15, 12 to 17 years old, and blood type compatible
17	Region or Circle	MELD at least 15, at least 18 years old, and blood type compatible
18	Region or Circle	MELD less than 15, 12 to 17 years old, and blood type compatible
19	Region or Circle	MELD less than 15, at least 18 years old, and blood type compatible
20	Nation	Any PELD and blood type compatible
21	Nation	Any MELD, 12 to 17 years old, and blood type compatible
22	Nation	Any MELD, at least 18 years old, and blood type compatible
23	Region or Circle	Adult or pediatric status 1A, and in need of other method of hepatic support
24	Region or Circle	Pediatric status 1B and in need of other method of hepatic support
25	Region or Circle	Any MELD or PELD, and in need of other method of hepatic support
26	Nation	Adult or pediatric status 1A, and in need of other method of hepatic support
27	Nation	Pediatric status 1B and in need of other method of hepatic support
28	Nation	Any MELD or PELD, and in need of other method of hepatic support
29	Region or Circle	Any MELD or PELD, in need of other method of hepatic support, and blood type compatible
30	Nation	Any MELD or PELD, in need of other method of hepatic support, and blood type compatible

9.8.~~G~~H Allocation of Livers from Non-DCD Deceased Donors Less than 11 Years Old

Livers from non-DCD donors less than 11 years old are allocated to candidates according to *Table 9-~~5~~6* below.

Table 9-~~56~~: Allocation of Livers from Non-DCD Deceased Donors less than 11 Years Old

~~Classification~~	~~Candidates that are within the…~~	~~And are…~~
~~1~~	~~OPO's region~~	~~Pediatric status 1A~~
~~2~~	~~Nation~~	~~Pediatric status 1A (0-11)~~
~~3~~	~~OPO's DSA~~	~~Adult status 1A~~
~~4~~	~~OPO's Region~~	~~Adult status 1A~~
~~5~~	~~OPO's Region~~	~~Pediatric status 1B~~
~~6~~	~~OPO's Region~~	~~Any PELD~~
~~7~~	~~OPO's DSA~~	~~MELD of at least 15 and 12 to 17 years old~~
~~8~~	~~OPO's DSA~~	~~MELD of at least 15 and at least 18 years old~~
~~9~~	~~OPO's Region~~	~~MELD of at least 15 and at least 12 to 17 years old~~
~~10~~	~~OPO's Region~~	~~MELD of at least 15 and at least 18 years old~~
~~11~~	~~OPO's DSA~~	~~MELD less than 15 and 12 to 17 years old~~
~~12~~	~~OPO's DSA~~	~~MELD less than 15 and at least 18 years old~~
~~13~~	~~OPO's Region~~	~~MELD less than 15 and 12 to 17 years old~~
~~14~~	~~OPO's Region~~	~~MELD less than 15 and at least 18 years old~~
~~15~~	~~Nation~~	~~Status 1A and 12 to 17 years old~~
~~16~~	~~Nation~~	~~Status 1A and at least 18 years old~~
~~17~~	~~Nation~~	~~Status 1B and 0 to 17 years old~~
~~18~~	~~Nation~~	~~Any PELD~~
~~19~~	~~Nation~~	~~Any MELD and 12 to 17 years old~~
~~20~~	~~Nation~~	~~Any MELD and at least 18 years old~~
~~21~~	~~OPO's Region~~	~~Any PELD and compatible blood type~~
~~22~~	~~OPO's DSA~~	~~MELD of at least 15, 12 to 17 years old, and compatible blood type~~
~~23~~	~~OPO's DSA~~	~~MELD of at least 15, at least 18 years old, and compatible blood type~~
~~24~~	~~OPO's Region~~	~~MELD of at least 15, 12 to 17 years old, and compatible blood type~~
~~25~~	~~OPO's Region~~	~~MELD of at least 15, at least 18 years old, and compatible blood type~~
~~26~~	~~OPO's DSA~~	~~MELD less than 15, 12 to 17 years old, and compatible blood type~~
~~27~~	~~OPO's DSA~~	~~MELD less than 15, at least 18 years old, and compatible blood type~~
~~28~~	~~Region~~	~~MELD less than 15, 12 to 17 years old, and compatible blood type~~
~~29~~	~~Region~~	~~MELD less than 15, at least 18 years old, and compatible blood type~~
~~30~~	~~Nation~~	~~Any PELD and compatible blood type~~

~~Classification~~	~~Candidates that are within the…~~	~~And are…~~
~~31~~	~~Nation~~	~~Any MELD, 12 to 17 years old, and compatible blood type~~
~~32~~	~~Nation~~	~~Any MELD, at least 18 years old, and compatible blood type~~
~~33~~	~~OPO's DSA~~	~~Adult or pediatric status 1A and in need of other method of hepatic support~~
~~34~~	~~OPO's DSA~~	~~Pediatric status 1B and in need of other method of hepatic support~~
~~35~~	~~OPO's DSA~~	~~Any MELD/PELD and in need of other method of hepatic support~~
~~36~~	~~OPO's region~~	~~Adult or pediatric status 1A and in need of other method of hepatic support~~
~~37~~	~~OPO's region~~	~~Pediatric status 1B and in need of other method of hepatic support~~
~~38~~	~~OPO's region~~	~~Any MELD/PELD, any age, and in need of other method of hepatic support~~
~~39~~	~~Nation~~	~~Adult or pediatric status 1A and in need of other method of hepatic support~~
~~40~~	~~Nation~~	~~Pediatric status 1B and in need of other method of hepatic support~~
~~41~~	~~Nation~~	~~Any MELD/PELD, any age, and in need of other method of hepatic support~~
~~42~~	~~OPO's DSA~~	~~Any MELD/PELD, any age, in need of other method of hepatic support, and compatible blood type~~
~~43~~	~~OPO's region~~	~~Any MELD/PELD, any age, in need of other method of hepatic support, and compatible blood type~~
~~44~~	~~Nation~~	~~Any MELD/PELD, any age, in need of other method of hepatic support, and compatible blood type~~

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Classification	Candidates that are within the OPO's:	And are…
1	Region or Circle	Pediatric status 1A
2	Nation	Pediatric status 1A and 0 to 11 years old
3	Region or Circle	Adult status 1A
4	Region or Circle	Pediatric status 1B
5	Region or Circle	Any PELD
6	Region or Circle	MELD of at least 15 and 12 to 17 years old
7	Region or Circle	MELD of at least 15 and at least 18 years old
8	Region or Circle	MELD less than 15 and 12 to 17 years old
9	Region or Circle	MELD less than 15 and at least 18 years old

Classification	Candidates that are within the OPO's:	And are…
10	Nation	Pediatric status 1A and 12 to 17 years old
11	Nation	Adult status 1A
12	Nation	Pediatric status 1B and 0 to 17 years old
13	Nation	Any PELD
14	Nation	Any MELD and 12 to 17 years old
15	Nation	Any MELD and at least 18 years old
16	Region or Circle	Any PELD and compatible blood type
17	Region or Circle	MELD of at least 15, 12 to 17 years old and blood type compatible
18	Region or Circle	MELD of at least 15, at least 18 years old and blood type compatible
19	Region or Circle	MELD less than 15, 12 to 17 years old and blood type compatible
20	Region or Circle	MELD less than 15, at least 18 years old, and blood type compatible
21	Nation	Any PELD and blood type compatible
22	Nation	Any MELD, 12 to 17 years old, and blood type compatible
23	Nation	Any MELD, at least 18 years old, and blood type compatible
24	Region or Circle	Adult or pediatric status 1A, and in need of other method of hepatic support
25	Region or Circle	Pediatric status 1B and in need of other method of hepatic support
26	Region or Circle	Any MELD or PELD, and in need of other method of hepatic support
27	Nation	Adult or pediatric status 1A, and in need of other method of hepatic support
28	Nation	Pediatric status 1B and in need of other method of hepatic support
29	Nation	Any MELD or PELD, and in need of other method of hepatic support
30	Region or Circle	Any MELD or PELD, and in need of other method of hepatic support, and blood type compatible
31	Nation	Any MELD or PELD, and in need of other method of hepatic support, and blood type compatible

9.8.I Allocation of Livers and Liver-Intestines from DCD Donors or Donors at Least 70 Years Old

Livers and liver-intestines from DCD donors or donors at least 70 years old are allocated to candidates according to *Table 9-7* below.

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Classification	Candidates that are within the OPO's:	And are:
1	Region or Circle	Adult or Pediatric status 1A
2	Region or Circle	Pediatric status 1B
3	DSA	MELD or PELD of at least 15
4	Region or Circle	MELD or PELD of at least 15
5	Nation	Adult or Pediatric status 1A
6	Nation	Pediatric status 1B
7	Nation	MELD or PELD of at least 15
8	DSA	MELD or PELD less than 15
9	Region or Circle	MELD or PELD less than 15
10	Nation	MELD or PELD less than 15
11	DSA	MELD or PELD of at least 15, and blood type compatible
12	Region or Circle	MELD or PELD of at least 15, and blood type compatible
13	Nation	MELD or PELD of at least 15, and blood type compatible
14	DSA	MELD or PELD less than 15, and blood type compatible
15	Region or Circle	MELD or PELD less than 15, and blood type compatible
16	Nation	MELD or PELD less than 15, and blood type compatible
17	DSA	Adult or pediatric status 1A, and in need of other method of hepatic support
18	DSA	Pediatric status 1B and in need of other method of hepatic support
19	DSA	Any MELD or PELD, and in need of other method of hepatic support
20	Region or Circle	Adult or pediatric status 1A, and in need of other method of hepatic support
21	Region or Circle	Pediatric status 1B and in need of other method of hepatic support
22	Region or Circle	Any MELD or PELD, and in need of other method of hepatic support
23	Nation	Adult or pediatric status 1A, and in need of other method of hepatic support
24	Nation	Pediatric status 1B and in need of other method of hepatic support
25	Nation	Any MELD or PELD, and in need of other method of hepatic support

Classification	Candidates that are within the OPO's:	And are:
26	DSA	Any MELD or PELD, and in need of other method of hepatic support, and blood type compatible
27	Region or Circle	Any MELD or PELD, and in need of other method of hepatic support, and blood type compatible
28	Nation	Any MELD or PELD, and in need of other method of hepatic support, and blood type compatible

9.8.~~H~~J Allocation of Liver-Intestines from Non-DCD Deceased Donors at Least 18 Years Old and Less than 70 years old

Livers and intestines from non-DCD deceased donors at least 18 years old and less than 70 years old are allocated to candidates according to *Table 9-~~6~~8* below:

Table 9-~~6~~8: Allocation of Liver-Intestines from Non-DCD Deceased Donors at Least 18 Years Old

~~Classification~~	~~Candidates that are within the:~~	~~And are:~~
~~1~~	~~OPO's region~~	~~Liver or liver-intestine, adult or pediatric status 1A~~
~~2~~	~~OPO's region~~	~~Liver or liver-intestine, pediatric status 1B~~
~~3~~	~~OPO's DSA~~	~~Liver or liver-intestine, MELD/PELD of 40~~
~~4~~	~~OPO's region~~	~~Liver or liver-intestine, MELD/PELD of 40~~
~~5~~	~~OPO's DSA~~	~~Liver or liver-intestine, MELD/PELD of 39~~
~~6~~	~~OPO's region~~	~~Liver or liver-intestine, MELD/PELD of 39~~
~~7~~	~~OPO's DSA~~	~~Liver or liver-intestine, MELD/PELD of 38~~
~~8~~	~~OPO's region~~	~~Liver or liver-intestine, MELD/PELD of 38~~
~~9~~	~~OPO's DSA~~	~~Liver or liver-intestine, MELD/PELD of 37~~
~~10~~	~~OPO's region~~	~~Liver or liver-intestine, MELD/PELD of 37~~
~~11~~	~~OPO's DSA~~	~~Liver or liver-intestine, MELD/PELD of 36~~
~~12~~	~~OPO's region~~	~~Liver or liver-intestine, MELD/PELD of 36~~
~~13~~	~~OPO's DSA~~	~~Liver or liver-intestine, MELD/PELD of 35~~
~~14~~	~~OPO's region~~	~~Liver or liver-intestine, MELD/PELD of 35~~
~~15~~	~~OPO's DSA~~	~~Liver or liver-intestine, MELD/PELD of at least 29~~
~~16~~	~~Nation~~	~~Liver or liver intestine, LI/IN status 1A~~
~~17~~	~~Nation~~	~~Liver or liver-intestine, LI/IN status 1B~~
~~18~~	~~Nation~~	~~Liver or liver-intestine, LI/IN MELD/PELD (highest to lowest)~~
~~19~~	~~OPO's DSA~~	~~Liver or liver-intestine, MELD/PELD of at least 15~~
~~20~~	~~OPO's region~~	~~Liver or liver intestine, MELD/PELD less than 15~~

Classification	Candidates that are within the:	And are:
21	Nation	Liver or liver-intestine, adult or pediatric status 1A
22	Nation	Liver or liver-intestine, pediatric status 1B
23	Nation	Liver or liver-intestine, MELD/PELD of at least 15
24	OPO's DSA	Liver or liver-intestine, MELD/PELD less than 15
25	OPO's region	Liver or liver-intestine, MELD/PELD less than 15
26	Nation	Liver or liver-intestine, MELD/PELD less than 15
27	OPO's DSA	Liver or liver-intestine, MELD/PELD at least 40 and compatible blood type
28	OPO's region	Liver or liver-intestine, MELD/PELD at least 40 and compatible blood type
29	OPO's DSA	Liver or liver-intestine, MELD/PELD of 39 and compatible blood type
30	OPO's region	Liver or liver-intestine, MELD/PELD of 39 and compatible blood type
31	OPO's DSA	Liver or liver-intestine, MELD/PELD of 38 and compatible blood type
32	OPO's region	Liver or liver-intestine, MELD/PELD of 38 and compatible blood type
33	OPO's DSA	Liver or liver-intestine, MELD/PELD of 37 and compatible blood type
34	OPO's region	Liver or liver-intestine, MELD/PELD of 37 and compatible blood type
35	OPO's DSA	Liver or liver-intestine, MELD/PELD of 36 and compatible blood type
36	OPO's region	Liver or liver-intestine, MELD/PELD of 36 and compatible blood type
37	OPO's DSA	Liver or liver-intestine, MELD/PELD of 35 and compatible blood type
38	OPO's region	Liver or liver-intestine, MELD/PELD of 35 and compatible blood type
39	OPO's DSA	Liver or liver-intestine, MELD/PELD of at least 15 and compatible blood type
40	OPO's region	Liver or liver-intestine, MELD/PELD of at least 15 and compatible blood type
41	Nation	Liver or liver-intestine, MELD/PELD of at least 15 and compatible blood type
42	OPO's DSA	Liver or liver-intestine, MELD/PELD less than 15 and compatible blood type
43	OPO's region	Liver or liver-intestine, MELD/PELD less than 15 and compatible blood type

~~Classification~~	~~Candidates that are within the:~~	~~And are:~~
~~44~~	~~Nation~~	~~Liver or liver-intestine, MELD/PELD less than 15 and compatible blood type~~
~~45~~	~~OPO's DSA~~	~~Liver or liver-intestine, adult or pediatric status 1A and in need of other method of hepatic support~~
~~46~~	~~OPO's DSA~~	~~Liver or liver-intestine, pediatric status 1B and in need of other method of hepatic support~~
~~47~~	~~OPO's DSA~~	~~Liver or liver-intestine, any MELD/PELD and in need of other method of hepatic support~~
~~48~~	~~OPO's region~~	~~Liver or liver-intestine, adult or pediatric status 1A and in need of other method of hepatic support~~
~~49~~	~~OPO's region~~	~~Liver or liver-intestine, pediatric status 1B and in need of other method of hepatic support~~
~~50~~	~~OPO's region~~	~~Liver or liver-intestine, any MELD/PELD and in need of other method of hepatic support~~
~~51~~	~~Nation~~	~~Liver or liver-intestine, adult or pediatric status 1A and in need of other method of hepatic support~~
~~52~~	~~Nation~~	~~Liver or liver-intestine, pediatric status 1B and in need of other method of hepatic support~~
~~53~~	~~Nation~~	~~Liver or liver-intestine, any MELD/PELD and in need of other method of hepatic support~~
~~54~~	~~OPO's DSA~~	~~Liver or liver-intestine, any MELD/PELD in need of other method of hepatic support, and a blood type compatible with the donor~~
~~55~~	~~OPO's region~~	~~Liver or liver-intestine, any MELD/PELD in need of other method of hepatic support, and blood type compatible with the donor~~
~~56~~	~~Nation~~	~~Liver or liver-intestine, any MELD/PELD in need of other method of hepatic support, and blood type compatible with the donor~~

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Classification	Candidates that are within the OPO's:	And are:
1	Region or Circle	Liver or liver-intestine and adult or pediatric status 1A
2	Region or Circle	Liver or liver-intestine and pediatric status 1B

Classification	Candidates that are within the OPO's:	And are:
3	Region or Circle	Liver or liver-intestine and any of the following: •At least 18 years old at time of registration and calculated MELD of at least 32 including proximity points •At least 18 years old at time of registration and has an approved HAT exception •Less than 18 years old at time of registration and allocation MELD or PELD of at least 32 including proximity points
4	Nation	Liver-intestine and adult or pediatric status 1A
5	Nation	Liver-intestine and pediatric status 1B
6	Nation	Liver-intestine and any MELD or PELD
7	DSA	Liver and MELD or PELD of at least 15
8	Region or Circle	Liver and MELD or PELD of at least 15
9	Nation	Liver and adult or pediatric status 1A
10	Nation	Liver and pediatric status 1B
11	Nation	Liver and MELD or PELD of at least 15
12	DSA	Liver and MELD or PELD less than 15
13	Region or Circle	Liver and MELD or PELD less than 15
14	Nation	Liver and MELD or PELD less than 15
15	Region or Circle	Liver or liver-intestine, MELD or PELD of at least 32, and blood type compatible
16	Nation	Liver-intestine, any MELD or PELD, and blood type compatible
17	DSA	Liver, MELD or PELD of at least 15, and blood type compatible
18	Region or Circle	Liver, MELD or PELD of at least 15, and blood type compatible
19	Nation	Liver, MELD or PELD of at least 15, and blood type compatible
20	DSA	Liver, MELD or PELD less than 15, and blood type compatible
21	Region or Circle	Liver, MELD or PELD less than 15, and blood type compatible
22	Nation	Liver, MELD or PELD less than 15, and blood type compatible
23	DSA	Liver or liver-intestine, adult or pediatric status 1A, and in need of other method of hepatic support
24	DSA	Liver or liver-intestine, pediatric status 1B, and in need of other method of hepatic support
25	DSA	Liver or liver-intestine, any MELD or PELD, and in need of other method of hepatic support

Classification	Candidates that are within the OPO's:	And are:
26	Region or Circle	Liver or liver-intestine, adult or pediatric status 1A, and in need of other method of hepatic support
27	Region or Circle	Liver or liver-intestine, pediatric status 1B, and in need of other method of hepatic support
28	Region or Circle	Liver or liver-intestine, any MELD or PELD, and in need of other method of hepatic support
29	Nation	Liver or liver-intestine, adult or pediatric status 1A, and in need of other method of hepatic support
30	Nation	Liver or liver-intestine, pediatric status 1B, and in need of other method of hepatic support
31	Nation	Liver or liver-intestine, any MELD or PELD, and in need of other method of hepatic support
32	DSA	Liver or liver-intestine, any MELD or PELD, in need of other method of hepatic support, and blood type compatible
33	Region or Circle	Liver or liver-intestine, any MELD or PELD, in need of other method of hepatic support, and blood type compatible
34	Nation	Liver or liver-intestine, any MELD or PELD, in need of other method of hepatic support, and blood type compatible

~~**9.6.J Allocation of Liver-Intestine from Donors at Least 11 Years of age**~~

~~For combined liver-intestine allocation from donors at least 11 years of age, the liver must first be offered as follows:~~

~~1. According to *Policy 9.6.F: Allocation of Livers from Deceased Donors 11 to 17 Years Old*~~
~~2. Sequentially to *each* potential liver recipient, including all MELD/PELD potential recipients, through national Status 1A and 1B offers~~

~~The liver may then be offered to combined liver-intestine potential recipients sequentially according to the intestine match run.~~

9.8.K Allocation of Liver-Intestines from Non-DCD Donors 11 to 17 Years Old

For combined liver-intestine allocation from non-DCD donors 11 to 17 years old, the liver must first be offered as follows:

1. According to *Policy 9.8.G: Allocation of Livers from Non-DCD Deceased Donors 11 to 17 Years Old*
2. Sequentially to *each* liver candidate, including all MELD and PELD candidates, through national status 1A and 1B offers

The liver may then be offered to combined liver-intestine potential recipients sequentially according to the intestine match run.

9.8.~~I~~L Allocation of Liver-Intestines from Non-DCD Donors less than 11 Years Old

Livers and intestines from non-DCD donors less than 11 years old are allocated to candidates according to *Table 9-~~7~~9* below.

Table 9-~~7~~9: Allocation of Combined Liver-Intestines from Non-DCD Donors less than 11 Years Old

~~Classification~~	~~Candidates that are within the:~~	~~And are:~~
~~The following classifications appear for all blood types~~		
~~1~~	~~OPO's region~~	~~Liver or liver-intestine, Pediatric Status 1A~~
~~2~~	~~Nation~~	~~Liver or liver-intestine, Pediatric Status 1A, and 0 to less than 12 years of age~~
~~3~~	~~Nation~~	~~Liver-intestine, Pediatric Status 1A, and 12 to less than 18 years of age~~
~~4~~	~~OPO's DSA~~	~~Liver or liver-intestine, Adult Status 1A~~
~~5~~	~~OPO's region~~	~~Liver or liver-intestine, Adult Status 1A~~
~~6~~	~~OPO's region~~	~~Liver or liver-intestine, Pediatric Status 1B~~
~~7~~	~~OPO's region~~	~~Liver or liver-intestine, PELD greater than 20, and 0 to less than 12 years of age~~
~~8~~	~~Nation~~	~~Liver-intestine, Pediatric Status 1B~~
~~9~~	~~Nation~~	~~Liver-intestine, PELD greater than 20~~
~~10~~	~~OPO's region~~	~~Liver or liver-intestine, PELD of less than 21~~
~~11~~	~~OPO's DSA~~	~~Liver or liver-intestine, MELD of at least 15, and 12 to less than 18 years of age~~
~~12~~	~~OPO's DSA~~	~~Liver or liver-intestine, MELD of at least 15, and at least 18 years of age~~
~~13~~	~~OPO's region~~	~~Liver or liver-intestine, MELD of at least 15, and 12 to less than 18 years of age~~
~~14~~	~~OPO's region~~	~~Liver or liver-intestine, MELD of at least 15, and at least 18 years of age~~
~~15~~	~~OPO's DSA~~	~~Liver or liver-intestine, MELD less than 15, and 12 to less than 18 years of age~~
~~16~~	~~OPO's DSA~~	~~Liver or liver-intestine, MELD less than 15, and at least 18 years of age~~
~~17~~	~~OPO's region~~	~~Liver or liver-intestine, MELD less than 15, and 12 to less than 18 years of age~~
~~18~~	~~OPO's region~~	~~Liver or liver-intestine, MELD less than 15, and at least 18 years of age~~

Classification	Candidates that are within the:	And are:
19	Nation	Liver, Pediatric Status 1A, and 12 to less than 18 years of age
20	Nation	Liver or liver-intestine, Adult Status 1A
21	Nation	Liver, Pediatric Status 1B
22	Nation	Liver or liver-intestine, with any PELD
23	Nation	Liver or liver-intestine, with any MELD/PELD, and 12 to less than 18 years of age
24	Nation	Liver or liver-intestine, with any MELD, and at least 18 years of age
The following classifications only appear on O blood type donor matches		
25	OPO's region	Liver or liver-intestine, with any PELD, and compatible blood type match with the donor
26	OPO's DSA	Liver or liver-intestine, MELD of at least 15, 12 to less than 18 years of age, and compatible blood type match with the donor
27	OPO's DSA	Liver or liver-intestine, MELD of at least 15, at least 18 years of age, and compatible blood type match with the donor
28	OPO's region	Liver or liver-intestine, MELD of at least 15, 12 to less than 18 years of age, and compatible blood type match with the donor
29	OPO's region	Liver or liver-intestine, MELD of at least 15, at least 18 years of age, and compatible blood type match with the donor
30	OPO's DSA	Liver or liver-intestine, MELD less than 15, 12 to less than 18 years of age, and compatible blood type match with the donor
31	OPO's DSA	Liver or liver-intestine, MELD less than 15, at least 18 years of age, and compatible blood type match with the donor
32	OPO's region	Liver or liver-intestine, MELD less than 15, 12 to less than 18 years of age, and compatible blood type match with the donor
33	OPO's region	Liver or liver-intestine, MELD less than 15, at least 18 years of age, and compatible blood type match with the donor
34	Nation	Liver or liver-intestine, with any PELD, and compatible blood type match with the donor

Classification	Candidates that are within the:	And are:
35	Nation	Liver or liver-intestine, with any MELD, 12 to less than 18 years of age, and compatible blood type match with the donor
36	Nation	Liver or liver-intestine, with any MELD, at least 18 years of age, and compatible blood type match with the donor
The following classifications appear for all blood types		
37	OPO's DSA	Liver or liver-intestine, Adult or Pediatric Status 1A, and in need of other method of hepatic support
38	OPO's DSA	Liver or liver-intestine, Pediatric Status 1B, and in need of other method of hepatic support
39	OPO's DSA	Liver or liver-intestine, with any MELD/PELD, and in need of other method of hepatic support
40	OPO's region	Liver or liver-intestine, Adult or Pediatric Status 1A, and in need of other method of hepatic support
41	OPO's region	Liver or liver-intestine, Pediatric Status 1B, and in need of other method of hepatic support
42	OPO's region	Liver or liver-intestine, with any MELD/PELD, and in need of other method of hepatic support
43	Nation	Liver or liver-intestine, Adult or Pediatric Status 1A, and in need of other method of hepatic support
44	Nation	Liver or liver-intestine, Pediatric Status 1B, and in need of other method of hepatic support
45	Nation	Liver or liver-intestine, with any MELD/PELD, and in need of other method of hepatic support
The following classifications only appear on O blood type donor matches		
46	OPO's DSA	Liver or liver-intestine, with any MELD/PELD, in need of other method of hepatic support, and compatible blood type match with the donor
47	OPO's region	Liver or liver-intestine, with any MELD/PELD, in need of other method of hepatic support, and compatible blood type match with the donor

~~Classification~~	~~Candidates that are within the:~~	~~And are:~~
~~48~~	~~Nation~~	~~Liver or liver-intestine, with any MELD/PELD, in need of other method of hepatic support, and compatible blood type match with the donor~~

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Classification	Candidates that are within the OPO's:	And are:
1	Region or Circle	Liver or liver-intestine and pediatric status 1A
2	Nation	Liver or liver-intestine, pediatric status 1A, and 0 to 11 years old
3	Nation	Liver-intestine, pediatric status 1A, and 12 to 17 years old
4	Region or Circle	Liver or liver-intestine and adult status 1A
5	Region or Circle	Liver or liver-intestine and pediatric status 1B
6	Region or Circle	Liver or liver-intestine and PELD greater than 20
7	Nation	Liver-intestine and pediatric status 1B
8	Nation	Liver-intestine and PELD greater than 20
9	Region or Circle	Liver or liver-intestine and PELD less than or equal to 20
10	Region or Circle	Liver or liver-intestine, MELD of at least 15, and 12 to 17 years old
11	Region or Circle	Liver or liver-intestine, MELD of at least 15, and at least 18 years old
12	Region or Circle	Liver or liver-intestine, MELD less than 15, and 12 to 17 years old
13	Region or Circle	Liver or liver-intestine, MELD less than 15, and at least 18 years old
14	Nation	Liver, pediatric status 1A, and 12 to 17 years old
15	Nation	Liver or liver-intestine and adult status 1A
16	Nation	Liver and pediatric status 1B
17	Nation	Liver or liver-intestine and any PELD
18	Nation	Liver or liver-intestine, any MELD, and 12 to 17 years old
19	Nation	Liver or liver-intestine, any MELD, and at least 18 years old

Classification	Candidates that are within the OPO's:	And are:
20	Region or Circle	Liver or liver-intestine, PELD greater than 20, and blood type compatible
21	Nation	Liver-intestine, PELD greater than 20, and blood type compatible
22	Region or Circle	Liver or liver-intestine, PELD less than or equal to 20, and blood type compatible
23	Region or Circle	Liver or liver-intestine, MELD of at least 15, 12 to 17 years old, and blood type compatible
24	Region or Circle	Liver or liver-intestine, MELD of at least 15, at least 18 years old, and blood type compatible
25	Region or Circle	Liver or liver-intestine, MELD less than 15, 12 to 17 years old, and blood type compatible
26	Region or Circle	Liver or liver-intestine, MELD less than 15, at least 18 years old, and blood type compatible
27	Nation	Liver or liver-intestine, any PELD, and blood type compatible
28	Nation	Liver or liver-intestine, any MELD, 12 to 17 years old, and blood type compatible
29	Nation	Liver or liver-intestine, any MELD, at least 18 years old, and blood type compatible
30	Region or Circle	Liver or liver-intestine, adult or pediatric status 1A, and in need of other method of hepatic support
31	Region or Circle	Liver or liver-intestine, pediatric status 1B, and in need of other method of hepatic support
32	Region or Circle	Liver or liver-intestine, any MELD or PELD, and in need of other method of hepatic support
33	Nation	Liver or liver-intestine, adult or pediatric status 1A, and in need of other method of hepatic support
34	Nation	Liver or liver-intestine, pediatric status 1B, and in need of other method of hepatic support
35	Nation	Liver or liver-intestine, any MELD or PELD, and in need of other method of hepatic support
36	Region or Circle	Liver or liver-intestine, any MELD or PELD, in need of other method of hepatic support, and blood type compatible
37	Nation	Liver or liver-intestine, any MELD or PELD, in need of other method of hepatic support, and blood type compatible

~~Blood type matches for combined liver-intestine allocation are determined according to *Policy 9.6.C: Allocation of Livers by Blood Type*.~~

[*Cross-references to headings and table captions affected by the re-numbering of this policy will also be changed as necessary.*]

FURTHER RESOLVED, that changes to Policy 9.11 (Variances), as set forth below, are hereby approved, effective pending implementation and notice to OPTN members.

9.11.B Closed Variance for Allocation of Blood Type O Deceased Donor Livers in Hawaii

This is a closed variance that applies only to OPOs and transplant programs in Hawaii due to its geographical location. This variance permits the allocation of blood type O deceased donor livers simultaneously to liver candidates within the DSA with compatible blood types in addition to identical blood types.

9.11.C Closed Variance for Allocation of Livers Procured in Region 9

This is a closed variance that applies to livers procured in Region 9. This variance replaces all references to "DSA" with "region" throughout *Policy 9.8: Liver Allocation, Classifications, and Rankings.*

FURTHER RESOLVED, that the new Policy 9.11.B (Closed Variance for Allocation of Blood Type O Deceased Donor Livers in Hawaii) and 9.11.C (Closed Variance for Allocation of Livers Procured in Region 9) expires two years following implementation.

FURTHER RESOLVED, that the following variances, as set forth below, are terminated, effective pending implementation and notice to OPTN members.

Region 1-AAS
Original Implementation- 8/1/1990
Last Modification- 7/9/2008
Region 1 uses the standard distribution and allocation system with the following exception. The region shares for Status 1 patients on a common regional list. Adult and pediatric donor livers are offered first to Status 1 patients within Region 1, i.e. there are no "OPO LI, Status 1A" or "OPO LI, Status 1B" classifications.

Region 10-AAS
Original Implementation- 1/30/1998
Last Modification- 7/9/2008
Region 10 uses the standard distribution and allocation system for the allocation of livers with the following differences. The region shares for Status 1 patients on a common regional list. Adult and pediatric donor livers are offered first to Status 1 patients within Region 10, i.e. there are no "OPO LI, Status 1A" or "OPO LI, Status 1B" classifications.

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