OPTN | UNOS

Public Comment Proposal

Liver and Intestine Distribution Using Distance from Donor Hospital

OPTN/UNOS Liver and Intestine Transplantation Committee

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Liver and Intestine Distribution Using Distance from Donor Hospital

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Sponsoring Committee:	*Liver and Intestine Transplantation*
Public Comment Period:	*October 8, 2018 – November 1, 2018*

Executive Summary

The United States Secretary of Health and Human Services (HHS) received critical comments regarding compliance with the National Organ Transplant Act (NOTA)[1] and associated regulations under the OPTN Final Rule[2] with respect to the geographic units used in liver distribution. As of July 2018, HHS and the OPTN are named defendants in a lawsuit regarding this issue.[3]

The OPTN Final Rule sets requirements for allocation polices developed by the OPTN, including sound medical judgement, best use of organs, ability for transplant hospitals to decide whether to accept an organ offer, avoiding wasting organs, and promoting efficiency. The Final Rule also includes a requirement that policies "shall not be based on the candidate's place of residence or place of listing, except to the extent required"[4] by the other requirements of the Final Rule listed above.

The liver organ distribution policies currently use donation service areas (DSAs) and OPTN regions as geographic units. These are not good proxies for geographic distance between donors and transplant candidates because the disparate sizes, shapes, and populations of DSAs and regions result in an inconsistent application for all candidates. This presents a potential conflict with the Final Rule.

In response to a directive from the HHS Secretary, the Liver and Intestinal Transplantation Committee (Committee) worked to develop a proposal that does not include DSA or region in liver allocation or in scoring liver candidate exceptions. The Board also committed to considering such a proposal in December 2018.

This proposal, developed at that direction, eliminates the use of DSA and region in liver, liver-intestine, intestine, and liver-kidney allocation policies. This proposal would allocate livers to candidates within 150, 250, or 500 nautical miles (nm) of donor hospitals before offering them nationally to allow for efficient placement of donor organs and to avoid organ wastage. (Referred to as the "broader 2-circle" framework.) Livers would be allocated to status 1A and 1B candidates within 500nm first. Candidates with a Model for End-Stage Liver Disease (MELD) score of at least 32 would then be offered livers if they were within 250nm of the donor hospital. Then livers would be offered to candidates with a MELD of 15-31, first within 150nm, then within 250nm, then within 500nm. After that, livers would be offered to status 1A and 1B candidates and candidates with MELD or PELD scores of at least 15 across the nation.

Additionally, the broader 2-circle proposal replaces median MELD at transplant (MMaT) in the DSA or region in the calculation of exception scores with the MMaT within a 250 nm circle around the transplant hospital for patients that are at least 12 years old, and with the median Pediatric End-Stage Liver Disease

[1] NOTA, 42 U.S.C. § 273 et. seq.
[2] OPTN Final Rule, 42 C.F.R. § 121.
[3] Cruz et al v. U.S. Dept. of Health and Human Services, (S.D.N.Y 18-CV-06371).
[4] 42 C.F.R. § 121.

(PELD) at transplant in the nation for patients less than 12 years old. It also recommends changes to existing liver allocation variances, provides additional priority for pediatric candidates when there is a pediatric donor, clarifies treatment of blood type B candidates when the donor is blood type O, simplifies allocation of livers for other methods of hepatic support and MELD <6, and clarifies other references to local, DSA, and region.

Is the sponsoring Committee requesting specific feedback or input about the proposal?

1. The community is asked what MELD sharing threshold they recommend.
2. The community is asked whether the sizes of the fixed distance circles should be larger, smaller, or remain the same.
3. The community is asked whether they prefer the broader 2-circle model (this is the model preferred by the committee), or the acuity circles model.
4. Members are asked to comment on both the immediate and long term budgetary impact of resources that may be required if this proposal is approved. This information assists the Board in considering the proposal and its impact on the community

What problem will this proposal address?

The OPTN Final Rule sets requirements for allocation polices developed by the OPTN, including sound medical judgement, best use of organs, the ability for centers to decide whether to accept an organ offer, to avoid wasting organs, and to promote efficiency.[5] The Final Rule also includes a requirement that policies "shall not be based on the candidate's place of residence or place of listing, except to the extent required" by the other requirements of the Rule.[6] Finally, the OPTN Final Rule contains a performance goal for "Distributing organs over as broad a geographic area as feasible under paragraphs (a)(1)-(5) of this section, and in order of decreasing medical urgency."[7]

In 2017, patients in New York challenged the use of donation service areas (DSAs) in lung allocation.[8] This challenge contended that the use of DSAs for lung distribution purposes was arbitrary and capricious and not consistent with obligations specified in the OPTN Final Rule. The OPTN/UNOS Executive Committee made emergency changes to remove the use of DSAs in lung allocation.[9] On May 30, 2018, HHS received a critical comment with similar concerns about the liver distribution system.[10] Specifically, the commenter asserted that livers from deceased donors were allocated to candidates based on arbitrary geographic boundaries instead of medical priority. The author then requested that HHS direct the OPTN to revise those distribution policies. Subsequently, HRSA requested a response from the OPTN on the critical comment.[11]

OPTN policy development requires reasoned, evidence-based decision making. In administrative rulemaking, this rationality requirement stems from the concept that changes to regulatory law must be based on reasoned analysis. The courts have developed an "arbitrary and capricious" standard for the review of agency rulemaking.[12] Under this standard, an agency issuing a regulation must "examine the relevant data and articulate a satisfactory explanation for its action" including a 'rational connection between the facts found the choice made.'"[13] An agency regulation is arbitrary and capricious where the agency (1) has relied on factors that Congress did not intend to consider, (2) entirely failed to consider an important aspect of the problem, (3) offered an explanation for its decision that runs counter to the evidence before it, or (4) is so implausible that it could not be the result of a difference in view or agency expertise.[14]

Applying the above test to the current framework for liver distribution, there are concerns with the use of DSAs and regions for organ distribution.[15] First, it appears that at least some members considered factors that Congress did not intend for the OPTN to consider when designing organ allocation rules. During Committee conversations and public comment, some members stated that deceased donor organs should be a local resource as opposed to a national resource. This principle is not included in NOTA or the OPTN Final Rule. Specifically, it is not included in the list of factors for developing organ allocation policies in 42 C.F.R § 121.8. Additionally, several entities have considered this issue, with the consensus understanding that organs are a national resource meant to be allocated based on patient's medical

[5] 42 C.F.R §121.8.
[6] 42 C.F.R §121.8(a)(8).
[7] 42 C.F.R. §121.8(b)(3).

[8] Holman v U.S. Dept. of Health and Human Services, (S.D.N.Y 17-CV-09041).
[9] OPTN/UNOS Thoracic Organ Transplantation Committee, "Modifications to the Distribution of Deceased Donor Lungs." June 2018, https://optn.transplant.hrsa.gov/media/2523/thoracic_boardreport_201806_lung.pdf (accessed October 1, 2018).
[10] Motty Shulman, letter to Sec. Alex Azar, May 30, 2018.
[11] George Sigounas, letter to Yolanda Becker, OPTN President, June 8, 2018.
[12] Motor Vehicles Mfrs. Assn. v. State Farm Mut., 463 U.S. 29 (1983).
[13] *Ibid.*
[14] *Ibid.*
[15] Alexandra Glazier, "The Lung Lawsuit: A Case Study in Organ Allocation Policy and Administrative Law." *Journal of Health and Biomedical Law*, no XIV (2018).

need. Specifically, the 1986 Task Force stated that, "The principle that donated cadaveric organs are a national resource implies that, in principle, and to the extent technically and practically achievable, any citizen or resident of the United States in need of a transplant should be considered as a potential recipient of each retrieved organ on a basis equal to that of a patient who lives in the area where the organs or tissues are retrieved. Organs and tissues ought to be distributed on the basis of objective priority criteria, and not on the basis of accidents of geography."[16] The Institute of Medicine (IOM) made this same conclusion in 1999.[17] In 2012, the AMA Code of Medical Ethics stated that, "Organs should be considered a national, rather than a local or regional resource. Geographical priorities in the allocation of organs should be prohibited except when transportation of organs would threaten their suitability for transplantation."[18] HHS has stated this same principle several times in public rulemaking.[19, 20] Most recently, the OPTN/UNOS Board of Directors adopted new Principles of Organ Distribution. Those principles reaffirm that "Deceased donor organs are a national resource to be distributed as broadly as feasible."[21]

Additionally, at least some members offered explanations for the use of DSA and regional boundaries that are unsupported by evidence. During several Committee conversations and public comments, it was posited that DSA boundaries should be used for organ distribution because they result in strengthened relationships between transplant hospitals and OPOs which in turn result in improved utilization rates. While some studies have shown that improved relationships between donor hospitals and OPOs can result in improve organ donation rates,[22] it is conceivable that improved relationships between transplant hospitals and OPOs could result in improved organ placement. However, a literature search identified no research that shows DSA boundaries facilitate these relationships.

The OPTN Final Rule aims to distribute organs to the most medically urgent candidates. The DSA and regional boundaries were not designed with the intent to optimize any of the OPTN goals in NOTA or the Final Rule. Nor have these boundaries been successful in distributing organs to the most medically urgent candidates. Instead, the current distribution framework results in geographic variability in access to transplant. The OPTN/SRTR's 2016 Annual Data Report: Liver stated, "there is wide geographic variability in the degree of sickness, based on median MELD scores, in candidates for deceased donor transplants. The highest reported median MELD score was 39 in Los Angeles, California (CAOP), and the lowest 20 in Indianapolis, Indiana (INOP)."[23] Several articles have repeated this finding over time.[24]

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[16] U.S. Dept. of Health & Human Services, Public Health Service, Health Resources and Services Administration, Office of Organ Transplantation, "Organ Transplantation: Issues and Recommendations: Report of the Task Force on Organ Transplantation." Rockville, MD., p. 91, 1987, quoting Hunsicker, LG.

[17] National Academies Press, "Organ Procurement and Transplantation." (1999).

[18] American Medical Association, "Opinion 2.16. Organ Transplantation Guidelines." *Journal of Ethics.* March 2012, Volume 14, Number 3: 204-214. doi: 10.1001/virtualmentor.2012.14.3.coet1-1203.

[19] 98 FR 16490, June 22, 1988. Page 33863. "We know that hospitals, OPOs, and tissue and eye banks share our view that organs and tissues are a precious national resource and that only through the collaborative efforts of all parties can lives be saved." https://www.gpo.gov/fdsys/pkg/FR-1998-06-22/html/98-16490.htm

[20] 76 FR 78216. Dec. 16, 2011. Page 78218. "One of the major reasons NOTA was enacted and affirmed by several amendments was to establish an organ allocation system that functions equitably on a nationwide basis with provisions for outcomes reporting and evaluation. Prior to the enactment of NOTA, deceased donor organs were allocated regionally, based on relationships between transplant programs and donor hospitals."

[21] OPTN/UNOS Ad Hoc Committee on Geography. "Geographic Organ Distribution Principles and Models Recommendations Report." June 2018.

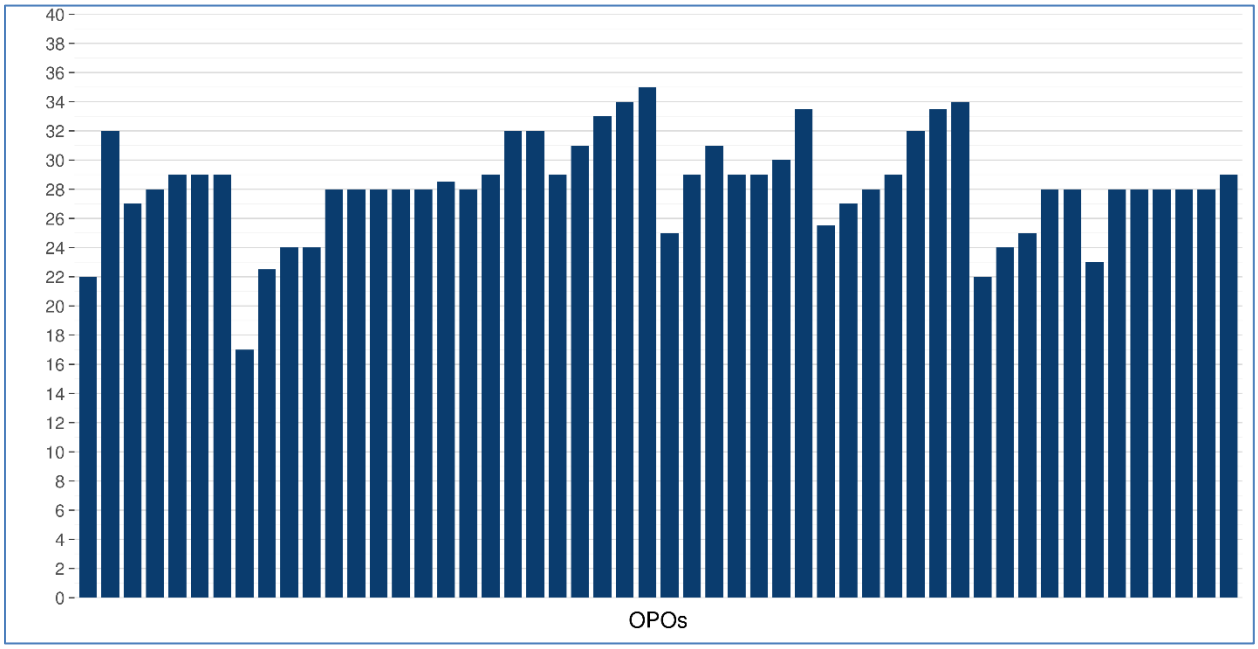
[22] Rayburn, Ann B. "A Multipronged Approach to Addressing the Organ Shortage." *The Journal of Cardiovascular Nursing* No. 20 Supplement (2005). doi:10.1097/00005082-200509001-00003. "The common theme in addressing the problem of organ shortages is relationship building. To be successful, OPOs must develop effective relationships with hospitals, the public and, most importantly, potential donor families."

[23] Motty Shulman, letter to Sec. Alex Azar, May 30, 2018 citing OPTN/SRTR 2016 Annual Data Report Liver (first published January 2, 2018)

[24] Gentry, S. E., Massie, A. B., Cheek, S. W., Lentine, K. L., Chow, E. H., Wickliffe, C. E., Dzebashvili, N. , Salvalaggio, P. R., Schnitzler, M. A., Axelrod, D. A. and Segev, D. L. (2013), "Addressing Geographic Disparities in Liver Transplantation Through Redistricting." *American Journal of Transplantation*, 13: 2052-2058 doi:10.1111/ajt.12301; Yeh, H., Smoot, E., Schoenfeld, D. A., & Markmann, J. F. (2011). "Geographic Inequity in

Current OPTN data continues to show the variability in organ access. Figure 1 shows the lowest median MELD score by transplant center is 17 and the highest median MELD score is 35.[25]

Figure 1: MMaT by DSA for Adult Cohort, 7/1/2017-6/30/2018



The OPTN and others have commented on the use of DSAs and regions for organ distribution. In 2010, the Advisory Council on Organ Transplantation (ACOT) recommended "that the Secretary take steps to ensure that the OPTN develop evidence based distribution policies that are not determined by arbitrary administrative boundaries such as OPO service areas…"[26] In November 2012, the OPTN Board adopted the following resolution… "The existing geographic disparity in access to allocation of organs for transplant is unacceptably high." In 2017, the OPTN Executive Committee recognized that "DSAs might not be the best proxy for geography, as DSAs have disparate sizes, shapes, and populations. DSAs as drawn today do not appropriately address those concerns in a way that is rationally determined, consistently applied, and equal for all candidates."[27]

On July 31, 2018, the Secretary of HHS wrote that "the OPTN has not justified and cannot justify the use of donation service areas (DSAs) and OPTN Regions in the current liver allocation policy and the revised liver allocation policy approved by the OPTN Board of Directors (OPTN Board) on December 4, 2017 under the HHS Final Rule affecting the OPTN."[28] The Secretary continued that "geographic constraints may be appropriate if they can be justified in light of regulatory requirements, but that DSAs and Regions have not and cannot be justified under such requirements.[29] On this basis, the OPTN Board is directed to adopt a liver allocation policy that eliminates the use of DSAs and OPTN Regions and that is compliant

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Access to Livers for Transplantation." *Transplantation*, 91(4), 479–486. http://doi. /10.1097/TP.0b013e3182066275; Schwartz A, Schiano T, Kim-Schluger L, Florman S. Geographic disparity: the dilemma of lower socioeconomic status, multiple listing, and death on the liver transplant waiting list; Kilambi, Vikram, and Sanjay Mehrotra. "Improving Liver Allocation Using Optimized Neighborhoods." *Transplantation* 101, no. 2 (2017): 350-59. doi:10.1097/tp.0000000000001505

[25] MMaT by DSA for Adult Cohort, 7/1/2017 to 6/30/2018, excludes national shares, Status 1s, living donors, and DCD donors. Based on OPTN data

[26] ACOT Recommendation 51 (August 2010).

[27] OPTN/UNOS Executive Committee. "Broader Sharing of Adult Donor Lungs". Nov. 2017.

[28] George Sigounas, letter to Sue Dunn, OPTN President, July 31, 2018.

[29] *Ibid.*

with the OPTN Final Rule."[30] The letter contained a deadline for the Board to adopt a new liver allocation policy by its December 2018 meeting.

Why should you support this proposal?

The problem facing the transplant community is also *who* should make decisions regarding organ distribution policies. The July 2018 HHS letter stated, that "If the OPTN Board fails to adopt a liver allocation policy that eliminates DSAs and Regions and that is otherwise consistent with the requirements of the OPTN Final Rule, the Secretary may exercise further options or direct further action consistent with his authority under 42 C.F.R 121.4(d)." The OPTN believes that organ allocation and distribution decisions are best decided by the experts in the transplant community. Therefore, it is important that the transplant community work together to resolve this issue. In the alternative, we risk having these decisions made by the legislature,[31] the judiciary,[32] or our colleagues in HHS.

The proposed broader 2-circle solution removes the DSAs and Regions as units of distribution in liver allocation policy, and replaces them with rationally determined units of distribution that are intended to ensure that the most urgent candidates are prioritized. It also strikes an appropriate balance of the other Final Rule requirements by mitigating the logistical issues associated with distributing organs across further distances, and ensuring that organs are not wasted. This proposal seeks to make the best use of each donated organ.

How was this proposal developed?

The Committee was directed by the President of the OPTN Board of Directors on June 25, 2018 to "propose revisions to [approved liver] policy that provide Final Rule compliant replacements for:

1) The use of Region and DSA in liver and liver-intestine allocation
2) The use of DSA in the awarding of proximity points
3) The use of Region and DSA in the median MELD/PELD at transplant scoring for exception patients
4) The use of Region and DSA in simultaneous liver kidney (SLK) allocation" [33]

The Committee collaborated with multiple OPTN/UNOS Committees representing particular patient groups or perspectives during the development of this proposal. Members of the Pediatric Transplantation Committee joined the Committee and contributed to discussions about the impact of each change considered on pediatric candidates. Members of the Kidney Transplantation Committee joined for discussions about how to amend SLK allocation. Members of the Minority Affairs Committee and the Geography Committee provided input on how to address allocation to and from areas of the non-contiguous United States. The Patient Affairs Constituent Council provided feedback to the Committee on how to explain this proposal to the patients who would be affected, and expressed a desire to treat candidates similarly, regardless of their location. The Geography Committee received regular updates on the work of the Committee, and provided feedback about whether some of the solutions the Committee considered were compliant with the OPTN Final Rule.

While the Liver Committee began work to remove DSAs and regions from liver and intestine distribution, the Executive Committee charged several other Committees to begin similar work. The Kidney and Pancreas Transplantation Committees were charged to remove DSAs and regions from their distribution systems. The Thoracic Organ Transplantation Committee was charged to remove DSAs from heart allocation. The Vascular Composite Allograft (VCA) Transplant Committee was charged to remove

[30] *Ibid.*

[31] For example, see H.R. 6458, 115th Congress, (2018) and H.R. 6517, 155th Congress (2018).

[32] For example, *see* Cruz et al v. U.S. Dept. of Health and Human Services, (S.D.N.Y 18-CV-06371) and Holman v U.S. Dept. of Health and Human Services, (S.D.N.Y 17-CV-09041).

[33] Yolanda Becker, OPTN President, letter to the OPTN Liver and Intestinal Organ Transplant Committee, June 25, 2018.

regions from their distribution system. These changes are scheduled for spring 2019 public comment. Additionally, the Ad Hoc Geography Committee was charged with ensuring that the Committees maintained rapid progress on these projects with consistent interpretation and application of our requirements under NOTA, the OPTN Final Rule, and the new OPTN Principles of Organ Distribution. Figure 2 shows the timeline for the committees to make these changes.

Table 1: Timeline Overview of the Geography Projects

Project	Jul-18	Aug-18	Sep-18	Oct-18	Nov-18	Dec-18	Jan-19	Feb-19	Mar-19	Apr-19	May-19	Jun-19
Distribution Frameworks		PC				BOD						
Liver & Intestine Distribution	Modeling			PC		BOD						
Kidney-Pancreas Distribution				Modeling			PC					BOD
Thoracic Distribution				Modeling			PC					BOD
VCA Distribution							PC					BOD
Develop												
SRTR Modeling												
Public Comment												
Board												

Liver Allocation

The primary goal of the Committee was to remove DSA and Region from allocation policy, and determine whether or not a replacement for those units of distribution is required. The Committee's secondary goal was to ensure that any newly proposed system performed as well as or better than the December 2017 proposal with regard to variance in median MELD at transplant.

1. Frameworks

In response to the Board directive, the Committee began considering the basic framework for the revised distribution system. The Ad Hoc Geography Committee recently sponsored a public comment proposal to identify a single distribution framework for all organs.[34] Because that project is a long-term efficiency project for the OPTN, it was not necessary to choose a single distribution framework for all organs first; however, the Liver Committee was instructed to develop their revised framework consistent with one of the frameworks being considered by the Ad Hoc Geography Committee. Over the last several years, the Liver Committee considered the several frameworks for organ distribution. The Committee and the Board will consider any proposal that has been modeled by the SRTR and meets the dual requirements to 1) replace DSAs and regions with rational boundaries and 2) reduce the variance in geographic disparities to access.

[34] Frameworks for Organ Distribution, OPTN/UNOS Ad Hoc Committee on Geography, August, 2018 https://optn.transplant.hrsa.gov/governance/public-comment/frameworks-for-organ-distribution/, (accessed October 1, 2018).

1. National allocation without any geographic consideration
2. Mathematically Optimized BoundariesReplacing references to DSA and region with references to a fixed distance
3. Population-based circles around donor hospitals
4. Distance-based circles that adjust based on population around donor hospitals
5. Distance-based circles with small bands of a few MELD/PELD points
6. Distance-based circles with a larger circle for higher MELD/PELD, and multiple circles for remaining MELD/PELD

1. National allocation without any geographic consideration

The Committee considered whether it would be possible to allocate livers nationally, without any consideration for geography. This would fulfill the Final Rule requirement that allocation "not be based on the candidate's place of residence or place of listing, except to the extent required …". However, it may not be consistent with the Final Rule requirements regarding efficiency, organ wastage and making the best use of organs to completely disregard the impact of geography on organ allocation. Although liver allocation modeling does not have the ability to predict discards, there is some correlation between an increased allocation area and a decrease in organ transplant rates. The committee could not support an allocation plan that would be very likely to decrease the number of organs transplanted. Therefore, the Committee opted to pursue a policy that would include some consideration of location, to fulfill the Final Rule requirement to have allocation "designed to avoid wasting organs" and "promote the efficient management of organ placement".[35]

2. Mathematically Optimized Boundaries

In August 2016, the Committee released a proposal for public comment that used mathematically optimized districts for organ distribution.[36] 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. During the fall 2016 regional meetings, eight of 11 regions opposed the proposal with three regions in support. In 2017, the Committee requested SRTR modeling on a different variation of mathematically optimized districts for organ distribution.[37] The model, called neighborhoods, did not rely upon supply and demand metrics in the construction of geographic areas of distribution.

During the most recent 2018 Committee discussions, the Committee considered the possible options and opted for a circle based model. However, since they can achieve the legal mandates to 1) replace DSAs and regions with rational boundaries and 2) reduce the variance in geographic disparities to access they remain options for the community, Committee, and Board to consider.

3. Replacing references to DSA and region with references to a fixed distance

The Committee considered simply keeping the allocation sequences the same as was passed by the Board of Directors in December 2017, but replacing DSA and region with fixed-distance circles. However, it was not possible to use the same classifications given the use of DSAs and regions in the 2017

[35] 42 C.F.R § 121.8(a)(5).

[36] OPTN/UNOS Liver and Intestinal Organ Transplantation Committee. "Enhancing Liver Distribution" November 2017.

[37] Scientific Registry of Transplant Recipients, "LI2016_04" June 7, 2017. Kilambi, Vikram, and Sanjay Mehrotra. "Improving Liver Allocation Using Optimized Neighborhoods." *Transplantation* 101, no. 2 (2017): 350-59. doi:10.1097/tp.0000000000001505

proposal. Therefore, the Committee chose to use this opportunity to build an allocation system for livers that would be fully compliant with the Final Rule, and especially improve disparity.

4. Population-based circles around donor hospitals

The Committee considered using a population-based circle around a donor hospital. Population-based circles are another example of a mathematically optimized boundaries framework; in this situation, the boundaries equalize the population of each distribution unit. This was a more complicated framework than the Committee could develop during this expedited timeframe. There were discussions about how to define population. Options considered were census population or some measure of donor potential. However, using population as the only factor in determining allocation areas could treat two candidates who are otherwise similarly situated differently. A population-based circle around a large metropolitan area (ex. New York City or Los Angeles) would be considerably smaller than a population based circle around a less densely populated area of the country. This could lead to wide variations in the distance organs would travel. Instead, the committee considered ways that differences in population could be accounted for while using distance-based circles.

5. Distance-based circles that adjust based on population around donor hospitals

The Committee considered a population density adjusting circle concept. It would allocate livers in circles of 150, 250 and 500nm (or 150, 300 and 600nm), in bands of three MELD points, and in sparsely populated areas, the first unit of allocation for most livers would be the larger circles, while in densely populated areas the first unit would be a smaller circle around the donor hospital. The Committee discussed the sizes of the bands, and also considered larger bands, such as five MELD points. The theory behind this framework was that the Committee could justify fixed distance based circles of small diameters (ex. 150 nm); however, compared to the current system, this would result in less access to transplant for some areas of the country. In order not to decrease access for any patients, the size of the circles could be increased in rural areas (which tend to have the largest DSAs now). However, the Committee chose to pursue modeling on a similar, simpler concept – distance-based circles with small bands of a few MELD/PELD points.

6. Distance-based circles with small bands of a few MELD/PELD points ("acuity circles")

One of the two concepts the Committee chose to model was distance-based circles with small bands of a few MELD/PELD points (referred to here as "acuity circles"). The goal of this concept was to prioritize the most efficient placement (transplant and donor hospitals that are closer together) among candidates with a similar need, and when there is a greater need (shown by higher MELD or PELD), allow candidates who are further away to have increased access. By allocating to candidates within 150, then 250 or 300, then 500 or 600 nm, this concept naturally adjusts for population density. In densely populated areas, there will be less travel required, because there will always be candidates of the various urgency levels in the first circle. However, in more sparsely-populated areas where travel would be more routinely required anyway, organs would be offered more quickly to a larger area.

The Committee discussed how many MELD/PELD points should be grouped together in each band, and considered three, four, or five for this concept. The Committee used bands of four MELD/PELD points for MELD/PELD of at least 29, which is in line with past decisions awarding three proximity points. The Committee considered candidates within a range of four points to be medically similar enough to group together in this way (candidates are still ordered by score within each classification).[38]

The Committee chose to group the MELD or PELD scores from 15 to 28 together, and the scores less than 15 together. MELD of 28 is the point when the difference in 90 day mortality rate goes up to 5% between scores. MELD scores less than 15 have 1% or less difference in mortality rate between scores.

[38] See *Figure 3: Mortality Risk by MELD Score.*

For these two groups, that include a larger range of MELD scores, the difference a single point reflects is smaller.[39]

The Committee chose to preserve the concept of offering to status 1A and 1B candidates over a larger area initially. The SRTR modeled allocation using the sequence below.

Table 2: Allocation of Livers from Non-DCD Deceased Donors at Least 18 Years Old and Less than 70 Years Old

Classification	Candidates that are within this proximity of the donor hospital:	And are:
1	[500/600]nm	Adult or pediatric status 1A
2	[500/600]nm	Pediatric status 1B
3	150nm	MELD or PELD of at least 37
4	[250/300]nm	MELD or PELD of at least 37
5	[500/600]nm	MELD or PELD of at least 37
6	150nm	MELD or PELD of at least 33
7	[250/300]nm	MELD or PELD of at least 33
8	[500/600]nm	MELD or PELD of at least 33
9	150nm	MELD or PELD of at least 29
10	[250/300]nm	MELD or PELD of at least 29
11	[500/600]nm	MELD or PELD of at least 29
12	150nm	MELD or PELD of at least 15
13	[250/300]nm	MELD or PELD of at least 15
14	[500/600]nm	MELD or PELD of at least 15
15	National	Adult or Pediatric Status 1A
16	National	Pediatric Status 1B
17	National	MELD or PELD of at least 15
18	150nm	MELD or PELD less than 15
19	[250/300]nm	MELD or PELD less than 15
20	[500/600]nm	MELD or PELD less than 15
21	National	MELD or PELD less than 15

The Committee expressed concern that this model may potentially increase air travel, for the organs and for the organ procurement teams. Although the SRTR modeling does not provide a prediction for changes in the number of organs discarded, the Committee was concerned that increased travel would ultimately increase the number of discarded livers in addition to increasing the costs of transplantation and decreasing efficiency.

[39] *Ibid.*

7. *Distance-based circles with a larger circle for higher MELD/PELD, and multiple circles for remaining MELD/PELD ("broader 2-circle")*

The Committee considered and is recommending a concept that would allocate livers to candidates with a MELD/PELD of at least 32 or 35 within 250 nm of the donor hospital, then candidates with a MELD/PELD of at least 15 within 150 nm, and then throughout the nation. (Referred to as the "broader 2-circle" framework." The Committee chose to preserve the concept of offering to status 1A and 1B candidates over a larger area initially, because the Committee wants to ensure that candidates with the highest medical urgency have the highest priority and broadest access to available donor organs. The Committee modeled the sharing thresholds of 32 and 35 in an effort to preserve the patient access to transplantation[40] that candidates with MELD/PELD of at least 35 currently experience with regional sharing. The Committee also considered a sharing threshold of 29, based on the fact that 29 is an inflection point in the difference in mortality rates between MELD scores.[41] This possibility was considered after modeling was available, and was not modeled.

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

Classification	Candidates that are within this proximity of the donor hospital:	And are:
1	500nm	Adult or pediatric status 1A
2	500nm	Pediatric status 1B
3	250nm	MELD or PELD of at least [35/32]
4	150nm	MELD or PELD of at least 15
5	250nm	MELD or PELD of at least 15
6	500nm	MELD or PELD of at least 15
7	National	Adult or Pediatric Status 1A
8	National	Pediatric Status 1B
9	National	MELD or PELD of at least 15
10	150nm	MELD or PELD less than 15
11	250nm	MELD or PELD less than 15
12	National	MELD or PELD less than 15

There were some concerns about whether it is appropriate to prioritize a candidate with a MELD of 28, 31 or 34 who was 151nm away from the donor hospital after candidates with a MELD of 15 who were 149nm away from the donor. This could create situations in areas of the midwest or middle south where donor livers could be allocated to less sick candidates who are physically closer to the donor than in the current system, because donors that are currently in the same DSA or region would not be in the same 150 or 500nm circles as one another.

The Committee recommends this model because it balances the Final Rule considerations of promoting patient access to transplantation and the efficient management of organ placement[42] and proposes a sharing threshold of 32. There was no solution that perfectly equalized disparity in MMaT and eliminated the risks and costs of flying. However, this concept reduces the variability in MMaT by location slightly

[40] 42 C.F.R. § 121.8(a)(5) requires that allocation policies "Shall be designed … to promote patient access to transplantation".
[41] See Figure 3.
[42] 42 C.F.R. § 121.8(a).

more than a sharing threshold of 35 and somewhat less than the acuity circles modeled, while also increasing the numbers of organs that are flown slightly more than a sharing threshold of 35 and less than acuity circles models. Some members of the Committee preferred a sharing threshold of 35 and others preferred a sharing threshold of 29. Although members of the Committee had different opinions on the best way to balance all of the Final Rule considerations, the majority supported this concept, with a sharing threshold of 32.

2. Circle Sizes

The Committee discussed different circle sizes. Proximity circles already in policy were based on 150 and 500 nautical miles.

Although distance is not a perfect measure of travel time, it is a relative approximation. Based on their own collective practices, the Committee agreed that 150 nm was approximately the distance at which the transplant surgeon was more likely to fly to recover the organ rather than drive. Flying represents a significant jump in costs of transportation for a transplant, and increased costs make the process less efficient.[43] The Committee balanced this need for efficiency as directed in the Final Rule with the need to share as broadly as possible.[44]

95% of livers are currently transplanted within 586 nautical miles of the donor hospital.[45] This is relevant for two reasons. First, models used large circles of 500 and 600 nautical miles, to respect the OPTN Final Rule directive to “avoid wasting organs”, because the data show that most livers are used within 600 nm.[46] Additionally, the Committee sought to balance the need to distribute organs as broadly as feasible against the inefficiencies of a national organ distribution. They therefore included a distribution unit greater than the 150 nm mentioned above. In selecting the size of this distribution unit, the Committee did not want to decrease access for patients compared to the current system. Since 95% of livers travel less than 598nm, and most travel less than 500nm, this choice should not decrease access for most patients compared to the current system. The Committee did consider the impact on currently waiting candidates and did not want to place them in a position to be treated less favorably than they already are.[47]

The committee also selected a circle size roughly in the middle between 150 and 500nm to provide for variations in geography and logistics across the county. Using different sized circles allows for some geographical variation while attempting to minimize the additional costs and risks of flying that impact the efficiency of organ placement. A range of 250nm from the donor hospital provided a distance at which most, but not all programs would use air transportation if a donor was at the edge of the range. This balanced the efficiency of avoiding air travel and the variation of hospital and OPO practice.

The Operations and Safety Committee also conducted a series of interviews with OPOs while this proposal was under development. The interviews are not yet complete as of October 1, 2018. 34 have so far provided information on what their policy is regarding when they fly instead of drive. Of these, 23 have a threshold for when they fly of 150 miles or less. Another eight fly if the organ will travel at least 180 or 200 miles, two fly if they are travelling at least 300 miles, and another one will only fly distances longer

[43] Dubay, D. A., P. A. Maclennan, R. D. Reed, M. Fouad, M. Martin, C. B. Meeks, G. Taylor, M. L. Kilgore, M. Tankersley, S. H. Gray, J. A. White, D. E. Eckhoff, and J. E. Locke. "The Impact of Proposed Changes in Liver Allocation Policy on Cold Ischemia Times and Organ Transportation Costs." *American Journal of Transplantation* 15, no. 2 (2015): 541-46. doi:10.1111/ajt.12981. “The median transportation cost of a local donor within driving distance was only $101 while the median transportation cost of a local donor requiring air travel was $1993. The composite median cost of a local donor (including all local driving and local flying transportation episodes) was $548.Median liver procurement transportation costs increased significantly for regional flight travel, ranging from $8324 for flights less than 3 h to $27810 for flights longer than 3 h.”

[44] 42 C.F.R 121.8(a)(5) requires that allocation policies be designed “to promote the efficient management of organ placement.” Therefore, the cost of transportation is a relevant factor to consider when developing an organ distribution system.

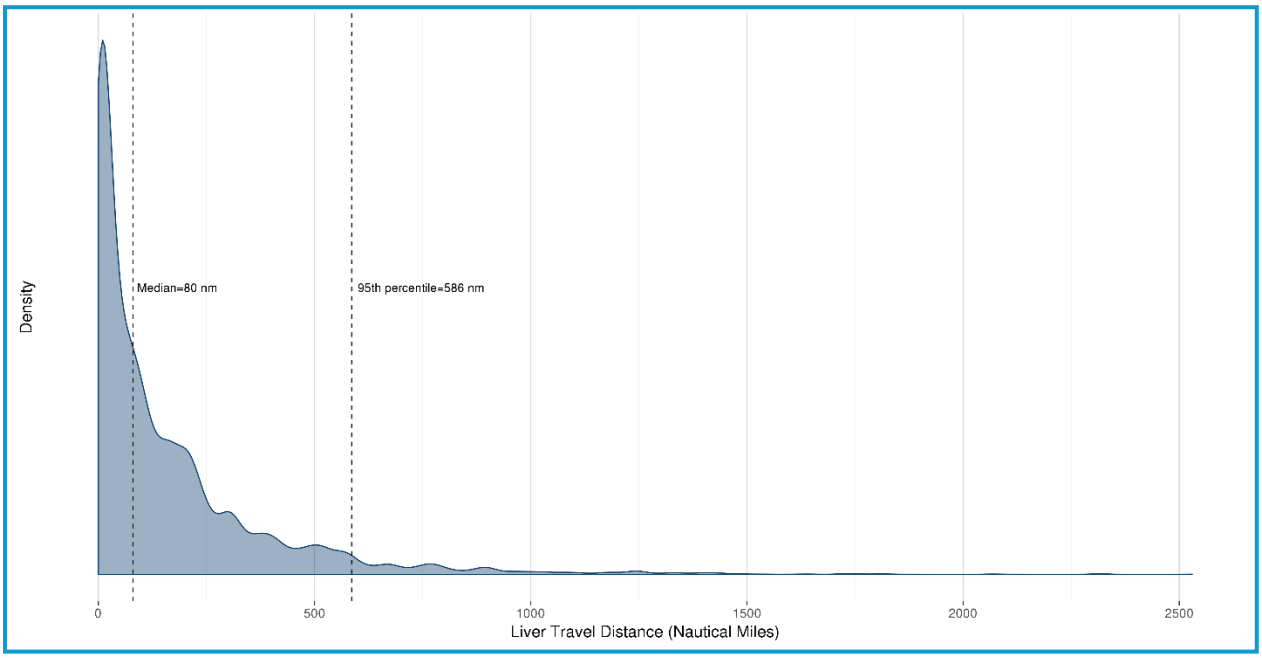
[45] See Figure 2.

[46] 42 C.F.R § 121.8(a)(5).

[47] 42 C.F.R § 121.8(d).

than 500 miles. This appears to support the range that the Committee selected as the circle sizes – that some fly over short distances, but others drive much farther.

Figure 2: Distribution of Travel Distances from Donor Hospital to Transplant Hospital, Deceased Donor Liver Transplant Recipients in the U.S. During 1/1/2017 to 5/31/2018



Committee members discussed including larger circles as well, but decided that there was not enough difference in the efficiency of recovering a liver from 800nm away and one that is 1,500nm away because in either case, it is a significant flight. In both cases, a more desirable liver can withstand the cold ischemic time. The Committee members agreed that it was appropriate to group the national offers together once the 500nm threshold was passed.

Ultimately, the Committee proposes distributing livers to the most urgent candidates, those at statuses 1A and 1B, within a 500 nm circle, to provide the greatest amount of access while still balancing the risks of decreased utilization. The Committee proposes allocating to MELD/PELD 32 and higher within 250nm and then within 500nm, to reduce the amount of unnecessary flights and limit the impact of flight risk and costs on the efficiency of the system. It further proposes allocating to MELD 15-31 candidates within 150nm first, then 250nm and then 500nm. This allows the allocation system to balance the urgency of the candidate with the distance from the donor – balancing Final Rule considerations for efficiency, access and avoiding wastage of organs[48] by lowering travel for less urgent candidates so that the system can absorb more travel for the most urgent candidates.

The Committee discussed whether it would be better to use recovery centers or donor hospitals as the donor location when a recovery center is used. The Committee considered whether the more relevant geographic location was this recovery center. The advantage of using the recovery center is that is the point from which any cold ischemic time will begin and where travel will originate. The advantage of using the donor hospital is that is where the donor is admitted, this is currently how thoracic allocation works, and this would not be as easily manipulated. If the distance between the recovery center and donor hospital is great, then to use the location of the recovery center could benefit the population around the recovery center at the expense of the population around the donor hospital. If the distance between the two is minimal, then the impact on travel will likewise be minimal. Therefore, the Committee chose not to

[48] 42 C.F.R § 121.8(a)(5).

change this approach in this proposal. The Committee recommends continued discussion by other Committees that have begun considering this dilemma.

The Committee is specifically requesting feedback on whether the sizes off the fixed distance circles should be increased, decreased, or remain the same.

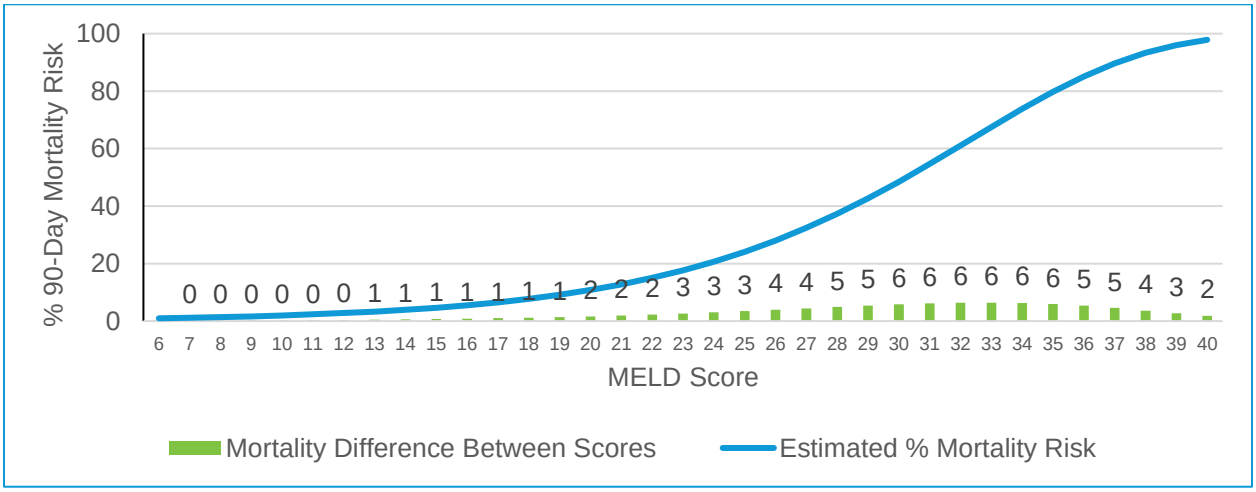
3. Sharing Threshold

In order to more efficiently place organs, the committee chose to continue the practice of having a different order of allocation for candidates with different ranges of scores. This includes sharing organs across a larger geographic area for the most medically urgent patients, and providing more priority based on location for candidates with less medical urgency. This is based on the observation that if an organ has been offered to enough candidates already who are higher on the match, the organ is likely less desirable and cold time may be accumulating, so there is more of a need to try to place it more quickly, which can be done by offering to closer hospitals earlier.

For Status 1A and 1B candidates, this means they are shared to the largest circle, hospitals within 500nm. The committee then chose to have another group of candidates that are shared to the next largest circle first, 250nm. In deciding which candidates should be included in this group of candidates, the committee had to decide what the threshold should be for sharing at this level, or what the sharing threshold should be. For candidates below this sharing threshold, the first circle would be even smaller, 150nm.

For MELD scores between 28 and 36, a one point MELD score increase is associated with at least a five-percentage point increase in 3-month mortality risk. Based on the fact that the mortality curve increases more steeply at that point, the Committee previously selected 32 as the sharing threshold for the 2017 December proposal. The committee also awarded up to three proximity points in that proposal, so a candidate with a MELD of 29 and 3 proximity points would appear on the match as a 32.

Figure 3: Mortality Risk by MELD score



The Committee chose to model the laddered circle allocation with two possible sharing thresholds to evaluate the difference the different thresholds make. For the first threshold, the model kept the same sharing threshold, 32. The second model used a sharing threshold of 35, close to the high end of the MELD scores with a larger difference between each score.

In comparing the two models (share 32 vs 35), the change in the sharing threshold showed no significant impacts to the variance in MMaT (6.54 vs 6.74), median allocation MELD/PELD at transplant (29.5 vs. 29), transplant counts (6616 vs. 6620), transplant rates (0.437 vs. 0.438), or waitlist mortality rates (0.094 vs. 0.095). The lower sharing threshold showed a slight increase in transport time (117.1 vs. 107.7) and

distance as well as the percent of organs flown (60.8 vs. 58.4). Because there was an improvement in the variance in MMaT with no significant detriment in most of the clinical metrics, and the increase in the system efficiency metrics were not too significant compared to the 2017 proposal, the committee felt that the MELD 32 threshold represented the best balance of the competing needs of the OPTN Final Rule.

Even though the Committee did not request it as part of its modeling request, the committee also considered a threshold of 29 after looking at the modeling results for 32 and 35. A threshold of 29 is more in line with the inflection point when the difference in waiting list mortality by MELD scores is at least 5%, and would mean more organs shared at the 250nm distance earlier.[49] As shown in the 2018 modeling request, lowering the sharing threshold typically improves the variance in MMaT but also increases the distance organs travel and the amount of organs that travel by air. The Committee earlier commented that transporting 70% of organs by air was not feasible.[50] Therefore,The Committee was concerned with the amount a lower sharing threshold might increase air travel, and without modeling was uncertain how great the benefit would be from the change. The selection of 32 as the proposed sharing threshold was based on the additional access it allows patients when compared with the current or the December 2017 allocation while only increasing air travel and its associated risks and costs an acceptable amount. This was the approach the Committee took to balancing efficiency and access by urgency.

The Committee is specifically requesting feedback on whether the sharing threshold should be raised, lowered, or remain at 32.

4. Pediatric Donor Allocation

The Pediatric Committee provided feedback that pediatric candidates were disadvantaged and would benefit from having increased priority for pediatric donor livers. In response, the Committee proposes changing the pediatric allocation sequences so that all of the pediatric candidates on the match will appear before adult candidates with a MELD score for pediatric liver donors. Additionally, the proposed allocation of pediatric donors uses only a 500nm circle. There are significantly fewer pediatric donors, candidates and transplants than there are adult donors, candidates and transplants. In 2017, there were 499 transplants into pediatric recipients.[51] Due to the smaller numbers, the Committee agreed with the Pediatric Committee's recommendation to only use the larger circle for pediatric donors. Because there are fewer transplants within this population, and they typically need to travel more often, there is less efficiency gained by limiting to a smaller geographic area and the balance of factors shifts from those considered with the adult population.

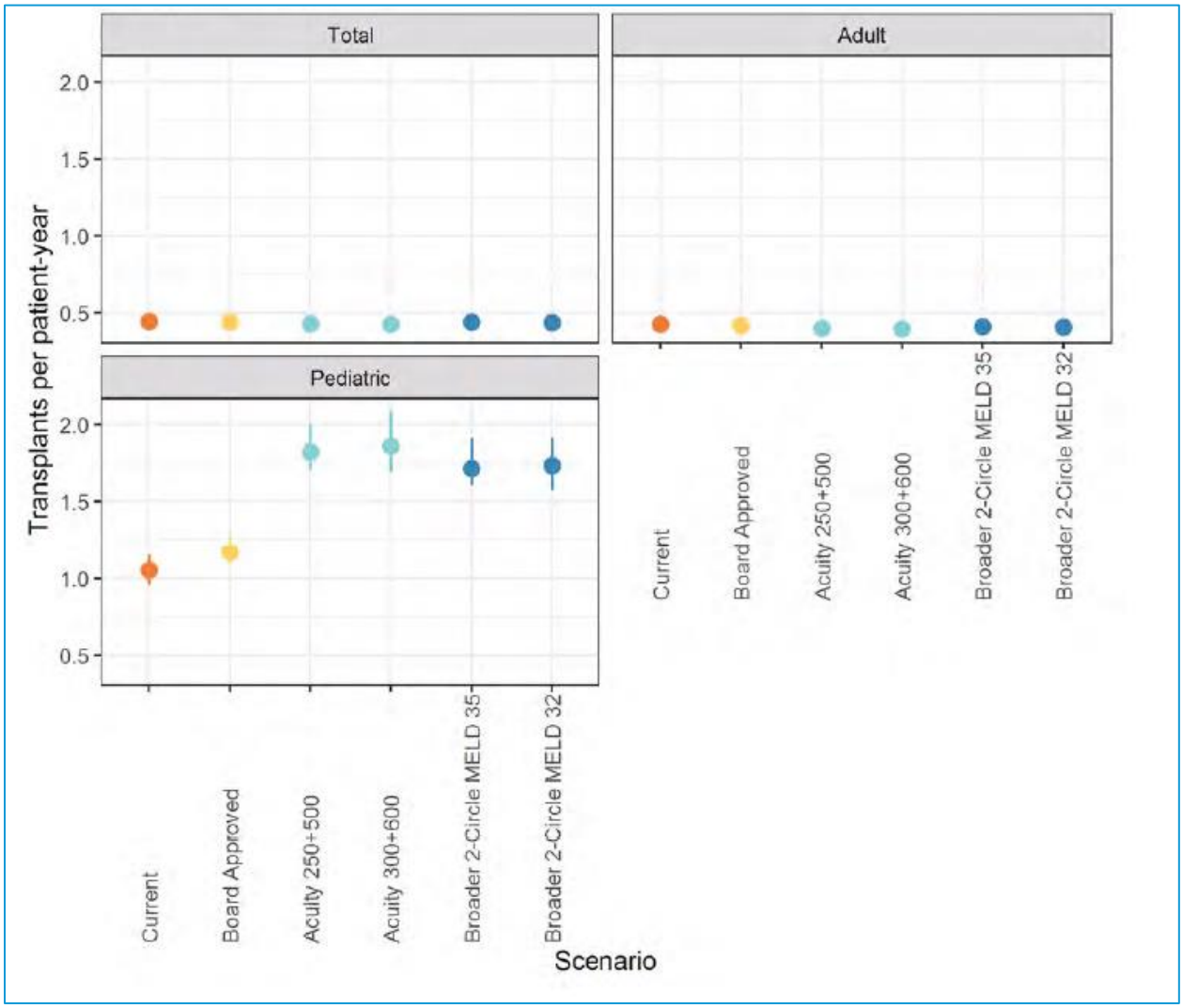
[49] See Figure 3, above.

[50] See notes 61-69 about challenges related to air travel.

[51] Based on OPTN/UNOS data.

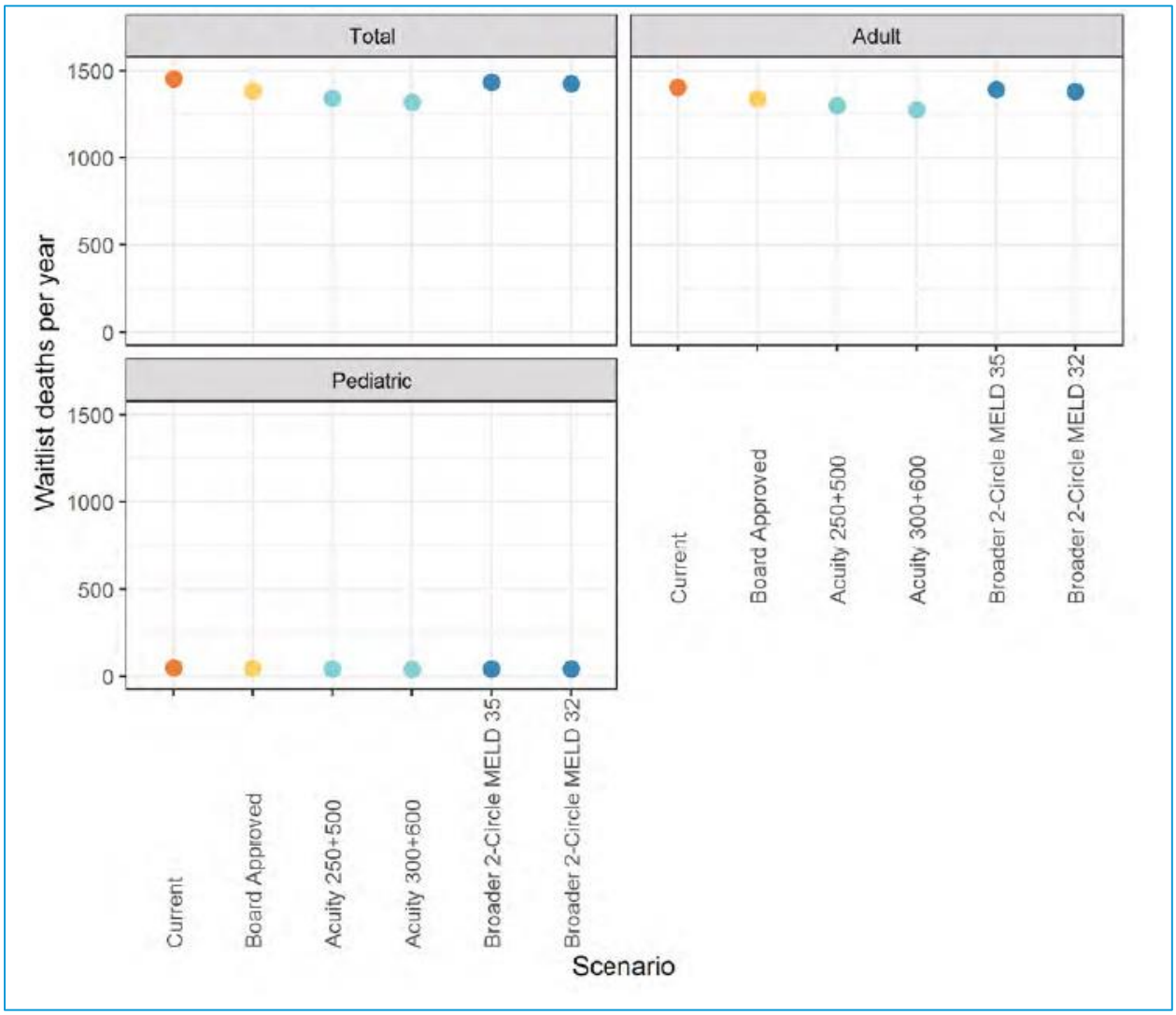
The models did show the desired result, and in each of the models, the transplant rates for pediatric patients increased compared to the current allocation and the December 2017 allocation.

Figure 4: Transplant Rates by Age



Additionally, the waitlist mortality for pediatric candidates did not show a statistically significant change.

Figure 5: Mortality Counts by Age



5. Allocation of organs from DCD donors and donors over 70 years old

In December 2017, the Board passed an allocation that used a smaller area of distribution for donation after cardiac death (DCD) and donors over 70 years old as these organs have better outcomes with shorter cold ischemic times.[52] This is consistent with the OPTN Final Rule requirement to make the best

[52] Kalisvaart, Marit, Andrea Schlegel, and Paolo Muiesan. "Attitudes and Barriers to the Use of Donation after Cardiac Death Livers: Comparison of a United States Transplant Center Survey to the United Network for Organ Sharing Data." *Liver Transplantation* 24, no. 1 (2017): 144-45. doi:10.1002/lt.24978. Croome, Kristopher P., Amit K. Mathur, David D. Lee, Adyr A. Moss, Charles B. Rosen, Julie K. Heimbach, and C. Burcin Taner. "Outcomes of Donation After Circulatory Death Liver Grafts From Donors 50 Years or Older." *Transplantation* 102, no. 7 (2018): 1108-114. doi:10.1097/tp.0000000000002120. "From logistic standpoint, an attempt to keep CIT shorter than 6 hours should be made."

use of donated organs.[53] The Committee chose to maintain that approach in this proposal, and the allocation sequences for this group prioritize candidates within 150nm of the donor hospital even for higher MELD/PELD candidates than the sequences for other donors.

6. Proximity points

The December 2017 proposal awarded three proximity points to candidates within 150 nm or in the same DSA as the donor hospital.[54] In the models that the Committee decided to request, instead of using proximity points within another geographic boundary, the Committee simplified the approach and incorporated the 150 nautical mile circle in the allocation tables. Therefore, no proximity points are proposed.

7. Blood Type O donors

Blood type O donors are currently offered first to all of the O candidates and all of the B candidates with at least a MELD or PELD of 30 before any A or AB candidates in order to correct for the disadvantages candidates with these blood types would otherwise experience because they are able to accept fewer of the available organs. The Committee discussed whether it would be appropriate to simplify allocation to the compatible A and AB candidates to a national share. Committee members were uncertain which approach would be most efficient or how many livers that aren't accepted by any O or B candidates earlier on the match would be transplanted into A or AB candidates. In the absence of more information, the Committee opted to keep the full sequences for these candidates at this point in time. However, the allocation tables were previously unclear about where on the list blood type B candidates with a MELD <30 would appear, and the expectation of the Committee members was not the same as what the system is currently doing. In this proposal, treatment of B candidates is clarified, and all blood type B candidates appear before any A or AB candidates.

8. Other methods of hepatic support

The Committee discussed the current allocation of livers for other methods of hepatic support. Livers must first be offered for transplantation before they can be offered for "use in other methods of hepatic support."55 Currently, this is being used for hepatocyte transplantation, which is rarely done.56 It is rare that there are even active programs performing transplants for hepatic support, but when they are performed, the Committee wanted to preserve the preference for these before other research. The Committee considered changing the terminology, but wanted to preserve the ability to have other similar treatments to fall into this category. The Committee proposes national allocation for these livers since there are few programs performing these types of transplantation and there is no additional efficiency in creating geographically-based priority for any of these offers

9. SRTR modeling results

The optimization of organ allocation and distribution can be described as a non-deterministic polynomial-time hardness (NP-hardness) problem.[57] Once the Committee determined that national distribution is not feasible, it must determine the appropriate, rational, and effective boundaries that must be used in liver distribution. To do so, it must use multiple inputs to optimize multiple outputs including equity, utility, efficiency, etc. In other words, the problem is so complex that we cannot a priori determine the optimal

[53] 42 C.F.R § 121.8(a)(2).
[54] OPTN/UNOS Liver and Intestinal Organ Transplantation Committee. "Enhancing Liver Distribution" November 2017.
[55] OPTN/UNOS Policy 9.6.B: Allocation of Livers for Other Methods of Hepatic Support.
[56] For background on hepatocyte transplantation, *see* Fox, Ira J., "Hepatocyte Transplantation". *Gastroenterology & Hepatology*, Vol.10 Issue 9, (2014) pp. 594–596.
[57] Finding long chains in kidney exchange, Ross Anderson, Itai Ashlagi, David Gamarnik, Alvin E. Roth, *Proceedings of the National Academy of Sciences* Jan 2015, 112 (3) 663-668; DOI: 10.1073/pnas.1421853112. This paper explains that KPD optimization is an NP-hardness problem. Since deceased donor allocation utilizes additional inputs and must optimize additional outputs, it is a more complicated NP-hardness problem.

solution to the problem. There are multiple methods to solve these types of problems. One method is to use a heuristic with approximate inputs so that we can model the outcomes in a timely fashion. This is, in essence, how the Liver Committee selected some of their fixed distance based circles for the SRTR modeling. The Committee then relied upon the modeling results to refine the liver distribution proposal.[58]

The Committee considered the predicted results of the acuity circles (smaller bands) and the broader two circle concepts. While the SRTR provides many analyses, in recent years the Committee has focused on a few key metrics when considering distribution proposals.[59]

- Variance in MMaT: This metric is one of the metrics used by the Committee to assess whether transplant candidates have equal access to transplant. This is in line with 42 C.F.R 121.8(a)(5) ("promote patient access") & (a)(8) ("Shall not be based on the candidate's place of residence or place of listing").
- Transplant Count: This metric is relevant because a goal of the OPTN is to increase the number of transplants. This is in line with the requirement of 42 C.F.R 121.8(a)(2) to make the best use of donated organs.
- Transportation time: This metric is relevant when considering the amount of CIT on transplanted organs and is in line with the requirement of 42 C.F.R 121.8(a)(2) to make the best use of donated organs.
- Percent of Organs Flown: This metric is relevant considering the cost of transporting organs by air instead of ground transportation.[60] One article looked at the 2016 redistricting proposals and found that, "Despite no additional livers being transplanted, the exporting and subsequent importing of 50% or 70% of livers increased the costs on the cost report attributed to livers for each OPO from a low of 43% to a high of 206%."[61] Another article looked at the economic impact of the 2016 redistricting proposals and found that transportation costs could increase over $70 million a year.[62] This is in line with the requirement of 42 C.F.R 121.8(a)(5) to consider the "efficient management of organ placement."

  In addition to the costs of transportation, the availability of pilots and flights presents operational challenges as the number of flights needed increases. Several committee members shared anecdotal information about transportation challenges. These challenges could increase as the number of organs travelling by air increases. In response, the Operations and Safety Committee is collecting more information about the frequency and types of these challenges and is preparing guidance regarding effective practices for increased distribution. Recent changes in the airline industry are impacting the ability of the organ transplantation community to rely upon more air travel. "North American airlines saw freight demand increase by 5.4% in December 2017 year-on-year and capacity

[58] Analysis Report Data Request on Circle Based Allocation, September 24, 2018, https://optn.transplant.hrsa.gov/media/2640/li2018_01_analysis-report_20180924.pdf (accessed October 1, 2018)

[59] In evaluating the efficiency of the transplantation system, it is important to consider both the financial cost and the quality outcomes for the system. For this reason, the committee has focused on the below metrics which are a combination of financial cost and quality outcome metrics. This is consistent with current practices in evaluating healthcare efficiency. "The AQA, a consortium of physician professional groups, insurance plans, and others, has adopted a principle that measures can only be labeled "efficiency of care" if they incorporate a quality metric; those without quality incorporated are labeled "cost of care" measures." Hussey PS, de Vries H, Romley J, et al. A Systematic Review of Health Care Efficiency Measures. *Health Services Research*. 2009;44(3):784-805. doi:10.1111/j.1475-6773.2008.00942.x. *citing* AQA, "AQA Principles of 'Efficiency' Measures." (2009).

[60] See note 39.

[61] Kappel, D. F., W. C. Chapman, S. Conrad, A. Reed, R. Linderer, S. Dunn, P. Niles, M. F. Levy, and T. Cawiezell. "Organ Procurement Organization Liver Acquisition Costs Could More Than Double With Proposed Redistricts." *American Journal of Transplantation* 15, no. 8 (2015): 2269-270. doi:10.1111/ajt.13346.

[62] Gentry, S. E., E. K. H. Chow, N. Dzebisashvili, M. A. Schnitzler, K. L. Lentine, C. E. Wickliffe, E. Shteyn, J. Pyke, A. Israni, B. Kasiske, D. L. Segev, and D. A. Axelrod. "The Impact of Redistricting Proposals on Health Care Expenditures for Liver Transplant Candidates and Recipients." *American Journal of Transplantation* 16, no. 2 (2016): 583-93. doi:10.1111/ajt.13569.

increase of 2.2%."[63] The capacity is not increasing proportionately to the demand for flights. This may be in part because of a lack of available pilots, as the number of pilots decreases. The Federal Aviation Agency concludes "both private and commercial pilot certificates are projected to decrease at an average annual rate of 0.8 and 0.5 percent, respectively until 2038."[64] "The [pilot] shortage has been caused by a recent increase in the flying hours required for commercial pilots,[65] the aging pilot workforce,[66] fewer new pilots coming out of the military,[67] and a general decline of interest in the career."[68], [69] Committee members also expressed additional transportation challenges resulting from new regulations governing crew duty and rest times.[70, 71] Given the increasing scarcity of both flights and pilots, the Committee considered the percentage of organs flown in each scenario. Significant increases in the need to flights could lead to an increase in organ offers that were unable to be accepted because flights or pilots were not available. In that case, additional offers to candidates further away from the donor hospital would only increase allocation time, and decrease efficiency of offer, and would not show as great an improvement in disparity as modeled. Committee members concluded transporting 70% of the organs by air was not feasible at this time.

In regards to the variance in MMaT, all of the models showed improvement compared to the current system and the 2017 Board approved policy. The Committee set this as a threshold requirement for any proposal that they would consider for public comment. The two acuity circle models showed the greatest improvement in variance in MMaT.

In regards to transplant count, all of the models showed a slight decrease in transplant count. It is worth noting that this same impact was predicted for Share-35. But because the LSAM does not account for changes in member behavior, this impact did not occur for Share-35.[72] Therefore, it stands to reason that a decrease in transplant count is not a guaranteed outcome of any of the modeled systems.

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[63] IATA. "Air Freight Demand up 9% in 2017, Strongest Growth Since 2010 ." IATA - Live Animals Regulations. January 31, 2018. Accessed October 01, 2018. https://www.iata.org/pressroom/pr/Pages/2018-01-31-01.aspx.

[64] Federal Aviation Administration. "FAA Aerospace Forecast: Fiscal Years 2018-2038." Accessed October 1, 2018. https://www.faa.gov/data_research/aviation/aerospace_forecasts/media/FY2018-38_FAA_Aerospace_Forecast.pdf

[65] Silk, Robert. "How the 1,500-hour Rule Created a Pilot Shortage: Travel Weekly." Travel Weekly- The Travel Industry's Trusted Voice. August 18, 2017. Accessed October 1, 2018. https://www.travelweekly.com/Robert-Silk/How-1500-hour-rule-created-pilot-shortage.

[66] Air Safety Institute, Aging and the General Aviation Pilot: Research and Recommendations, https://www.aopa.org/-/media/Files/AOPA/Home/Pilot-Resources/Safety-and-Proficiency/Accident-Analysis/Special-Reports/1302agingpilotreport.pdf Accessed Oct. 1, 2018. "Like the nation as a whole, the pilot population is growing older. Between 1990 and 2010, the average age of U.S. pilots increased from 40.5 to 44.2. This shift—partly a reflection of broad demographic trends; partly a result of changes in the industry and culture—poses serious challenges for the industry, and raises important questions about the viability of our current flight training model, the perception of general aviation (GA) among non-pilots, and other factors."

[67] Maria Garcia, Forbes, Advocates Worry that Changes to GI Bill Will Make Pilot Crisis Worse, https://www.forbes.com/sites/marisagarcia/2018/08/02/advocates-worry-that-changes-to-gi-bill-will-make-pilot-crisis-worse/#6ededdb7d524 (Accessed Oct. 5, 2018).

[68] Rachel Premack. "Airlines are 'desperate' for new pilots, and the shortage is contributing to canceled routes that are taking a toll on smaller cities." https://www.businessinsider.com/airlines-pilot-shortage-cancelled-routes-2018-8 (Accessed Oct. 5, 2018).

[69] "The Pilot Shortage Is A Reality In Business Aviation." Clay Lacy Aviation. https://www.claylacy.com/insights/pilotshortagebusinessaviation/ (Accessed October 1, 2018.).

[70] See generally 14 C.F.R. § 135. A RAND Corporation study of this regulation predicted higher labor costs for the airlines with more impact being felt on smaller, charter airlines. Michael McGee. Air Transport Pilot Supply and Demand: Current State and Effects of Recent Legislation. RAND Corporation. P.81. March, 2015.

[71] The Impact of Pilot Shortages On Air Service To Smaller And Rural Markets, 106th Congress. (1999) (Statement of Robert Palmersheim, Director Of Flight Operations And Secretary-Treasurer, Lynch Flying Service, Inc.).

[72] The Impact of Broader Regional Sharing of Livers: 2-Year Results of "Share 35", Erick B. Edwards, Ann M. Harper, Ryutaro Hirose, and David C. Mulligan, *Liver Transplantation* 22 399-409 2016 AASLD.

In regards to transport distance and the percent of organs flown, the acuity circles model was predicted to increase the percentage of organs flown to 71.4-74%, which would decrease the efficiency of the organ transplant system by causing increases to costs of procurement. The broader two circle model was predicted to increase flying by less, to only 58.4-60.8%.

Table 4: Overview of the SRTR Modeling Report

Scenario	Variance in Median Allocation MELD/PELD at Transplant	Transplant Count	Median Transport Time (hours)	Median Transport Distance (miles)	Percent of Organs Flown
Current	9.97	6651	1.7	88.5	50.7
2017 Board Approved	7.41	6643	1.7	100.4	54.4
Acuity 250+500	4.33	6594	1.9	183.5	71.4
Acuity 300+600	4.07	6583	2	211.3	74
Broader 2-Circle MELD 35	6.74	6620	1.8	107.7	58.4
Broader 2-Circle MELD 32	6.54	6616	1.8	117.1	60.8

National Liver Review Board (NLRB)

The Committee chose to remove median MELD at transplant in the DSA as the basis for exception scores to meet the goal of removing considerations of DSA from allocation. Additionally, the Committee addressed several areas of the NLRB scoring and reporting that were identified as needed clarification following the passage of the NLRB proposal in 2017. Since the NLRB implementation would be dependent on these changes, the committee wanted to ensure that the new exception scoring system was as clear as possible and would work as intended.

1. Median MELD at Transplant (MMaT)
2. Review of 1A and 1B Applications
3. Timing of Extension Submission
4. Hepatocellular Carcinoma (HCC) in Pediatrics
5. Cholangiocarcinoma
6. Familial Amyloid Polyneuropathy (FAP)
7. Hepatic Artery Thrombosis for Pediatrics
8. Primary Hyperoxaluria
9. Portopulmonary Hypertension
10. Downgrading & Recertification
11. MELD Transition Language
12. Times

1. Median MELD at Transplant (MMaT)

The Committee considered several options for how to remove MMaT for the DSA from policy. The Committee considered whether to keep the concept of MMaT. Prior to the 2017 proposal, exception

scores were awarded without consideration for the median score in the area, and instead adjusted scores through regular increases to the score based on how long the candidate waited. However, the Committee believes that MMaT is still a superior concept and modeling from last year showed that it can correct for variance in median MELD across the country.[73]

The Committee considered MMaT for the nation, a 500nm circle, a 250nm circle, or a 150nm circle around the transplant hospital. The national MMaT failed to account for the variation in MMaT based on location. Since that variance is the problem that MMaT-based scores address, a national score was inappropriate. The Committee then considered the different radius circles. It was important to balance keeping the area small enough to reflect geographic differences with keeping it large enough that the number would not fluctuate wildly with each recalculation and with providing a framework that would move away from geographic differences over time instead of inflating them.

The 150 and 250nm cohorts showed similar differences in the lowest and highest MMaTs that would result, and similar numbers of centers in which the MMaT was close to what it would have been if based on the center's DSA. The relationship to DSA is relevant because the benefit of using a MMaT system was based on modeling that used MMaT in the DSA. Since there is no modeling on this specific solution, it is reasonable to assume that a system that was at least in some ways similar to the one that was modeled would perform similarly. The 500nm cohort has a slightly smaller range of MMaT scores and is less aligned with what they would be if based on DSA.

Table 5: Geographic Grouping for Basis of MMaT

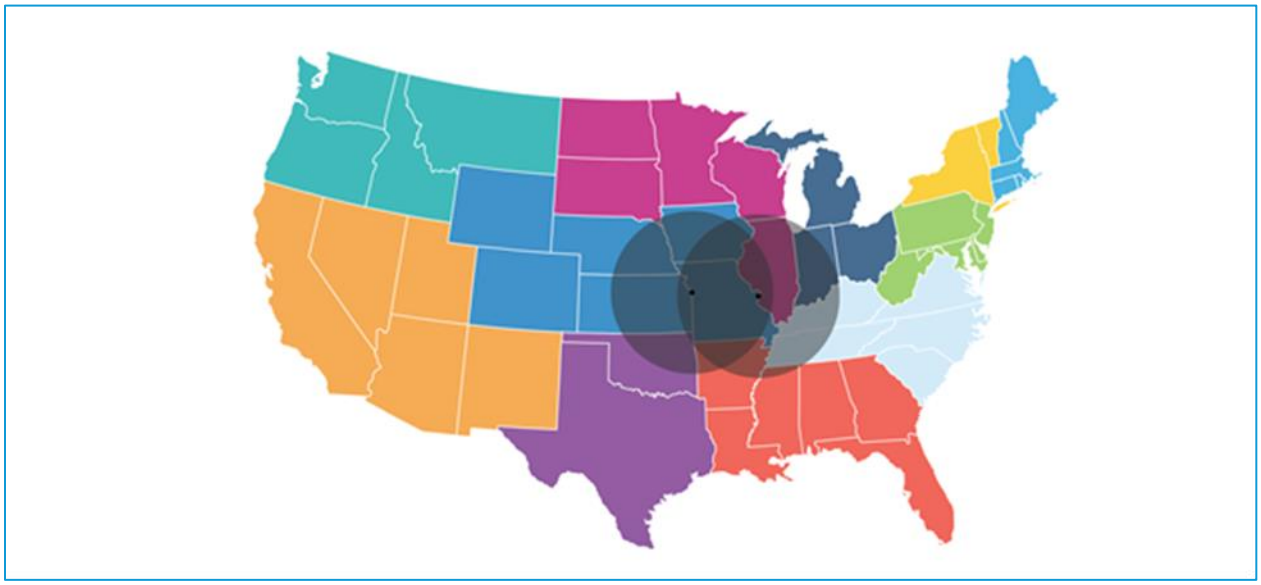
	By Transplant Center + all TXCs within 150 NM	By Transplant Center + all TXCs within 250 NM	By Transplant Center + all TXCs within 500 NM	By DSA	By Region
Minimum MMaT	19	19	19	19	26
Maximum MMaT	36	36	35	37	34
# Centers with MMaT=DSA MmaT	50 of 138 (36%)	50 of 138 (36%)	46 of 138 (33%)	-	-
# Centers with MMaT ±2 of DSA MMaT	119 of 138 (86%)	119 of 138 (86%)	86 of 138 (62%)	-	-

Although the circles would not perfectly overlap the allocation circles (since one is drawn around the donor hospital and the other is drawn around the transplant hospital), these distances were considered the most reasonable measures of similarly situated candidates who the candidate would be competing with.

As in the illustration below, a transplant hospital could be in the 250nm area around a donor hospital, but the MMaT used for patients at that hospital would be based on a 250nm circle around the hospital. Therefore, there could be multiple candidates within 250nm of the donor hospital who each have exceptions that are MMaT-3, but who have different exception score numbers. Over time, this would be expected to even out, once the impacts of the NLRB and new allocation have helped to even out the MMaT across the nation.

[73] Scientific Registry of Transplant Recipients,, "LI2015_03 DR1." October 14, 2016.

Figure 6: 250nm Radius Circles Around a Liver Program And Donor Hospital



The Committee proposes using a cohort of the MMaT of recipients within 250 nautical miles of the transplant hospital for all candidates with a MELD score (any candidates registered at age 12 or older). A larger physical area means that each cohort is more likely to include more transplant hospitals, and therefore more recipients. The larger number of individuals included makes a 250nm radius more stable than a 150nm radius while still preserving the concept of using candidates that would draw from the same donor pool. A 500nm radius was rejected because once the circle gets that big, the pool is so large that it flattens out closer to a national median. This would disadvantage exception candidates who are in a high MELD area and non-exception candidates in areas with a low median MELD.

There are far fewer patients with a PELD score (candidates registered before their 12th birthday), and those patients tend to have higher scores at transplant. The Committee considered the numbers of transplants that would be included in a median PELD at transplant (MPaT) calculation for these candidates. Because there are significantly fewer transplants among this group and the bigger disparity for them is based on their age rather than their location, the Committee proposes using a national cohort for PELD candidates.

Table 6: Number of Transplants and National MMaT by Age Group Cohort

Specific Cohort Age and MELD/PELD Composition	National MMaT	# of Transplants
All Ages, MELD or PELD Scores	29	6,435
Ages 0-17, MELD or PELD Scores	34	286
Ages 12+, MELD Scores	29	6,217
Ages 12-17, MELD Scores	32	68
Ages 0-11, PELD Scores	35	218

The Committee proposes that the following groups be excluded from the calculation of MMaT and MPaT because the scores at transplant for these recipients tend to be outliers:

1. Living donors
2. DCD donors
3. Transplants from donor hospitals more than 500nm away

Most living donor recipients do not receive their transplant based on their MELD or PELD score, because they are often recipients of directed donations, where the donor names the recipient rather than the recipient being allocated following a match run. DCD donors and donors from outside the region currently tend to be transplanted in candidates lower on the match, at lower MELD or PELD scores. Under the new allocation plan, candidates with 500nm of the donor hospital would likely be transplanted lower on the match as well, since they will be in lower allocation sequences. They are more aggressive transplants, and including them in the MMaT calculation could potentially serve as a disincentive to use of these organs.

The Committee also proposes excluding status 1 recipients from the calculation since they are not transplanted at a MELD or PELD score.

The Committee proposes that exception scores automatically adjust relative to MMaT and MPaT each time the MMaT and MPaT is recalculated. The MMaT and MPaT will be recalculated ever ## days. The Committee would except those exception scores that are awarded for standard exceptions for 40, or by the NLRB for 40 or higher, as these are intended to place a candidate at the top of the list, and are not awarded relative to MMaT or MPaT.

2. Review of 1A and 1B Applications

Policy language currently states that the Committee will review all status 1A and 1B applications. This was not intentional and the Committee proposes to change it to reflect that only those that do not meet standard criteria need to be reviewed by the Liver Committee. This is a correction of an inadvertent change.

3. Timing of Extension Submission

Extensions that are submitted within 3 days of the deadline are not given the exception score while they await review by the review board. Extensions submitted before that cutoff are proactively given the exception score while they await the review board decision.

The Committee considered the possibility of a hospital waiting until the last moment to submit an extension application when they do not expect the extension to be granted in order to ensure that the candidate keeps the exception score for longer. However, it was agreed that this was less likely to present a problem with extensions than appeals because they are more likely to be granted, and the longest a candidate could keep the exception would be 7 days (while the NLRB votes).

The Committee proposes eliminating the difference and giving all candidates the score on extension until the review board reaches a decision. This would put all candidates whose exceptions are extended on equal footing and be easier to explain to patients.

4. Hepatocellular Carcinoma (HCC) in Pediatrics

It is unclear in existing policy language whether pediatric patients with HCC automatically get an exception score of 40 or go to the NLRB for consideration. The Committee proposes that pediatric patients who meet Milan criteria for HCC receive a standard score of 40. However, there are other pediatric patients who the committee considers equally as sick and in need of an exception who would not meet Milan criteria. The idea of creating separate criteria for pediatric candidates was considered. However, after considering the small numbers of these patients, the Committee proposes that pediatric candidates who have HCC but don't meet Milan criteria go to the NLRB, with the recommendation to the NLRB that a score of 40 should be considered.

5. Cholangiocarcinoma

The policy language is currently unclear whether a candidate must have at least one or only one of the criteria listed. The Committee members proposed changing the list header to state that "at least one" is

required. This is in line with what the requirement has been historically, and the committee believed that the change was inadvertent.

6. Familial Amyloid Polyneuropathy (FAP)

On initial application, candidates can qualify for an FAP exception by being on the heart waiting list or having an ejection fraction of less than 40%. At the time of extension, ejection fraction is required. Extension criteria currently includes no mention of a heart registration as an option to meet criteria like the initial criteria does. The Committee members propose that a candidate be able to continue to qualify based on being listed for a heart on extension. If a candidate needs a heart transplant, that should be a reason to continue to grant an exception for FAP. The Committee did not see any benefit to forcing a candidate to appeal to the NLRB in that case, since they would advise that the NLRB grant the exception.

7. Hepatic Artery Thrombosis for Pediatrics

Pediatric candidates qualify for status 1A as long as they have HAT within 14 days. The requirements for a HAT MELD exception also require that the candidate have HAT within 14 days. The Committee proposes removing the option for a standard MELD/PELD exception for pediatric candidates for a HAT score of 40, because those candidates should be applying for status 1A instead. This will eliminate a potentially misleading section, and help direct liver programs to the exception that is most relevant and appropriate for pediatric candidates. It will help avoid similar patients being treated differently because one program read the MELD exception policy and assumed that was the appropriate exception to apply for while another program read the Status 1A exception policy and their patient received a higher exception.

8. Primary Hyperoxaluria

The Committee proposes that candidate should be required to continue to be registered for a combined liver-kidney on extension as well as on initial request. For candidates who receive an exception score based on primary hyperoxaluria, the Committee expects that they would continue to need a kidney transplant as well. It is possible that the candidate is not really sick enough to warrant the exception score if they do not continue to need a kidney transplant as well.

9. Portopulmonary Hypertension

The Committee proposes removing duplicative language about post-treatment laboratory values in the interest of clarity.

10. Downgrading & Recertification

Currently, when a candidate is downgraded from a status 1A or status 1B to a MELD of 25 or greater (regardless of whether or not the candidate's lab score is current or has expired), the system provides a grace period of 7 days to benefit sickest patients by allowing an additional 7 days for center to enter candidate's labs before the system downgrades the candidate any further.

When MELD was originally implemented in 2002, the Liver Committee discussed this situation and decided to allow the candidate to remain at the 25 or greater MELD for another week. However, this rule was never placed in policy. The Committee now proposes that this operational rule be removed and candidates be downgraded on the schedule as spelled out in policy. This is not a policy change, but will be an operational change.

11. MELD Transition Language

There is a clause in Policy 9.1.D *MELD Score* that was placed in policy to explain how candidates would be handled in a prior transition. It is no longer applicable, and the Committee proposes its removal to make policy clearer.

12. Times

Time periods are currently written in terms of days, months, and hours. The Committee proposes bringing these in line with policy conventions and making them clearer by changing all of the time periods in the impacted policies to periods of days.

Other Allocation Changes

The Committee also proposes removing DSA and Region in allocation of liver-intestines, intestines, and liver-kidneys. In order to support the changes to allocation, the Committee proposes a cap on exception scores, recommends discontinuing one variance and continuing two others, and considered whether geographically isolated programs needed to be treated differently.

1. Liver-Intestine priority
2. Intestine allocation
3. Simultaneous Liver-Kidney (SLK)
4. Cap on Exception Points
5. Sorting Within Allocation Sequences
6. Variances

1. Liver-Intestine priority

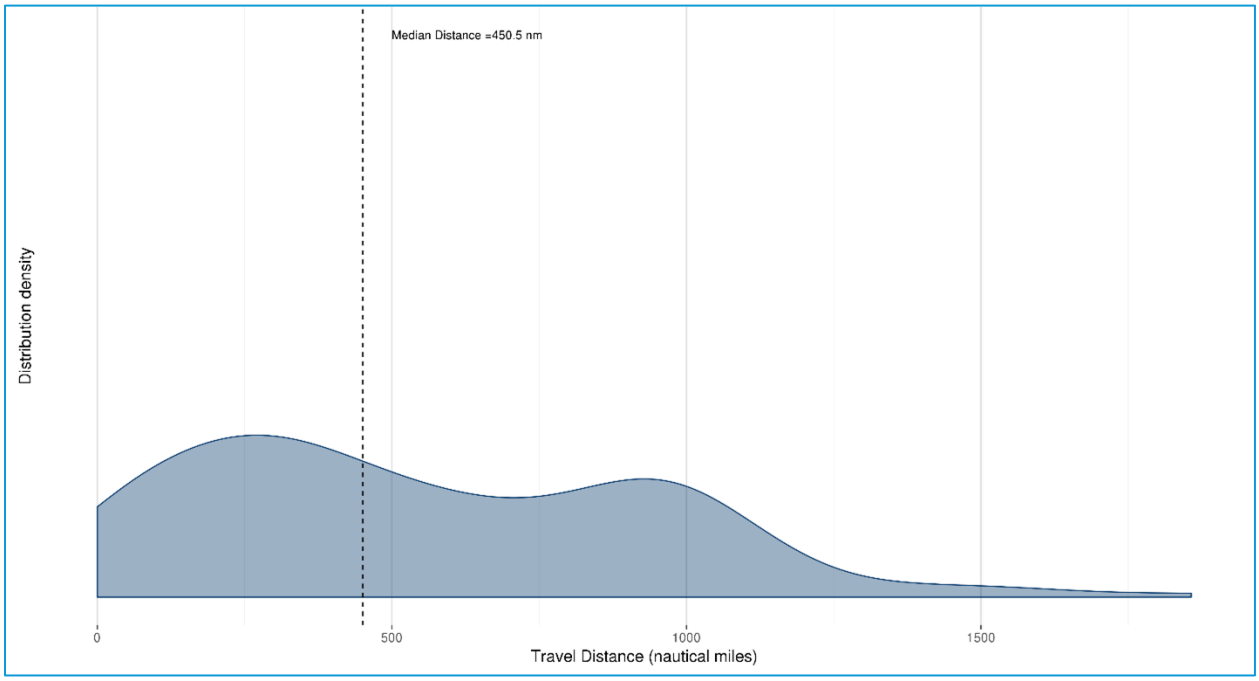
The Committee discussed the priority received on the match and in points for candidates who also need an intestine. Although the numbers are smaller[74], the Committee agreed that these candidates still need priority, and there is insufficient data to conclude that there is a need to change the amount of priority they receive at this time. The Committee is proposing that the points awarded to liver-intestine candidates stay the same, and that they receive priority in the allocation sequences that is as close as possible to the priority they had under previous allocation plans. The Committee proposes no changes to the requirement for hospitals to maintain documentation of a justification for listing liver-intestine in case the need for the intestine in any case is called into question.

2. Intestine Allocation

Between January 1, 2017 and May 31, 2018 there were 468 patients ever waiting for an intestine transplant, and 152 deceased donor intestine transplants. 88% of the transplants were of status 1 candidates. 72% of the transplants were accepted from outside the region. Since most of the transplants were of status 1 candidates, the Committee proposes prioritizing status 1 candidates.

[74] From 1/1/2017 through 5/31/2018 there were 10 patients waiting for a liver-intestine, 204 patients waiting for a liver-intestine-pancreas, and 15 patient waiting for a liver-intestine-pancreas-kidney.

Figure 7: Deceased Donor Intestine Transplant Travel Distances, 1/1/2017 to 5/31/2018



The median distance that distance that intestines currently travel is 450 nautical miles. This distance is close to the 500 nautical miles distance proposed to be used in liver allocation. Since there are fewer intestine transplants, and many of them are at greater distances, the Committee proposes using only one circle, of 500 nautical miles, and then allocating nationally. The use of the smaller circle that would include most of the intestines currently transplanted respects the OPTN Final Rule directive to "avoid wasting organs"[75], while quickly moving to a national allocation sequence to ensure that organs are shared as broadly as possible respects the Final Rule directive not to base access on a candidate's place of listing unless needed.[76]

The Committee proposes the following intestine allocation sequence:

Table 7: Intestine Allocation Sequence

Classification	Candidates within this distance from the donor hospital:	Who are:
1	500/600nm of the donor hospital	Status 1 and a blood type identical to the donor
2	500/600nm of the donor hospital	Status 1 and a blood type compatible with the donor
3	Nation	Status 1 and a blood type identical to the donor
4	Nation	Status 1 and a blood type compatible with the donor
5	500/600nm of the donor hospital	Status 2 and a blood type identical to the donor
6	500/600nm of the donor hospital	Status 2 and a blood type compatible with the donor
7	Nation	Status 2 and a blood type identical to the donor

[75] 42 C.F.R § 121.8(a)(5).
[76] *Ibid.*

Classification	Candidates within this distance from the donor hospital:	Who are:
8	Nation	Status 2 and a blood type compatible with the donor

3. Simultaneous Liver-Kidney (SLK)

The current SLK policy references local and regional candidates. While the Kidney Committee is considering changes to their distribution system, those changes will not be in effect until after this proposal is implemented. Therefore, the Liver Committee consulted with members of the Kidney Committee regarding how to modify the SLK policy. Both groups agreed that it would be best to keep the requirements for when kidneys must be shared with liver candidates as similar as possible to the current system so that no existing candidates are disadvantaged.[77] The Committee proposes that available kidneys must be offered to liver candidates who either:

- Have a MELD of 15 or higher and are listed at a transplant hospital within 150nm of the donor hospital
- Have a MELD of at least 32 and are listed at a transplant hospital within 250nm of the donor hospital

The MELD thresholds and areas were chosen because these organs are allocated off the liver match run, and aligning with the allocation sequences makes administration of this rule easier, and therefore more likely to be applied consistently, treating similar candidates similarly. It is already difficult for OPOs to know which organs receive priority relative to one another when there are several organs available that could be used for multi-organ transplants. The Committee proposes keeping these in alignment in an effort to keep within the Final Rule guidance not to create new inefficiencies in the administration of organ placement.[78]

4. Cap on Exception Points

The Committee remains sensitive to concerns about wide variations in exception scores and about score inflation in areas where there are more exceptions. Exception candidates are typically transplanted at a lower calculated MELD than candidates with standard scores. In order to protect against automatically approved exception scores getting more priority than is appropriate for the medical condition, the Committee proposes a cap on the standard exception scores. This cap would prevent any standard exception from being assigned over 31, except where a specific set score (such as 40) is assigned. However, the Committee recognizes that there are times when it would be appropriate to award a higher score based on the specific situation, so the Committee proposes that the NLRB remain able to award a higher exception score and the cap only apply to automatically-awarded standard exception scores.

5. Sorting Within Allocation Sequences

The Committee proposes adding a new level of sorting in which candidates are sorted according to the first time they were granted an exception. Since exception scores will be recalculated and individual scores will be updated every 6 months as a group, it is more likely that there will be multiple candidates with exactly the same amount of waiting time at a certain score. This new level of sorting will allow for a way of ordering these candidates in a way that prioritizes the candidates that have been the most medically urgent for the longest. The committee also considered ordering these by the date of the initial application that they are extending, but was concerned that would disadvantage patients who merely lapsed in renewing for a day or had any other gap in their exception that was not clinically significant.

The Committee also proposes that all candidates should be sorted in the same way, and the different sorting rules for low MELD/PELD should be removed. The sorting rules for candidates with a MELD or

[77] 42 C.F.R § 121.8(a)(5).
[78] 42 C.F.R § 121.8(d) provides that the OPTN "shall consider whether to adopt transition procedures that would treat people on the waiting list and awaiting transplantation prior to the adoption or effective date of the revised policies no less favorably than they would have been treated under the previous policies."

PELD less than six listed in policy were not aligned perfectly with the way sorting was programmed for this group, and there was no reason to have different sorting rules for this group.

6. Variances

The July 31 letter from HHS also instructed the OPTN to revisit variances in liver allocation. There currently exist three variances in liver allocation.

- *Split liver*: The split liver variance is described in OPTN Policy 9.9.A. It does not contain any references to DSAs or regions; it includes a research plan; and includes structured conditions for its review. (Due to the projected small volume of this variance, its review is dependent upon the volume of participation instead of a specific timeline.)
- *ABO*: There exists a variance in Hawaii regarding the allocation of blood type O donors. The Liver Committee is proposing changes to this variance as part of this proposal. The Minority Affairs Committee (MAC) reviewed the similarities between Hawaii and Puerto Rico, in terms of their geographic isolation and ethnic populations. They recommend that Puerto Rico be added to this variance. A version of this variance has been in place since 1994. In 2009, Hawaii's justification for the variance included 1) their geographic isolation and 2) a predominantly Asian population. Their application stated, "Asians have a higher proportion of blood type B. Our current waiting list reflects the assertion as 6 of the 44 patients (13.6%) have blood type B. Unfortunately, the blood type distribution of our donor population displays a different pattern. Since 2005, only 8 of 63 donors (12.7%) were blood type B. As a result, of the last 23 donors available in Hawaii, we made use of the variance nine (9) times."[79]
  By comparison, the current waiting list in Puerto Rico reflects 4 of 39 (10.3%) patients have blood type B. In 2016 and 2017, 18 of 155 (11.6%) livers recovered in Puerto Rico were blood type B.[80] The Committee is still considering whether to extend this variance to Puerto Rico, and welcomes feedback on whether to extend it.
- *Region 9*: The 2017 liver distribution proposal made changes to the New York / Region 9 liver sharing variance. The Committee now recommends removing that variance.

Operational Changes

In order to remove the use of DSAs and regions from liver and intestine allocation, changes are required to other operational policies and definitions. UNOS staff reviewed the OPTN policies and bylaws for any references to DSA, local, region, or regional. Many of these references are administrative in nature (ex. the composition of regional review boards.) Staff recommended changes to any policies or bylaws that use DSA or regional boundaries to influence whether a candidate will receive an organ offer.

1. Policy and Bylaw definitions
2. Variances
3. OPTN computer match program outages
4. Order of allocation
5. Other multi-organ combinations

1. Policy and Bylaw definitions

DSAs and regions are used in three definitions that will need to be changed.

- *Policy 1.2 Definition of Geographical Area* – This definition references DSA and regions as geographical areas for organ allocation. The recommendation is to delete the clarifying clauses since DSAs and regions are being eliminated as units of allocation. This clarification is not necessary for this definition therefore this will not impact other organs which will continue to use DSAs or regions for distribution purposes for the time being. (i.e., hearts, kidneys, and VCAs).

[79] OPTN/UNOS Liver and Intestinal Organ Transplantation Committee. "Select Recommendations of the OPTN/UNOS Liver and Intestinal Organ Transplantation Committee to the Board of Directors" November, 2008.
[80] Based on OPTN/UNOS data as of September 24, 2018.

- *Policy 1.2. Definition of Regions* and *Bylaws Appendix M: Definition of Regions* – This definition currently states that regions are used for "the administration of organ allocation." The recommendation is to remove the reference to organ allocation and simply state that OPTN membership is divided into geographic regions for "administrative purposes.
- *Bylaws Appendix M: Definition of Waiting List* – This definition clarifies the criteria used to generate a match run. The recommendation is to delete the clarifying clauses since they include "geographic local and regional area."

2. Variances

Policy 1.3.A *Acceptable Variances* addresses the permissible variances as well as the principles that must apply to all variances. The recommendation is to delete the requirement for a single waiting list for each organ within each DSA since it is an outdated requirement. Additionally, there is a recommendation to delete the process for allocating organs to the remainder of the DSA if an alternative local unit is the first unit of allocation under a variance.

3. Computer Outages

Policy 1.4.E *OPTN Computer Match Program Outages* outlines the process for allocating organs if the match system is unavailable. It references the ranking of "local" transplant candidates and using "local" transplant program waiting lists. The recommendation is to remove both references to "local" because OPOs should be using the most recent match run available and not specifically local transplant candidates and programs.

4. The Order of Allocation

Policy 5.4.B *Order of Allocation* addresses the process for allocating deceased donor organs. This includes an outdated process that the Organ Center no longer uses if they receive a request to allocate organs. The Organ Center allocates organs according the applicable allocation policies. The recommendation is to delete this section of the policy.

5. Multi-Organ Combinations

Policy 5.10.C *Other Multi-Organ Combinations* addresses the allocation of the second organ when a multi-organ candidate registered for a heart, lung, or liver is located within or outside the same DSA as the donor. The recommendation is to replace DSA with the smallest unit of allocation for heart, lung, and liver. This will include 150 nautical miles for liver and 250 nautical miles for lung. DSA will remain in the policy for heart but will be modified with an upcoming heart distribution proposal.

Which populations are impacted by this proposal?

All liver transplant candidates will be impacted by this proposal. There are currently 13,722 candidates. Of those, 434 are pediatric and 13,288 are adults[81]. The committee also evaluated the impact of the proposed changes on specific populations.

Age, Sex, and Race/Ethnicity

The SRTR modeling looks at the impact of the proposal on multiple subgroups. Specifically, the SRTR found that "Overall, trends in the demographic characteristics' (age, sex, and race/ethnicity) subgroups were similar between frameworks to the total population. The exception to this was the pediatric subgroup, which saw reductions in MMAT and increases in transplant rate that differed directionally from the overall population. The trends in the transportation metrics were common across age ranges (adult

[81] Based on OPTN/UNOS data, accessed October 4, 2018.

and pediatric)."[82] In assessing age, the SRTR compared pediatric (aged less than 18 years old at registration) against adults (aged at least 18 years old at registration). For sex, the SRTR compared males against females. In assess race/ethnicity, the SRTR group populations by African American, Asian/Pacific Islander, Hispanic, multiracial, and white.

Socio Economic Status (SES)

The OPTN Final Rule charges that the OPTN shall develop "policies that reduce inequities resulting from socioeconomic status, including … [the] reform of allocation policies."[83] Additionally, the OPTN shall develop allocation policies that "promote patient access."[84] In considering patient access, the OPTN has interpreted these requirements to apply to patients who are registered for organ transplantation – as opposed to all patients with end stage organ failure, who may or may not be registered for organ transplantation. This is consistent with the OPTN's authority under NOTA to focus on organ transplantation as opposed to broader access to healthcare.[85] Overall, modeling showed that "the trends for the socio-economic status characteristics (education, insurance type, cumulative community risk score, and urbanicity) subgroups were similar between frameworks to the total population."[86]

In developing this proposal, the Committee with UNOS and SRTR staff examined several different methodologies to perform SES analysis. They reviewed data currently collected by the OPTN and also merging OPTN geographic data with other data sets. Their analysis began with patient level data that the OPTN currently collects. The OPTN does not classify patients' SES nor does the OPTN collect variables typically necessary to determine an individual's SES (ex. income level); however, the OPTN does collect patients' education level and insurance status. In assessing education level, the SRTR grouped populations by high school or less against more than high school. In assessing insurance status, the SRTR grouped populations by public vs. private insurance. In looking at the variance in MMaT, the broader 2-circle model will, compared to the current and 2017 Board approved systems, improve the variance in MMaT for all education levels. The same is true for both public and private insurance.

UNOS and SRTR staff also reviewed the ability to merge OPTN geographic data with outside datasets concerning SES. "The Committee also requested that SRTR assess the new subgroup based on Cumulative Community Risk Score (CCRS), which SRTR had not previously assessed with respects to the liver allocation modeling data, to determine the effect on candidates living in counties with differing socioeconomic characteristics. The CCRS is assigned by county and ranges from 0 to 40, with 0 representing the lowest risk. Please reference the original publication for details on how the CCRS is compiled. [1] For this subgroup analysis, the CCRS was categorized into four groups of ten-unit increments (0-10, 11-20, 21-30, and 31-40), which aligns with the subgrouping used by OPTN. CCRS subgroupings are presented nationally and by region."[87]

The SRTR research report describes the limitations of this analysis.

> This report presents two subgrouping metrics defined for geographic areas: the CCRS, which is defined by county, and the urbanicity classification, which is defined by census tract. The CCRS is based on population-level attributes, and the authors recommend caution in its interpretation: "it is…important for interpretation of our study findings that

[82] Scientific Registry of Transplant Recipients, *SRTR LI_2018_01*, Sept. 24, 2018, https://optn.transplant.hrsa.gov/media/2640/li2018_01_analysis-report_20180924.pdf (accessed Oct. 1, 2018)

[83] 42 C.F.R § 121.4(a)(3)(iv).
[84] 42 C.F.R § 121.8(a)(5).
[85] 42 USC § 274(b).
[86] Scientific Registry of Transplant Recipients, *SRTR LI_2018_01*, Sept. 24, 2018, https://optn.transplant.hrsa.gov/media/2640/li2018_01_analysis-report_20180924.pdf (accessed Oct. 1, 2018)
[87] Scientific Registry of Transplant Recipients, *LI2017_03,* Nov. 14, 2017, *citing* Schold JD, Buccini LD, Kattan MW, et al. "The Association of community health indicators with outcomes for kidney transplant recipients in the United States." *Arch surg*. 2012;147(6):520-526. doi:10.1001/archsurg.2011.2220.

> ascribing broad area risks to each individual within that area is an ecological fallacy. Thus…it is inappropriate to directly assign risks to individuals within that community." [1] Thus, readers should think of CCRS results as applying to candidates in high-risk counties, not to high-risk candidates Because urbanicity classification applies to the entire population within the defined geographical area, "urban populations" and "those living in urban areas" are interchangeable.[88]

Staff and Committee members recommended merging OPTN geographic data with other datasets to do this analysis. However, those datasets were would have been limited to even broader geographic areas (ex. states) which would further exacerbate the limitations described above. Future data collection could enhance the ability of the OPTN and SRTR to analyze SES.

Non-Contiguous Programs

The Liver Committee considered the potential impact of changes to liver geographic allocation on candidates in non-contiguous states and territories of the U.S. Under the proposed changes that use the fixed distance framework, candidates on Hawaii and Puerto Rico would no longer receive regional offers, meaning they would receive local offers and then national offers (because the circle sizes wouldn't encompass both the non-contiguous areas and the mainland). Status 1A or high MELD candidates in non-contiguous areas could wait to receive offers until the national level. This could increase the cold ischemic time of the liver before the Status 1A/high MELD non-contiguous candidates receive an offer, which in turn can impact the discard rate and whether the liver is still viable to travel to Puerto Rico (980 miles away from the continental U.S.) or Hawaii (2390 miles from the continental US). Similarly, livers traveling from Hawaii and Puerto Rico will already have a longer cold ischemic time from travel, and shifting from regional to national share for these areas may decrease the number of livers flown from non-contiguous areas (including Alaska, which doesn't have a transplant program but does have donor hospitals).

Figure 8: Depiction of 500, 1000, and 1500 nm circles around Alaska, Hawaii, and Puerto Rico

[88] Scientific Registry of Transplant Recipients, *SRTR LI2017_03*, Nov. 14, 2017, https://transplantpro.org/wp-content/uploads/sites/3/SRTR_Liver_Analysis_Report_20171114.pdf (accessed Oct. 1 2018).

Because of the logistical challenges for non-contiguous candidates to be registered elsewhere, these candidates could be vulnerable to experiencing disparity in allocation compared to the current system, which shows no disparity in access to transplant for non-contiguous candidates.[89] To ensure equitable treatment of non-contiguous candidates, the Liver Committee asked the Minority Affairs Committee (MAC) in August 2018 to review the potential impact on these candidates and non-contiguous liver programs. To ensure a consistent approach across the organs, the Ad Hoc Geography Committee examined this issue and issued guidance to all of the organ specific Committees.

The MAC recommended that the Liver Committee continue an exception allowing Hawaii to keep blood type O livers for compatible candidates in Hawaii and extend that exception so it applies to Puerto Rico as well. In addition, the MAC recommended that the Liver Committee consider the impact on discard rates for non-contiguous areas in the post-implementation plan of the proposal. The MAC provided its recommendation after extensive discussion about the potential impact of discards that could occur due to the removal of regional sharing, the lack of current data on Puerto Rico candidate and donor trends, and the similar logistical challenges that candidates on Puerto Rico and Hawaii face. Overall, the MAC felt that the potential impact on low SES and minority populations warranted extending a blood type O extension to Puerto Rico and keeping one for Hawaii. Because discard rates could go up by removing regional share, the Liver Committee should monitor these trends in its post-implementation monitoring plan.

The Liver Committee carefully considered the MAC's feedback and discussed the impact of providing an exception for blood type O livers to go to compatible candidates in Puerto Rico with a MELD of 15 or higher. The Committee agreed an exception may be needed to apply to Puerto Rico as well, but certain members expressed concern that high MELD blood type O candidates on the continental US would receive a blood type O liver offer after compatible Puerto Rican candidates with a lower MELD. The Committee did not extend the blood type O exception to Puerto Rico because the Committee felt the justification for the exception was not demonstrated. However, the Committee is still asking the community during public comment whether it agrees with that decision. This question is asked in the "Is the sponsoring Committee requesting specific feedback or input about the proposal?" section.

The Ad Hoc Geography Committee focused on the issue of travel time between the continental United States and these geographically isolated programs and the impact of organs offered to or from these locations. The Geography Committee considered four potential options.

1. Do not make any specific policy accommodation for these organs.
2. For the purposes of calculating the distance based circles described above, assume that these three states are closer to the continental United States. (Ex. Assume that Alaska is right next to Seattle.)
3. Include in the distribution system, a fixed distance based circle that is large enough to cover these three states but smaller than national offers. (Ex. 2000 nm)
4. Include in the distribution system a fixed distance based circle that is large enough to cover these states - but only use it for organs offered to/from these states. (Ex. Use this circle for organs that could travel between Hawaii and the continental United States but don't apply it to organs from other parts of the country.)

After consideration, the Geography Committee agreed that there should not be any specific policy accommodations for these organs. This is how thoracic allocation zones have operated for many years. This recognizes and respects the logistical issues represented by these programs. The Committee also commented that if organs are able to travel these broader distances, then perhaps the smaller distance based circles should be expanded to reflect these possibilities and those distances should be applied to all organs – not just those to/from geographically isolated programs.

[89] OPTN/UNOS Descriptive Data Request. "Geographically Isolated Programs Access to Liver Transplant." Prepared for MAC Non-Contiguous Programs Work Group Conference Call, September 5, 2018.

How does this proposal impact the OPTN Strategic Plan?

1. Increase the number of transplants: As indicated in the SRTR modeling results, this proposal should neither increase nor decrease the number of transplants.
2. Improve equity in access to transplants: This proposal will improve the disparity in MMaT across the country.
3. Improve waitlisted patient, living donor, and transplant recipient outcomes: There is no impact on this goal.
4. Promote living donor and transplant recipient safety: There is no impact on this goal.
5. Promote the efficient management of the OPTN: This proposal will alleviate the legal risk to the OPTN regarding the use of DSAs and regions, which is an important and time sensitive issue regarding the management of the OPTN. This proposal will also impact the percentage of liver transplants that require air transportation.

How will the OPTN implement this proposal?

The OPTN will offer learning opportunities to specific audiences related to policy and system changes in advance of implementation. The changes in this proposal will be incorporated in the education already planned for the original NLRB and Liver Distribution projects passed by the Board of Directors in 2017. The OPTN will deliver communications to the membership when instructional offerings are available.

This proposal will require programming in UNet℠ and monitoring of the effects. The OPTN will coordinate implementation efforts so that the NLRB will be in place before or at the same time as this revised liver distribution proposal. As mentioned earlier, this proposal will move forward concurrently with a proposal from the Ad Hoc Geography Committee to select a single, unified distribution framework for future organ distribution projects. Additionally, as mentioned above, the other organ specific Committees are developing policy proposals to remove DSAs and regions from those organ allocation policies. Those will be released for public comment in spring 2019 and considered by the Board in June 2019.

How will members implement this proposal?

Transplant Hospitals

The order that candidates appear on a waiting list will change as a result of this proposal. Transplant hospitals can expect to see different patterns in the offers they receive and the location of offers they receive. Transplant hospitals may need to develop or strengthen relationships with additional OPOs and recovery hospitals. It may require adjustments to travel and education to patients.

OPOs

OPOs may notice that the hospitals they currently work with most frequently may change and the patterns of travel may change. OPOs may need to plan for different kinds of transportation and develop new relationships.

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 routine monitoring of OPTN members. Any data submitted to the OPTN Contractor may be subject to OPTN review, and the OPTN Contractor will continue to review deceased donor match runs to ensure that allocation is carried out according to OPTN policy. Members are required to provide documentation as requested.

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

Because this proposal impacts multiple areas of policy, the post implementation plan has been split into three components.

National Liver Review Board Post-Implementation Evaluation Plan

Using pre vs. post comparisons, analyses will be performed post-implementation at approximate 6-month intervals as appropriate, up to 2 years, to assess the efficacy of the National Liver Review Board (NLRB). Analysis of specific diagnoses that currently require review by the Regional Review Board (RRB) chair that will be automated under the NLRB system may not be directly comparable pre- to post-era. Analyses will be performed by specialty board type (i.e., HCC, Pediatric, Other), and nationally and regionally where feasible and appropriate.
Relevant analyses:

- Total number of exception cases automatically approved and those reviewed by the NLRB, overall and by exception diagnosis
- Number and percent of Approved/Denied/Appealed exception forms, overall and by diagnosis
- Number of exception cases reviewed by the NLRB with a new initial form submitted and approved after previously denied initial form
- Distribution of MELD/PELD scores of exception cases reviewed by the NLRB, by approved/denied status, initial/extension/appeal form type, and exception diagnosis
- Waiting list drop-out rates (death or too sick) for candidates with approved exceptions versus those without exceptions
- Waiting list drop-out rates for candidates with denied initial exception (and no re-submitted, subsequently approved exception)
- Distribution of deceased donor transplants by exception status (yes/no) and exception type (e.g., HCC, other standard exception, other specify)
- Distribution of MELD and PELD scores at transplant by exception status (yes/no) and exception type (e.g., HCC, other standard exception, other specify)Other metrics deemed relevant and necessary to the evaluation of the policy by the Liver and Intestinal Transplantation Committee at time of analysis

Redistribution Post-Implementation Evaluation Plan

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 score at transplant by appropriate geographic areas

- Waiting list mortality rates and transplant rates
- Transplant recipient demographics (age, gender, diagnosis, ethnicity, socioeconomic factors as available for analysis)
- Transplants by exception status (yes/no) and exception type (e.g., HCC, other standard exception, other specify)
- Post-transplant survival rates
- Post-transplant length of stay
- Liver discard rates (Number of livers recovered for transplanted and not transplanted)
- Number of livers not recovered
- Organ travel distance, cold ischemia time, donor risk index
- Changes in transplant center or DSA-level transplant outcomes
- Number and percent of livers transplanted within first classification tier of allocation
- Other metrics deemed relevant and necessary to the evaluation of the policy by the Liver and Intestinal Transplantation Committee at time of analysis

Hawaii Variance

Using pre. and post comparisons, analyses will be performed at approximate 3-month intervals as appropriate, up to three years, to identify trends and potentially unanticipated consequences of the variance. Metrics to be evaluated include:

- Number of deceased donor liver transplants (within these geographically isolated areas in comparison to the national transplant network)
- Size and composition of the waiting list (within these geographically isolated areas in comparison to the national transplant network)
- Waiting list mortality rates and transplant rates by ABO (within these geographically isolated areas in comparison to the national transplant network)
- Number and percent of organs distributed to and from Hawaii

Policy or Bylaws Language

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

[Subsequent headings affected by the re-numbering of this policy will also be changed as necessary.]

1.2 Definitions

Allocation MELD or PELD Score

The highest exception or calculated MELD or PELD score available to the candidate according to Policy. Allocation MELD or PELD Score includes liver-intestine points.

Calculated MELD or PELD Score

The highest non-exception MELD or PELD score available to the candidate according to Policy. Calculated MELD or PELD score excludes liver-intestine points.

Geographical Area

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

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~~.

Region

For ~~the administration of organ allocation and appropriate geographic representation within the OPTN policy structure, the~~ administrative purposes, OPTN membership is divided into 11 geographic regions. Members belong to the Region in which they are located. The Regions are as follows:

Region 1: Connecticut, Maine, Massachusetts, New Hampshire, Rhode Island, and Eastern Vermont
Region 2: Delaware, District of Columbia, Maryland, New Jersey, Pennsylvania, West Virginia, and the part of Northern Virginia in the Donation Service Area served by the Washington Regional Transplant Community (DCTC) OPO.
Region 3: Alabama, Arkansas, Florida, Georgia, Louisiana, Mississippi, and Puerto Rico
Region 4: Oklahoma and Texas
Region 5: Arizona, California, Nevada, New Mexico, and Utah
Region 6: Alaska, Hawaii, Idaho, Montana, Oregon, and Washington
Region 7: Illinois, Minnesota, North Dakota, South Dakota, and Wisconsin
Region 8: Colorado, Iowa, Kansas, Missouri, Nebraska, and Wyoming
Region 9: New York and Western Vermont
Region 10: Indiana, Michigan, and Ohio
Region 11: Kentucky, North Carolina, South Carolina, Tennessee, and Virginia

1.3.A Acceptable Variances

Permissible variances include, but are not limited to:

- Alternative allocation systems
- Alternative local units
- Sharing arrangements
- Alternative point assignment systems

The following principles apply to *all* variances:

1. Variances must comply with the NOTA and the Final Rule.
2. Members participating in a variance must follow all rules and requirements of the OPTN Policies and Bylaws.
3. If the Board later amends an OPTN Policy to contradict with a variance, the Policy amendment will not affect the existing variance.
~~4. There must be a single waiting list for each organ within each DSA.~~
~~5. Where the alternative local unit created by a variance is a subdivision of the OPO's DSA the OPO will allocate organs to the remainder of the DSA after allocating organs to this alternative local unit.~~
~~6.~~ 4. If a member's application to create, amend, or join a variance will require other members to join the variance, the applicant must solicit their support.
~~7.~~ 5. The Board of Directors may extend, amend, or terminate a variance at any time.

1.4.E OPTN Computer Match Program Outages

If the OPTN Contractor and members cannot communicate by any method and the OPTN computer match program is either not accessible or not operational, affected OPOs:

1. Must refer to recent matches of similar blood type and body size for ranking ~~local~~ transplant candidates.
2. Must use ~~local~~ transplant program waiting lists to match the best organ with waiting transplant candidates.
3. Must document and report to the OPTN Contractor their process for allocation during the outage.

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 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.*~~
~~6.~~ 5. 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.

5.10.C Other Multi-Organ Combinations

When multi-organ candidates are registered on the heart, lung, or liver waiting list, the second required organ will be allocated to the multi-organ candidate from the same donor according to

Table 5-4 below: ~~if the donor's DSA is the same DSA where the multi-organ candidate is registered.~~

Table 5-4: Allocation of Multi-Organ Combinations

Organ	Candidate is registered within the following geographical area:
Heart	Same DSA as the donor hospital
Liver	150 nautical miles from the donor hospital
Lung	250 nautical miles from the donor hospital

If the multi-organ candidate is on a waiting list outside the ~~donor's DSA~~ geographical areas listed above, it is permissible to allocate the second organ to the multi-organ candidate receiving the first organ.

7.3.B Allocation of Intestines

Intestines are allocated to candidates according to *Table 7-1* below.

Table 7-1: Allocation of Intestines

~~Classification~~	~~Candidates that are within the:~~	~~And are:~~
~~1~~	~~OPO's DSA~~	~~Status 1 and a blood type identical to the donor~~
~~2~~	~~OPO's DSA~~	~~Status 1 and a blood type compatible with the donor~~
~~3~~	~~OPO's DSA~~	~~Status 2 and a blood type identical to the donor~~
~~4~~	~~OPO's DSA~~	~~Status 2 and a blood type compatible with the donor~~
~~5~~	~~OPO's region~~	~~Status 1 and a blood type identical to the donor~~
~~6~~	~~OPO's region~~	~~Status 1 and a blood type compatible with the donor~~
~~7~~	~~OPO's region~~	~~Status 2 and a blood type identical to the donor~~
~~8~~	~~OPO's region~~	~~Status 2 and a blood type compatible with the donor~~
~~9~~	~~Nation~~	~~Status 1 and a blood type identical to the donor~~
~~10~~	~~Nation~~	~~Status 1 and a blood type compatible with the donor~~
~~11~~	~~Nation~~	~~Status 2 and a blood type identical to the donor~~
~~12~~	~~Nation~~	~~Status 2 and a blood type compatible with the donor~~

Classification	Candidates within this distance from the donor hospital:	Who are:
1	500nm of the donor hospital	Status 1 and a blood type identical to the donor
2	500nm of the donor hospital	Status 1 and a blood type compatible with the donor
3	Nation	Status 1 and a blood type identical to the donor
4	Nation	Status 1 and a blood type compatible with the donor
5	500nm of the donor hospital	Status 2 and a blood type identical to the donor
6	500nm of the donor hospital	Status 2 and a blood type compatible with the donor
7	Nation	Status 2 and a blood type identical to the donor
8	Nation	Status 2 and a blood type compatible with the donor

Policy 9: Allocation of Livers and Liver-Intestines

9.1.A Adult Status 1A Requirements

To assign a candidate adult status 1A, the candidate's transplant hospital must submit a *Liver Status 1A Justification Form* to the OPTN Contractor. A candidate is not registered as status 1A until this form is submitted. When reporting laboratory values to the OPTN Contractor, transplant hospitals must submit the most recent results including the dates of the laboratory tests.

The candidate's transplant program may assign the candidate adult status 1A if *all* the following conditions are met:

1. The candidate is at least 18 years old at the time of registration
2. The candidate has a life expectancy without a liver transplant of less than 7 days and has at least *one* of the following conditions:

    a. Fulminant liver failure, without pre-existing liver disease and currently in the intensive care unit (ICU), defined as the onset of hepatic encephalopathy within 56 days of the first signs or symptoms of liver disease, and has at least *one* of the following criteria:
        i. Is ventilator dependent
        ii. Requires dialysis, continuous veno-venous hemofiltration (CVVH), or continuous veno-venous hemodialysis (CVVHD)
        iii. Has an international normalized ratio (INR) greater than 2.0

    b. Anhepatic

c. Primary non-function of a transplanted whole liver within 7 days of transplant, with aspartate aminotransferase (AST) greater than or equal to 3,000 U/L and at least *one* of the following:
   - International normalized ratio (INR) greater than or equal to 2.5
   - Arterial pH less than or equal to 7.30
   - Venous pH less than or equal to 7.25
   - Lactate greater than or equal to 4 mmol/L

   All laboratory results reported for the tests required above must be from the same blood draw taken 24 hours to 7 days after the transplant.

d. Primary non-function within 7-days of transplant of a transplanted liver segment from a deceased or living donor, evidenced by at least *one* of the following:
   i. INR greater than or equal to 2.5
   ii. Arterial pH less than or equal to 7.30
   iii. Venous pH less than or equal to 7.25
   iv. Lactate greater than or equal to 4 mmol/L

e. Hepatic artery thrombosis (HAT) within 7-days of transplant, with AST greater than or equal to 3,000 U/L and at least *one* of the following:
   - INR greater than or equal to 2.5
   - Arterial pH less than or equal to 7.30
   - Venous pH less than or equal to 7.25
   - Lactate greater than or equal to 4 mmol/L

   All laboratory results reported for the tests required above must be from the same blood draw taken 24 hours to 7 days after the transplant.

   ~~Candidates with HAT in a transplanted liver within 14 days of transplant not meeting the above criteria will be listed with a MELD of 40.~~

f. Acute decompensated Wilson's disease

9.1.C Pediatric Status 1B Requirements

To assign a candidate pediatric status 1B, the candidate's transplant hospital must submit a *Liver Status 1B Justification Form* to the OPTN Contractor. A candidate is not registered as status 1B until this form is submitted.

The candidate's transplant program may assign the candidate pediatric status 1B if *all* the following conditions are met:

1. The candidate is less than 18 years old at the time of registration. This includes candidates less than 18 years old at the time of registration, who remain on the waiting list after turning 18 years old, but does not include candidates removed from the waiting list at any time who then return to the waiting list after turning 18 years old.

2. The candidate has *one* of the following conditions:

   a. The candidate has a biopsy-proven hepatoblastoma without evidence of metastatic disease.

b. The candidate has an organic acidemia or urea cycle defect and an approved MELD or PELD exception meeting standard criteria ~~score~~ for metabolic disease ~~score of 30 points~~ for at least 30 days.

c. Chronic liver disease with a calculated MELD ~~greater than 25for adolescent candidates 12 to 17 years old,~~ or ~~a calculated~~ PELD greater than 25 ~~for candidates less than 12 years old~~, and has at least *one* of the following criteria:
   i. Is on a mechanical ventilator
   ii. Has gastrointestinal bleeding requiring at least 30 mL/kg of red blood cell replacement within the previous 24 hours
   iii. Has renal failure or renal insufficiency requiring dialysis, continuous veno-venous hemofiltration (CVVH), or continuous veno-venous hemodialysis (CVVHD)
   iv. Has a Glasgow coma score (GCS) less than 10 within 48 hours before the status 1B assignment or extension.

d. Chronic liver disease and is a combined liver-intestine candidate with an adjusted MELD or PELD score greater than 25 according to *Policy 9.1.F: Liver-Intestine Candidates* and has at least *one* of the following criteria:
   i. Is on a mechanical ventilator
   ii. Has gastrointestinal bleeding requiring at least 10 mL/kg of red blood cell replacement within the previous 24 hours
   iii. Has renal failure or renal insufficiency requiring dialysis, continuous veno-venous hemofiltration (CVVH), or continuous veno-venous hemodialysis (CVVHD)
   iv. Has a Glasgow coma score (GCS) less than 10 within 48 hours before the status 1B assignment or extension.

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~~

9.1.F Liver-Intestine Candidates

Candidates ~~awaiting a liver-intestine transplant~~ who are also registered and active on ~~both waiting lists~~ the waiting list for an intestine transplant at that transplant hospital will automatically receive an additional increase in their MELD or PELD score equivalent to a 10 percentage point increase in risk of 3-month mortality. Candidates less than 18 years old will receive 23 additional points to their calculated MELD or PELD score instead of the 10 percentage point increase. The transplant hospital must document in the candidate's medical record the medical justification for the combined liver-intestine transplant and that the transplant was completed.

9.2 Status and Laboratory Values Update Schedule

The OPTN Contractor will notify the transplant hospital within 2 days ~~48 hours~~ of the deadline for recertification when a candidate's laboratory values need to be updated. Transplant hospitals must recertify a candidate's values according to *Table 9-1*. ~~These data must be based on the most recent clinical information, laboratory tests, and diagnosis and include the dates of all laboratory tests~~.

When reporting laboratory values to the OPTN Contractor, transplant hospitals must submit the most recent results including the dates of the laboratory tests. In order to change a MELD or PELD score voluntarily, all laboratory values must be obtained within the same 2 day ~~48-hour~~ period.

Table 9-1: Liver Status Update Schedule

If the candidate is:	The new laboratory values must be reported every:	And when reported, the new laboratory values must be no older than :
Status 1A or 1B	7 days	~~48 hours~~2 days
MELD 25 or greater (ages 18 or older)	7 days	2 days ~~48 hours~~
MELD/PELD 25 or greater (less than 18 years old)	14 days	~~72 hours~~ 3 days
MELD/PELD 19 to 24	30 days ~~1 Month~~	7 days
MELD/PELD 11 to 18	90 days ~~3 months~~	14 days
MELD/PELD 10 or less	365 days ~~12 months~~	30 days

Status 1B candidates have these further requirements for certification:

- Candidates with a gastrointestinal bleed as the reason for the initial status 1B upgrade criteria must have had another bleed in the past 7 days immediately before the upgrade in order to recertify as status 1B.

- Candidates indicating a metabolic disease or a hepatoblastoma require recertification every 90 days ~~three months~~ with lab values no older than 14 days.

If a candidate is not recertified by the deadline according to *Table 9-1*, the candidate will be re-assigned to their previous lower MELD or PELD score. The candidate may remain at that previous lower score for the period allowed based on the recertification schedule for the previous lower score, minus the time spent in the uncertified score.

If the candidate remains uncertified past the recertification due date for the previous lower score, the candidate will be assigned a MELD or PELD score of 6. If a candidate has no previous lower MELD or PELD score, and is not recertified according to the schedule, the candidate will be reassigned to a MELD or PELD score of 6, or will remain at the uncertified PELD score if it is less than 6.

9.2.A Recertification of Status 1A or 1B

Transplant hospitals must submit a completed *Liver Status 1A or 1B Justification Form* to the OPTN Contractor for *each* recertification as a status 1A or 1B. A request to continue as status 1A or 1B beyond 14 days accumulated time will result in a review of all status 1A or 1B liver candidate registrations ~~within the donation service area (DSA)~~ at the transplant hospital. A review will not occur if the request was for a candidate meeting the requirements for hepatoblastoma in *Policy* or a metabolic disease in *Policy 9.5.F: Requirements for Metabolic Disease MELD or PELD Score Exceptions*.

9.3 Status Exceptions

The Liver and Intestinal Organ Transplantation Committee establishes guidelines for review of status and MELD/PELD score exception requests.

If a candidate's transplant program believes that a candidate's current status does not appropriately reflect the candidate's medical urgency for transplant, the transplant program may register a candidate at an exceptional status. However, the Liver and Intestinal Organ Transplantation Committee will retrospectively review all exception candidates registered as status 1A or 1B and may refer these cases to the Membership and Professional Standards Committee (MPSC) for review according to *Appendix L* of the OPTN Bylaws.

9.4.A MELD or PELD Score Exception Requests

A MELD or PELD score exception request must include *all* the following:

1. A request for a specific MELD or PELD score
2. A justification of how the medical criteria supports that the candidate has a higher MELD or PELD score
3. An explanation of how the candidate's current condition and potential for benefit from transplant would be comparable to that of other candidates with that MELD or PELD score

Approved MELD or PELD exception scores are valid for 90 days.

9.4.C MELD or PELD ~~Score~~ Exception Extensions

~~Transplant hospitals may submit a MELD/PELD Exception Score Request Form to the NLRB every 90 days.~~

A candidate's approved exception ~~score~~ will be maintained if the transplant hospital enters a MELD or PELD Exception Score Extension Request ~~the extensionrequest between 3 and 30~~ before the due date ~~according to *Table 9-1: Liver Status Update Schedule,*~~ even if the NLRB

does not act before the due date. If the extension request is ~~later~~ denied or if no MELD or PELD Exception Score Extension Request is submitted before the due date, then the candidate will be assigned the calculated MELD or PELD score based on the most recent reported laboratory values.

Approved MELD or PELD exception extensions are valid for 90 days from the date the MELD or PELD Exception Score Extension Request is submitted.

9.4.D Calculation of Median MELD or PELD at Transplant

Median MELD at transplant (MMaT) is calculated by using the median of the MELD scores at the time of transplant of all recipients at least 12 years old who were transplanted at hospitals within 250 nautical miles of the candidate's listing hospital in the last 365 days.

Median PELD at transplant (MPaT) is calculated by using the median of the PELD scores at the time of transplant of all recipients less than 12 years old in the nation.

The MMaT and MPaT calculations exclude recipients who are either of the following:

1. Transplanted with livers from living donors, DCD donors, and donors from donor hospitals more than 500 nautical miles away from the transplant hospital
2. Status 1A or 1B at the time of transplant.

The OPTN Contractor will recalculate the MMaT and MPaT every 180 days using the previous 365-day cohort. If there have been fewer than 10 qualifying transplants within 250 nautical miles of a transplant hospital in the previous 365 days, the MMaT will be calculated based on the previous 730 days.

Exceptions scores will be updated to reflect changes in MMaT or MPaT each time the MMaT or MPaT is recalculated. The following exception scores are not awarded relative to MMaT or MPaT and will not be updated:

1. Exception scores of 40 or higher awarded by the NLRB according to *Policy 9.4.A: MELD or PELD Score Exception Requests*
2. Any exception awarded according to *Policy 9.5.D: Requirements for Hepatic Artery Thrombosis (HAT) MELD Score Exceptions*
3. Exceptions awarded to candidates less than 18 years old according to *Policy 9.5.I: Requirements for Hepatocellular Carcinoma (HCC) MELD or PELD Score Exceptions*
4. Initial and first exceptions awarded to candidates at least 18 according to *Policy 9.5.I: Requirements for Hepatocellular Carcinoma (HCC) MELD or PELD Score Exceptions*

9.5 Specific Standardized MELD or PELD Score Exceptions

Candidates are eligible for MELD or PELD score exceptions or extensions that do not require evaluation by the NLRB if they meet *any* of the following requirements for a specific diagnosis of *any* of the following:

- Cholangiocarcinoma (CCA), according to *Policy 9.5.A: Requirements for Cholangiocarcinoma MELD or PELD Score Exceptions*
- Cystic fibrosis, according to *Policy 9.5.B: Requirements for Cystic Fibrosis MELD or PELD Score Exceptions*
- Familial amyloid polyneuropathy, according to *Policy 9.5.C: Requirements for Familial Amyloid Polyneuropathy (FAP) MELD or PELD Score Exceptions*
- Hepatic artery thrombosis, according to *Policy 9.5.D: Requirements for Hepatic Artery Thrombosis (HAT) MELD ~~or PELD~~ Score Exceptions*
- Hepatopulmonary syndrome, according to *Policy 9.5.E: Requirements for Hepatopulmonary Syndrome (HPS) MELD or PELD Score Exceptions*

- Metabolic disease, according to *Policy 9.5.F: Requirements for Metabolic Disease MELD or PELD Score Exceptions*
- Portopulmonary hypertension, according to *Policy 9.5.G: Requirements for Portopulmonary Hypertension MELD or PELD Score Exceptions*
- Primary hyperoxaluria, according to *Policy 9.5.H: Requirements for Primary Hyperoxaluria MELD or PELD Score Exceptions*
- Hepatocellular carcinoma, according to *Policy 9.5.I: Requirements for Hepatocellular Carcinoma (HCC) MELD or PELD Score Exception*

If a candidate is at least 18 years old and the exception score based on the score assignments relative to MMaT in this section would be higher than 31, the candidate's exception score will be 31. If a candidate's exception score based on the score assignments relative to MMaT or MPaT in this section would be lower than 15, the candidate's exception score will be 15.

9.5.A Requirements for Cholangiocarcinoma (CCA) MELD or PELD Score Exceptions

A candidate will receive a MELD or PELD score exception for CCA, if the candidate's transplant hospital meets *all* the following qualifications:

1. Submits a written protocol for patient care to the Liver and Intestinal Organ Transplantation Committee that must include *all* of the following:
2. Candidate selection criteria
3. Administration of neoadjuvant therapy before transplantation
4. Operative staging to exclude any patient with regional hepatic lymph node metastases, intrahepatic metastases, or extrahepatic disease
5. Any data requested by the Liver and Intestinal Organ Transplantation Committee

6. Documents that the candidate meets the diagnostic criteria for hilar CCA with a malignant appearing stricture on cholangiography and at least *one* of the following:
    - Biopsy or cytology results demonstrating malignancy
    - Carbohydrate antigen 19-9 greater than 100 U/mL in absence of cholangitis
    - Aneuploidy

    The tumor must be considered un-resectable because of technical considerations or underlying liver disease.

7. Submits cross-sectional imaging studies. If cross-sectional imaging studies demonstrate a mass, the mass must be single and less than three cm.
8. Documents the exclusion of intrahepatic and extrahepatic metastases by cross-sectional imaging studies of the chest and abdomen within 90 days prior to submission of the initial exception request.
9. Assesses regional hepatic lymph node involvement and peritoneal metastases by operative staging after completion of neoadjuvant therapy and before liver transplantation. Endoscopic ultrasound-guided aspiration of regional hepatic lymph nodes may be advisable to exclude patients with obvious metastases before neo-adjuvant therapy is initiated.
10. Transperitoneal aspiration or biopsy of the primary tumor (either by endoscopic ultrasound, operative or percutaneous approaches) must be avoided because of the high risk of tumor seeding associated with these procedures.

A candidate who meets the requirements for a standardized MELD or PELD score exception will be assigned a score according to *Table 9-2* below.

Table 9-2: CCA Exception Scores

Age	Age at registration	Score
At least 18 years old	At least 18 years old	3 points below MMaT

At least 12 years old	Less than 18 years old	Equal to MMaT
Less than 12 years old	Less than 12 years old	Equal to MPaT

~~A liver candidate at least 18 years old at the time of registration that meets the requirements for a standardized MELD score exception will be assigned a score that is 3 points below the median MELD at transplant for liver recipients at least 18 years old in the DSA where the candidate is registered.~~

~~A liver candidate 12 to 17 years old at the time of registration that meets the requirements for a standardized MELD score exception will be assigned a score equal to the median MELD at transplant for all liver recipients in the DSA where the candidate is registered.~~

~~A liver candidate less than 12 years old at the time of registration that meets the requirements for a standardized PELD score exception will be assigned a score equal to the median MELD at transplant for all liver recipients in the region where the candidate is registered.~~

In order to be approved for an extension of this MELD or PELD score exception, transplant hospitals must submit an exception extension request according to *Policy 9.4.C: MELD or PELD Score Exception Extensions,* and provide cross-sectional imaging studies of the chest and abdomen that exclude intrahepatic and extrahepatic metastases. These required imaging studies must have been completed within 30 days prior to the submission of the extension request.

9.5.B Requirements for Cystic Fibrosis MELD or PELD Score Exceptions

A candidate will receive a MELD or PELD score exception for cystic fibrosis if the candidate's diagnosis has been confirmed by genetic analysis, and the candidate has a forced expiratory volume at one second (FEV1) below 40 percent of predicted FEV1 within 30 days prior to submission of the initial exception request.

A candidate who meets the requirements for a standardized MELD or PELD score exception will be assigned a score according to *Table 9-3* below.

Table 9-3: Cystic Fibrosis Exception Scores

Age	Age at registration	Score
At least 18 years old	At least 18 years old	3 points below MMaT
At least 12 years old	Less than 18 years old	Equal to MMaT
Less than 12 years old	Less than 12 years old	Equal to MPaT

~~The OPTN Contractor will re-calculate the median MELD at transplant every 180 days using the previous 365-day cohort. If there have been fewer than 10 transplants in the DSA in the previous 365 days, the median MELD at transplant will be calculated for the region where the candidate is registered. At each 180 day update, candidates with existing standardized score exceptions will be assigned the score to match the re-calculated median MELD at transplant. The median MELD at transplant calculation excludes recipients transplanted with livers recovered by OPOs outside the recipient transplant hospital's region.~~

In order to be approved for an extension of this MELD or PELD score exception, transplant hospitals must submit an exception extension request according to *Policy 9.4.C: MELD or PELD Score Exception Extensions.*

9.5.C Requirements for Familial Amyloid Polyneuropathy (FAP) MELD or PELD Score Exceptions

A candidate will receive a MELD or PELD score exception for FAP if the candidate's transplant hospital submits evidence of *all* of the following:

1. Either that the candidate is also registered and active on the waiting list for a heart transplant at that transplant hospital, or has an echocardiogram performed within 30 days prior to submission of the initial exception request showing the candidate has an ejection fraction greater than 40 percent.
2. That the candidate can walk without assistance.
3. That a transthyretin (TTR) gene mutation has been confirmed.
4. A biopsy-proven amyloid.

A candidate who meets the requirements for a standardized MELD or PELD score exception will be assigned a score according to *Table 9-4* below.

Table 9-4: FAP Exception Scores

Age	Age at registration	Score
At least 18 years old	At least 18 years old	3 points below MMaT
At least 12 years old	Less than 18 years old	Equal to MMaT
Less than 12 years old	Less than 12 years old	Equal to MPaT

~~A liver candidate at least 18 years old at the time of registration that meets the requirements for a standardized MELD score exception will be assigned a score that is 3 points below the median MELD at transplant for liver recipients at least 18 years old in the DSA where the candidate is registered. If the candidate's exception score would be higher than 34 based on this calculation, the candidate's score will be capped at 34.~~

~~A liver candidate 12 to 17 years old at the time of registration that meets the requirements for a standardized MELD score exception will be assigned a score equal to the median MELD at transplant for all liver recipients in the DSA where the candidate is registered.~~

~~A liver candidate less than 12 years old at the time of registration that meets the requirements for a standardized PELD score exception will be assigned a score equal to the median MELD at transplant for all liver recipients in the region where the candidate is registered.~~

~~The OPTN Contractor will re-calculate the median MELD at transplant every 180 days using the previous 365-day cohort. If there have been fewer than 10 transplants in the DSA in the previous 365 days, the median MELD at transplant will be calculated for the region where the candidate is registered. At each 180 day update, candidates with existing standardized score exceptions will be assigned the score to match the re-calculated median MELD at transplant. The median MELD at transplant calculation excludes recipients transplanted with livers recovered by OPOs outside the recipient transplant hospital's region.~~

In order to be approved for an extension of this MELD or PELD score exception, transplant hospitals must submit an exception extension request according to *Policy 9.4.C: MELD or PELD Score Exception Extensions* and meet one of the following criteria:

1. ~~and an echocardiogram that meets *both* of the following criteria~~:An echocardiogram that shows ~~Shows~~ that the candidate has an ejection fraction greater than 40 percent within the last 120 days
2. Registered on the waiting list for a heart transplant at that hospital ~~every six months~~
3. ~~Has been performed within 30 days prior to submission of the extension request~~

9.5.D Requirements for Hepatic Artery Thrombosis (HAT) MELD ~~or PELD~~ Score Exceptions

A candidate will receive a MELD ~~or PELD~~ score exception for HAT if the candidate is at least 18 years old at registration and has HAT within 14 days of transplant but does not meet criteria for status 1A in *Policy 9.1.A: Adult Status 1A Requirements*.

Candidates who meet these requirements will receive a MELD ~~or PELD~~score of 40.

In order to be approved for an extension of this MELD ~~or PELD~~ score exception, transplant hospitals must submit an exception extension request according to *Policy 9.4.C: MELD or PELD Score Exception Extensions.*

9.5.E Requirements for Hepatopulmonary Syndrome (HPS) MELD or PELD Score Exceptions

A candidate will receive a MELD or PELD score exception for HPS if the candidate's transplant hospital submits evidence of *all* of the following:

1. Ascites, varices, splenomegaly, or thrombocytopenia.
2. A shunt, shown by either contrast echocardiogram or lung scan.
3. PaO_2 less than 60 mmHg on room air within 30 days prior to submission of the initial exception request.
4. No clinically significant underlying primary pulmonary disease.

A candidate who meets the requirements for a standardized MELD or PELD score exception will be assigned a score according to *Table 9-5* below.

Table 9-5: HPS Exception Scores

Age	Age at registration	Score
At least 18 years old	At least 18 years old	3 points below MMaT
At least 12 years old	Less than 18 years old	Equal to MMaT
Less than 12 years old	Less than 12 years old	Equal to MPaT

~~The OPTN Contractor will re-calculate the median MELD at transplant every 180 days using the previous 365-day cohort. If there have been fewer than 10 transplants in the DSA in the previous 365 days, the median MELD at transplant will be calculated for the region where the candidate is registered. At each 180 day update, candidates with existing standardized score exceptions will be assigned the score to match the re-calculated median MELD at transplant. The median MELD at transplant calculation excludes recipients transplanted with livers recovered by OPOs outside the recipient transplant hospital's region~~.

In order to be approved for an extension of this MELD or PELD score exception, transplant hospitals must submit an exception extension request according to *Policy 9.4.C: MELD or PELD Score Exception Extensions,* ~~and~~ with evidence that the candidate's PaO_2 remained at less than 60 mmHg on room air within the 30 days prior to submission of the extension request.

9.5.F Requirements for Metabolic Disease MELD or PELD Score Exceptions

A liver candidate less than 18 years old at the time of registration will receive a MELD or PELD score exception for metabolic disease if the candidate's transplant hospital submits evidence of urea cycle disorder or organic acidemia.

~~A liver candidate 12 to 17 years old at the time of registration that meets the requirements for a standardized MELD score exception will be assigned a score equal to the median MELD at transplant for all liver recipients in the DSA where the candidate is registered. If the candidate does not receive a transplant within 30 days of being registered with the exception score, then the candidate's transplant physician may register the candidate as a status 1B.~~

A candidate who meets the requirements for a standardized MELD or PELD score exception will be assigned a score according to *Table 9-6* below.

Table 9-6: Metabolic Disease Exception Scores

Age	Age at registration	Score
At least 12 years old	Less than 18 years old	Equal to MMaT
Less than 12 years old	Less than 12 years old	Equal to MPaT

~~A liver candidate less than 12 years old at the time of registration that meets the requirements for a standardized PELD score exception will be assigned a score equal to the median MELD at transplant for all liver recipients in the region where the candidate is registered.~~ If the candidate does not receive a transplant within 30 days of being registered with the exception score, then the candidate's transplant physician may register the candidate as a status 1B.

~~If a candidate has a metabolic disease other than urea cycle disorder or organic academia, and the candidate's transplant program believes that a candidate's MELD/PELD score does not appropriately reflect the candidate's medical urgency, then the transplant physician may request an exception according to *Policy 9.4.A: MELD or PELD Score Exception Requests*.~~
In order to be approved for an extension of this MELD or PELD score exception, transplant hospitals must submit an exception extension request according to *Policy 9.4.C: MELD or PELD Score Exception Extensions.*

9.5.G Requirements for Portopulmonary Hypertension MELD or PELD Score Exceptions

A candidate will receive a MELD or PELD score exception for portopulmonary hypertension if the transplant hospital submits evidence of *all* of the following:

1. Initial mean pulmonary arterial pressure (MPAP) level
2. Initial pulmonary vascular resistance (PVR) level
3. Initial transpulmonary gradient to correct for volume overload
4. Documentation of treatment
5. Post-treatment MPAP less than 35 mmHg within 90 days prior to submission of the initial exception
6. Post treatment PVR less than 400 dynes*sec/cm^5 ~~dynes/sec/cm^{-5}~~, or less than 5.1 Wood units (WU), on the same test date as post-treatment MPAP less than 35 mmHg

A candidate who meets the requirements for a standardized MELD or PELD score exception will be assigned a score according to T*able 9-7* below.

Table 9-7: Portopulmonary Hypertension Exception Scores

Age	Age at registration	Score
At least 18 years old	At least 18 years old	3 points below MMaT
At least 12 years old	Less than 18 years old	Equal to MMaT
Less than 12 years old	Less than 12 years old	Equal to MPaT

In order to be approved for an extension of this MELD or PELD score exception, transplant hospitals must submit an exception extension request according to *Policy 9.4.C: MELD or PELD Score Exception Extensions* ~~and perform a repeat~~ with evidence of a heart catheterization ~~every three months~~ since the last exception or extension request that confirms the mean pulmonary arterial pressure (MPAP) remains less than 35 mmHg.

9.5.H Requirements for Primary Hyperoxaluria MELD or PELD Score Exceptions

A candidate will receive a MELD or PELD score exception for primary hyperoxaluria if the candidate's transplant hospital submits evidence of all of the following:

~~1.~~ The candidate is registered for a liver and kidney at the listing transplant hospital ~~combined liver-kidney transplant~~
2. Alanine glyoxylate aminotransferase (AGT) deficiency proven by liver biopsy using sample analysis or genetic analysis
3. Estimated glomerular filtration rate (eGFR) by six variable Modification of Diet in Renal Disease formula (MDRD6), or glomerular filtration rate (GFR) measured by iothalamate or iohexol, is less than or equal to 25 mL/min on 2 occasions at least 42 days apart

A candidate who meets the requirements for a standardized MELD or PELD score exception will be assigned an exception score according to T*able 9-8* below.

Table 9-8: Primary Hyperoxaluria Scores

Age	Age at registration	Score
At least 18 years old	At least 18 years old	Equal to MMaT
At least 12 years old	Less than 18 years old	3 points above MMaT
Less than 12 years old	Less than 12 years old	3 points above MPaT

~~A liver candidate at least 18 years old at the time of registration that meets the requirements for a standardized MELD score exception will be assigned a score equal to the median MELD at transplant for liver recipients at least 18 years old in the DSA where the candidate is registered. If the candidate's exception score would be higher than 34 based on this calculation, the candidate's score will be capped at 34.~~

~~A liver candidate 12 to 17 years old at the time of registration that meets the requirements for a standardized MELD score exception will be assigned a score that is 3 points above the median MELD at transplant for all liver recipients in the DSA where the candidate is registered.~~

~~A liver candidate less than 12 years old at the time of registration that meets the requirements for a standardized MELD or PELD score exception will be assigned a score that is 3 points above the median MELD at transplant for all liver recipients in the region where the candidate is registered.~~

~~The OPTN Contractor will re-calculate the median MELD at transplant every 180 days using the previous 365-day cohort. If there have been fewer than 10 transplants in the DSA in the previous 365 days, the median MELD at transplant will be calculated for the region where the candidate is registered. At each 180 day update, candidates with existing standardized score exceptions will be assigned the score to match the re-calculated median MELD at transplant. The median MELD at transplant calculation excludes recipients transplanted with livers recovered by OPOs outside the recipient transplant hospital's region.~~

In order to be approved for an extension of this MELD or PELD score exception, transplant hospitals must submit an exception extension request according to Policy 9.4.C: MELD or PELD

Score Exception Extensions with evidence that the candidate is registered for a liver and kidney at the listing transplant hospital.

9.5.I Requirements for Hepatocellular Carcinoma (HCC) MELD or PELD Score Exceptions

Upon submission of the first exception request, a candidate with hepatocellular carcinoma (HCC) will be provided a score according to Policy *9.5.I.vii: Extensions of HCC Exceptions* if the candidate ~~is:~~

~~At least 18 years old and~~ meets the criteria according to *Policies 9.5.I.i through 9.5.I.vi.*

- ~~Twelve to 17 years old, and the National Liver Review Board (NLRB) has determined that the candidate's calculated MELD score does not reflect the candidate's medical urgency.~~
- ~~Less than 12 years old, and the NLRB has determined that the candidate's calculated PELD score does not reflect the candidate's medical urgency.~~

9.5.I.i Initial Assessment and Requirements for HCC Exception Requests

Prior to applying for a standardized MELD or PELD exception, the candidate must undergo a thorough assessment that includes *all* of the following:

1. An evaluation of the number and size of lesions before local-regional therapy that meet Class 5 criteria using a dynamic contrast enhanced computed tomography (CT) or magnetic resonance imaging (MRI)
2. A CT of the chest to rule out metastatic disease
3. A CT or MRI to rule out any other sites of extrahepatic spread or macrovascular involvement
4. An indication that the candidate is not eligible for resection
5. An indication whether the candidate has undergone local-regional therapy
6. The candidate's alpha-fetoprotein (AFP) level

The transplant hospital must maintain documentation of the radiologic images and assessments of all OPTN Class 5 lesions in the candidate's medical record. If growth criteria are used to classify a lesion as HCC, the radiology report must contain the prior and current dates of imaging, type of imaging, and measurements of the lesion.

For those candidates who receive a liver transplant while receiving additional priority under the HCC exception criteria, the transplant hospital must submit the *Post-Transplant Explant Pathology Form* to the OPTN Contractor within 60 days of transplant. If the pathology report does not show evidence of HCC, the transplant hospital must also submit documentation or imaging studies confirming HCC at the time of assignment. The Liver and Intestinal Organ Transplantation Committee will review a transplant hospital when more than 10 percent of the HCC cases in a one-year period are not supported by the required pathologic confirmation or submission of clinical information.

9.5.I.ii Eligible Candidates Definition of T2 Lesions

Candidates with T2 HCC lesions are eligible for a standardized MELD or PELD exception if they have an alpha-fetoprotein (AFP) level less than or equal to 1000 ng/mL and *either* of the following:

- One lesion greater than or equal to 2 cm and less than or equal to 5 cm in size.
- Two or three lesions each greater than or equal to 1 cm and less than or equal to 3 cm in size.

A candidate who has previously had an AFP level greater than 1000 ng/mL at any time must qualify for a standardized MELD or PELD exception according to Policy 9.5.I.iv: Candidates with Alpha-fetoprotein (AFP) Levels Greater than 1000.

9.5.I.iii Lesions Eligible for Downstaging Protocols

Candidates are eligible for a standardized MELD or PELD exception if, before completing local-regional therapy, they have lesions that meet *one* of the following criteria:

- One lesion greater than 5 cm and less than or equal to 8 cm
- Two or three lesions each greater than 3 cm or less than or equal to 5 cm, and a total diameter of all lesions less than or equal to 8 cm
- Four or five lesions each less than 3 cm, and a total diameter of all lesions less than or equal to 8 cm

For candidates who meet the downstaging criteria above and then complete local-regional therapy, their residual lesions must subsequently meet the requirements for T2 lesions according to *Policy 9.5.I.ii: Eligible Candidates Definition of T2 Lesions* to be eligible for a standardized MELD or PELD exception. Downstaging to meet eligibility requirements for T2 lesions must be demonstrated by CT or MRI performed after local-regional therapy. Candidates with lesions that do not initially meet the downstaging protocol inclusion criteria who are later downstaged and then meet eligibility for T2 lesions are not automatically eligible for a standardized MELD or PELD exception and must be referred to the NLRB for consideration of a MELD or PELD exception.

9.5.I.iv Candidates with Alpha-fetoprotein (AFP) Levels Greater than 1000

Candidates with lesions meeting T2 criteria according to *Policy 9.5.I.ii Eligible Candidates Definition of T2 Lesions* but with an alpha-fetoprotein (AFP) level greater than 1000 ng/mL may be treated with local-regional therapy. If the candidate's AFP level falls below 500 ng/mL after treatment, the candidate is eligible for a standardized MELD or PELD exception as long as the candidate's AFP level remains below 500 ng/mL. Candidates with an AFP level greater than or equal to 500 ng/mL following local-regional therapy at any time must be referred to the NLRB for consideration of a MELD or PELD exception.

9.5.I.v Requirements for Dynamic Contrast-enhanced CT or MRI of the Liver

CT scans and MRIs performed for a Hepatocellular Carcinoma (HCC) MELD or PELD score exception request must be interpreted by a radiologist at a transplant hospital. If the scan is inadequate or incomplete then the lesion will be classified as OPTN Class 0 and imaging must be repeated or completed to receive an HCC MELD or PELD exception.

9.5.I.vii Extensions of HCC Exceptions

In order for a candidate to maintain an approved exception for HCC, the transplant program must submit an updated MELD/PELD Exception Score Request Form ~~every 90 days~~ that contains the following:

1. Documentation of the tumor using a CT or MRI

2. The type of treatment if the number of tumors decreased since the last request
3. The candidate's alpha-fetoprotein (AFP) level

The candidate will then receive the additional priority unless *any* of the following occurs:

- The candidate's lesions progress beyond T2 criteria, according to *9.5.I.ii: Eligible Candidates Definition of T2 Lesions*
- The candidate's alpha-fetoprotein (AFP) level was less than or equal to 1,000 ng/mL on the initial request but subsequently rises above 1,000 ng/mL
- The candidate's AFP level was greater than 1,000 ng/mL, the AFP level falls below 500 ng/mL after treatment but before the initial request, then the AFP level subsequently rises to greater than or equal to 500 ng/mL
- The candidate's tumors have been resected since the previous request

~~A liver candidate at least 18 years old at the time of registration that meets the requirements for a standardized MELD score exception will be assigned the candidate's calculated MELD score upon initially requesting a MELD score exception, and upon submitting the first exception request. For each subsequent request, the candidate will receive a MELD score that is 3 points below the median MELD at transplant for liver recipients at least 18 years old in the DSA where the candidate is registered. If the candidate's exception score would be higher than 34 based on this calculation, the candidate's score will be capped at 34.~~

When a liver candidate at least 18 years old at the time of registration submits an initial request or the first extension request that meets the requirements for a standardized MELD score exception, the candidate will receive a MELD score of 6, and appear on the match according to that exception score or the calculated MELD score, whichever is higher.

A candidate who meets the requirements for a standardized MELD or PELD score exception will be assigned a score according to *Table 9-9* below.

Table 9-9: HCC Exception Scores

Age	Age at registration	Exception Request	Score
At least 18 years old	At least 18 years old	Initial and first extension	6
At least 18 years old	At least 18 years old	Any extension after the first extension	3 points below MMaT
At least 12 years old	Less than 18 years old	Any	40
Less than 12 years old	Less than 12 years old	Any	40

~~The OPTN Contractor will re-calculate the median MELD at transplant every 180 days using the previous 365-day cohort. If there have been fewer than 10 transplants in the DSA in the previous 365 days, the median MELD at transplant will be calculated for the region where the candidate is registered. At each 180 day update, candidates with existing standardized score exceptions will be assigned the score to match the re-calculated median MELD. The median MELD at transplant calculation excludes recipients transplanted with livers recovered by OPOs outside the recipient transplant hospital's region.~~

~~A liver candidate less than 18 years old at the time of registration that meets the requirements for a standardized MELD or PELD score exception will be assigned a MELD or PELD score of 40.~~

~~To receive an extension, the transplant program must submit an updated MELD/PELD Exception Score Request Form that contains all of the following:~~

~~4. An updated narrative~~
~~5. Document the tumor using a CT or MRI~~
~~6. Specify the type of treatment if the number of tumors decreased since the last request~~
~~7. The candidate's alpha-fetoprotein (AFP) level~~

~~If a candidate's tumors have been resected since the previous request, then the transplant program must submit an updated MELD/PELD Exception Score Request Form to the NLRB for prospective review.~~

~~9.5.I.viii Appeal for Candidates not Meeting HCC Criteria~~

~~If the NLRB denies the initial HCC MELD/PELD Exception Score Request Form, the transplant program may appeal with the NLRB but the candidate will not receive the additional MELD or PELD priority until approved by the NLRB. The NLRB will refer the matter to the Liver and Intestinal Organ Transplantation Committee for further review and possible action if the NLRB finds the transplant program to be noncompliant with these Policies.~~

~~Requests and appeals not resolved by the NLRB within 21 days will be referred to the Liver and Intestinal Organ Transplantation Committee for review. The Liver and Intestinal Organ Transplantation Committee may refer these matters to the MPSC for appropriate action according to *Appendix L* of the OPTN Bylaws.~~

9.8.C Allocation of Livers by Blood Type

~~Livers from blood type O 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 all blood type O and B candidates on the match run have been exhaustedat the region plus circle, and national level.~~

Livers from blood type O donors must be offered in the following order:

1. Status 1A and 1B candidates, blood type O candidates, and blood type B candidates with a MELD or PELD score of at least 30
2. Blood type B candidates with a MELD or PELD score less than 30
3. Any remaining blood type compatible candidates

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.~~E~~D Sorting Within Each Classification

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

1. 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 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 MELD or PELD score allocation classification, candidates with a MELD or PELD less than or equal to 6 are sorted in the following order:~~

~~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 MELD or PELD score allocation classification, all 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(highest to lowest)
4. Time since submission of initial approved MELD or PELD exception request (highest to lowest)
5. Total waiting time (highest to lowest)

9.8.EF 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 9-410* below.

Table 9-410: Allocation of Livers from Non-DCD Deceased Donors at Least 18 Years Old and Less than 70 Years Old

Classification	Candidates within this distance from the donor hospital:	Who are:	And the donor is this blood type:
1	500nm	Status 1A	Any
2	500nm	Status 1B	Any
3	250nm	MELD or PELD of at least 32	Any
4	150nm	MELD or PELD of at least 15	Any
5	250nm	MELD or PELD of at least 15	Any
6	500nm	MELD or PELD of at least 15	Any
7	Nation	Status 1A	Any
8	Nation	Status 1B	Any
9	Nation	MELD or PELD of at least 15	Any
10	150nm	Any MELD or PELD	Any
11	250nm	Any MELD or PELD	Any
12	500nm	Any MELD or PELD	Any
13	Nation	Any MELD or PELD	Any
14	150nm	MELD or PELD of at least 15 and blood type B	O
15	250nm	MELD or PELD of at least 15 and blood type B	O
16	500nm	MELD or PELD of at least 15 and blood type B	O
17	Nation	MELD or PELD of at least 15 and blood type B	O
18	150nm	Any MELD or PELD and blood type B	O
19	250nm	Any MELD or PELD and blood type B	O
20	500nm	Any MELD or PELD and blood type B	O
21	Nation	Any MELD or PELD and blood type B	O
22	150nm	MELD or PELD of at least 15 and blood type A or AB	O
23	250nm	MELD or PELD of at least 15 and blood type A or AB	O
24	500nm	MELD or PELD of at least 15 and blood type A or AB	O

25	Nation	MELD or PELD of at least 15 and blood type A or AB	O
25	150nm	Any MELD or PELD and blood type A or AB	O
26	250nm	Any MELD or PELD and blood type A or AB	O
27	500nm	Any MELD or PELD and blood type A or AB	O
28	Nation	Any MELD or PELD and blood type A or AB	O
29	Nation	Status 1A, for other method of hepatic support	Any
30	Nation	Status 1B, for other method of hepatic support	Any
31	Nation	Any MELD or PELD for other method of hepatic support	Any

9.8.FG 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 9-5*11 below.

Table 9-511**: Allocation of Livers from Non-DCD Deceased Donors 11 to 17 Years Old**

~~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~~
~~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~~

Classification	Candidates that are within the OPO's:	And are:
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

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Classification	Candidates within this distance from the donor hospital:	Who are:	And the donor is this blood type:
1	500nm	Status 1A and less than 18 years old at registration	Any
2	500nm	Status 1A and at least 18 years old at registration	Any
3	500nm	Status 1B	Any
4	500nm	Any PELD	Any
5	500nm	Any MELD and less than 18 years old at registration	Any
6	Nation	Status 1A and less than 18 years old at registration	Any
7	Nation	Status 1A and at least 18 years old at registration	Any
8	Nation	Status 1B	Any
9	Nation	Any PELD	Any
10	Nation	Any MELD and less than 18 years old at registration	Any
11	500nm	Any MELD and at least 18 years old at registration	Any
12	Nation	Any MELD and at least 18 years old at registration	Any
13	500nm	Any PELD and blood type B	O
14	500nm	Any MELD, less than 18 years old at registration and blood type B	O
15	Nation	Any PELD and blood type B	O
16	Nation	Any MELD, less than 18 years old at registration and blood type B	O
17	500nm	Any MELD, at least 18 years old at registration and blood type B	O
18	Nation	Any MELD, at least 18 years old at registration and blood type B	O
19	500nm	Any PELD and blood type A or AB	O
20	500nm	Any MELD, less than 18 years old at registration and blood type A or AB	O
21	Nation	Any PELD and blood type A or AB	O
22	Nation	Any MELD, less than 18 years old at registration and blood type A or AB	O

23	500nm	Any MELD, at least 18 years old at registration and blood type A or AB	O
24	Nation	Any MELD, at least 18 years old at registration and blood type A or AB	O
25	Nation	Status 1A, for other method of hepatic support	Any
26	Nation	Status 1B, for other method of hepatic support	Any
27	Nation	Any MELD or PELD for other method of hepatic support	Any

9.8.GH 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 9-612* below.

Table 9-612: Allocation of Livers from Non-DCD Deceased Donors Less than 11 Years Old

Classification	Candidates within this distance from the donor hospital:	Who are:	And the donor is this blood type:
1	500nm	Pediatric status 1A	Any
2	Nation	Status 1A and less than 12 years old	Any
3	Nation	Status 1A, at least 12 years old and less than 18 years old at registration	Any
4	500nm	Status 1A and at least 18 years old at registration	Any
5	500nm	Status 1B	Any
6	500nm	PELD of at least 20	Any
7	500nm	Any PELD	Any
8	500nm	Any MELD, at least 12 years old, and less than 18 years old at registration	Any
9	Nation	Status 1A, at least 12 years old, and less than 18 years old at registration	Any
10	Nation	Status 1A and at least 18 years old at registration	Any
11	Nation	Status 1B	Any
12	Nation	Any PELD	Any

Classification	Candidates within this distance from the donor hospital:	Who are:	And the donor is this blood type:
13	Nation	Any MELD and less than 18 years old at registration	Any
14	500nm	Any MELD and at least 18 years old at registration	Any
15	Nation	Any MELD and at least 18 years old at registration	Any
16	500nm	Any PELD, blood type B	O
17	500nm	Any MELD, less than 18 years old at registration and blood type B	O
18	Nation	Any PELD and blood type B	O
19	Nation	Any MELD, less than 18 years old at registration and blood type B	O
20	500nm	Any MELD, at least 18 years old at registration and blood type B	O
21	Nation	Any MELD, at least 18 years old at registration and blood type B	O
22	500nm	Any PELD, blood type A or AB	O
23	500nm	Any MELD, less than 18 years old at registration and blood type A or AB	O
24	Nation	Any PELD and blood type A or AB	O
25	Nation	Any MELD, less than 18 years old at registration and blood type A or AB	O
26	500nm	Any MELD, at least 18 years old at registration and blood type A or AB	O
27	Nation	Any MELD, at least 18 years old at registration and blood type A or AB	O
28	Nation	Status 1A, for other method of hepatic support	Any
29	Nation	Status 1B, for other method of hepatic support	Any

Classification	Candidates within this distance from the donor hospital:	Who are:	And the donor is this blood type:
30	Nation	Any MELD or PELD for other method of hepatic support	Any

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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
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

~~Classification~~	~~Candidates that are within the OPO's:~~	~~And are:~~
~~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.HI 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~~13* below.

Table 9-~~7~~13: Allocation of Livers ~~and liver-intestines~~ from DCD Donors or Donors at Least 70 Years Old

~~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~~

Classification	Candidates that are within the OPO's:	And are:
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
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

Classification	Candidates within this distance from the donor hospital:	Who are:	And the donor is this blood type:
1	500nm	Status 1A	Any
2	500nm	Status 1B	Any
3	150nm	MELD or PELD of at least 15	Any
4	500nm	MELD or PELD of at least 15	Any
5	Nation	Status 1A	Any
6	Nation	Status 1B	Any
7	Nation	MELD or PELD of at least 15	Any
8	150nm	Any MELD or PELD	Any
9	500nm	Any MELD or PELD	Any
10	Nation	Any MELD or PELD	Any
11	150nm	MELD or PELD of at least 15 and blood type B	O
12	500nm	MELD or PELD of at least 15 and blood type B	O
13	Nation	MELD or PELD of at least 15 and blood type B	O
14	150nm	Any MELD or PELD and blood type B	O
15	500nm	Any MELD or PELD and blood type B	O
16	Nation	Any MELD or PELD and blood type B	O
17	150nm	MELD or PELD of at least 15 and blood type A or AB	O
18	500nm	MELD or PELD of at least 15 and blood type A or AB	O
19	Nation	MELD or PELD of at least 15 and blood type A or AB	O
20	150nm	Any MELD or PELD and blood type A or AB	O
21	500nm	Any MELD or PELD and blood type A or AB	O
22	Nation	Any MELD or PELD and blood type A or AB	O
23	Nation	Status 1A, for other method of hepatic support	Any
24	Nation	Status 1B, for other method of hepatic support	Any

25	Nation	Any MELD or PELD for other method of hepatic support	Any

9.8.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-~~8~~14* below:

Table 9-~~8~~14: Allocation of Liver-Intestines from Non-DCD Deceased Donors at Least 18 Years Old

~~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~~
~~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~~

Classification	Candidates that are within the OPO's:	And are:
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
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

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Classification	Candidates within this distance from the donor hospital:	Who are:	And the donor is this blood type:
1	500nm	Status 1A	Any
2	500nm	Status 1B	Any
3	250nm	MELD or PELD of at least 32	Any
4	Nation	Status 1A and also registered for an intestine	Any
5	Nation	Status 1B and also registered for an intestine	Any
6	Nation	Any MELD or PELD and also registered for an intestine	Any
7	150nm	MELD or PELD of at least 15	Any
8	250nm	MELD or PELD of at least 15	Any
9	500nm	MELD or PELD of at least 15	Any
10	Nation	Status 1A	Any
11	Nation	Status 1B	Any
12	Nation	MELD or PELD of at least 15	Any
13	150nm	Any MELD or PELD	Any
14	250nm	Any MELD or PELD	Any
15	500nm	Any MELD or PELD	Any
16	Nation	Any MELD or PELD	Any
17	Nation	Any MELD or PELD, also registered for an intestine and blood type B	O
18	150nm	MELD or PELD of at least 15 and blood type B	O
19	250nm	MELD or PELD of at least 15 and blood type B	O
20	500nm	MELD or PELD of at least 15 and blood type B	O
21	Nation	MELD or PELD of at least 15 and blood type B	O
22	150nm	Any MELD or PELD and blood type B	O
23	250nm	Any MELD or PELD and blood type B	O
24	500nm	Any MELD or PELD and blood type B	O
25	Nation	Any MELD or PELD and blood type B	O
25	Nation	Any MELD or PELD, also registered for an intestine and blood type A or AB	O
26	150nm	MELD or PELD of at least 15 and blood type A or AB	O
27	250nm	MELD or PELD of at least 15 and blood type A or AB	O
28	500nm	MELD or PELD of at least 15 and blood type A or AB	O

29	Nation	MELD or PELD of at least 15 and blood type A or AB	O
30	150nm	Any MELD or PELD and blood type A or AB	O
31	250nm	Any MELD or PELD and blood type A or AB	O
32	500nm	Any MELD or PELD and blood type A or AB	O
33	Nation	Any MELD or PELD and blood type A or AB	O
34	Nation	Status 1A, for other method of hepatic support	Any
35	Nation	Status 1B, for other method of hepatic support	Any
36	Nation	Any MELD or PELD for other method of hepatic support	Any

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.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-~~9~~15* below.

Table 9-~~9~~15: Allocation of Combined Liver-Intestines from Donors Less than 11 Years Old

~~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~~

Classification	Candidates that are within the OPO's:	And are:
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
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

~~Classification~~	~~Candidates that are within the OPO's:~~	~~And are:~~
~~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~~

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Classification	Candidates within this distance from the donor hospital:	Who are:	And the donor is this blood type:
1	500nm	Pediatric status 1A	Any
2	Nation	Status 1A and less than 12 years old	Any
3	Nation	Status 1A, Age 12 or greater, less than 18 years old at registration, and registered for both a liver and intestine	Any
4	500nm	Status 1A and at least 18 years old at registration	Any
5	500nm	Status 1B	Any
6	500nm	PELD of at least 20	Any

Classification	Candidates within this distance from the donor hospital:	Who are:	And the donor is this blood type:
7	Nation	Status 1B, and registered for both a liver and intestine	Any
8	Nation	PELD of at least 20 and registered for both a liver and intestine	Any
9	500nm	Any PELD	Any
10	500nm	Any MELD, at least 12 years old, and less than 18 years old at registration	Any
11	Nation	Status 1A, at least 12 years old, and less than 18 years old at registration	Any
12	Nation	Status 1A and at least 18 years old at registration	Any
13	Nation	Status 1B	Any
14	Nation	Any PELD	Any
15	Nation	Any MELD and less than 18 years old at registration	Any
16	500nm	Any MELD and at least 18 years old at registration	Any
17	Nation	Any MELD and at least 18 years old at registration	Any
18	500nm	PELD of at least 20	O
19	Nation	PELD of at least 20 and registered for both a liver and intestine	O
20	500nm	Any PELD, blood type B	O
21	500nm	Any MELD, less than 18 years old at registration and blood type B	O
22	Nation	Any PELD and blood type B	O
23	Nation	Any MELD, less than 18 years old at registration and blood type B	O
24	500nm	Any MELD, at least 18 years old at registration and blood type B	O
25	Nation	Any MELD, at least 18 years old at registration and blood type B	O
26	500nm	PELD of at least 20	O
27	Nation	PELD of at least 20 and registered for both a liver and intestine	O
28	500nm	Any PELD, blood type A or AB	O
29	500nm	Any MELD, less than 18 years old at registration and blood type A or AB	O
30	Nation	Any PELD and blood type A or AB	O

Classification	Candidates within this distance from the donor hospital:	Who are:	And the donor is this blood type:
31	Nation	Any MELD, less than 18 years old at registration and blood type A or AB	O
32	500nm	Any MELD, at least 18 years old at registration and blood type A or AB	O
33	Nation	Any MELD, at least 18 years old at registration and blood type A or AB	O
34	Nation	Status 1A, for other method of hepatic support	Any
35	Nation	Status 1B, for other method of hepatic support	Any
36	Nation	Any MELD or PELD for other method of hepatic support	Any

9.9 Liver-Kidney Allocation

If a host OPO procures a kidney along with other organs, the host OPO must first offer the kidney according to *one* of the following policies before allocating the kidney to kidney alone candidates according to *Policy 8*: *Allocation of Kidneys*:

- *Policy 5.10.C: Other Multi-Organ Combinations*
- *Policy 9.9: Liver-Kidney Allocation*
- *Policy 11.4.A: Kidney-Pancreas Allocation Order*

~~If a host OPO is offering a kidney and a liver from the same deceased donor, then the host OPO must offer the kidney and liver according to *both* of the following:~~

~~1. Before allocating the kidney to kidney alone candidates, the host OPO must offer the kidney with the liver to local candidates who meet eligibility according to *Table 9-11: Medical Eligibility Criteria for Liver-Kidney Allocation* and regional candidates who meet eligibility according to *Table 9-11* and have a MELD score of at least 35 or status 1A.~~
~~2. The host OPO may then do *either* of the following:~~
~~a. The host OPO may offer the kidney and liver to any candidates who meet eligibility in *Table 9-11: Medical Eligibility Criteria for Liver-Kidney Allocation*.~~
~~b. After completing #1 above, the host OPO may offer the liver to liver alone candidates according to *Policy 9: Allocation of Livers and Liver-Intestines* and offer the kidney to kidney alone candidates according to *Policy 8: Allocation of Kidneys*.~~

If a host OPO is offering a kidney and a liver from the same deceased donor, then before allocating the kidney to kidney alone candidates, the host OPO must offer the kidney with the liver to candidates who meet eligibility according to *Table 9-16: Medical Eligibility Criteria for Liver-Kidney Allocation* and are one of the following:

a. Within 150 nautical miles of the donor hospital and have a MELD or PELD of 15 or higher
b. Within 250 nautical miles of the donor hospital and have a MELD or PELD of at least 32
c. Within 250 nautical miles of the donor hospital and status 1A or 1B.

The host OPO may then do *either* of the following:

a. Offer the kidney and liver to any candidates who meet eligibility in *Table 9-11: Medical*

Eligibility Criteria for Liver-Kidney Allocation.

b. Offer the liver to liver alone candidates according to *Policy 9: Allocation of Livers and Liver-Intestines* and offer the kidney to kidney alone candidates according to *Policy 8: Allocation of Kidneys*.

9.10 Administrative Rules

9.10.A Registration Accuracy

If a member questions the accuracy or appropriateness of a liver allocation or candidate status, the member may report it with reasons for the concern to the ~~host OPO's~~ ~~applicable~~ national liver review board (NLRB) ~~regional review board (RRB)~~. The ~~RRB~~ NLRB will retrospectively review the allocation or status.

If the ~~RRB~~ NLRB receives two or more reports about a member within any one year period, the ~~RRB~~ NLRB will report it to the Membership and Professional Standards (MPSC) Committee and request an on-site review of the member.

9.10.B Review of Status 1A and 1B Candidate Registrations

If ~~the regional review boards reject~~ three or more status 1A or 1B candidate registrations at a transplant program are rejected and each of the candidates receives a transplant while registered at the rejected status, then the OPTN Contractor will conduct an on-site review of the transplant program's status 1A and 1B candidate registrations. If the OPTN Contractor finds a Policy violation or inappropriate registrations, the transplant program will reimburse all necessary and reasonable expenses incurred by the OPTN Contractor in performing this review.

9.11 Variances

9.11.A Open Variance for Segmental Liver Transplantation

This variance only applies when a transplant program transplants a right lobe or right tri-segment of the liver.

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

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

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~~ donors in Hawaii due to ~~its~~ geographic~~al~~ location. This variance supersedes the treatment of blood type O donors according to *9.8.C Allocation of Livers by Blood Type*, and instead permits the allocation of blood type O donors recovered in Hawaii to any blood type candidates without requirements to offer to blood type O or B candidates first. ~~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.*~~

Bylaws Appendix M: Definitions

Regions

For ~~the administration of organ allocation and appropriate geographic representation within the OPTN policy structure, the~~ administrative purposes, OPTN membership is divided into 11 geographic regions. Members belong to the region in which they are located.

The regions are as follows:

Region 1	Connecticut, Maine, Massachusetts, New Hampshire, Rhode Island, Eastern Vermont
Region 2	Delaware, District of Columbia, Maryland, New Jersey, Pennsylvania, Northern Virginia, West Virginia
Region 3	Alabama, Arkansas, Florida, Georgia, Louisiana, Mississippi, Puerto Rico
Region 4	Oklahoma, Texas
Region 5	Arizona, California, Nevada, New Mexico, Utah
Region 6	Alaska, Hawaii, Idaho, Montana, Oregon, Washington
Region 7	Illinois, Minnesota, North Dakota, South Dakota, Wisconsin
Region 8	Colorado, Iowa, Kansas, Missouri, Nebraska, Wyoming
Region 9	New York, Western Vermont
Region 10	Indiana, Michigan, Ohio
Region 11	Kentucky, North Carolina, South Carolina, Tennessee, Virginia

Waiting List

The list of candidates registered with the OPTN to receive organ transplants. When a donor organ becomes available, the matching system generates a new, more specific list of potential recipients based on the criteria defined in that organ's allocation policy. ~~The criteria include, for example, organ type, geographic local and regional area, genetic compatibility measures, details about the condition of the organ, the candidate's disease severity, and time spent waiting.~~

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