Liver and Intestine Distribution Using Distance from Donor Hospital

Briefing Paper

OPTN/UNOS Liver and Intestine Transplantation Committee

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Sponsoring Committee:	*Liver and Intestine Transplantation*
Public Comment Period:	*October 8, 2018 – November 1, 2018*
Board of Directors Date:	*December 3-4, 2018*

Executive Summary

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, promoting patient access to transplant, avoiding futile transplants, and promoting efficiency. The Final Rule also includes a requirement that allocation policies "shall not be based on the candidate's place of residence or place of listing, except to the extent required"[1] by the other requirements of the Final Rule listed above.

The United States Secretary of Health and Human Services (HHS) received critical comments regarding compliance with the National Organ Transplant Act (NOTA)[2] and associated regulations under the OPTN Final Rule[3] with respect to the geographic units used in liver distribution. As of July 2018, HHS, UNOS and the OPTN are named defendants in a lawsuit regarding this issue.[4]

The liver organ distribution policies currently use donation service areas (DSAs) and OPTN regions as geographic units of distribution. 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 distribution or in scoring liver candidate exceptions. The Board also committed to considering such a proposal in December 2018. Therefore, the Liver Committee worked to develop a policy consistent with the OPTN Final Rule and the Secretary's directive. As explained in this briefing paper, this proposal aims to reduce as much as possible the role of a candidate's place of listing in liver allocation while considering the best use of organs, organ wastage, patient access, and the efficient management of organ placement. In reviewing the best use of organs and organ wastage, the committee looked at the number of transplants. The LSAM cannot predict organ discards, therefore the Committee focused on the number of transplants performed for each model; the modeling show no substantial differences in the number of transplants performed between the models. While the Final Rule also permits the consideration of futile transplants, that is not the focus of this proposal and it was not considered by the Committee. In considering patient access, the Committee looked at the several metrics including the variance in MMaT. In considering the efficient management of organ placement, the Committee focused on the percentage of organs flying because increased flights increase the time and costs associated with procurement and place additional burden on limited pilot and plane resources. The committee based their decision in sound medical

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

judgement through the use of OPTN descriptive data reports, SRTR inferential modeling, published literature, and community feedback. At the conclusion of their deliberations, the committee chose the B2C model with a MELD 29 threshold. The committee determined that this model represented the optimal balance of the competing Final Rule requirements.

This proposal eliminates the use of DSA and region in liver, liver-intestine, intestine, and liver-kidney allocation policies. This proposal, referred to as the "broader 2-circle framework," would allocate livers to candidates within 150, 250, or 500 nautical miles (nm) of donor hospitals before offering them nationally. 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 29 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 15-28, 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 (PELD) at transplant in the nation for patients less than 12 years old. It includes a change to intestine allocation that will replace DSA and region with a single 500nm circle and a change to simultaneous liver-kidney allocation to replace DSA and region with 150 and 250 nm circles. 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.

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, promoting patient access to transplant, avoiding futile transplants, and to promote efficiency.[5] The Final Rule also includes a requirement that allocation 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 Section 121.8 of the Final Rule.[6] Finally, the OPTN Final Rule contains a performance goal for allocation policies of "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]

The requirement to distribute over a broad geographic area reflects a consensus understanding that organs are a national resource meant to be allocated based on patients' medical 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."[8] The Institute of Medicine (IOM) made this same conclusion in 1999.[9] 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

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

except when transportation of organs would threaten their suitability for transplantation."[10] HHS has stated this same principle several times in public rulemaking.[11, 12] 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."[13]

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."[14] In fact, the OPTN agrees that the use of DSAs and regions in the December 2017 proposal was not the best proxy for efficiency, as discussed further in **Appendix A**.[15] 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.[16] 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 with the OPTN Final Rule."[17] The letter contained a deadline for the Board to adopt a new liver allocation policy by its December 2018 meeting. Additionally, the Secretary of HHS explained that the OPTN may consider adopting transition policies and then refine or modify the proposal in the future.[18]

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, the community risks having these decisions made by the legislature,[19] the judiciary,[20] or HHS.

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[10] 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.

[11] 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

[12] 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."

[13] *Geographic Organ Distribution Principles and Models Recommendations Report*, OPTN/UNOS Ad Hoc Committee on Geography, June 2018, https://optn.transplant.hrsa.gov/media/2506/geography_recommendations_report_201806.pdf (accessed Nov. 16, 2018).

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

[15] See Appendix A: Analysis of December 2017 Proposal

[16] Ibid.

[17] Ibid.

[18] "The OPTN may also implement transition patient protections. See 42 CFR § 121.8(d)(1) (providing that when the OPTN revises organ allocation policies, it shall consider whether to adopt transition procedures that would treat people on the waiting list and await 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). Of course, the OPTN will also have opportunities in the future to refine, modify, and improve any OPTN liver allocation policy." George Sigounas, letter to Sue Dunn, OPTN President, July 31, 2018.

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

[20] 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).

The proposed broader 2-circle solution removes 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, thereby promoting patient access to transplantation. It also strikes an appropriate balance of the other Final Rule requirements by distributing organs as broadly as feasible while promoting the efficient management of organ placement by mitigating the logistical issues associated with distributing organs across further distances, and avoiding organ wastage.

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" [21]

The Committee is comprised of representatives of transplant hospitals, OPOs, transplant coordinators, transplant patients, and each OPTN region.[22] The members were selected for their expertise in the field of liver transplantation, and have decades of collective experience in transplantation. When evaluating the data available, they used the benefit of that experience and the wisdom gained through experience to interpret it and balance it. They relied on one another for the benefit of understanding the differences in practice and the different challenges faced by the patient population and the transplant communities across the country.

Additionally, 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 Ad Hoc Geography Committee[23] 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 principles of geography. In particular, the Geography Committee considered an idea proposed during public comment to use states as the first unit of allocation and adjoining states as the interim unit. The Geography Committee noted that states were similar to DSAs in that they were another pre-existing administrative boundary that were not optimized for the allocation of organs, and it is therefore unlikely that using states as units of distribution for livers is more compliant with the Final Rule than using DSAs or regions.[24] The Geography Committee provided feedback on issues that were applicable to other organs as well, such as the treatment of non-contiguous states.

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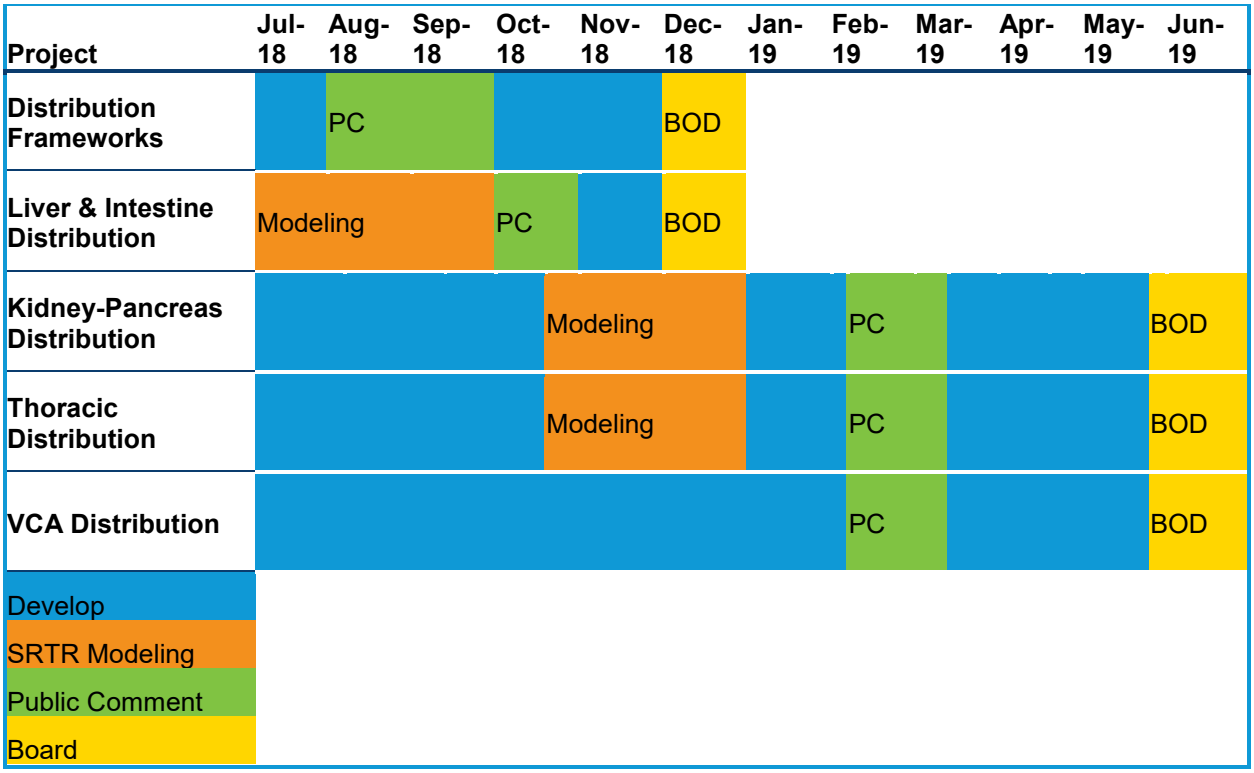
[21] Yolanda Becker, OPTN President, letter to the OPTN Liver and Intestinal Organ Transplant Committee, June 25, 2018.
[22] As required by OPTN Bylaws Article VII, 7.1: Composition of Standing Committees
[23] The Ad Hoc Committee on Geography (the Geography Committee) was formed in December 2017 to examine the principles of geographic distribution of organs. The Geography Committee was charged with establishing guiding principles for the use of geographic constraints in organ allocation, reviewing and recommending models for incorporating geographic principles into allocation policies, and identifying uniform concepts for organ specific allocation policies in light of the requirements of the OPTN Final Rule.
[24] Meeting Summary for October 23, 2018 meeting, OPTN/UNOS Ad Hoc Geography Committee, https://optn.transplant.hrsa.gov/members/committees/ad-hoc-geography-committee/ (Awaiting publication)

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 regions from their distribution system. These changes are scheduled for spring 2019 public comment. Additionally, the 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 1** shows the timeline for the committees to make these changes.

Figure 1: Timeline Overview of the Geography Projects



In public comment and in the Committee's discussions, the components of this proposal were debated at length.[25] There was no clear, unanimous path forward, but unanimity is not required.[26] Instead of relying on unanimity the Committee's recommendation is based on a balance of the Final Rule factors. Ultimately, the Board of Directors will be responsible for adopting a solution after balancing the Final Rule factors at the December 2018 Board meeting.

Liver Allocation

The primary goal of the Committee was to remove DSA and region from allocation policy, and select a distribution policy consistent with NOTA and the OPTN Final Rule. The Committee's secondary goal was

[25] See Appendix D: Public Comment Analysis

[26] "We understand that liver allocation policy is complicated and that there is an absence of unanimity among transplant stakeholders and the public concerning the optimal methods of liver allocation. It appears that achieving consensus for a new liver allocation policy may not be possible. Such consensus is not required under the OPTN final rule and should not be a barrier to adopting a liver allocation policy that complies with the OPTN final rule." George Sigounas, letter to Sue Dunn, OPTN President, July 31, 2018.

to ensure that any newly proposed system performed as well as or better than the December 2017 proposal with regard to reducing variance in median MELD at transplant as a measure of equity in access to transplant among candidates.

1. Frameworks

In response to the Board directive, the Committee began considering the basic framework for the revised distribution system. The Geography Committee recently sponsored a public comment proposal to identify a single distribution framework for all organs.[27][28] 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 Geography Committee. Over the last several years, the Liver Committee considered several frameworks for organ distribution. The Committee was willing to consider any proposal supported by evidence such as modeling by the SRTR and that meets the dual requirements to 1) replace DSAs and regions with rational boundaries and 2) reduce the variance in access by geography as measured by variance in median MELD at transplant.

The Committee initially considered whether it would be possible to allocate livers 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…". During public comment, the Attorney Generals of New York and California, and some other commenters supported a system without geographic constraints.[29] They contend that any geographic boundaries would continue to disadvantage some patients based on their listing location because there would still be areas of the country where the likelihood of death from liver disease is higher than other locations.

However, a system that does not consider geography at all may not be consistent with the Final Rule requirements regarding efficiency and organ wastage. As discussed in more detail below, allocating organs to candidates who are closer to the donor hospital reduces the costs of transportation, reduces the logistical difficulties that could lead to discards, and reduces the amount of ischemic time for an organ. Therefore, the Committee opted to pursue a policy that would include some consideration of location, to fulfill the Final Rule requirements to have allocation "designed to avoid wasting organs" and "promote the efficient management of organ placement".[30]

After determining that *some* geographic constraint is likely necessary in order to avoid wasting organs and to promote the efficient management of organ placement, the Committee considered several approaches.[31] Most did not meet the Committee's goals, but two, described as acuity circles and broader 2 circle (B2C) throughout this proposal, both using a fixed nautical mile distance from the donor hospital to place organs more efficiently, appeared promising and the Committee decided to request modeling for each.

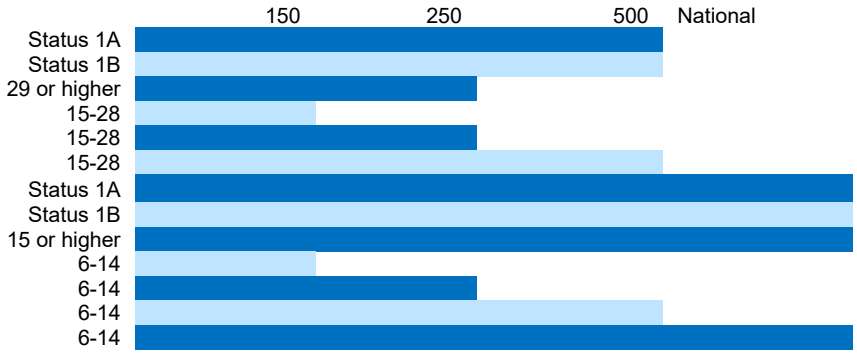
1. Broader 2 Circle (B2C)

The Committee considered and is recommending a concept that would allocate livers to status 1 candidates within 500 nautical miles (nm) of the donor hospital, then to candidates with a MELD/PELD of at least 29 within 250 nm of the donor hospital, then to candidates with a MELD/PELD of at least 15 within 150 nm, then 250 nm, then within 500 nm, and finally to candidates throughout the nation.[32] The Committee chose to preserve the concept of offering to status 1A and 1B candidates over a larger area

[27] *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).
[28] For additional analysis of the public comment responses, see Appendix D: Public Comment Analysis
[29] Becerra, Xavier and Underwood, Barbara. Letter submitted as public comment. 1 Nov. 2018
[30] 42 C.F.R § 121.8(a)(5).
[31] Appendix B: Other Allocation Options Considered
[32] Unless otherwise stated, distances in this proposal refer to the distance between the donor hospital and the transplant hospital where the candidate is registered.

initially, to ensure that candidates with the highest medical urgency have the highest priority and broadest access to available donor organs. **Figure 2** demonstrates the order of allocation for the B2C model. Each line shows the area of allocation at that sequence, with larger bands representing larger spreads of scores

Figure 2: Broader 2 Circles Order of Allocation



This model groups the candidates together in larger bands of MELD/PELD scores than the acuity circles approach. The larger bands group together roughly the top .05%, then the top 5%, then the top 40% of liver candidates on the wait list.[33] This grouping balances sound medical judgment and efficient placement by avoiding adding travel time and logistics for a smaller and less medically significant difference in MELD scores.[34] The Committee's choice of the thresholds of 29, 15-28, and 6-14, for grouping is discussed in detail below, in the section entitled "MELD Threshold."

The order of allocation as proposed by the Committee is shown in classification sequences in Table 1.

Table 1: 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 29
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

[33] See below, Table 7: Number of candidates on the liver waiting list on 10/4/2018
[34]Figure 15: Mortality Risk by MELD score

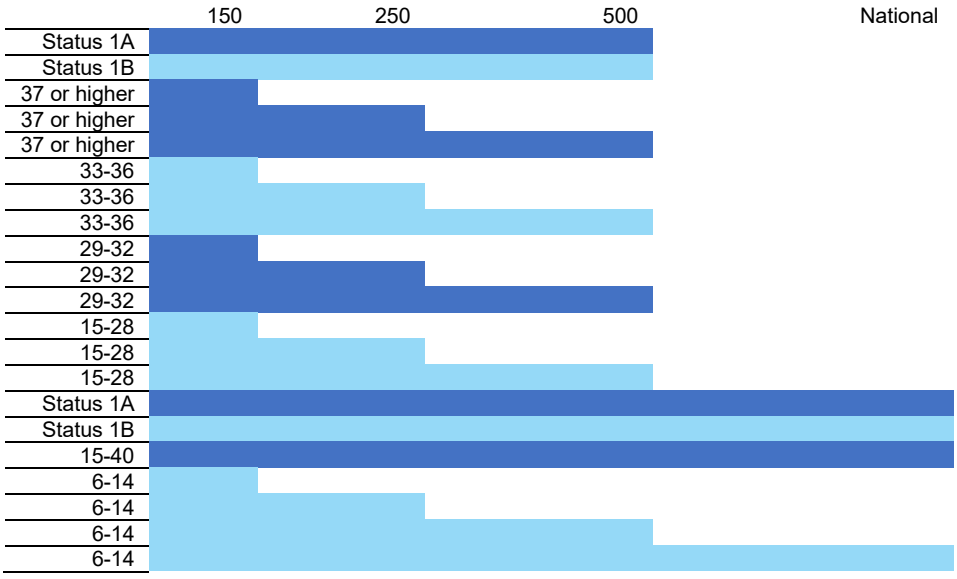
Classification	Candidates that are within this proximity of the donor hospital:	And are:
10	150nm	MELD or PELD less than 15
11	250nm	MELD or PELD less than 15
12	500nm	MELD or PELD less than 15
13	National	MELD or PELD less than 15

2. *Acuity Circles*

The second concept the Committee chose to model was acuity circles, which uses distance-based circles with small bands of a few MELD/PELD points. The goal of this concept was to prioritize the most efficient placement (minimizing transport time and logistics by prioritizing 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 score), allow candidates who are further away to have increased access. The approach places more emphasis on the difference in MELD/PELD score, even when the differences are smaller. By allocating to candidates within 150, then 250, then 500nm of donor hospitals, this concept is intended to adjust for population density. In densely populated areas, there would be less travel required, because there will more likely be candidates of the various urgency levels within 150 nm for the donor hospital. This would mitigate additional costs, potential limits on available planes, pilots and recovery teams, and other inefficiencies. However, in more sparsely populated areas where travel would be more routinely required anyway, organs would be offered more quickly to a larger area because instead of offering livers to candidates with lower scores within the same size circle first, the livers would be offered within the larger circles for the candidates with MELD scores that are more similar before being offered in the smaller circle for lower scores.

Figure 3 demonstrates the order of allocation in the acuity circles model. Each line shows the area of allocation at that sequence, with larger bands representing larger spreads of scores.

Figure 3: Acuity Circles Order of Allocation



The Committee discussed how many MELD/PELD points would be grouped together in each band, and considered three, four, or five for this concept. The Committee reviewed data and determined that 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).[35]

The Committee chose to include the concept of offering to status 1A and 1B candidates over a larger area initially in this model and to group the MELD or PELD scores from 15 to 28 together, and the scores less than 15 together. The choice of threshold for this grouping is discussed further in the section below entitled "MELD Threshold."

The SRTR modeled allocation using the sequences below. Two versions were modeled – one with distances of 150, 250, and 500 nm, and another with distances of 150, 300, and 600 nm.

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

[35] See *Figure 15: Mortality Risk by MELD Score.*

3. SRTR modeling results

The optimization of organ allocation and distribution can be described as a non-deterministic polynomial-time hardness (NP-hardness) problem.[36] Having determined that a system with no geographic constraints is not feasible, the Committee must determine the appropriate, rational, and effective boundaries to 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 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.[37]

The Committee considered the predicted results of the acuity circles 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.

- 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") and (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.
- Post-transplant Mortality: This metric is relevant in determining futility and the best use of donated organs in line with the requirements of 42 C.F.R. § 121.8(a)(2) and (a)(5).
- Transportation time: This metric is relevant when considering the fact that the amount of CIT on an organ impacts transplant outcomes, is in line with the requirements of 42 C.F.R § 121.8(a)(5) to make the best use of organs and avoid wasting organs.
- Percent of Organs Flown: This metric is relevant considering the costs related to efficiency in transporting organs by air instead of ground transportation.[38] This is in line with the requirement of 42 C.F.R. § 121.8(a)(5).

In regards to the variance in MMaT, all of the models showed improvement overall compared to the current system and the 2017 Board approved policy. However, the broader two circle models only showed an improvement in variance for patients with exception scores, not those non-exception patients. The two acuity circle models showed the greatest improvement in variance in MMaT for both groups.

All of the models showed a slight decrease in transplant count. The Liver Simulated Allocation Model (LSAM) accounts for acceptances based on historical acceptance practices related to distance. If historically an organ was not accepted beyond a certain distance, then when modeling changes to distance in distribution, the LSAM assumes that a program is not going to accept that organ if it comes from a further distance. However, in reality, this tends not to bare out in practice because programs do change their acceptance behaviors in response to allocation changes. For example, the LSAM for Share 35 predicted that the transplant count would decrease.[39] Because the LSAM does not account for changes in member behavior, this impact did not occur once Share 35 was implemented.[40] Therefore, a

[36] 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.
[37] 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)
[38] See note 35.
[39] SRTR "Report as of June 26, 2009 to the OPTN Liver-Intestine Transplantation Committee".
[40] 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.

decrease in transplant count is not a guaranteed outcome of any of the modeled systems. For this reason, the Committee feels comfortable recommending this proposal to the Board, despite this result shown in the modeling.

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 efficient management of organ placement by causing increases to costs of procurement.[41] The broader two circle model was predicted to increase flying by less, to only 58.4-60.8%.

Table 3: Overview of the SRTR Modeling Report[42]

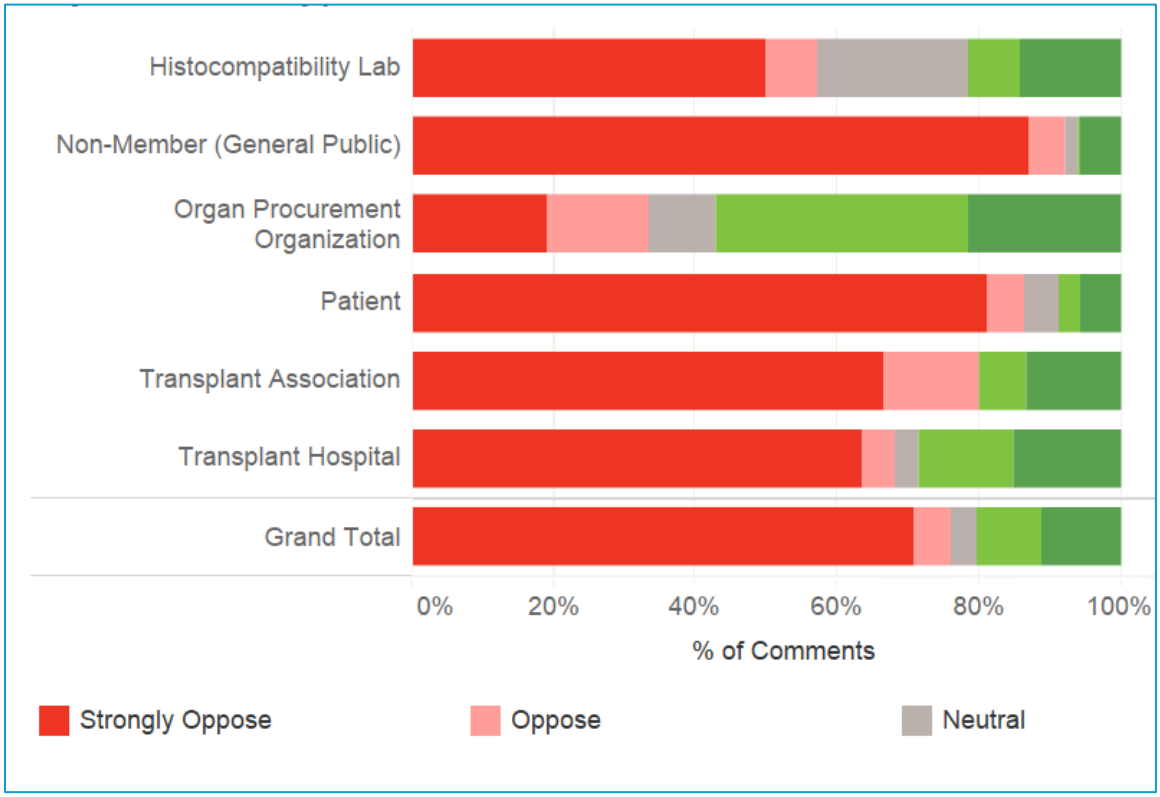
Scenario	Variance in Median Allocation MELD/PELD at Transplant	Transplant Count	Median Transport Time (hours)	Median Transport Distance (miles)	Percent of Organs Flown
Current	9.97	6651	1.7	88.5	50.7
2017 Board Approved	7.41	6643	1.7	100.4	54.4
Acuity 250+500	4.33	6594	1.9	183.5	71.4
Acuity 300+600	4.07	6583	2.0	211.3	74.0
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

4. Public Comment Reactions to B2C and Acuity Circles

After receiving the modeling, the Committee distributed a proposal for public comment that discussed both B2C and acuity circles. During public comment, OPOs as a group expressed the most support for B2C. Less than 50% of any other group supported or strongly supported this approach. The majority of each group except for OPOs and histocompatibility labs strongly opposed B2C.

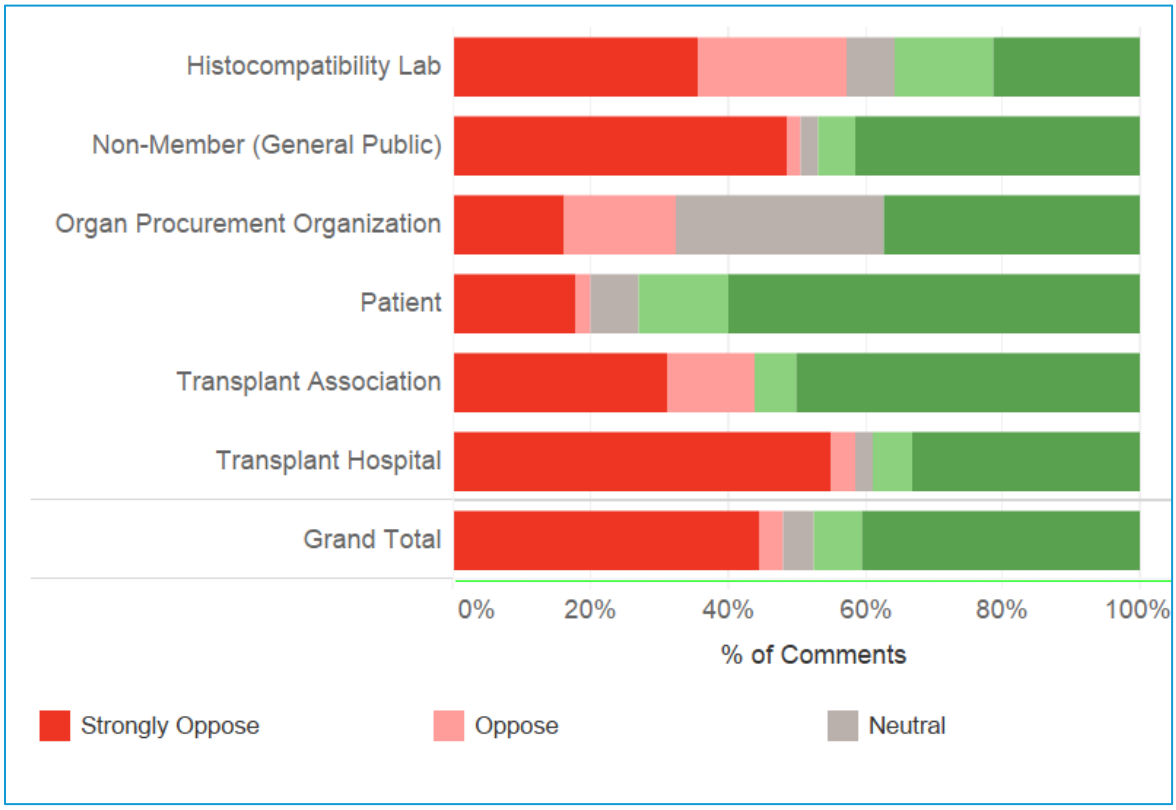
[41] Procurement costs include the funds needed to fly a transplant team to the organ recovery hospital. The further recovery teams must travel to procure an organ, the more likely it becomes those teams will need to fly, which leads to increase costs for securing those flights.
[42] Scientific Registry 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)

Figure 4: Sentiment of B2C Framework by Member Type



During public comment, patients as a group registered the largest support for acuity circles. Transplant hospitals and histocompatibility lab commenters registered slightly more opposition than support, and all of the groups were divided.

Figure 5: Sentiment of Acuity Circles Framework by Member Type



The figure below shows how commenters' opinions on each framework intersect. Commenters that support B2C are counted on the top row, and those that strongly oppose B2C are on the bottom row, with commenters who strongly support acuity circles in the left column and those who strongly oppose acuity in the right column. Those who strongly oppose both (37.11%) are in the bottom right corner, and those who strongly support both (2.06%) are in the top left corner. Of the commenters that opposed or strongly opposed B2C, 16% also supported or strongly supported acuity circles and 40.21% opposed or strongly opposed both frameworks.

Figure 6: Framework Preference

B2C	Strongly Support	Support	Neutral	Oppose	Strongly Oppose
Strongly Support	2.06%	0.75%	0.75%	0.75%	6.37%
Support	4.22%	0.56%	0.75%	0.84%	2.53%
Neutral	0.75%	0.37%	1.97%	0.09%	0.56%
Oppose	1.69%	0.94%	0.56%	1.41%	0.75%
Strongly Oppose	29.62%	2.91%	0.75%	0.94%	37.11%

A. Flying

During public comment, commenters who preferred B2C over acuity circles were concerned that modeling results for acuity circles show increases to flying of more than 10% compared to B2C and more than 20% compared to the current system. In addition to increasing costs of organ placement, which relates to the efficient placement of organs, some were concerned that additional flying to recover organs could also increase the risk of organ wastage because if a plane crashes, the organ it is transporting is lost.[43] Some of the committee members used their expertise based on years of practice to recall the deaths of two members of a recovery team and pilot in a helicopter crash in 2011 that also resulted in the wastage of the heart they were on the way to recover,[44] and cited other fatalities.[45]

Table 4: Overview of Transportation Metrics, SRTR Analysis Report on Circle Based Allocation[46]

	Median Transport Time (hours)	Median Transport Distance (miles) Percent of Organs	Percent of Organs Flown
Current	1.7 (1.7,1.7)	88.5 (86.9,90)	50.7 (50.2,51.1)
Board Approved	1.7 (1.7,1.7)	100.4 (98.7,101.9)	54.4 (53.8,54.9)
Acuity 250+500	1.9 (1.9, 1.9)	183.5 (180.4,187)	71.4 (70.6,71.9)
Acuity 300+600	2 (2, 2)	211.3 (207.5,217)	74 (73.6,74.4)
B2C MELD 35	1.8 (1.7, 1.8)	107.7 (106.1,110.2)	58.4 (58,59.1)
B2C MELD 32	1.8 (1.8,1.8)	117.1 (115.8,118.6)	60.8 (60.3,61.5)

SRTR, LI2018_01 Analysis Report 9/24/2018.

The efficiency of organ placement may also be affected by the availability of pilots and flights if the number of flights needed increases too dramatically. 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 increase of 2.2%.”[47] 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.”[48]“The [pilot] shortage has been caused by a recent

[43] One study estimates 54.8 fatalities per million flight hours between 1990 and 2007, compared to a 0.055 per million flight hours for scheduled commercial flights and 7.1 per million flight hours for unscheduled commercial flights. Michael J. Englesbe, R.M. Merion, “The Riskiest Job in Medicine: Transplant Surgeons and Organ Procurement Travel,” *Am J Transplant*, no. 9 (Oct 2009) pg. 2406-2415, https://doi.org/10.1111/j.1600-6143.2009.02774.x.
[44] Associated Press “Mayo Clinic Workers Die in Fla. Helicopter Crash,” Accessed November 9, 2018, https://www.cbsnews.com/news/mayo-clinic-workers-die-in-fla-helicopter-crash/ (accessed November 9, 2018).
[45] There have been at least 3 publically reported fatal organ procurement accidents between 1990 and 2007 in the United States, with 9 fatalities between them. There were an additional 4 crashes in that time period in other countries, with an additional 18 fatalities. See Englesbe, “Riskiest Job in Medicine,” at note 43.
[46] 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)
[47] International Air Transportation Association, "Air Freight Demand up 9% in 2017, Strongest Growth Since 2010," *IATA - Live Animals Regulations*, (January 31, 2018), https://www.iata.org/pressroom/pr/Pages/2018-01-31-01.aspx.
[48] Federal Aviation Administration, “FAA Aerospace Forecast: Fiscal Years 2018-2038,” Accessed October 1, 2018,

increase in the flying hours required for commercial pilots,[49] the aging pilot workforce,[50] fewer new pilots coming out of the military,[51] and a general decline of interest in the career."[52, 53] Committee members also expressed additional transportation challenges resulting from new regulations governing crew duty and rest times.[54, 55]

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 for 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 increase allocation time, and decrease efficiency of organ placement.

In the absence of definitive data about the effect of the availability of pilots and flights on organ recovery, the Committee relied on their cumulative experience in transplant and flying to recovery organs, and the results of interviews conducted by the Operations and Safety Committee with staff at OPOs and some transplants hospitals.

The Operations and Safety Committee interviews showed mixed results, with some of the interviewees responding that there have been times when they were unable to find a pilot for a surgeon (56.3%) or for an organ (66.2%), or unable to find a plane for a surgeon (56.3%) or an organ (67.6%). In three regions, there were no interviewees who reported that they were ever unable to find a pilot or plane for transporting an organ, and there was only one region in which no interviewees ever reported being unable to find a plane or pilot for a surgeon. 19.7% of interviewees reported airport restrictions influencing recovery, and 42% reported pilot duty hours ever influencing organ recovery.[56] Overall, it appeared that there have been times when some OPOs experience difficulty finding airports, pilots, or planes, although it is unknown how many times that happened or what the circumstances were.

Committee members did acknowledge that increased use of local recovery teams or organ recovery centers could be one way to mitigate additional travel since transporting an organ is simpler than transporting a recovery team roundtrip.[57] However, not all areas have procurement centers or are set up

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https://www.faa.gov/data_research/aviation/aerospace_forecasts/media/FY2018-38_FAA_Aerospace_Forecast.pdf

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

[50] See Air Safety Institute, "Aging and the General Aviation Pilot: Research and Recommendations," Accessed October 1, 2018, https://www.aopa.org/-/media/Files/AOPA/Home/Pilot-Resources/Safety-and-Proficiency/Accident-Analysis/Special-Reports/1302agingpilotreport.pdf, ("[l]ike 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.").

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

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

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

[54] 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).

[55] 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.).

[56] See Appendix C: Operations and Safety Committee Transportation Report

[57] In the case of one procurement center, patient and graft survival were similar whether the liver was procured at the hospital or the recovery center, travel time was reduced from 8 to 2.7 h ($p < 0.0001$), with a reduction of surgeon fly outs by 93% (14/15) in 2011 and liver organ donor charges generated by the donor were reduced by 37% overall for

to ensure that there are recovery surgeons available at every donor hospital. In the future, if more OPOs use recovery centers or develop their local recovery teams, then recovery teams may not need to travel for as many cases, and even broader initial allocation may become more feasible.

Some commenters were also concerned there would be an increase in unfavorable outcomes of transplants if livers incurred more cold ischemic time as a result of transportation. Despite these concerns, the SRTR modeling results did not show a predicted change in post-transplant mortality between the current system, the December 2017 proposal, or any of the modeled frameworks.[58] This is evidence that the proposal would not result in futile transplants and contributes to making the best use of donated organs.

Commenters also expressed concern that additional flying would result in additional discarded organs. Although the SRTR modeling does not provide a prediction regarding the number of organs discarded, there is not a statistically significant difference in the predicted transplant counts.[59]

Table 5: Overview of Transplant, Waitlist Mortality, and Post-Transplant Mortality Metrics, SRTR Analysis Report on Circle Based Allocation [60]

	Transplant Rate	Transplant Count	Waitlist Mortality Rate	Waitlist Mortality Count	Post Transplant Mortality Rate	Post Transplant Mortality Count
Current	0.443 (0.435,0.451)	6651 (6575,6727)	0.097 (0.095,0.1)	1455 (1425,1504)	0.077 (0.075,0.08)	686 (666,721)
Board Approved	0.438 (0.43,0.448)	6643 (6561,6728)	0.091 (0.09,0.093)	1386 (1358,1419	0.077 (0.075,0.079)	684 (662,712)
Acuity 250+500	0.428 (0.422,0.436)	6594 (6491,6672)	0.087 (0.085,0.088)	1341 (1310,1364)	0.078 (0.076,0.08)	687 (664,718)
Acuity 300+600	0.426 (0.419,0.434)	6583 (6492,6662)	0.085 (0.083,0.086)	1318 (1278,1346)	0.079 (0.078,0.08)	688 (676,719)
Broader 2-Circle MELD 35	0.438 (0.432,0.448)	6620 (6543,6706)	0.095 (0.093,0.096)	1433 (1404,1463)	0.077 (0.073,0.08)	676 (647,717)
Broader 2-Circle MELD 32	0.437 (0.43,0.446)	6616 (6556,6692)	0.094 (0.092,0.095)	1423 (1391,1442)	0.077 (0.076,0.08)	682 (661,721)

SRTR LI2018_01 Analysis Report 9/24/2018.

B. Costs

Some commenters weighed in on the costs to the healthcare system. Costs are relevant to this proposal because the Final Rule permits the consideration of the "efficient management of organ placement."[61] Costs related to the efficient management of organ *placement* are a subset of the total cost to care for end stage organ failure patients or organ transplantation. The OPTN does not routinely collect cost information from members nor does the LSAM predict transplantation costs. The LSAM can predict the

donors recovered at the OPO facility versus acute care hospital. Doyle MB, et al. "A novel organ donor facility: a decade of Experience with live donors. Am. J Transplant. 2010; 14(3):615-620.

[58] Table 2: Overview of Transplant, Waitlist Mortality, and Post-Transplant Mortality Metrics, SRTR Analysis Report on Circle Based Allocation

[59] Ibid.

[60] 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)

[61] 42 C.F.R. §121.8(a)(5).

percent of organs flown. The percent of organs flown is relevant because flights add costs to organ placement.

While some were concerned that the increases in flying would increase the costs of procurement, others opined that the cost savings associated with reducing waiting list deaths would more than offset any additional costs associated with additional flights. 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%."[62] Another article looked at the economic impact of the 2016 distribution proposals and found that transportation costs could increase over $70 million a year.[63] However, modeling cannot predict changes to behavior such as changes in transplant hospital behavior and acceptance practices. The Committee considered the expected change to costs as directed by 42 C.F.R 121.8(a)(5) to consider the "efficient management of organ placement" as it balanced the Final Rule factors. Even if there is an ultimate offset in costs in the healthcare system, the up-front costs associated with increased flying are more directly related to less efficient management of organ *placement*.

C. Variance in Median MELD at Transplant (MMaT)

The Committee used MMaT by DSA as a metric to evaluate the difference in access to transplant in different areas of the country. The Final Rule requires that allocation policies prioritize candidates using "objective and measurable medical criteria."[64] The MELD score is a calculated using relevant medical criteria to prioritize candidates for liver transplants based on medical urgency.[65] Within each geographic unit of distribution, candidates are prioritized for offers in order of decreasing MELD score, in alignment with the Final Rule requirement that candidates "be ordered from most to least medically urgent."[66]

The MELD scores at which candidates waiting are transplanted should not vary by much across geographic areas. The MMaT represents the "middle" point of transplanted MELD scores. The MMaT across various geographic areas demonstrates the variation in the MELD score at which candidates are being transplanted. If two candidates are in different areas of the country, but have the same objective clinical factors, they will have the same MELD score, so in an equitable system, they should also have the same likelihood of transplant. Since MELD score is a surrogate for medical urgency, variation in MMaT shows that candidates in some geographic areas have to reach a higher level of medical urgency to receive a transplant compared to others.[67] Some candidates' objective medical criteria have to be worse than others before they are likely to be transplanted, simply because of where they live or can list.

Modeling showed that both B2C and acuity circles would result in less variance in MMaT than the current allocation system (See Table 6). However, acuity circles improved the variance more significantly, and also showed an increase in the overall MMaT, with more candidates with higher MELD/PELD scores getting transplanted.

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[62] 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.

[63] 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.

[64] 42 CFR §121.8(b)(2).

[65] Leise, Michael D. et al. "A Revised Model for End-Stage Liver Disease Optimizes Prediction of Mortality Among Patients Awaiting Liver Transplantation". *Gastroenterology* , Volume 140 , Issue 7 , 1952 – 1960. Doi: 10.1053/j.gastro.2011.02.017

[66] See note 63.

[67] Edwards, E. B., Harper, A. M., Hirose, R., & Mulligan, D. C. (2016). The impact of broader regional sharing of livers: 2-year results of "Share 35". *Liver Transplantation*, 22(4), 399-409. doi:10.1002/lt.24418

Table 6: Overview of Median MELD/PELD at Transplant, SRTR Analysis Report on Circle Based Allocation[68]

	Variance in Median Allocation MELD/PELD at Transplant	Median Allocation MELD/PELD at Transplant
Current	9.97 (8.74, 11.9)	29 (29,29)
Board Approved	7.41 (6.36,8.47)	29.1 (29,30)
Acuity 250+500	4.33 (3.23,6.27)	31 (31,31)
Acuity 300+600	4.07 (3.13,6.18)	31 (31,31)
B2C MELD 35	6.74 (5.85,8.83)	29 (29,29)
B2C MELD 32	6.54 (5.37,8)	29.5 (29,30)

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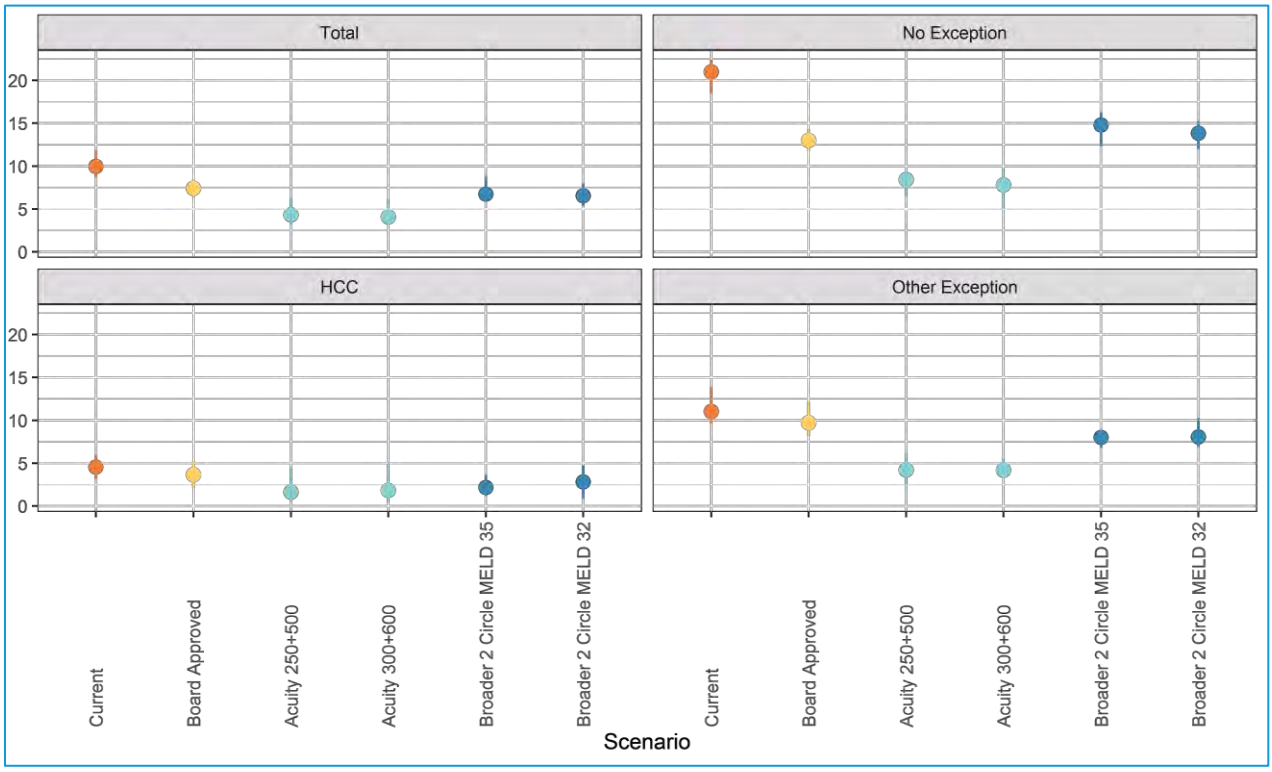
Commenters who supported acuity circles pointed to the fact that it improves variance in MMaT by DSA more than B2C, and would therefore better promote access to transplant for candidates more similarly regardless of their listing location.[69]

Some of the commenters who preferred acuity circles to B2C specifically pointed to the difference in the expected improvement in variance in MMaT for exception patients compared to candidates with a MELD score based on a calculated value. (**Figure 7**). They argued that the difference amounted to providing less access to transplant for candidates without exceptions. According to the SRTR modeling report, the variance in MMaT appears to be higher for patients without an exception in the B2C models than in the December 2017 proposal or the acuity circles model. Some commenters were especially concerned with this population because it is less susceptible to variation based on local agreements than the MMaT for exception patients.

[68] Ibid.
[69] Table 4: Overview of Median MELD/PELD at Transplant and Transportation Metrics, SRTR Analysis Report on Circle Based Allocation

Figure 7: Variance in MMaT by Exception Status[70]



The difference between the B2C and December 2017 modeled variance was within the margin of error and the division of exception and non-exception candidates is subject to change when the changes to exception scoring went into effect with the implementation of the National Liver Review Board (NLRB), which could not be included in this modeling. The Committee agreed that there would be an improvement to disparity in MMaT overall and that the change was unlikely to disadvantage candidates with a lab MELD.

Ultimately, the Committee recognized the value of improving the variance in order to promote access to transplant, but ultimately balanced that against other concerns, particularly related to organ wastage and efficient management of organ placement.

D. Number of Transplants

Although liver allocation modeling does not have the ability to predict discards, older SRTR analysis reports illustrate a pattern of lower transplant rates as the distribution area decreases.[71] A decrease in the number of transplanted organs or increase in discarded transplantable organs would not be the best use of those organs. Therefore the Committee considered the number of organs transplanted to ensure that there was no decrease in the number of transplants. B2C and acuity circles modeling results each show no significant change in the number of livers transplanted.

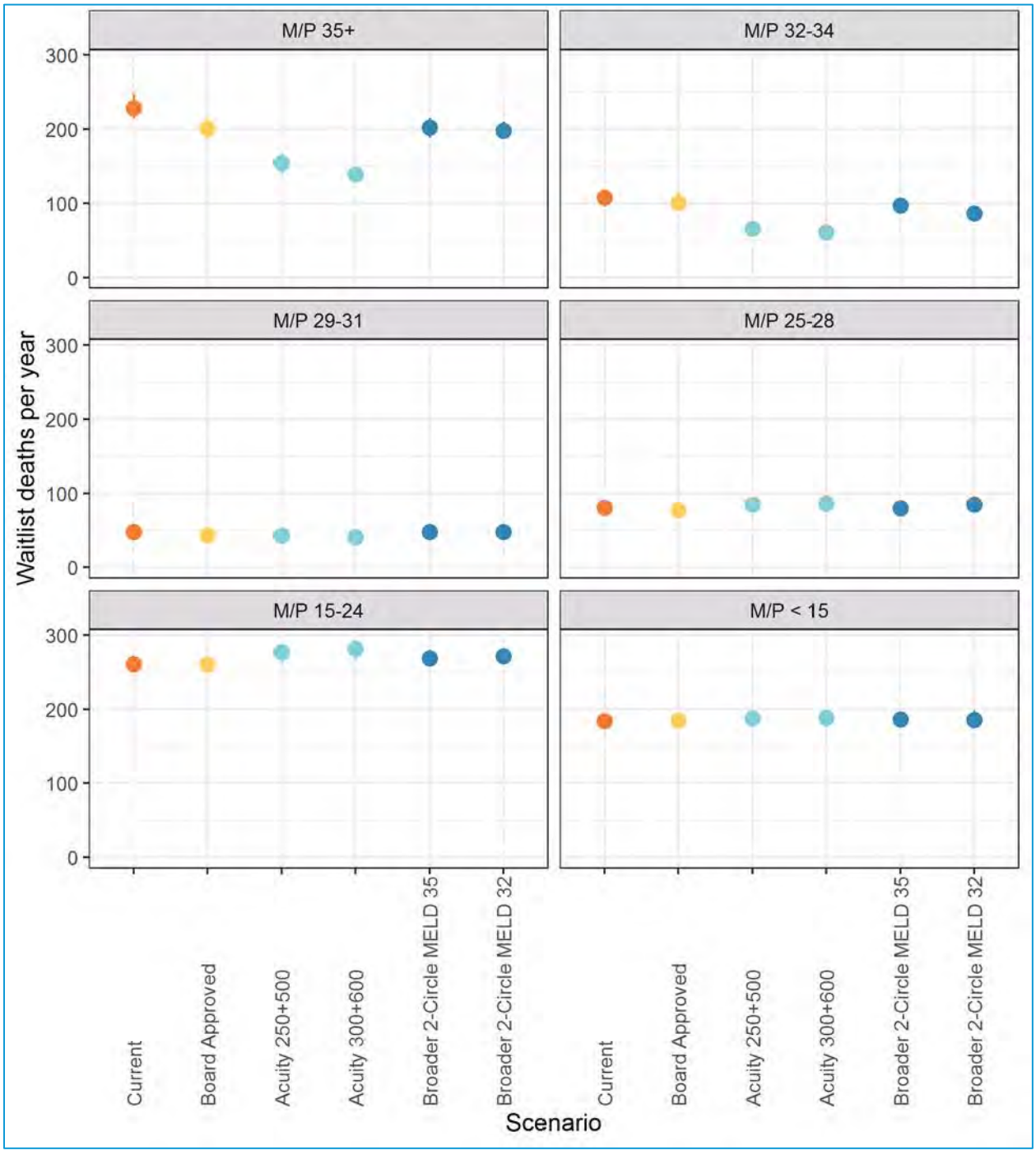
E. Waitlist Mortality

The primary group of concern when evaluating the access to transplant was the sickest patients, as indicated by higher MELD scores, since they have the most urgent need for transplant. The Committee reviewed the waitlist mortality numbers for the models and noted that B2C performed at least as well as

[70] 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)
[71] Scientific Registry of Transplant Recipients, *SRTR LI_2016_01*, Oct. 11, 2016, https://optn.transplant.hrsa.gov/media/2684/201610_srtr_liver_analysis_report.pdf (accessed Nov. 9, 2018)

the December 2017 proposal for these groups. The Committee then looked at the other measures in order to attempt to balance the other considerations.

Figure 8: Waitlist Mortality Counts by Allocation MELD/PELD[72]



Some commenters who preferred acuity circles focused on the fact that acuity circles showed lower waitlist mortality in modeling results, especially among the highest MELD/PELD patients. Some

[72] Ibid.

commenters argued that the reduced waitlist mortality under acuity circles[73] indicates that the candidates most in need would receive transplants first while those whose medical urgencies may allow it will wait a little longer without suffering mortality on the waitlist. Commenters believed this may be an appropriate measure for improved use of donated organs. This was a compelling point for the Committee members, who deliberated how to weigh this difference. However, the Committee ultimately gave more weight to efficiently managing organ placement and avoiding organ wastage by making an incremental change that would be less likely to have unintended consequences and requiring less flying for liver procurements.[74]

F. SES/Rural

Other commenters had concerns that acuity circles did not adequately address access to transplantation for patients in rural areas, who, commenters suggested, tend to be of lower socioeconomic statutes. In some rural DSAs, the modeling was more likely to predict increased numbers of livers exported and decreased numbers of transplants under acuity circles. While the Committee was sensitive to this way of considering access to transplant, the measures of socio-economic status are not tracked at a patient level, and often areas where some of the population is very wealthy also include people in poverty. Conversely, there may be wealthy people living in rural areas. The Committee reviewed the modeling results, which did not show any subset of the population expected to be particularly disadvantaged by the changes in acuity circles or B2C as further discussed in *Socioeconomic Status* below.

G. Incremental Change

During public comment, the American Society for Transplantation (AST), the American Society of Transplant Surgeons (ASTS), Association of Organ Procurement Organizations (AOPO) and NATCO expressed a desire for incremental change.[75] In particular, some commenters pointed to the consequences of the recent changes in lung allocation which replaced the DSA and region with 250 and 500 nm circles around the donor hospital.[76] Though there are conflicting reports regarding the impact so far, the Thoracic Committee reviewed the data at 6-months post-implementation and concluded that there was no increase in discarded organs that could be clearly attributed to the allocation changes.[77] Early analysis of the results by one center indicate that that there may be a significant increase in travel and ischemic time and a doubling of median organ cost without any significant change in the patients that are transplanted.[78] There are significantly more liver programs (145) than lung programs (71), and it is not certain that the impact of the changes on lung programs and lung transplantation would be the same. With more programs and a smaller initial circle, the patterns of travel may not be the same for livers. The Committee decided that there was the possibility of unintended consequences but not any certainty and committed to monitoring the impact moving forward.

H. Donor families

Some commenters suggested that organ donors would not donate if they did not believe their liver would be used locally (including some commenters who said they themselves felt this way). However, a national survey conducted by the U.S. Department of Health and Human Services in 2012 showed that 81.7% of respondents would prefer for their “organs to go to more medically urgent patients regardless of where they live in the U.S.”[79] This survey was in line with the Committee members’ experience. The Committee

[73] Table 2: Overview of Transplant, Waitlist Mortality, and Post-Transplant Mortality Metrics, SRTR Analysis Report on Circle Based Allocation
[74] Table 4: Overview of Transportation Metrics, SRTR Analysis Report on Circle Based Allocation
[75] https://optn.transplant.hrsa.gov/governance/public-comment/liver-and-intestine-distribution-using-distance-from-donor-hospital/
[76] *Broader Sharing of Adult Donor Lungs*, OPTN/UNOS Executive Committee, November 2017, https://optn.transplant.hrsa.gov/media/2314/broader_sharing_lungs_20171124.pdf (Accessed Nov. 16, 2018)
[77] Meeting Summary for July 19, 2018 meeting, OPTN/UNOS Thoracic Transplantation Committee, https://optn.transplant.hrsa.gov/media/2616/20180719_thoracic_meetingsummary.pdf
[78] Varun Puri, et al. *Unintended Consequences of Changes to Organ Allocation Policy,* (2018). Manuscript submitted for publication.
[79] U.S. Department of Health and Human Services, Health Resources and Services Administration, Healthcare Systems Bureau, 2012 National Survey of Organ Donation Attitudes and Behaviors. Rockville, Maryland: U.S.

decided that the risk of less donations was minimal and not a sufficient reason to limit organ allocation to a smaller area.

I. Committee Conclusion

The Committee recommends the B2C model because it balances the Final Rule considerations[80]. There was no solution that perfectly equalized disparity in MMaT and eliminated the risks and costs of flying. However, the B2C concept improves the variance in MMaT compared to the current system or the December 2017 proposal[81], while also increasing the numbers of organs that are flown less than the acuity circles models.[82] It also reduces post-transplant mortality without significantly reducing the number of transplants.[83]

1. Circle Sizes

After adopting the B2C framework, the Committee discussed different circle sizes. Proximity circles that were part of the December 2017 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 most transplant surgeons were 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 for managing organ placement less efficient.[84] The Committee balanced this need for efficiency as directed in the Final Rule with the need to distribute organs as broadly as possible.[85]

The Committee sought to balance the need to distribute organs as broadly as feasible against the inefficiencies of a system without geographic constraints. They therefore included a distribution unit greater than the 150 nm mentioned above. The Committee's collective experience was that the point at which travel changed from driving to flying varied depending on local factors such as access to airports, local traffic patterns, and surgeon, pilot and airplane availability. In some areas, surgeons routinely drive 250, or even 500 nm to recover a liver. The Committee used multiple circle sizes to factor in the potential increased efficiency even at these distances. It allows for an organ to be offered out to the largest area that a team is likely to drive to recover a liver after first offering it out to the area where most teams are likely to be able to drive for recovery.

The Operations and Safety Committee also conducted a series of interviews with representatives of 54 of the 58 OPOs in addition to 10 transplant hospitals[86] while this proposal was under development and provided the results to the Committee.[87] Of the 40 (33 OPOs and 7 transplant hospitals) that provided a

Department of Health and Human Services, 2013.

[80] 42 C.F.R. § 121.8(a).

[81] Table 4: Overview of Transportation Metrics, SRTR Analysis Report on Circle Based Allocation

[82] Ibid.

[83] Ibid.

[84] 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."

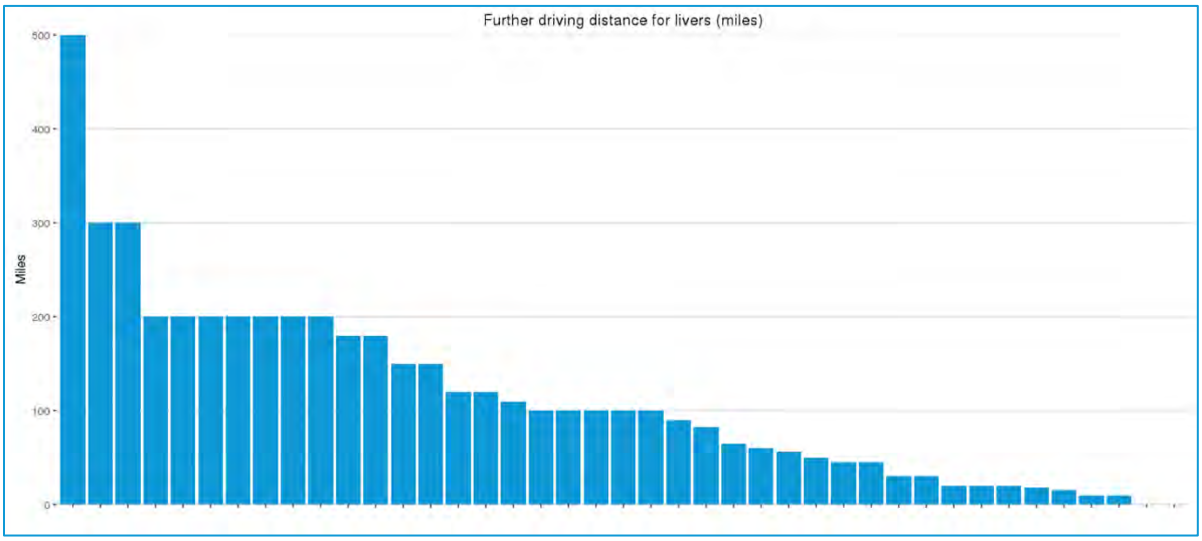
[85] 42 C.F.R § 121.8(a)(5) requires that allocation policies be designed "to promote the efficient management of organ placement." Therefore, the cost of transportation is a relevant factor to consider when developing an organ distribution system.

[86] See Appendix C: Operations and Safety Committee Transportation Report

[87] Meeting Summary for November 2, 2018 meeting, OPTN/UNOS Liver and Intestinal Transplantation Committee, https://optn.transplant.hrsa.gov/members/committees/liver-and-intestine-committee/ (Awaiting publication)

response regarding the furthest distance they might have to drive to deliver a liver, 29 are willing to drive 150 miles or less. Another eight will drive up to 180 or 200 miles, two will drive up to 300 miles, and another one may drive up to 500 miles.[88] This appears to support the range that the Committee selected as the circle sizes – that some fly over short distances, but others might drive as far as 500 miles.

Figure 9: The Furthest Distance an OPO might Have to Drive to Deliver a Liver



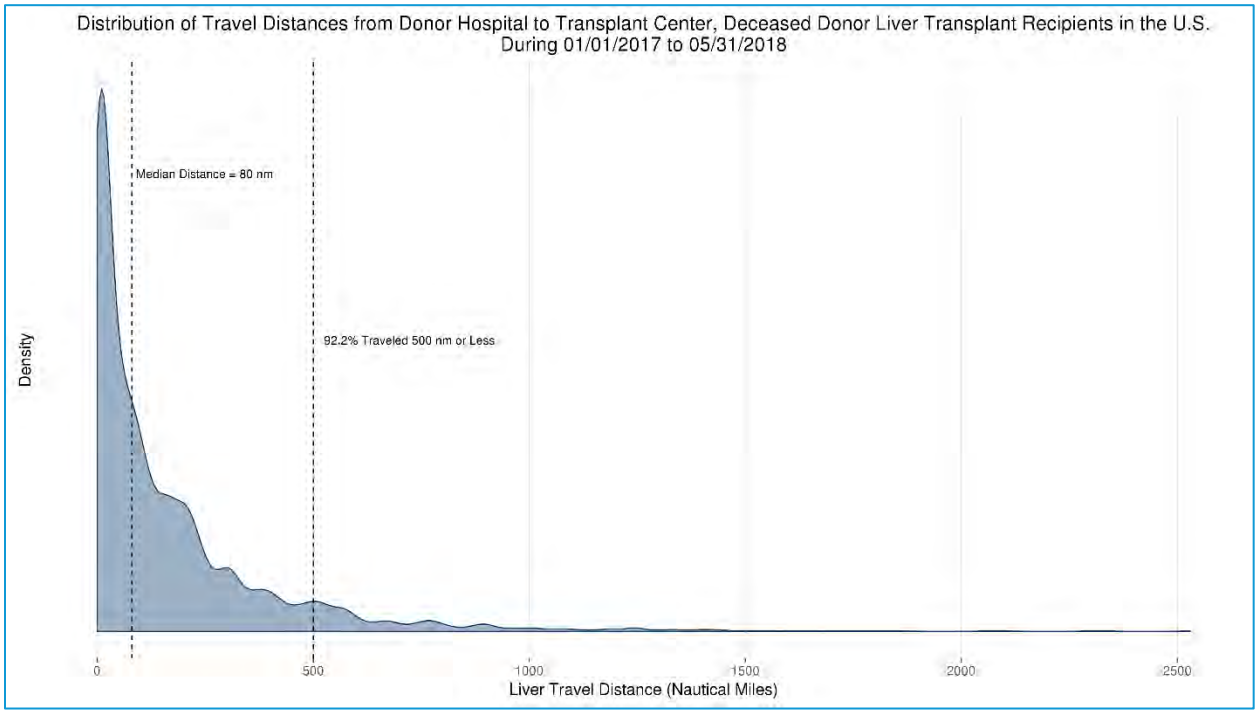
Based on OPTN/UNOS Plane Transportation Questionnaire.

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.

In selecting the size of this distribution unit, the Committee also did not want to decrease access for patients compared to the current system. Models used large circles of 500 and 600 nm, to respect the OPTN Final Rule directive to "avoid wasting organs."[89] because the data show that ninety-five percent of livers are currently transplanted within 586 nm and 92.2% are transplanted within 500 nm of the donor hospital.[90,] The Committee wanted to make sure that candidates who would currently have access to livers within 500 nautical miles of the donor hospital would continue to, as compared to a system where there was no circle bigger than 250 nm. In that case, the liver would be offered nationally, potentially bypassing some candidates who would currently have access due to their location within 500 nm of the donor hospital. 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.[91] This choice should not decrease access for most patients compared to the current system.

[88] See Appendix C: Operations and Safety Committee Transportation Report
[89] 42 C.F.R § 121.8(a)(5).
[90] Figure 10: 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
[91] 42 C.F.R § 121.8(d).

Figure 10: 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



Based on OPTN data as of November 2, 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 800 nm away and one that is 1,500 nm away because in either case, it is a significant flight. In both cases, a more desirable liver can withstand the cold ischemic time.[92] The Committee members agreed that there was no need to limit allocation by geography once the 500 nm 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 to these urgent candidates. The Committee proposes allocating to liver candidates with MELD/PELD 29 and higher in decreasing order of MELD score within 250 nm to reduce the amount of unnecessary flights and limit the impact of flight risks and costs on the efficiency of the system. It further proposes allocating to MELD 15-28 candidates within 150 nm first in decreasing order of MELD score, then 250 nm and then 500 nm. 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[93] by minimizing travel for less urgent candidates so that the system can absorb increases in travel for the most urgent candidates.

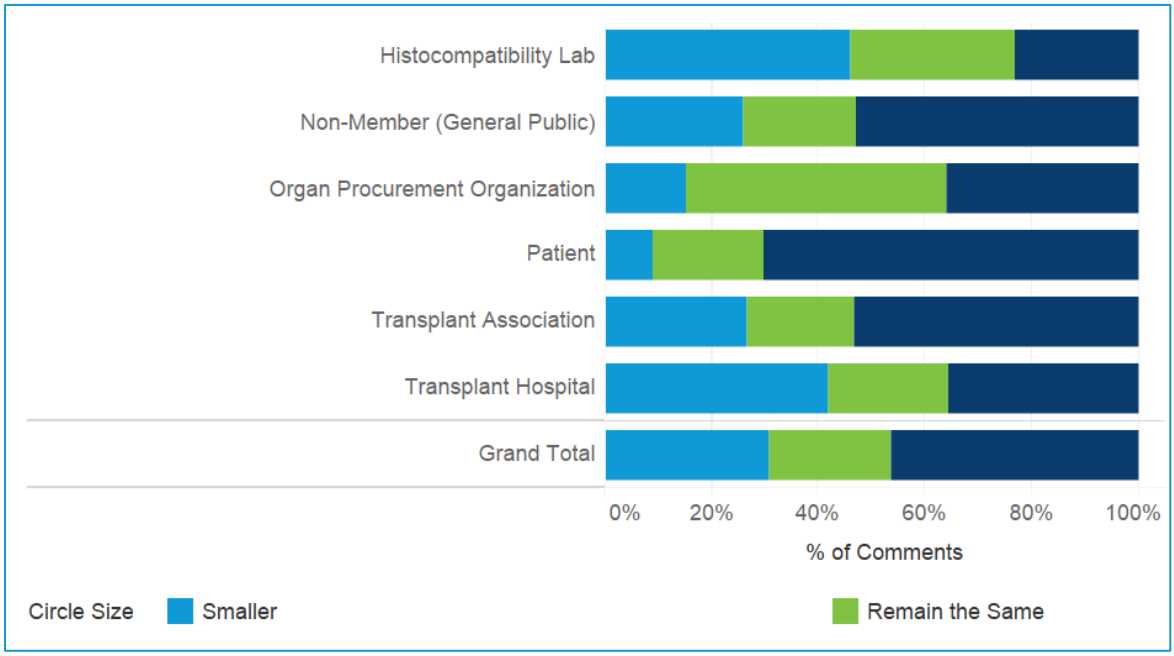
The Committee discussed whether it would be better to use recovery centers or donor hospitals as the donor location when a recovery center is used. The Committee considered whether the more relevant geographic location was this recovery center. The advantage of using the recovery center is that is the 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

[92] See note 78.
[93] 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 specifically asked for feedback during public comment on the size of circles. Several constituent groups were represented in public comment respondents. OPOs were the only constituent group that favored the Committee's proposed circles sizes the most. Histocompatibility labs and transplant hospitals favored smaller circles, and overall the public comment showed a split.

Figure 11: Feedback on Circle Sizes by Member Type



There appear to be trends in a commenter's feedback on circles size and their opinion on the MELD threshold. Commenters who favored larger circles tended to favor a lower threshold, and those who favored a smaller circle favored a higher threshold. This is not surprising since a larger circle size and lower threshold both create broader distribution and more travel, and a smaller circle and higher threshold result in less broad distribution and less travel. It does appear to show that most commenters either weigh efficiency, demonstrated by travel and logistics, or access to transplant, demonstrated by variance and waitlist deaths, more across the board.

Figure 12: MELD Threshold and Circle Size

	Sharing Threshold						
Circle Size	29	30	31	32	33	34	35
Larger	41.6%	0.9%		1.2%	0.1%	0.1%	2.2%
Remain the Same	4.2%	1.3%	0.3%	4.4%	0.3%	0.3%	10.2%
Smaller	2.0%	0.7%	0.1%	1.5%	0.3%	0.3%	27.8%

The majority of commenters preferred circles larger than the proposed 150/250/500 nm. Some commenters were concerned that the 150 nm circle was too small because their hospital would not be within the 150 nm circle of donor hospitals that are currently in the transplant hospital's DSA. Many suggested a circle of at least 250 or favored the 300/600 modeled with acuity circles, while others preferred 500 and 1000 nm. One commenter suggested a circle of 750 for MELD less than 35 and 1000 nm for MELD of 35 and higher. The specific alternatives proposed by commenters were:

1. 250/500 nm
2. 300/600 nm
3. 500/1000 nm
4. 750/1000 nm

Many of the commenters who responded in favor of larger circles provided written responses indicating a preference for modeling population-based circles and expressing concerns over the fact that the circle would include the ocean or another country for many hospitals. Additional comments mentioned that 150 nm circles would be smaller than many current DSA boundaries and would result in less access for certain patients. Others were concerned with maintaining access for areas of the country with high prevalence of liver disease. The comments about areas that include those without donors such as sparsely populated areas, areas covered in water or in another country speak to the fact that each area of the country deals with different logistical challenges. The distances for allocation are based on the location of the donor hospital, not the transplant hospital, so a population-based circle would not necessarily help transplant hospitals ensure access to a larger pool of donors, as they appear to expect. Instead, they would ensure that donors from sparsely populated areas were distributed over a larger area while allowing donors in large cities to be offered to a smaller area that might not include the transplant hospitals in more rural areas. This outcome would seem to be the opposite of that sought by the proponents of the idea.

A minority of commenters preferred a smaller circle. These commenters were concerned with the increased costs and difficulty with logistics such as finding pilots with the increases in flying predicted in the models. Many of the commenters who supported smaller circles also were opposed to all of the modeled options.

After considering all of the feedback received in public comment, the Committee did not opt to change the proposed circle sizes from those in the public comment proposal (150, 250 and 500 nm). Although there were many arguments based on the impact on a specific transplant hospital, there were no considerations raised in public comment that the Committee believed were compelling enough to justify a different circle size. Although different areas would be impacted differently by the change, this is the result of reducing existing inequities (demonstrated by MMaT), and is a positive direction.

2. MELD 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 MELD/PELD scores. This includes distributing 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 intended to achieve efficient placement of organs, because if an organ has been offered to enough candidates already who are higher on the match, it is taking more time to place the organ, 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.[94]

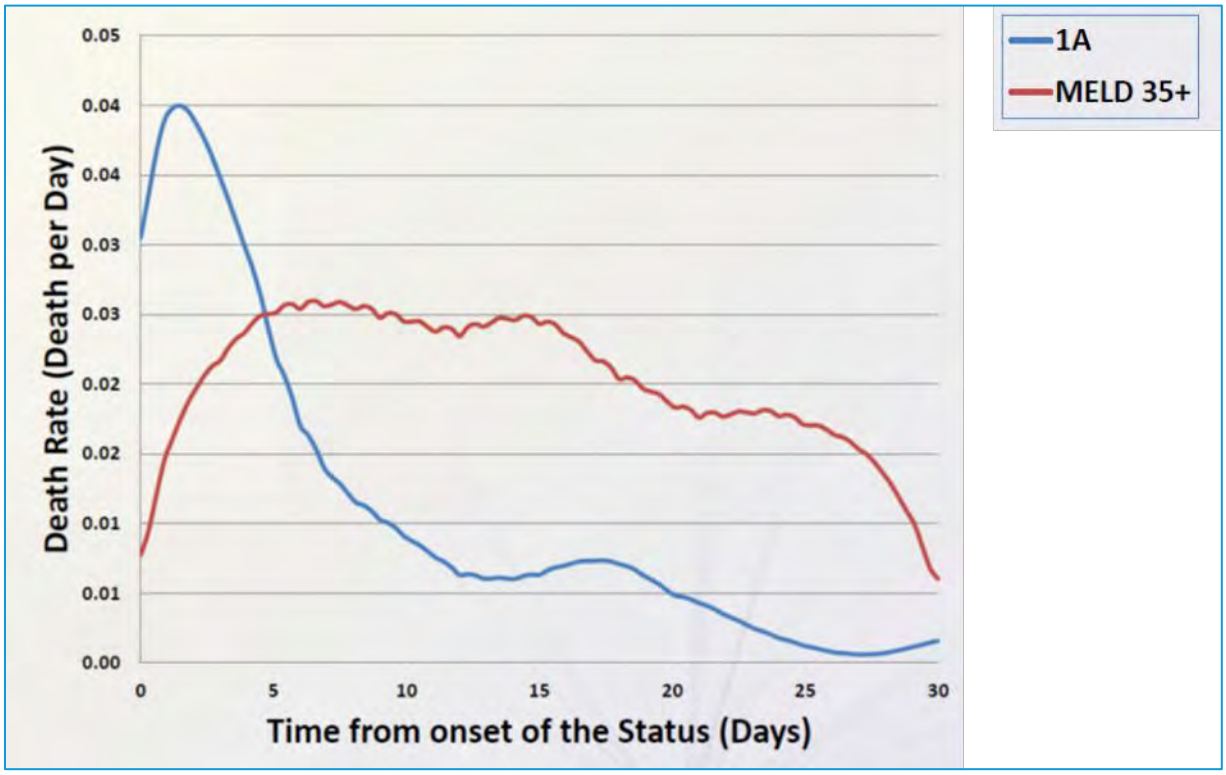
As indicated in **Figure 13**, Status 1 candidates have a life expectancy of less than 14 days, and their risk of death during the first 5 days after listing is significantly higher than that of candidates with MELD score of 35 or higher.[95] Because candidates assigned Status 1A or 1B need an organ so urgently, the Committee wanted to ensure that they continue to have the broadest access to transplant as fast as possible. Because of this urgency, the importance of waiting time at that status (which is a tie breaker

[94] Additionally, organs allocated at lower sequences are more likely to be older and obese. Edwards, E. B., Harper, A. M., Hirose, R., & Mulligan, D. C. (2016). The impact of broader regional sharing of livers: 2-year results of “Share 35”. *Liver Transplantation, 22*(4), 399-409. doi:10.1002/lt.24418

[95] Othoff, Kim, et al. 2012 High MELD/PELD Versus Status 1A: Who Lives, Who Dies, and When? The 12th Joint Annual Congress of the American Society of Transplant Surgeons and The American Society of Transplantation. https://www.srtr.org/media/1110/atc2012_olthoff.pdf

within classifications) is amplified and becomes a more important consideration than distance. Additionally, only a small number of candidates are listed with these statuses at any given time,[96] so there is less efficiency (in terms of time to make an individual offer or in terms of total numbers of organs being flown) to be gained by further stratifying this group.

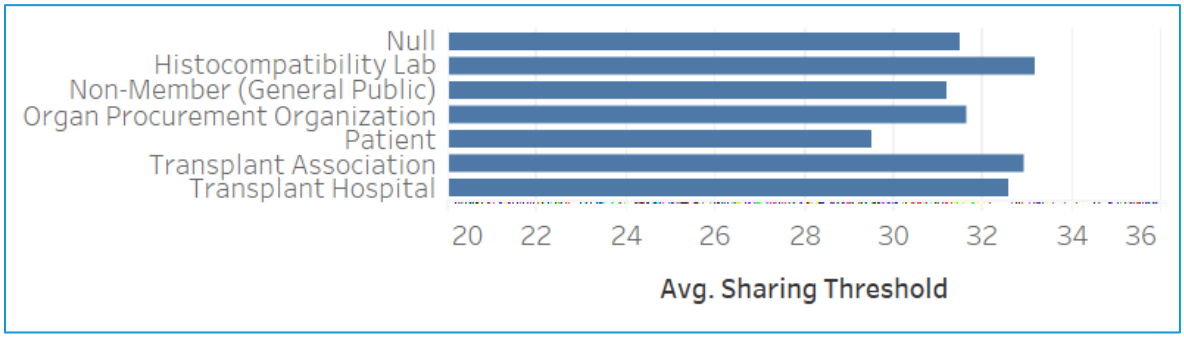
Figure 13: Waitlist Mortality Over Time



This means livers will be allocated to all Status 1A and 1B candidates registered at hospitals, within 500 nm of the donor hospital, the largest circle. The Committee then chose to distribute livers to another urgent group of candidates distributed in the next largest circle first, 250nm. The Committee had to decide what the threshold should be for allocating to this next largest circle. For candidates below this MELD/PELD threshold, the first circle would be even smaller, 150nm.

Most of the commenters who expressed an opinion on the MELD threshold were transplant hospitals.

Figure 14: Feedback on MELD Threshold by Member Type



[96] On Nov. 10, 2018, there were seven Status 1A candidates and thirty Status 1B candidates on the list. See https://optn.transplant.hrsa.gov/data/view-data-reports/national-data.

The public comment proposal included a MELD/PELD threshold of 32 for the 250nm circle. Roughly, 10% of commenters preferred this threshold.

The SRTR also modeled B2C with a MELD threshold of 35 for the 250nm, which was intended to be similar to the current policy.[97] This option was largely preferred by commenters who also supported smaller circles. It was supported by approximately 24% of commenters. Many of these commenters also preferred to keep the allocation as similar as possible to the version passed in December 2017.

The majority of commenters preferred a MELD threshold of 29, which is what the Committee now proposes. This option was not modeled by the SRTR, but appeared to be a point at which the difference in mortality rates increased more dramatically, thereby most effectively promoting access to transplantation for the most urgent candidates.[98]

One commenter proposed a threshold of 25, stating that it would decrease mortality rates and several commenters proposed a threshold of 15 in order to increase distribution and further reduce waitlist mortality and variance in median MELD at transplant. Some also asserted that they believed that any higher threshold was a violation of the Final Rule because it provided more access only for patients with higher scores.

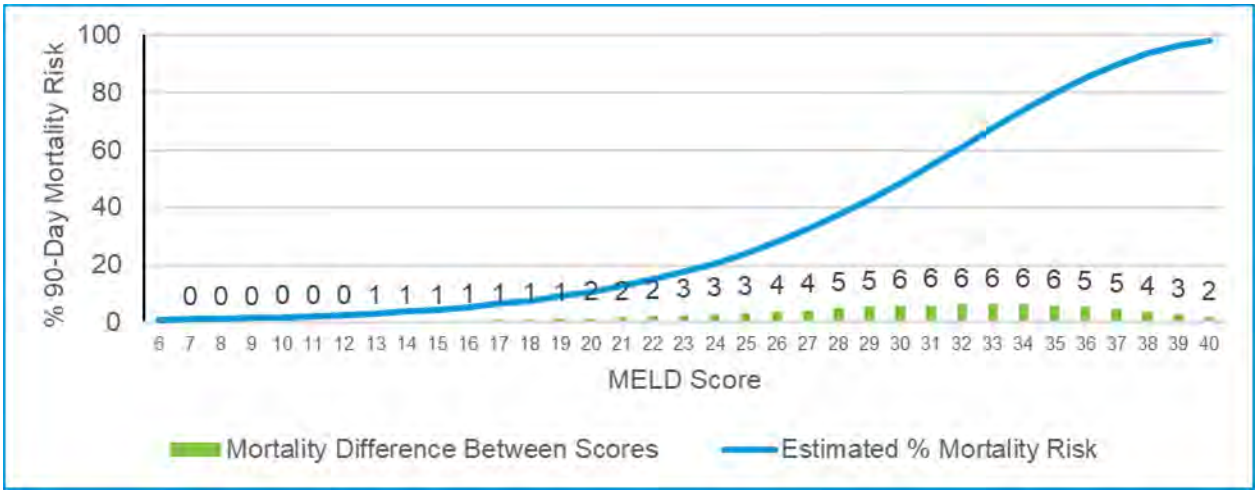
Several commenters suggested that there was no need for a threshold. Instead of offering livers to transplant hospitals within 250 nm of the donor hospital through MELD 29, they suggested eliminating the 150 nm circle and making the first circle size for allocation 250 nm. This would include all candidates together in broader distribution. However, the 150 nm circle improves the efficiency of placement for all of the reasons explained above in the *Circle Sizes* section and the Committee only excluded it for the patients whose urgency justified a different prioritization.

The Committee chose to model B2C with two possible MELD thresholds to evaluate the difference the different thresholds make.[99] For the first threshold, the model kept the same threshold, 32. The second model used a threshold of 35, close to the point where the difference between scores begins to decrease and the mortality curve begins to flatten out.

For MELD scores between 28 and 36, a one point MELD score increase is associated with at least a five-percentage point increase in 90-day mortality risk. Based on the fact that the mortality curve increases more steeply at that point, the Committee previously selected 32 as the threshold for the 2017 December proposal.[100] 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 under the December 2017 proposal.

[97] OPTN/UNOS Policy 9: Allocation of Livers and Liver-Intestines
[98] Figure 15: Mortality Risk by MELD score
[99] OPTN Liver and Intestinal Organ Transplantation Committee Data Analysis Request, https://optn.transplant.hrsa.gov/media/2639/updated-item_23_livercommittee_full_20180719.pdf (Accessed Nov. 9, 2018).
[100] *Enhancing Liver Distribution*, OPTN/UNOS Liver and Intestinal Transplantation Committee, December 2017, https://optn.transplant.hrsa.gov/media/2329/liver_boardreport_201712.pdf (Accessed Nov. 16, 2018).

Figure 15: Mortality Risk by MELD score



In comparing the two models (32 vs. 35), the change in the MELD threshold showed minimal impact 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) although the variance in MMaT was better with a threshold of 32 than 35. The lower 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).

A threshold of 32 is an improvement in the variance in MMaT compared to 35 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 used the two modeling results provided by modeling 32 and 35 to extrapolate that a threshold of MELD 29 would be similar in change and produce more of an improvement in variance.

A threshold of 29 is more in line with the inflection point between 28 and 29 at which the difference in waiting list mortality by MELD scores increases to at least 5%, and would mean more organs distributed at the 250nm distance earlier.[101] 35% of commenters preferred a MELD threshold of 29 for the 250 nm circle, which is what the Committee now proposes. This was also the preferred MELD threshold for patients during public comment.[102] This option was not modeled by the SRTR, but appeared to be a point at which the difference in waitlist mortality rates increased more dramatically, thereby most effectively promoting access to transplantation for the most urgent candidates.[103]

In addition to selecting a MELD 29 threshold for the 250 nm unit of distribution, the Committee also modeled thresholds for the next less urgent group. The Committee modeled distributing livers to all candidates with a MELD score of 15-28 within 150 nm of the donor. The Committee chose to group the MELD or PELD scores from 15 to 28 together, and the scores less than 15 together. Between MELD of 28 and 29 is the point when the difference in 90 day mortality rate first increases by at least 5% for each additional MELD point, so for candidates with MELD scores above 28, the difference between 4 points represents a larger difference in the candidate's severity of disease than a difference of 4 points below that. [104]

The Committee discussed whether it is appropriate to prioritize a candidate with a MELD of 28 who was 151 nm away from the donor hospital after candidates with a MELD of 15 who were 149 nm away from

[101] Figure 15: Mortality Risk by MELD score
[102] See Figure 14.
[103] Ibid.
[104] Ibid.

the donor. This could create situations where donor livers would be allocated to less medically urgent candidates who are located geographically closer to the donor. There is an increased need for efficiency in the placement of organs that have not been accepted in offers to MELD 29 and higher candidates. MELD scores less than 15 have 1% or less difference in 90-day mortality rate between scores and candidates are very unlikely to be transplanted at a score less than 15.[105]

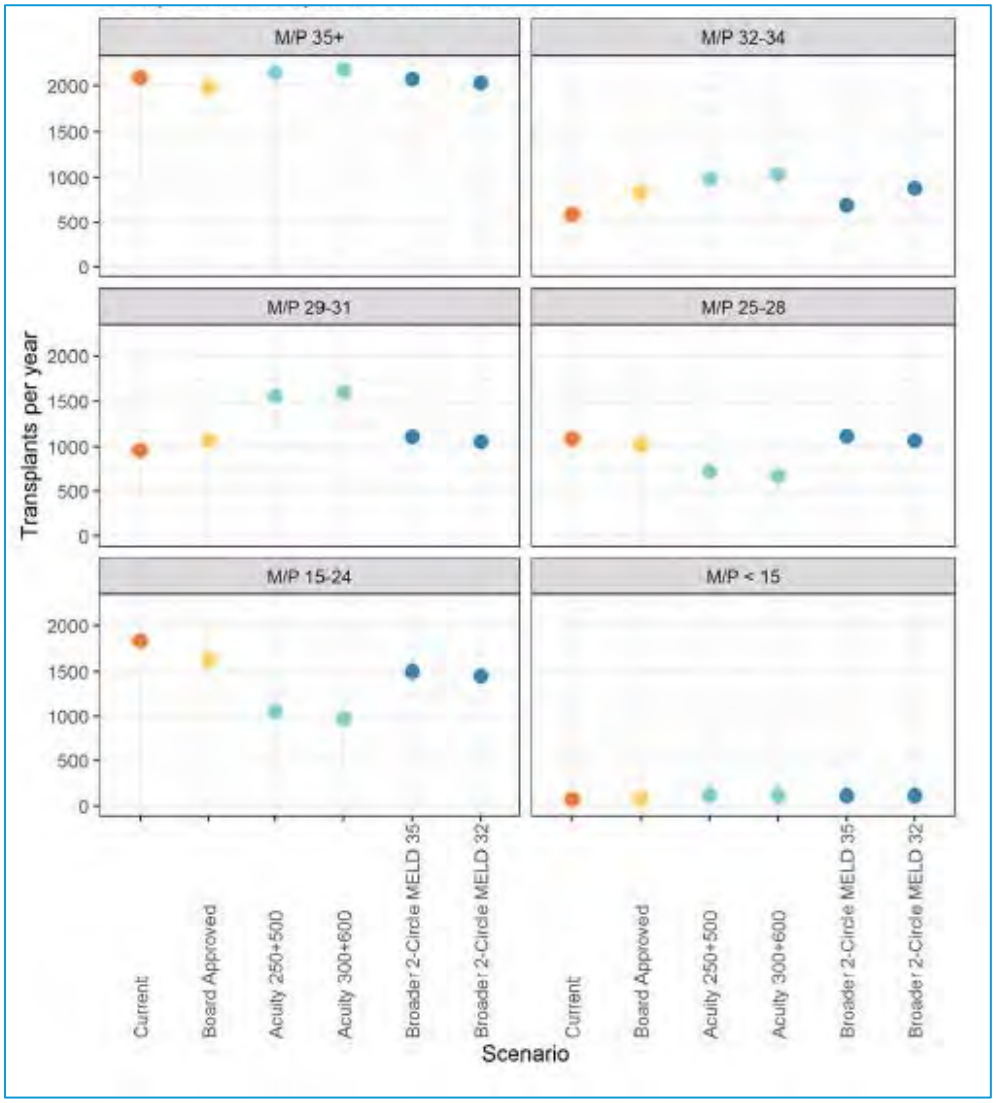
Table 7: Number of candidates on the liver waiting list on 10/4/2018

Liver Medical Urgency Status	N	Percent
Status 1A	13	0.1%
Status 1B	40	0.3%
MELD/PELD < 15	5,716	41.5%
MELD/PELD 15 – 19	2,275	16.5%
MELD/PELD 20 – 24	1,307	9.5%
MELD/PELD 25 – 28	741	5.4%
MELD/PELD 29 – 31	347	2.5%
MELD/PELD 32 – 34	183	1.3%
MELD/PELD 35+	116	0.8%
Temporarily Inactive (Status 7)	3,020	22.0%
Total	**13,758**	**100%**

Figure 16 shows the transplant counts by MELD/PELD score, for the current and December 2017 proposals as well as the modeled options. In all scenarios, the MELD/PELD less than 15 group is rarely transplanted.

[105] Figure 15: Mortality Risk by MELD score

Figure 16: Transplant Counts by Allocation MELD/PELD[106]



Given the apparent inflection point in waitlist mortality and the fact that it would include more patients in the broader distribution circle, the Committee proposes a MELD threshold of 29 as the best balance of the competing needs of efficient management of organ placement and promoting patient access in the OPTN Final Rule. The selection of 29 as the proposed threshold for the 250 nm circle was based on the additional access it allows patients when compared with the current policy or the December 2017 proposal while only increasing air travel and its associated risks and costs somewhat. This was the approach the Committee took in balancing efficiency and access by urgency.

3. Pediatric Donor Allocation

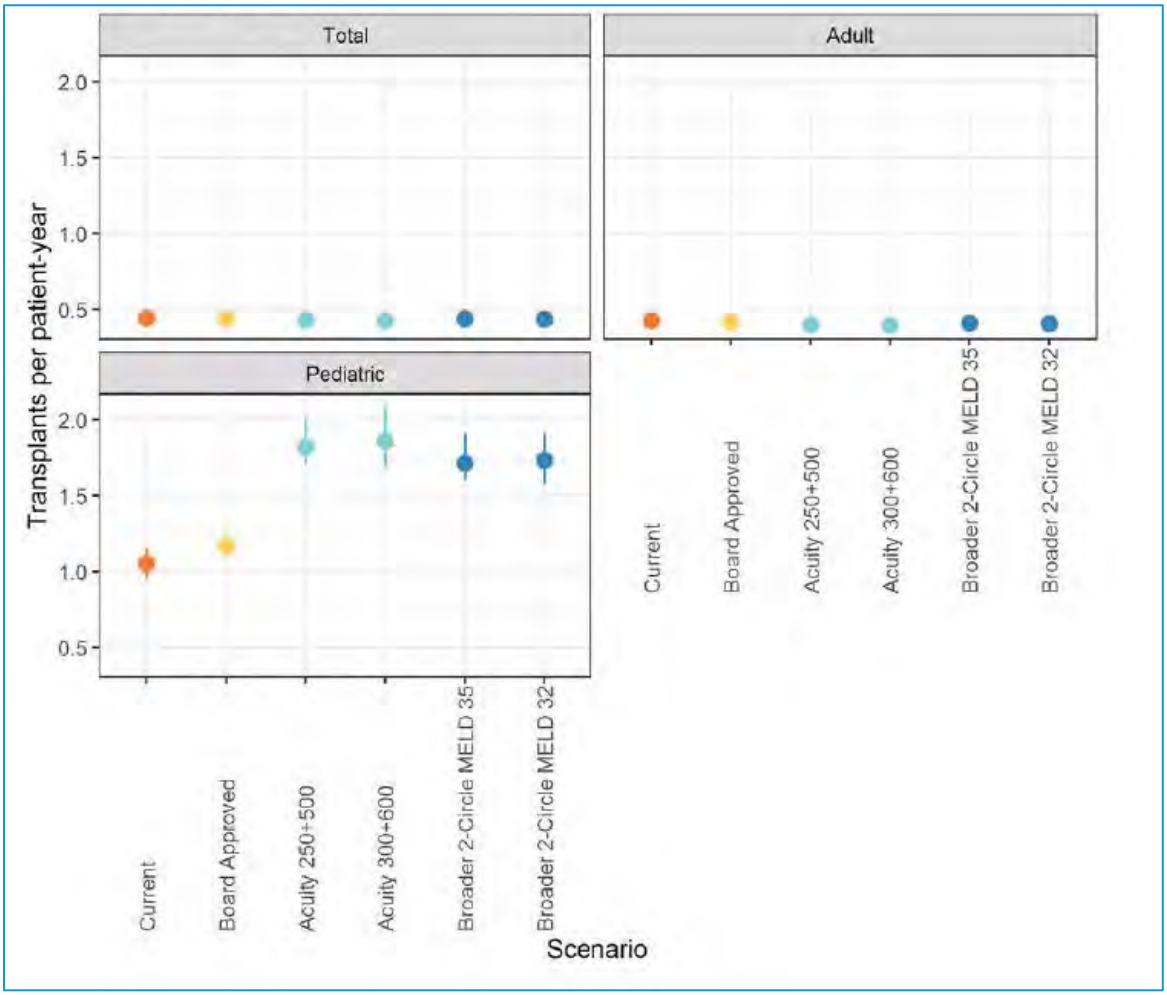
The Pediatric Committee provided feedback that pediatric candidates were disadvantaged and would benefit from having increased priority for pediatric donor livers. In response, the Committee proposes

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

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.[107] 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.[108] 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[109], and there are fewer transplant programs that perform pediatric transplants, there is less efficiency gained by limiting allocation to a smaller geographic area and the balance of factors shifts from those considered with the adult population.

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 17: Transplant Rates by Age



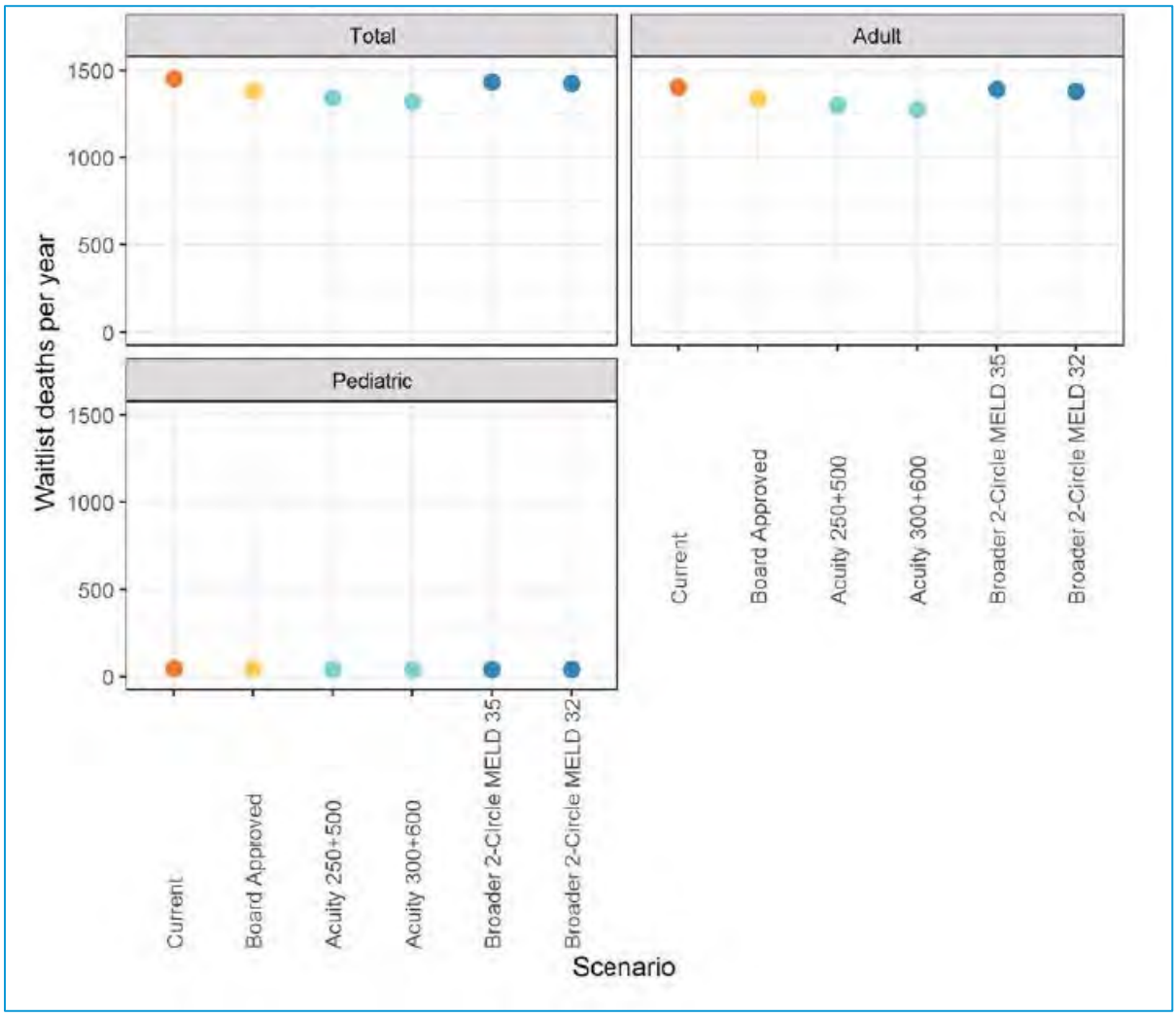
[107] There is a directive for the OPTN to "address the unique health care needs of children" in NOTA, 42 USC §273 et seq., and a statement "that there is a reasonable basis for giving preference to pediatric transplant candidates for allocation." in the OPTN/UNOS "Ethical Principles of Pediatric Allocation," https://optn.transplant.hrsa.gov/resources/ethics/ethical-principles-of-pediatric-organ-allocation/ (Accessed Nov. 10, 2018)

[108] Based on OPTN/UNOS data.

[109] In 2017, there were 8,082 liver transplants in the US, and of those only 599 were into candidates less than 18 years old. OPTN/UNOS National Data, accessed November 10, 2018, https://optn.transplant.hrsa.gov/data/view-data-reports/national-data.

Additionally, the waitlist mortality for pediatric candidates did not show a statistically significant change compared to the current state or the December 2017 proposal modeling results.

Figure 18: Mortality Counts by Age



In public comment, commenters responded favorably to both the separate pediatric allocation schedules and the concept of not capping pediatric standardized MELD scores.

4. Allocation of DCD and older than 70 year old donors

The Committee proposes a different allocation sequence for DCD donors and donors over 70 as this subset of donor livers is more likely to be discarded and more likely to be transplanted locally under the current allocation.[110] In order to reduce the likelihood of discard for these organs, the Committee provided more local priority, with all MELD/PELD scores of at least 15 allocated to 150 nm first.

[110] *Enhancing Liver Distribution*, OPTN/UNOS Liver and Intestinal Transplantation Committee, December 2017, https://optn.transplant.hrsa.gov/media/2329/liver_boardreport_201712.pdf (Accessed Nov. 16, 2018).

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.

The Committee proposes that the changes to NLRB take effect prior to the distribution changes in this proposal which will allow sufficient time between implementation dates for all existing exceptions to be reviewed under the new system. This will allow for correction of inequities and inefficiencies in exception scoring in the current regional review board system.[111]

The Committee proposes changes to the following areas of exception scoring policies.

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.[112]

The Committee considered MMaT for the nation, a 500 nm circle, a 250 nm circle, or a 150 nm 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 250 nm 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

[111] *Proposal to Establish a National Liver Review Board*, OPTN/UNOS Liver and Intestinal Transplantation Committee, June 2017, https://optn.transplant.hrsa.gov/media/2176/liver_boardreport_nlrb_201706.pdf (Accessed Nov. 16, 2018).
[112] Scientific Registry of Transplant Recipients, "LI2015_03 DR1." October 14, 2016.

modeled would perform similarly. The 500 nm cohort has a slightly smaller range of MMaT scores and is less aligned with what they would be if based on DSA.

Table 8: Geographic Grouping for Basis of MMaT

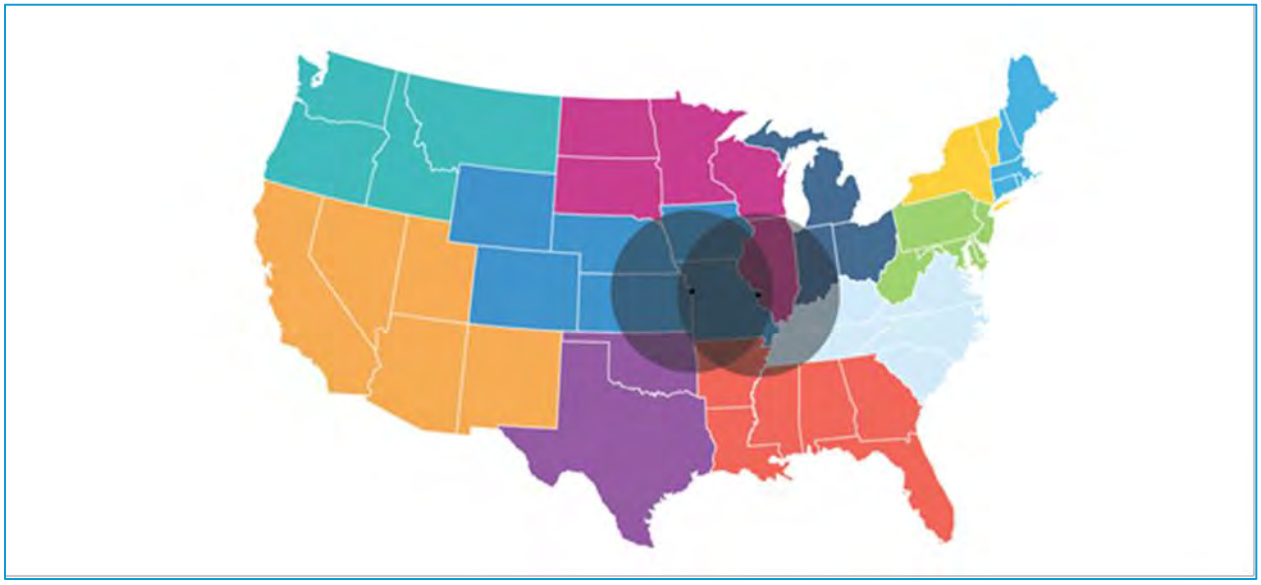
	By Transplant Center + all TXCs within 150 NM	By Transplant Center + all TXCs within 250 NM	By Transplant Center + all TXCs within 500 NM	By DSA	By Region
Minimum MMaT	19	19	19	19	26
Maximum MMaT	36	36	35	37	34
# Centers with MMaT=DSA MmaT	50 of 138 (36%)	50 of 138 (36%)	46 of 138 (33%)	-	-
# Centers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

Based on OPTN data as of July 20, 2018.

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

Figure 19: 250nm Radius Circles Around a Liver Program And Donor Hospital



The Committee proposes using a cohort of liver transplant recipients within 250 nm of the transplant hospital for all candidates with a MELD score (any candidates registered at age 12 or older) to calculate MMaT. 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 9: 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

Based on OPTN data as of August 3, 2018.

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 every 180 days. The Committee would not include 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.

Additionally, the Committee proposes that NLRB changes take effect at least 3 months before allocation changes, in order to provide sufficient time for exception scores to be adjusted and for members to handle the changes.

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. Time Periods

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. Allocation of organs from DCD donors and donors over 70 years old
6. Proximity Points
7. Other Methods of Hepatic Support
8. Allocation of O Donors
9. Sorting Within Allocation Sequences
10. Variances

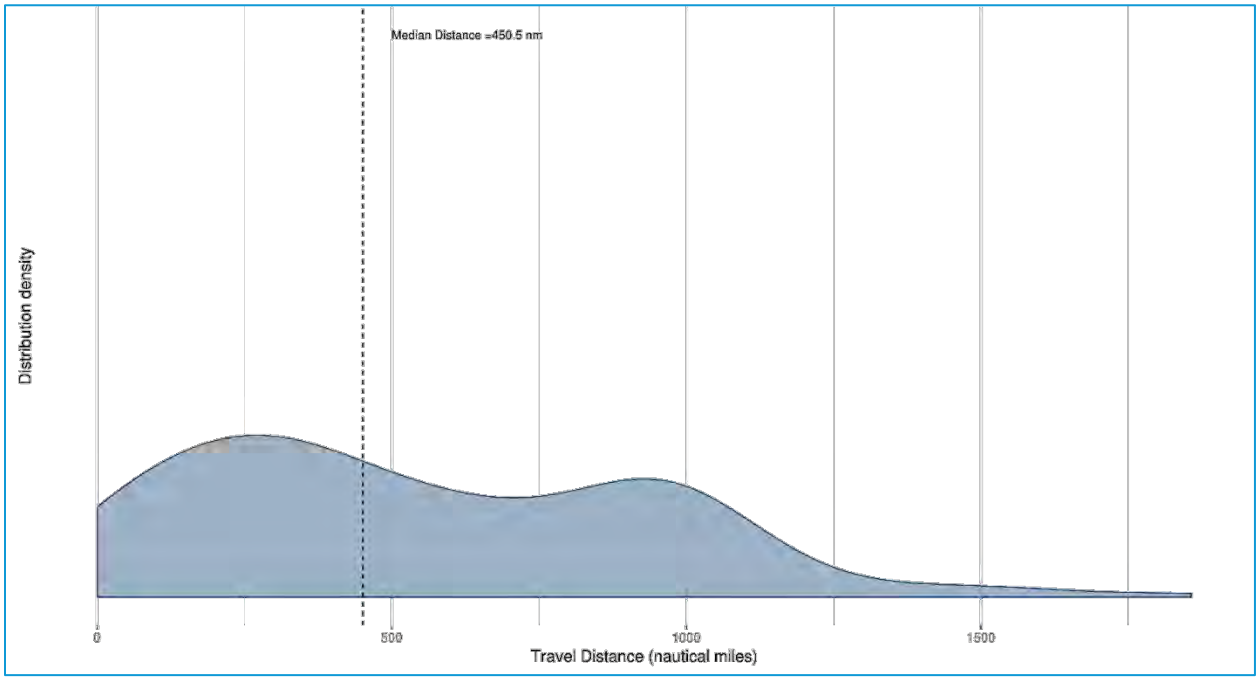
1. Liver-Intestine priority

The Committee discussed the priority received on the match and in points for candidates who also need an intestine. Although the numbers are smaller[113], 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. Eighty-eight percent of the transplants were of status 1 candidates. Seventy-two percent 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.

Figure 20: Distribution of Travel Distances from Donor Hospital to Transplant Hospital, Deceased Donor Intestine Transplant Recipients in the U.S. During, 1/1/2017 to 5/31/2018



Based on OPTN data as of September 21, 2018.

[113] 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.

The median 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"[114], while quickly moving to a nationwide allocation sequence to ensure that organs are distributed as broadly as possible respects the Final Rule directive not to base access on a candidate's place of listing unless needed.[115]

The Committee proposes the following intestine allocation sequence:

Table 10: Intestine Allocation Sequence

Classification	Candidates within this distance from the donor hospital:	Who are:
1	500nm	Status 1 and a blood type identical to the donor
2	500nm	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	Status 2 and a blood type identical to the donor
6	500nm	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

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 allocated to liver candidates as similar as possible to the current system so that no existing candidates are disadvantaged.[116] 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 29 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

[114] 42 C.F.R § 121.8(a)(5).
[115] Ibid.
[116] 42 C.F.R § 121.8(a)(5).

effort to keep within the Final Rule guidance not to create new inefficiencies in the administration of organ placement.[117]

The commenters that expressed an opinion during the public comment period were in support of the proposal in regard to SLK. The proposal as presented in public comment included a MELD threshold of 32 for 250 nm for SLK. After public comment, when the Committee chose to lower the threshold for allocating livers alone to 29, the threshold for SLK was also lowered.

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 for adults. This cap would prevent any standard exception from being assigned to an adult candidates over 28, 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. Allocation of organs from DCD donors and donors over 70 years old

In December 2017, the Board passed a policy 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.[118] This is consistent with the OPTN Final Rule requirement to make the best use of donated organs.[119] 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.

The responses in public comment were favorable on this concept.

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.[120] 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.

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[117] 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."

[118] 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."

[119] 42 C.F.R § 121.8(a)(2).

[120] *Enhancing Liver Distribution*, OPTN/UNOS Liver and Intestinal Organ Transplantation Committee, November 2017, https://optn.transplant.hrsa.gov/governance/public-comment/enhancing-liver-distribution/ (Accessed Nov. 16, 2018).

7. 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."[121] Currently, this is being used for hepatocyte transplantation, which is rarely done.[122] It is rare that there are any 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.

8. Allocation of O Donors

The Committee changed the allocation of blood type O donors. Previously, O donors were allocated to all O candidates, and B candidates with a MELD of at least 30 before being offered to any other blood type candidates. B Candidates with a MELD of 29 or lower were in the same category as all other blood type candidates. Instead, the Committee proposes that after offering these donors to all O candidates and B candidates with a MELD of at least 30, they would be offered to all other B candidates before the A and AB candidates. Following public comment, this change was incorporated into the allocation tables in order to make the order more clear.

9. 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 180 days 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 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 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.

10. 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.) Therefore, the committee recommends no change to this variance.

- *ABO*: There exists a variance in Hawaii regarding the allocation of blood type O donors.

[121] OPTN/UNOS Policy 9.6.B: Allocation of Livers for Other Methods of Hepatic Support.
[122] For background on hepatocyte transplantation, see Fox, Ira J., "Hepatocyte Transplantation". *Gastroenterology & Hepatology*, Vol.10 Issue 9, (2014) pp. 594–596.

The public comment proposal did not include a variance for Puerto Rico but did include one for Hawaii. For blood type O donors recovered in Hawaii, the variance changes the order of allocation to include any blood type recipients in the same classifications. This removes the priority for O and B candidates that would otherwise exist when allocating O donors and allows for allocation of O donors to A and AB candidates in Hawaii before national offers to O and B candidates. The Committee was still considering whether to apply the variance to Puerto Rico at the time of public comment and specifically requested feedback from the community.

The Liver Committee is now proposing changes to this variance that were recommended by the Minority Affairs Committee (MAC). The MAC reviewed the similarities between Hawaii and Puerto Rico, in terms of their geographic isolation and ethnic populations and recommended 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."[123]

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.[124]

Commenters who expressed an opinion on the variance all agreed that it should continue to apply to Hawaii. Those who thought it should not apply to Puerto Rico didn't believe the same logistical issues exist for traveling to the mainland from Puerto Rico that exist for Hawaii.

Although most commenters did not take a stance on this question, those that did were fairly evenly split, with slightly more favoring extending the variance to Puerto Rico.
Commenters who supported applying the same variance to Puerto Rico pointed to equity and assisting the population of Puerto Rico. Many comments regarding the ABO variance showed some confusion regarding the rationale for this variance and its relevance for Puerto Rico. Many commenters focused on the isolation of Puerto Rico.

The Committee proposes the blood type variance apply to organs recovered in Hawaii and Puerto Rico. The variance will be effective for two years. Research data is already collected as part of the information about donors and candidates already required. The plan for analysis of the variance is detailed in the section below entitled "How will the sponsoring Committee evaluate whether this proposal was successful post implementation?"

- *Region 9*: The 2017 liver distribution proposal made changes to the New York / Region 9 liver variance, which treated the region as the first unit of allocation instead of the DSA for livers recovered in Region 9. The Committee now recommends removing that variance since neither DSA nor region will be used for allocation under this proposal.

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.

[123] *Select Recommendations of the OPTN/UNOS Liver and Intestinal Organ Transplantation Committee to the Board of Directors*, OPTN/UNOS Liver and Intestinal Organ Transplantation Committee, Nov. 2008.
[124] Based on OPTN/UNOS data as of September 24, 2018.

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).
- *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.

Was this proposal changed in response to public comment?

The Committee made several changes in response to public comment. They included:

1. Changing the MELD threshold to 29 for liver allocation and SLK
2. Adding an exception to blood type O allocation for Puerto Rico
3. Adding a provision for treating livers from Alaska as if they were recovered in Seattle
4. A recommendation that the changes to allocation will not take effect until at least 3 months after the implementation of the NLRB.

The rationale for the changes to the MELD threshold and blood type variance are explained in more detail in other sections. (*See* MELD Threshold; Variances; and Non-Contiguous Programs.)

The Committee chose to request at least three months in between the implementation of the NLRB changes and the implementation of the allocation changes. This would allow the community additional time to absorb the changes to practice that will take place. For candidates with existing exception scores, those scores will continue until the exception is due to extend. The longest exceptions only need to be extended after 90 days. The changes to allocation are based on the assumption that exception scores are assigned according to the NLRB criteria. The Committee requested this delay between implementation dates so that the exception scores would all be in line with the new criteria before the allocation changes take effect.

Additionally, there were a few clerical changes made post-public comment. The content of Policy 9.8.K was inadvertently marked as removed in the public comment proposal. This language is no longer marked for removal. The committee intended to continue the rules for adolescent liver-intestine allocation. The definition of circle is removed now and was not in the public comment proposal. Since the proposal does not use that term, the definition is no longer necessary. Changes to adult allocation and proximity points were not marked as changes in the public comment proposal and are now marked as such. There were also changes to formatting and numbering.

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.[125] 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 and pediatric).”[126] 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.

[125] Based on OPTN/UNOS data, accessed October 4, 2018.
[126] 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)

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."[127] However, this requirement does not require that all proposals specifically reduce inequities. Sec. 121.4 lists a variety of policy proposals that that OPTN must address but it is unreasonable to expect that every proposal will simultaneously address all of these goals.[128] Additionally, the OPTN shall develop allocation policies that "promote patient access."[129] The group of patients for whom the proposal is intended to promote access are liver and intestine candidates on the waitlist, as this is an allocation policy developed under the auspices of §121.8(a) of the OPTN Final Rule, requiring the OPTN to develop "policies for the equitable allocation of cadaveric organs among potential transplant recipients."[130] Overall, modeling showed that, for candidates registered on the waiting list for liver, "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."[131]

For example, the modeling shows similar results for transplant rates, waitlist mortality, and post-transplant mortality regardless of public or private insurance, as seen in Figures 21-23[132].

[127] 42 C.F.R § 121.4(a)(3)(iv).
[128] For example, it is unlikely that an OPTN policy proposal would simultaneously address allocation policies, training requirements for surgeons, and the process for nominating officers of the Board of Directors.
[129] 42 C.F.R § 121.8(a)(5). In promoting patient access, OPTN policy proposals typically promote access for an identified class of patients. This is in line with the OPTN's incremental and evidence based approach to policy development. It would be unreasonable to expect every allocation proposal to increase access for all patients. At a minimum, allocation proposals typically focus on one organ system at a time. Frequently, allocation proposals will seek to increase access for specific vulnerable populations such as pediatrics or highly sensitized candidates.
[130] 42 C.F.R § 121.8(a). See also id. at §121.2 (defining "potential transplant recipient" as "a transplant candidate who has been ranked by the OPTN computer match program as the person to whom an organ from a specific cadaveric organ donor is to be offered; and defining "transplant candidate" as "an individual who has been identified as medically suited to benefit from an organ transplant and has been *placed on the waiting list by the individual's transplant program*." (emphasis added.))
[131] 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)
[132][132] Ibid.

Figure 21: Transplant Rates by Insurance Status

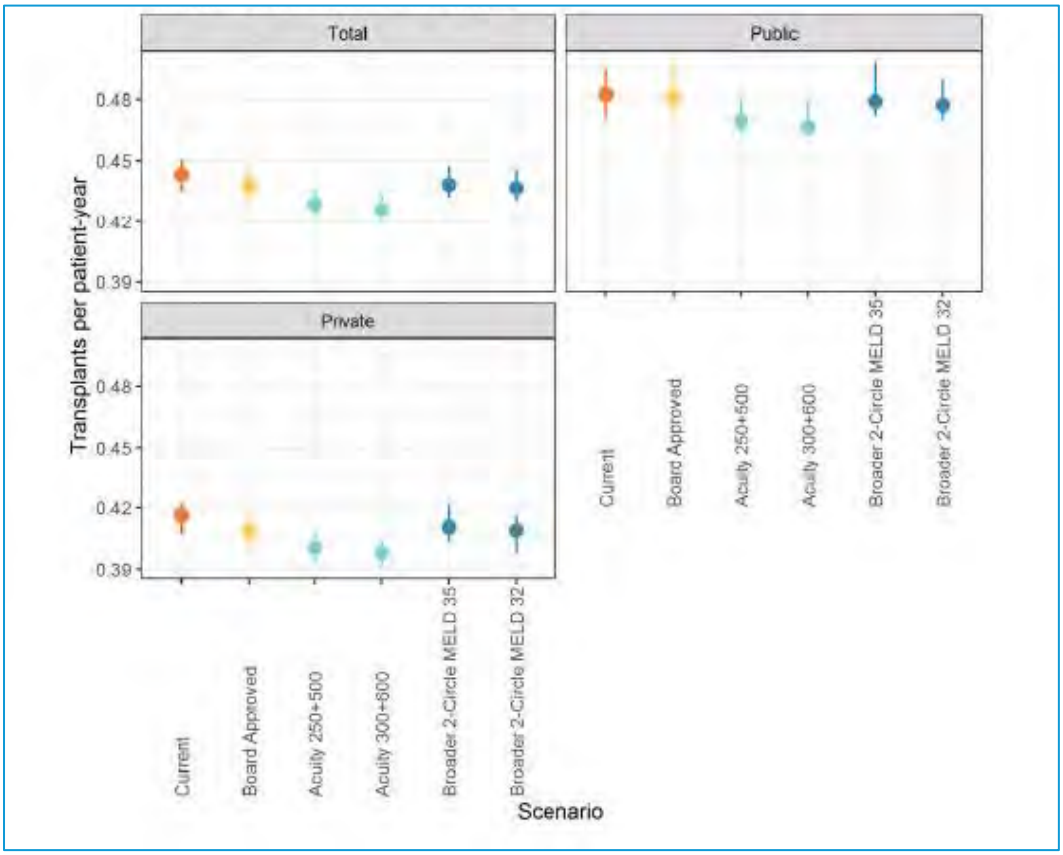


Figure 22: Waitlist Mortality Rates by DSA and Insurance Status

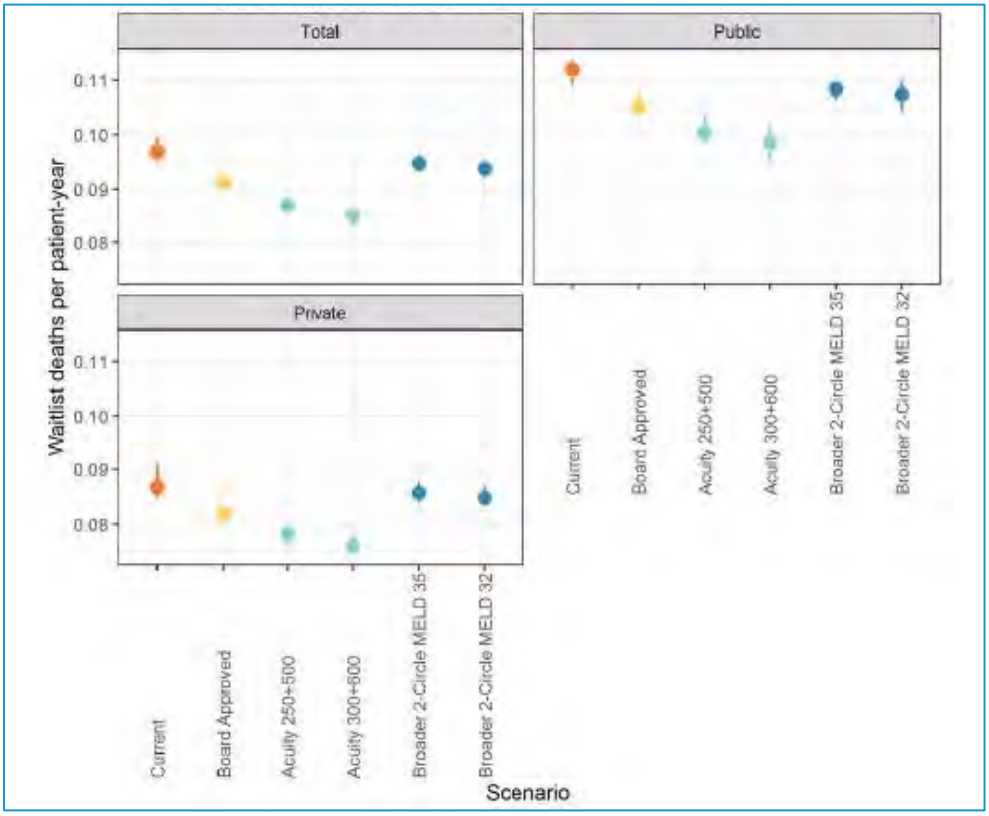
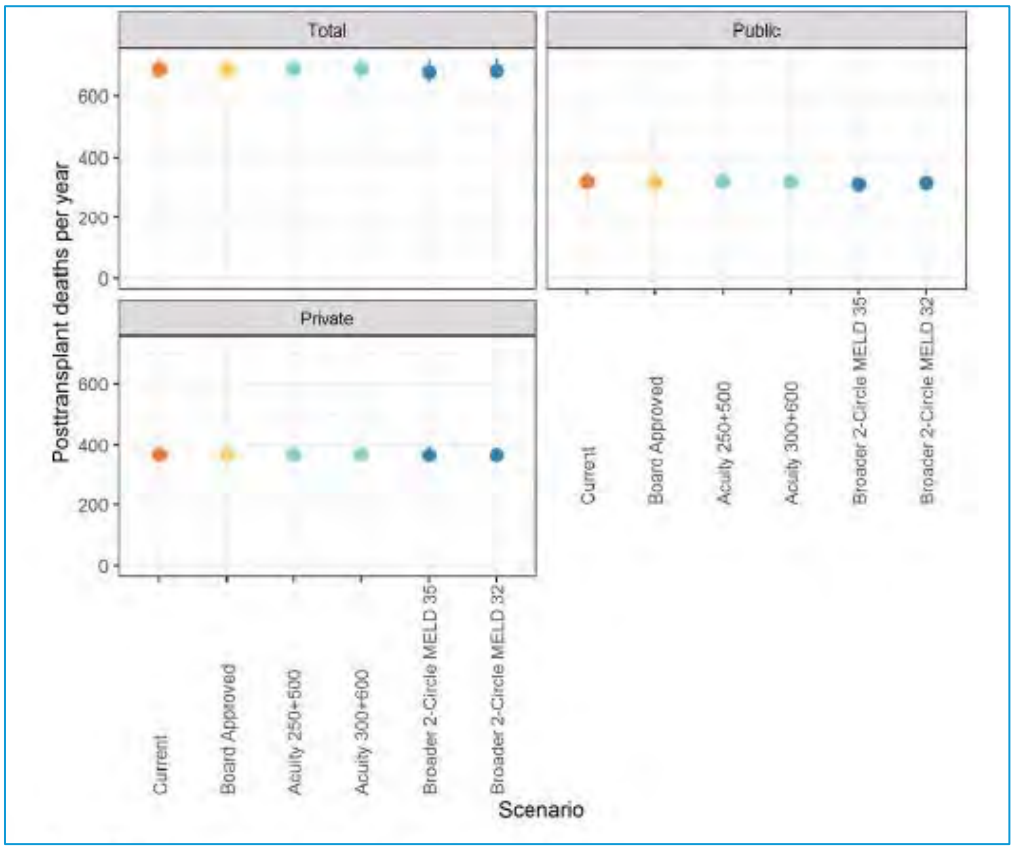


Figure 23: Post-transplant Mortality Counts by Insurance Status



Some of the commenters were concerned with the impact on patients with lower socio-economic status, particularly those in rural areas with less access to transplant care.

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 and acuity circle models 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. Some commenters suggested that the Committee consider assessing SES based on Cumulative Community Risk Score (CCRS). In fact, the Committee previously undertook such an analysis. "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."[133]

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 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.[134]

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 distribution 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).

[133] 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.
[134] 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).

Figure 24: Depiction of 500, 1000, and 1500 nm circles around Alaska, Hawaii, and Puerto Rico

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.[135] 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 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 distribution, 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. Because discard rates could go up by removing regional distribution, the Liver Committee should monitor these trends in its post-implementation monitoring plan.

The Ad Hoc Geography Committee reviewed the impact of distance-based allocation on Alaska, Hawaii, and Puerto Rico and 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)

[135] 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.

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 recommended individual organ-specific committees not create different rules that apply only to the noncontiguous states. Thoracic allocation zones have operated without special rules for noncontiguous states for many years. This recognizes and respects the logistical issues represented by these programs. The Geography 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.

The Committee also received comments from the public requesting an exception for Alaska. They proposed that since Alaska does not have any transplant hospitals and is geographically isolated that it is not feasible to transport them to some parts of the nation, livers recovered in Alaska be treated as if they were recovered in Seattle (where they are currently frequently flown). In order to avoid needless offers of livers from Alaska to distant transplant hospitals, and to make the best use of donated organs, the Committee proposes treating livers and intestines recovered in Alaska as if they were recovered at the Seattle-Tacoma Airport. The Committee chose the Seattle-Tacoma Airport as the virtual location for these donors because they would be flown in to this airport in most cases.

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?

This is an enterprise level effort for the OPTN.

Programming and member education:
IT programming work will be required and reflect the bulk of hours on 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.

Implementation and monitoring
The OPTN will coordinate implementation efforts so the NLRB changes will be in place at least 3 months before the liver distribution changes. This will include communication and member outreach on the changes, and monitoring the impact of the changes.

This proposal is replacing the not-yet-implemented *Enhancing Liver Distribution* from December 2017. The estimate for the 2017 project was 11,620 hours. The 2018 proposal is estimated to require 4,470 hours to implement. As a result, there is net savings of approximately 6,850 hours.

Other considerations:
If access to transplant is equalized across geography, there may be less incentive for patients to register at multiple transplant programs. If that happens, then there may be a slight decrease in the number of annual candidate registrations and registration fees paid. As of October 2018, there were 266 liver transplant candidates listed at more than one liver transplant program in the U.S.[136]

How will members implement this proposal?

Histocompatibility Laboratories

This proposal will have no operational or fiscal impact on histocompatibility laboratories.

Transplant Hospitals

Implementation costs will be minimal. Small amount of administrative time may be needed to on-board staff to the changes. The time frame for these changes may be one to three months; much of this would be educating transplant candidates on the new changes and developing materials for the same.

Ongoing costs were broken down by phase of transplant.

- Pre-transplant costs may increase slightly and will vary from program to program due to varying costing practices. SRTR modeling for this proposal noted that candidate waiting times will change across the U.S.; some programs may see longer waiting times and some programs may have shorter waiting times. Longer candidate waiting times may be associated with an increase in the cost of care.

- The greatest impact of costs is likely to be seen in the transplant phase. 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 OPOs outside their usual areas of operation.

  If a transplant program's case volume increases, or case volume remains unchanged and the percentage of fly-outs increases, an increased frequency of fly-outs will correlate with higher transportation costs. Flight costs currently range from $15,000-$25,000 per case may increase to $25,000-30,000 per case due to wider organ distribution and increases in flight time.[137] However, SRTR modeling noted median flight times were expected to change slightly between the current system and the B2C 35 model (MELD/PELD >/= 35 essentially unchanged, MELD/PELD 32-34 ~1.4 to ~1.8 hours, MELD/PELD 29-31 ~1.4 hours to ~1.65 hours, MELD/PELD 25-28 ~1.4 hours to ~1.68 hours, MELD/PELD 15-24 ~1.4 hours to ~1.75 hours, and MELD/PELD <15 ~2.1 hours to ~2.3 hours.)

  The distances and cold ischemic times may compel programs to invest in organ preservation technology to off-set the potential for delayed graft function. This investment is not required but would be a substantial capital purchase that varies across organs and device platforms. [138]

[136] Based on OPTN data as of October 31, 2018.
[137] Feedback from the Fiscal Impact Advisory Group in October 2018.
[138] Feedback from the Fiscal Impact Advisory Group in October 2018.

- Post-transplant costs for programs will be variable and reflective of case volume. Increases in post-transplant costs may be seen with organs having higher ischemic times and the potential for complications (higher levels of care, increase length of stay, return to OR, etc…).

In addition to the financial impact, transplant programs may feel strains on logistics from decreased availability of charter flights. Larger cities will have greater availability of commercial air traffic, and smaller cities will be more dependent on charter flights.

Payers' willingness to cover these increased costs is yet to be seen. A payer's contract period may determine the length of time until a transplant program is able to renegotiate changes to payer reimbursement. Recipients covered by commercial payers are excluded on the Medicare Cost Report, therefore not all of the increased costs will be allowed.

OPOs

OPOs may notice that the hospitals they currently work with most frequently may change and the patterns of travel may change. The fiscal impact of implementing this proposal will be minimal. A small amount of administrative time may be required to educate staff, though this can be accomplished through existing mechanisms. Staff time to research and make arrangements with other transportation providers may also be required.

Ongoing costs is the area where OPOs will likely experience the fiscal impact of this proposal. Existing costs for local cases should remain stable. Changes in ongoing costs will be associated with fly-outs, vary across OPOs, and are driven by case volume. These fly-out costs are passed through to the transplant centers in organ acquisition, transportation, and professional fees. The need for additional FTEs will also vary across OPOs. Variability in fly-outs will be seen across OPOs and may result in increased staff costs (communication center staff, perfusionist staff, facilities staff, quality staff, and data staff).

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. Analyses will be performed nationally and regionally where feasible and appropriate.
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
- Discard rates (Number of livers recovered for transplant and not transplanted)
- Utilization rates (Number of livers transplanted out of all organ donors)
- Organ travel distance, cold ischemia time, donor risk index
- Number and percent of livers transplanted within first classification tier of allocation following Status 1s
- Other metrics deemed relevant and necessary to the evaluation of the policy by the Liver and Intestinal Transplantation Committee at time of analysis

ABO Blood Type Variance

Using pre vs. post comparisons, analyses will be performed at approximate 6-month intervals as appropriate, up to 2 years, to identify trends and potentially unanticipated consequences of the variance. Analyses will be performed in comparison to the nation, and stratified by blood type where feasible and appropriate.
Metrics to be evaluated include:

- Number of deceased donor liver transplants
- Size and composition of the waiting list
- Waiting list mortality rates and transplant rates
- Discard rates (Number of livers recovered for transplant and not transplanted)

- Number and percent of organs distributed to and from Hawaii
- Number and percent of organs distributed to and from Puerto Rico

Policy or Bylaws Language

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

RESOLVED, that the creation of Policy 9.4D (Calculation of Median MELD or PELD at Transplant), as well as changes to Policies 1.2 (Definitions); 1.3.A (Acceptable Variances); 1.4.E (OPTN Computer Match Program Outages); 5.4.B (Order of Allocation); 5.10.C (Other Multi-Organ Combinations); 7.3.B (Allocation of Intestines); 9.1.A (Adult Status 1A Requirements); 9.1.C (Pediatric Status 1B Requirements); 9.1.D (MELD Score); 9.1.F (Liver-Intestine Candidates); 9.2 (Status and Laboratory Values Update Schedule); 9.2.A (Recertification of Status 1A or 1B); 9.3 (Status Exceptions); 9.4.A (MELD or PELD Score Exception Requests); 9.4.C (MELD or PELD Score Exception Extensions); 9.5 (Specific Standardized MELD or PELD Score Exceptions); 9.5.A (Requirements for Cholangiocarcinoma (CCA) MELD or PELD Score Exceptions); 9.5.B (Requirements for Cystic Fibrosis (CF) MELD or PELD Score Exceptions); 9.5.C (Requirements for Familial Amyloid Polyneuropathy (FAP) MELD or PELD Score Exceptions); 9.5.D (Requirements for Hepatic Artery Thrombosis (HAT) MELD or PELD Score Exceptions); 9.5.E (Requirements for Hepatopulmonary Syndrome (HPS) MELD or PELD Score Exceptions; 9.5.F (Requirements for Metabolic Disease MELD or PELD Score Exceptions); 9.5.G (Requirements for Portopulmonary Hypertension MELD or PELD Score Exceptions); 9.5.H (Requirements for Primary Hyperoxaluria MELD or PELD Score Exceptions); 9.5.I (Requirements for Hepatocellular Carcinoma (HCC) MELD or PELD Score Exceptions); 9.5.I.i (Initial Assessment and Requirements for HCC Exception Requests); 9.5.I.ii (Eligible Candidates Definition of T2 Lesions); 9.5.I.iii (Lesions Eligible for Downstaging Protocols); 9.7.B (Points Assigned by Blood Type); 9.8.C (Allocation of Livers by Blood Type); 9.8.D (MELD or PELD Points for Geographic Proximity to the Donor Hospital); 9.8.E (Sorting Within Each Classification); 9.8.E (Allocation of Livers from Non-DCD Deceased Donors at Least 18 Years Old and Less than 70 Years Old); 9.8.F (Allocation of Livers from Non-DCD Deceased Donors 11 to 17 Years Old); 9.8.G (Allocation of Livers from Non-DCD Deceased Donors Less than 11 Years Old); 9.8.H (Allocation of Livers and Liver-Intestines from DCD Donors or Donors at Least 70 Years Old); 9.8.J (Allocation of Liver-Intestines from Non-DCD Deceased Donors at Least 18 Years Old and Less than 70 Years Old); 9.8.K (Allocation of Liver-Intestines from Non-DCD Donors 11 to 17 Years Old); 9.8.L (Allocation of Liver-Intestines from Non-DCD Donors Less than 11 Years Old); 9.9 (Liver-Kidney Allocation); 9.10.A (Registration Accuracy); 9.10.B (Review of Status 1A and 1B Candidate Registrations); 9.10.C (Location of Donor Hospitals); 9.11.B (Closed Variance for Allocation of Blood Type O Deceased Donor Liver in Hawaii); 9.11.C (Closed Variance for Allocation of Livers Procured in Region 9) and changes to Bylaws Appendix M (Definitions) as set forth below, are hereby approved, effective pending notice to members and at least three months following the implementation of the National Liver Review Board.

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. ~~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. ~~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.

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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~~

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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

Classification	Candidates within this distance from the donor hospital:	Who are:
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

Adult liver c~~C~~andidates ~~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 9.1.C: Pediatric Status 1B* 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 from the date the exception is approved.

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.

Each approved MELD or PELD exception extension is valid for an additional 90 days beginning from the day that the previous exception or extension expired.

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 at time of registration 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 at time of registration 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'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:
   - Candidate selection criteria
   - Administration of neoadjuvant therapy before transplantation
   - Operative staging to exclude any patient with regional hepatic lymph node metastases, intrahepatic metastases, or extrahepatic disease
   - Any data requested by the Liver and Intestinal Organ Transplantation Committee

2. 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.

3. Submits cross-sectional imaging studies. If cross-sectional imaging studies demonstrate a mass, the mass must be single and less than three cm.
4. 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.
5. 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.
6. 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 (CF) 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 and active 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. PaO2 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 atransplant 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 *Table 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 liver candidate is registered on the waiting list for a kidney transplant at that 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 *Table 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 on the waiting list for a kidney transplant at that 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~~

1. 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.

2. 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 or 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.~~

~~**3.** 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.~~

9.7.B Points Assigned by Blood Type

For status 1A and 1B transplant candidates, those with the same blood type as the deceased liver donor will receive 10 points. Candidates with compatible but not identical blood types will receive 5 points, and candidates with incompatible types will receive 0 points. Blood type O candidates who will accept a liver from a blood type A, non-A_1 blood type donor will receive 5 points for blood type incompatible matching.

~~Within each MELD or PELD score, donor livers will be offered to transplant candidates with blood types identical to the deceased donor first, then to candidates who are blood type compatible, followed by candidates who are blood type incompatible with the deceased donor.~~

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~~, excluding proximity points~~ (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.E~~F~~ Allocation of Livers from Non-DCD Deceased Donors at Least 18 Years Old and Less than 70 Years Old

Livers from non-DCD deceased donors at least 18 years old and less than 70 years old are allocated to candidates according to *Table 9-10* below.

Table 9-10: Allocation of Livers from Non-DCD Deceased Donors at Least 18 Years Old and Less than 70 Years Old

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

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

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Classification	Candidates with a MELD/PELD score of at least	And within this distance from the donor hospital	Donor Type	Candidate Type
1	Adult or Pediatric Status 1A	500nm	Any	Any
2	Status 1B	500nm	Any	Any
3	30	250nm	O	O or B
4	29	250nm	O	O
5	29	250nm	Non-O	Any
6	15	150nm	O	O
7	15	150nm	Non-O	Any
8	15	250nm	O	O
9	15	250nm	Non-O	Any
10	15	500nm	O	O
11	15	500nm	Non-O	Any
12	Adult or Pediatric Status 1A	Nation	Any	Any
13	Status 1B	Nation	Any	Any
14	15	Nation	O	O
15	15	Nation	Non-O	Any
16	Any	150nm	O	O
17	Any	150nm	Non-O	Any
18	Any	250nm	O	O
19	Any	250nm	Non-O	Any
20	Any	500nm	O	O
21	Any	500nm	Non-O	Any
22	Any	Nation	O	O
23	Any	Nation	Non-O	Any
24	15	150nm	O	B
25	15	250nm	O	B
26	15	500nm	O	B
27	15	Nation	O	B
28	Any	150nm	O	B
29	Any	250nm	O	B
30	Any	500nm	O	B
31	Any	Nation	O	B
32	15	150nm	O	A or AB
33	15	250nm	O	A or AB
34	15	500nm	O	A or AB
35	15	Nation	O	A or AB
36	Any	150nm	O	A or AB
37	Any	250nm	O	A or AB
38	Any	500nm	O	A or AB
39	Any	Nation	O	A or AB
40	Adult or Pediatric Status 1A, for other method of hepatic support	Nation	Any	Any

41	Status 1B, for other method of hepatic support	Nation	Any	Any
42	Any MELD or PELD for other method of hepatic support	Nation	Any	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 9-11* below.

Table 9-11: 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
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

~~Classification~~	~~Candidates that are within the OPO's:~~	~~And are:~~
~~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 with a MELD/PELD score of at least	And within this distance from the donor hospital	Donor Type	Candidate Type
1	Pediatric Status 1A	500nm	Any	Any
2	Adult Status 1A	500nm	Any	Any
3	Pediatric Status 1B	500nm	Any	Any
4	PELD of at least 30	500nm	O	O or B
5	Any PELD	500nm	O	O
6	Any PELD	500nm	Non-O	Any
7	MELD of at least 30 and candidate is less than 18 years old at registration	500nm	O	O or B
8	Any MELD and candidate is less than 18 years old at registration	500nm	O	O
9	Any MELD and candidate is less than 18 years old at registration	500nm	Non-O	Any
10	Pediatric Status 1A	Nation	Any	Any
11	Adult Status 1A	Nation	Any	Any
12	Pediatric Status 1B	Nation	Any	Any
13	PELD score of at least 30	Nation	O	O or B
14	Any PELD	Nation	O	O
15	Any PELD	Nation	Non-O	Any
16	MELD of at least 30 and candidate is less than 18 years old at registration	Nation	O	O or B
17	Any MELD and candidate is less than 18 years old at registration	Nation	O	O
18	Any MELD and candidate is less than 18 years old at registration	Nation	Non-O	Any
19	MELD of at least 30 and candidate is at least 18 years old at registration	500nm	O	O or B
20	Any MELD and candidate is at least 18 years old at registration	500nm	O	O
21	Any MELD and candidate is at least 18 years old at registration	500nm	Non-O	Any
22	MELD of at least 30 and candidate is at least 18 years old at registration	Nation	O	O or B

23	Any MELD and candidate is at least 18 years old at registration	Nation	O	O
24	Any MELD and candidate is at least 18 years old at registration	Nation	Non-O	Any
25	Any PELD	500nm	O	B
26	Any MELD and candidate is less than 18 years old at registration	500nm	O	B
27	Any PELD	Nation	O	B
28	Any MELD and candidate is less than 18 years old at registration	Nation	O	B
29	Any MELD and candidate is at least 18 years old at registration	500nm	O	B
30	Any MELD and candidate is at least 18 years old at registration	Nation	O	B
31	Any PELD	500nm	O	A or AB
32	Any MELD and candidate is less than 18 years old at registration	500nm	O	A or AB
33	Any PELD	Nation	O	A or AB
34	Any MELD and candidate is less than 18 years old at registration	Nation	O	A or AB
35	Any MELD and candidate is at least 18 years old at registration	500nm	O	A or AB
36	Any MELD and candidate is at least 18 years old at registration	Nation	O	A or AB
37	Adult or Pediatric Status 1A, for other method of hepatic support	Nation	Any	Any
38	Pediatric Status 1B, for other method of hepatic support	Nation	Any	Any
39	Any MELD or PELD for other method of hepatic support	Nation	Any	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 9-12* below.

Table 9-12: Allocation of Livers from Non-DCD Deceased Donors Less than 11 Years Old

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
24	Region or Circle	Adult or pediatric status 1A, and in need of other method of hepatic support

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

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Classification	Candidates with a MELD/PELD score of at least	And within this distance from the donor hospital	Donor Type	Candidate Type
1	Pediatric status 1A	500nm	Any	Any
2	Pediatric Status 1A and candidate is less than 12 years old	Nation	Any	Any
3	Adult Status 1A	500nm	Any	Any
4	Pediatric Status 1B	500nm	Any	Any
5	PELD of at least 30	500nm	O	O or B
6	Any PELD	500nm	O	O
7	Any PELD	500nm	Non-O	Any
8	MELD of at least 30 and candidate is less than 18 years old at registration	500nm	O	O or B
9	Any MELD and candidate is less than 18 years old at registration	500nm	O	O
10	Any MELD and candidate is less than 18 years old at registration	500nm	Non-O	Any
11	Pediatric Status 1A and candidate is at least 12 years old	Nation	Any	Any
12	Adult Status 1A	Nation	Any	Any
13	Pediatric Status 1B	Nation	Any	Any
14	PELD of at least 30	Nation	O	O or B

Classification	Candidates with a MELD/PELD score of at least	And within this distance from the donor hospital	Donor Type	Candidate Type
15	Any PELD	Nation	O	O
16	Any PELD	Nation	Non-O	Any
17	MELD of at least 30 and candidate is less than 18 years old at registration	Nation	O	O or B
18	Any MELD and candidate is less than 18 years old at registration	Nation	O	O
19	Any MELD and less than 18 years old at registration	Nation	Non-O	Any
20	MELD of at least 30 and candidate is at least 18 years old at registration	Nation	O	O or B
21	Any MELD and candidate is at least 18 years old at registration	Nation	O	O
22	Any MELD and at least 18 years old at registration	500nm	Non-O	Any
23	Any MELD and at least 18 years old at registration	Nation	Non-O	Any
24	Any PELD	500nm	O	B
25	Any MELD and candidate is less than 18 years old at registration	500nm	O	B
26	Any PELD	Nation	O	B
27	Any MELD and candidate is less than 18 years old at registration	Nation	O	B
28	Any MELD and candidate is at least 18 years old at registration	500nm	O	B
29	Any MELD and candidate is at least 18 years old at registration	Nation	O	B
30	Any PELD	500nm	O	A or AB
31	Any MELD and candidate is less than 18 years old at registration	500nm	O	A or AB
32	Any PELD	Nation	O	A or AB
33	Any MELD and candidate is less than 18 years old at registration	Nation	O	A or AB
34	Any MELD and candidate is at least 18 years old at registration	500nm	O	A or AB

Classification	Candidates with a MELD/PELD score of at least	And within this distance from the donor hospital	Donor Type	Candidate Type
35	Any MELD and candidate is at least 18 years old at registration	Nation	O	A or AB
36	Status 1A, for other method of hepatic support	Nation	Any	Any
37	Status 1B, for other method of hepatic support	Nation	Any	Any
38	Any MELD or PELD for other method of hepatic support	Nation	Any	Any

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

Livers and liver-intestines from DCD donors or donors at least 70 years old are allocated to candidates according to *Table 9-13* below.

Table 9-13: 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~~
~~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~~

~~Classification~~	~~Candidates that are within the OPO's:~~	~~And are:~~
~~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 with a MELD/PELD score of at least	And within this distance from the donor hospital	Donor Type	Candidate Type
1	Adult or Pediatric Status 1A	500nm	Any	Any
2	Pediatric Status 1B	500nm	Any	Any
3	30	150nm	O	O or B
4	15	150nm	O	O
5	15	150nm	Non-O	Any
6	30	500nm	O	O or B
7	15	500nm	O	O
8	15	500nm	Non-O	Any
9	Adult or Pediatric Status 1A	Nation	Any	Any
10	Pediatric Status 1B	Nation	Any	Any
11	30	Nation	O	O or B
12	15	Nation	O	O
13	15	Nation	Non-O	Any
14	Any	150nm	O	O
15	Any	150nm	Non-O	Any
16	Any	500nm	O	O
17	Any	500nm	Non-O	Any
18	Any	Nation	O	O
19	Any	Nation	Non-O	Any
20	15	150nm	O	B
21	15	500nm	O	B
22	15	Nation	O	B
23	Any	150nm	O	B
24	Any	500nm	O	B
25	Any	Nation	O	B
26	15	150nm	O	A or AB
27	15	500nm	O	A or AB
28	15	Nation	O	A or AB
29	Any	150nm	O	A or AB
30	Any	500nm	O	A or AB
31	Any	Nation	O	A or AB
32	Adult or Pediatric Status 1A, for other method of hepatic support	Nation	Any	Any
33	Pediatric Status 1B, for other method of hepatic support	Nation	Any	Any
34	Any MELD or PELD for other method of hepatic support	Nation	Any	Any

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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 and Less than 70 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 with a MELD/PELD score of at least	And within this distance from the donor hospital	Donor Type	Candidate Type
1	Adult or Pediatric Status 1A	500nm	Any	Any
2	Pediatric Status 1B	500nm	Any	Any
3	30	250nm	O	O or B
4	29	250nm	O	O
5	29	250nm	Non-O	Any
6	Adult or Pediatric Status 1A and also registered for an intestine	Nation	Any	Any
7	Pediatric Status 1B and also registered for an intestine	Nation	Any	Any
8	30 and also registered for an intestine	Nation	O	O or B
9	Any MELD or PELD and also registered for an intestine	Nation	O	O
10	Any MELD or PELD and also registered for an intestine	Nation	Non-O	Any
11	15	150nm	O	O
12	15	150nm	Non-O	Any
13	15	250nm	O	O
14	15	250nm	Non-O	Any
15	15	500nm	O	O
16	15	500nm	Non-O	Any
17	Adult or Pediatric Status 1A	Nation	Any	Any
18	Pediatric Status 1B	Nation	Any	Any
19	15	Nation	O	O
20	15	Nation	Non-O	Any
21	Any	150nm	O	O
22	Any	150nm	Non-O	Any
23	Any	250nm	O	O
24	Any	250nm	Non-O	Any
25	Any	500nm	O	O
26	Any	500nm	Non-O	Any
27	Any	Nation	O	O
28	Any	Nation	Non-O	Any
29	Any MELD or PELD score and candidate is also registered for an intestine	Nation	O	B
30	15	150nm	O	B
31	15	250nm	O	B
32	15	500nm	O	B
33	15	Nation	O	B
34	Any	150nm	O	B
35	Any	250nm	O	B

36	Any	500nm	O	B
37	Any	Nation	O	B
38	Any MELD or PELD and candidate is also registered for an intestine	Nation	O	A or AB
39	15	150nm	O	A or AB
40	15	250nm	O	A or AB
41	15	500nm	O	A or AB
42	15	Nation	O	A or AB
43	Any	150nm	O	A or AB
44	Any	250nm	O	A or AB
45	Any	500nm	O	A or AB
46	Any	Nation	O	A or AB
47	Adult or Pediatric Status 1A, for other method of hepatic support	Nation	Any	Any
48	Pediatric Status 1B, for other method of hepatic support	Nation	Any	Any
49	Any MELD or PELD for other method of hepatic support	Nation	Any	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 9-15* below.

Table 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~~

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

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

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Classification	Candidates with a MELD/PELD score of at least	And within this distance from the donor hospital	Donor Type	Candidate Type
1	Pediatric Status 1A	500nm	Any	Any
2	Pediatric Status 1A and candidate is less than 12 years old	Nation	Any	Any
3	Pediatric Status 1A, candidate is at least 12 years old, and candidate is also registered for an intestine	Nation	Any	Any

Classification	Candidates with a MELD/PELD score of at least	And within this distance from the donor hospital	Donor Type	Candidate Type
4	Adult Status 1A	500nm	Any	Any
5	Pediatric Status 1B	500nm	Any	Any
6	PELD 30	500nm	O	O or B
7	PELD 20	500nm	O	O
8	PELD 20	500nm	Non-O	Any
9	Pediatric Status 1B, and candidate is also registered for an intestine	Nation	Any	Any
10	PELD of at least 30 and candidate is also registered for an intestine	Nation	O	O or B
11	PELD of at least 20 and candidate is also registered for an intestine	Nation	O	O
12	PELD of at least 20 and candidate is also registered for an intestine	Nation	Non-O	Any
13	Any PELD	500nm	O	O
14	Any PELD	500nm	Non-O	Any
15	MELD of at least 30 and less than 18 years old at registration	500nm	O	O or B
16	Any MELD and less than 18 years old at registration	500nm	O	O
17	Any MELD, candidate is less than 18 years old at registration	500nm	Non-O	Any
18	Pediatric Status 1A and at least 12 years old	Nation	Any	Any
19	Adult Status 1A	Nation	Any	Any
20	Pediatric Status 1B	Nation	Any	Any
21	PELD at least 30	Nation	O	O or B
22	Any PELD	Nation	O	O
23	Any PELD	Nation	Non-O	Any
24	MELD of at least 30 and less than 18 years old at registration	Nation	O	O or B
25	Any MELD and less than 18 years old at registration	Nation	O	O
26	Any MELD and less than 18 years old at registration	Nation	Non-O	Any
27	MELD of at least 30 and at least 18 years old at registration	500nm	O	O or B
28	Any MELD and at least 18 years old at registration	500nm	O	O

Classification	Candidates with a MELD/PELD score of at least	And within this distance from the donor hospital	Donor Type	Candidate Type
29	Any MELD and at least 18 years old at registration	500nm	Non-O	Any
30	MELD of at least 30 and at least 18 years old at registration	Nation	O	O or B
31	Any MELD and at least 18 years old at registration	Nation	O	O
32	Any MELD and at least 18 years old at registration	Nation	Non-O	Any
33	PELD 20	500nm	O	B
34	PELD of at least 20 and candidate is also registered for an intestine	Nation	O	B
35	Any PELD	500nm	O	B
36	Any MELD and candidate is less than 18 years old at registration	500nm	O	B
37	Any PELD	Nation	O	B
38	Any MELD and candidate is less than 18 years old at registration	Nation	O	B
39	Any MELD and candidate is at least 18 years old at registration	500nm	O	B
40	Any MELD and candidate is at least 18 years old at registration	Nation	O	B
41	PELD 20	500nm	O	A or AB
42	PELD of at least 20 and candidate is also registered for an intestine	Nation	O	A or AB
43	Any PELD	500nm	O	A or AB
44	Any MELD and candidate is less than 18 years old at registration	500nm	O	A or AB
45	Any PELD	Nation	O	A or AB
46	Any MELD, candidate is less than 18 years old at registration	Nation	O	A or AB
47	Any MELD, candidate is at least 18 years old at registration	500nm	O	A or AB
48	Any MELD, candidate is at least 18 years old at registration	Nation	O	A or AB
49	Adult or Pediatric Status 1A, for other method of hepatic support	Nation	Any	Any
50	Pediatric Status 1B, for other method of hepatic support	Nation	Any	Any

Classification	Candidates with a MELD/PELD score of at least	And within this distance from the donor hospital	Donor Type	Candidate Type
51	Any MELD or PELD for other method of hepatic support	Nation	Any	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 29
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 9-16: 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.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.

9.10.C Location of Donor Hospitals

For the purposes of determining the location of the donor hospital, livers, intestine, and liver-intestine organs procured in Alaska will be considered procured from the Seattle Tacoma Airport, Seattle Washington.

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~~ liver and liver-intestine organs allocated by the OPOs in Hawaii and Puerto Rico to transplant programs in Hawaii and Puerto Rico, respectively 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 the OPO will allocate these blood type O organs to all blood type candidates within the same classification. ~~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.~~ This variance permits Hawaii and Puerto Rico OPOs to offer blood type O organs to any candidates in Hawaii and Puerto Rico transplant programs, respectively before having to offer it outside Hawaii and Puerto Rico, respectively.

~~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.*~~

Bylaw Language:

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.~~

#

Appendix A: Analysis of December 2017 Proposal

In 2017, patients in New York challenged the use of donation service areas (DSAs) in lung allocation.[1] 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.[2] On May 30, 2018, HHS received a critical comment with similar concerns about the liver distribution system.[3] 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.[4]

The Secretary requested a response from the OPTN because administrative rulemaking requires reasoned, evidence-based decision making. 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.[5] 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.'"[6] 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.[7]

Applying the above test to the framework in place for liver distribution today, there are concerns with the use of DSAs and regions for organ distribution.[8] First, it appears that during the development of the liver distribution policy approved by the Board in December 2017, 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.

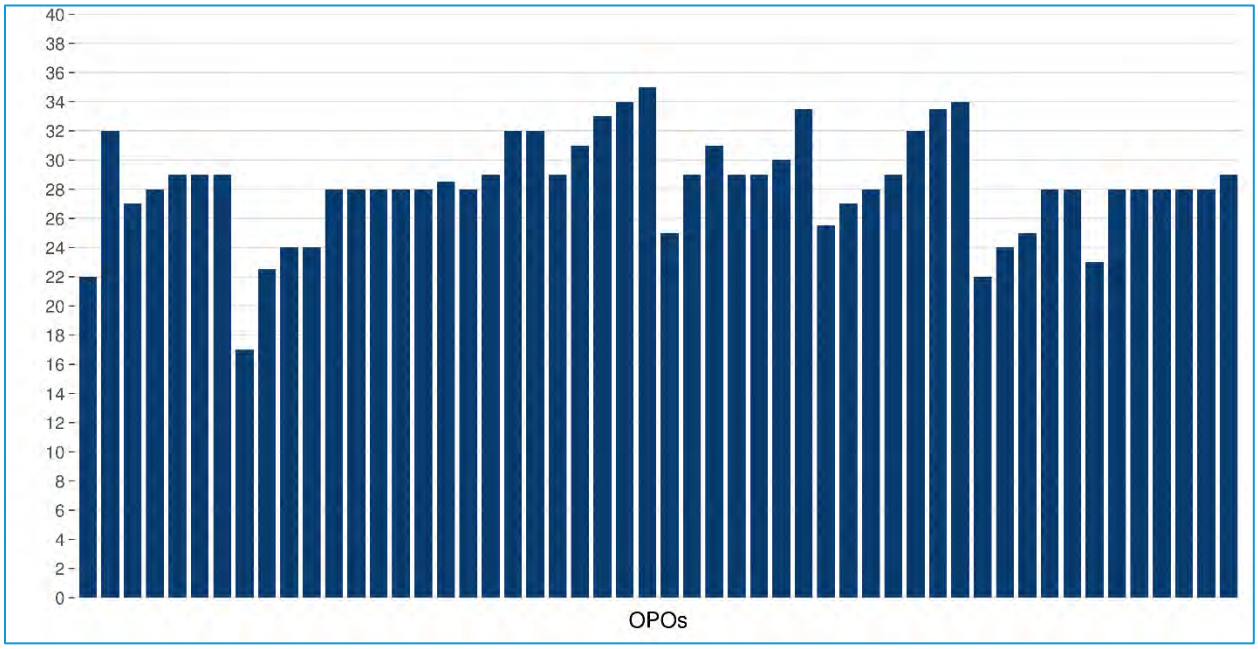
Additionally, at least some members of the Committee offered explanations for the use of DSA and regional boundaries in the December 2017 proposal that are unsupported by evidence. During several Committee conversations and public comments, it was posited that DSA boundaries should be used for organ 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,[9] it is conceivable that improved relationships between transplant hospitals and OPOs could also result in

[1] Holman v U.S. Dept. of Health and Human Services, (S.D.N.Y 17-CV-09041).
[2] 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).
[3] Motty Shulman, letter to Sec. Alex Azar, May 30, 2018.
[4] George Sigounas, letter to Yolanda Becker, OPTN President, June 8, 2018.
[5] Motor Vehicles Mfrs. Assn. v. State Farm Mut., 463 U.S. 29 (1983).
[6] Ibid.
[7] Ibid.
[8] Alexandra Glazier, "The Lung Lawsuit: A Case Study in Organ Allocation Policy and Administrative Law." *Journal of Health and Biomedical Law*, no XIV (2018).
[9] 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."

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)."[10] Several articles have repeated this finding over time.[11] Current OPTN data continues to show the variability in organ access. Figure 1 shows the lowest median MELD score by DSA is 17 and the highest median MELD score is 35.

Figure 1: MMaT by DSA for Adult (Age 18+) Cohort, 7/1/2017 to 6/30/2018, Excludes National Shares, Status 1s, Living Donors, and DCD Donors



Based on OPTN data as of September 21, 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…"[12] In November

[10] Motty Shulman, letter to Sec. Alex Azar, May 30, 2018 citing OPTN/SRTR 2016 Annual Data Report Liver (first published January 2, 2018)
[11] 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 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
[12] ACOT Recommendation 51 (August 2010).

2012, the OPTN Board adopted the following resolution… "The existing geographic disparity in access to allocation of organs for transplant is unacceptably high."[13] 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."[14]

[13] OPTN/UNOS Executive Committee. "Executive Summary of the Minutes OPTN/UNOS Board of Directors Meeting". https://optn.transplant.hrsa.gov/media/1801/executivesummary_1112.pdf. (Accessed Nov. 9, 2018)
[14] OPTN/UNOS Executive Committee. "Broader Sharing of Adult Donor Lungs". Nov. 2017.

Appendix B: Other Allocation Options Considered

In addition to the acuity circles and B2C approaches to allocation, the Committee also considered and decided not to pursue the following approaches.

1. Mathematically Optimized Boundaries

In August 2016, the Committee released a proposal for public comment that used mathematically optimized districts for organ distribution.[1] This proposal included an eight-district concept that changed the current 11 regions into eight mathematically-optimized districts. To address concerns with increased flying for procurement, the proposal included policy that provided three MELD proximity points to candidates within the district and within a 150-nautical mile radius proximity circle of the donor hospital. Additionally, the initial broader distribution 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.[2] 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 mathematically optimized boundaries 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 remained options for the community, Committee, and Board to consider.

2. 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 proposal. The December 2017 proposal was designed to optimize distribution among DSAs and regions. 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.

3. Population-based circles around donor hospitals

The Committee considered using a population-based circle around a donor hospital. Population-based circles are an 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, though there were discussions about how to define population, including 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 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 where the edges of the circle would be located, so that a candidate 100 nm away from a donor in one area would have access to that donor while a similarly situated candidate within the same distance of a similarly situated donor might not have the same access to that donor organ. These otherwise similarly situated candidates would be treated differently based on their location.

[1] OPTN/UNOS Liver and Intestinal Organ Transplantation Committee. “Enhancing Liver Distribution” November 2017.
[2] 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

This could also make it difficult for patients to understand since every donor hospital would have a different sized circle. Instead, the committee considered ways that differences in population could be accounted for while using distance-based circles. Many commenters believed that set distance circles would disadvantage areas where a circle would include water or another country or where there are large rural areas in between population centers. They believed that circles that adjust based on population would ensure access for those areas. There was some support for pursuing a population-based model in the future in the comments received during the public comment period and the committee is willing to consider this as a potential future iteration of liver allocation.

4. 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. 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 fixed distance based circles of small radii (ex. 150 nm) were appropriate because flying an organ involves additional cost and coordination of flights compared to when the team is able to drive to recover the organ; however, compared to the current system, this would result in less access to transplant for some areas of the country where 150 nm includes fewer donors than the current DSAs or regions. 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. There was some support for pursuing a model with circle sizes based on population in the future in the comments received during the public comment period and the committee is willing to consider this as a potential future iteration of liver allocation.

5. State-Based

Some commenters proposed a state-based allocation that would use the state as the first level of allocation. The commenters suggested that it would preserve access to transplant for candidates in areas of the country where there is a higher incidence of liver disease and mortality. Other commenters who supported state-based allocation suggested that they would not be willing to donate if their liver was not placed in their local area. The Ad Hoc Geography Committee reviewed this concept and found it too similar to boundaries currently in place by DSA and Region, which have been concluded not optimal for allocation of organs and inconsistent with the requirements of the Final Rule. The Liver Committee also discussed this topic and opted to consider only the frameworks that were in alignment with the requirements of NOTA and the Final Rule since the state based distribution model presented similar issues with compliance with the Final Rule.

6. Keep December 2017 Proposal

Approximately a quarter of the commenters did not support any change. These commenters include a group of centers that included Indiana University Health, The University of Kansas Health System, Vanderbilt, University Medical Center, and Washington University in St. Louis/Barnes-Jewish Hospital Transplant Center. The themes in their comments were:

- Concerns about the fact that a transplant hospital might have areas that are covered in water or are sparely populated within 150 nm
- Belief that it is more important to increase donation through methods like OPO performance goals and education for the general public than to change allocation
- Desire not to donate if their liver would not go to a local candidate
- Concerns that the process is moving too quickly
- Desire to prioritize offers to populations that have higher waitlist mortality rates
- Desire to prioritize offers to populations that have higher incidence of liver disease
- Desire to prioritize offers to populations that have less access to the waitlist

- Concerns about increased cold time
- Belief that MMaT is not appropriate way to measure disparity because MELD doesn't predict mortality risk
- Concerns about increased costs with additional travel
- Concerns that additional travel may result in additional discards
- Disbelief that there can be a decrease in transplant numbers and a simultaneous decrease in waitlist mortality
- Concerns that OPO performance is not a factor that is considered
- Belief that candidates can move to areas with more supply

However, without any changes, the December 2017 proposal would continue to pose issues of compliance with the Final Rule and would not be responsive to the directive from HRSA to remove DSA and region from allocation and scoring of liver and intestine candidates.

Appendix C: Operations and Safety Committee Transportation Report

OPERATIONS AND SAFETY COMMITTEE TRANSPORTATION REPORT

Introduction:

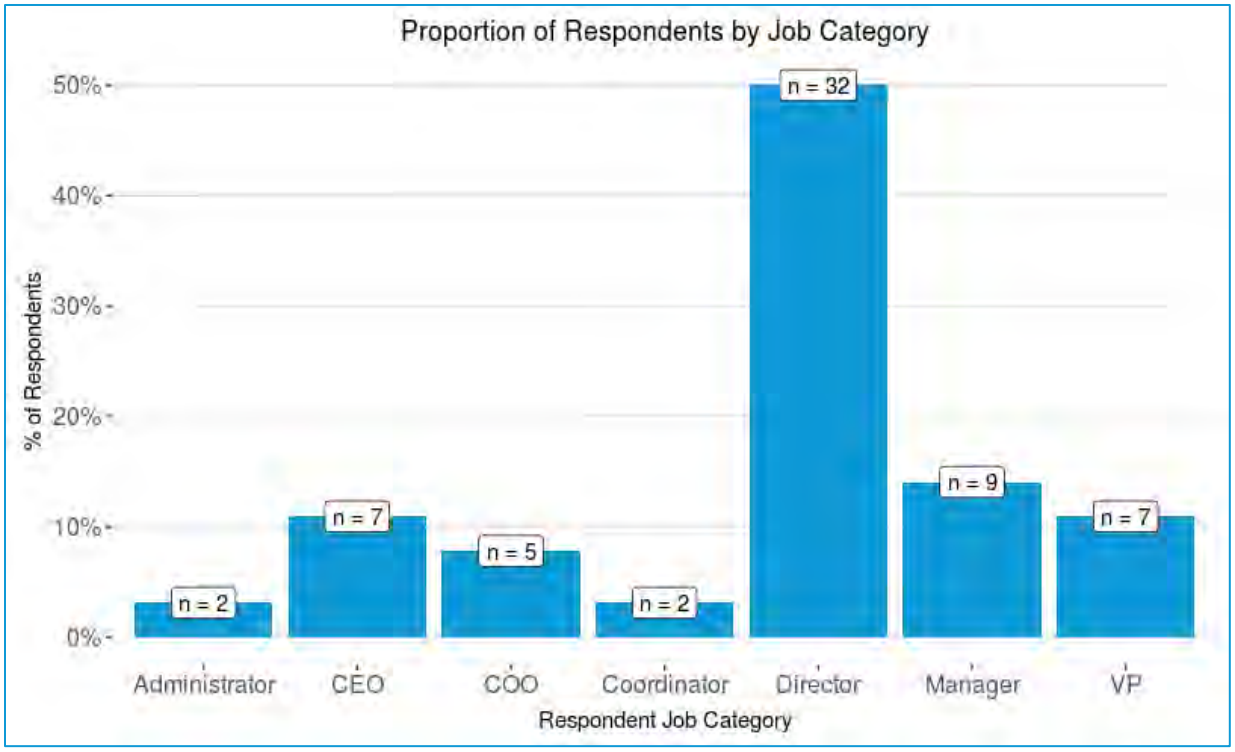
The OPTN/UNOS Operations and Safety Committee developed a questionnaire intended to assist the Ad Hoc Geography Committee and Organ-specific committees in their efforts to comply with the Department of Health and Human Services (HHS) directive[1] to eliminate DSA and Region as units of organ allocation. A major focus of the discussions regarding broader sharing is the likely increase in air travel that would be required if organs and surgical teams are travelling beyond "drivable" distances. To that end, our committee created a series of questions that focused on the operational aspects of broader sharing with a focus on ground and air travel logistics. Members of the committee then reached out to leadership in all 58 OPOs to determine the best individual(s) to answer the questions. For those OPOs that did not handle transportation for organ recovery, individual transplant centers were contacted to complete the questionnaire. The questionnaires were completed via a direct phone call with leadership of the OPO/Transplant Centers which allowed for both quantitative and qualitative data gathering. Once the questionnaires were completed, some of the questions were deemed "uninformative" by the committee and are not included in this document. Only those questions that the committee felt might be informative are included and focus on the issues that were included in the public comment proposal and some of the criteria used for SRTR modeling of allocation options (i.e. setting transition from driving to flying for liver at 200 nm). The full questionnaire is included in the appendix. Answers were analyzed nationally and by region as it was determined that significant regional variations in the answers to the questions was revealed.

Rationale for Study Questions:

1. Driving distance questions were included to determine the current state for decision making between when organ/team travel exceeded driving times/distances
2. Questions regarding requirements for teams vs organs flown were meant to determine if more local recovery efforts might influence needs for aircraft/pilots
3. Questions related to ability to find pilots/planes were included to determine if increasing the need for flying might delay donor recovery procedures thus increasing pre-donation hospital stays and/or increasing cold time in the event that delivery of organs is delayed due to pilot/plane availability

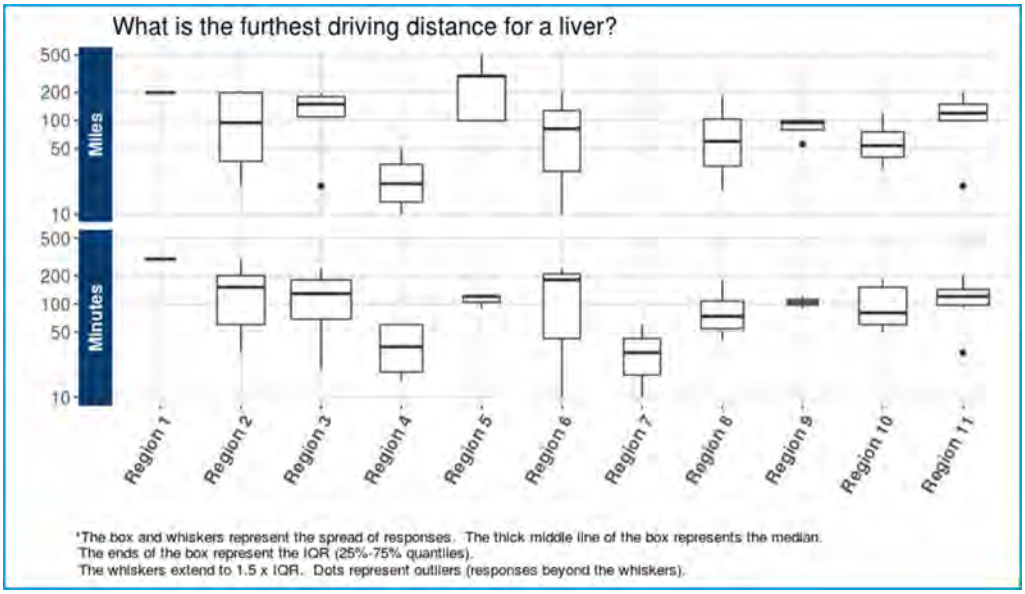
Contacts: Operations and Safety Committee members were able to complete questionnaires from 54 of the 58 OPOs and 10 transplant hospitals (where the transplant hospitals managed donor recovery transportation). The job roles of the respondents are depicted below:

[1] https://transplantpro.org/wp-content/uploads/sites/3/OPTN_letter_6.8.2018.pdf



Results:

Transition from driving to flying: Two hundred nautical miles was selected as the distance for modeling transition from driving to flying for liver allocation modeling. The graphic below supports the utilization of this distance.



Selected comments from respondents:

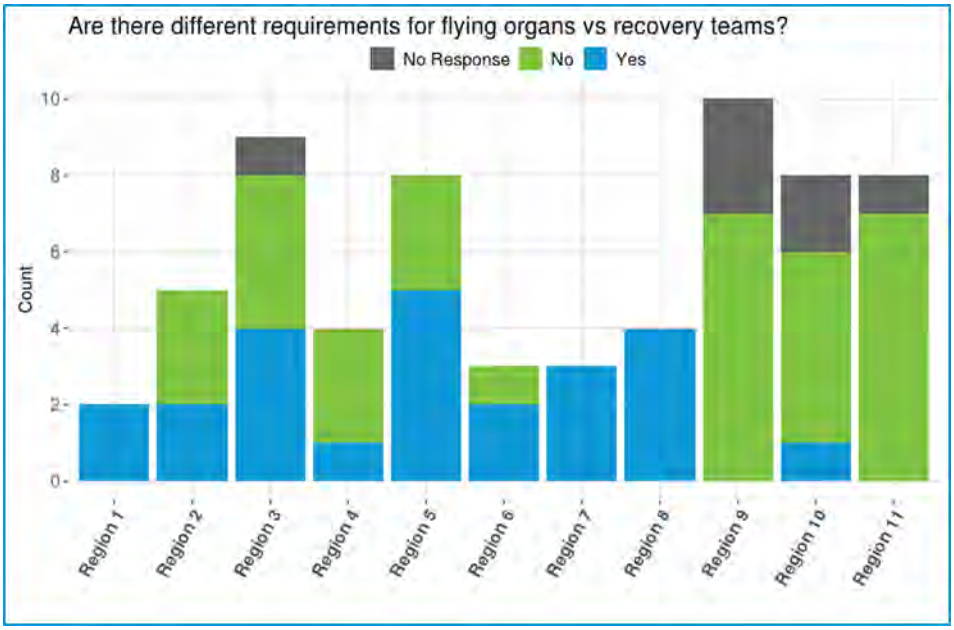
- *"Highly dependent upon traffic conditions"*

- *Often determined by "time of day"*
- *"Weather and surgeon preference drive this cut-off"*
- *"More a time factor than mileage"*
- *"Nothing defined in policy….case by case basis"*
- *"Varies with organ"*

Equipment requirements for flying teams vs organs: The graphics below depict the number/percentage of respondents who indicated a difference between requirements for airplane type and pilot staffing between flying surgical teams vs organs. Nearly 40% (37.5%) of respondents indicated a difference. The answers differed by region.

Table 1. Are there different requirements for flying organs vs recovery teams?

	N	Percent
No	33	51.6%
Yes	24	37.5%
No Response	7	10.9%



Selected comments from respondents:

- *"Double pilots for people only, not organs"*
- *"Jets must have 2 pilots"*
- *"Always have 2 pilots when people on board, permit single pilot when only flying organs"*
- *"Prop is used to fly staff to cases. Jet is used for organs/surgeons"*
- *"Always 2 pilots and always a jet"*
- *"Single pilot for organs – always double pilots for moving people"*

Availability of Planes/Pilots: The availability of planes/pilots is depicted below. There are differences if recovery teams vs organs are flying and indicate that at times, planes may be available and pilots are not, and vice versa.

Table 2. Are you ever unable to find a plane/pilot for recovery team/organ?

Are you ever unable to find…	No	Yes	No Response
Pilot for recovery team?	40 (56.3%)	24 (33.8%)	7 (9.9%)
Pilot for organ?	47 (66.2%)	15 (21.1%)	9 (12.7%)
Plane for recovery team?	40 (56.3%)	25 (35.2%)	6 (8.5%)
Plane for organ?	48 (67.6%)	17 (23.9%)	6 (8.5%)

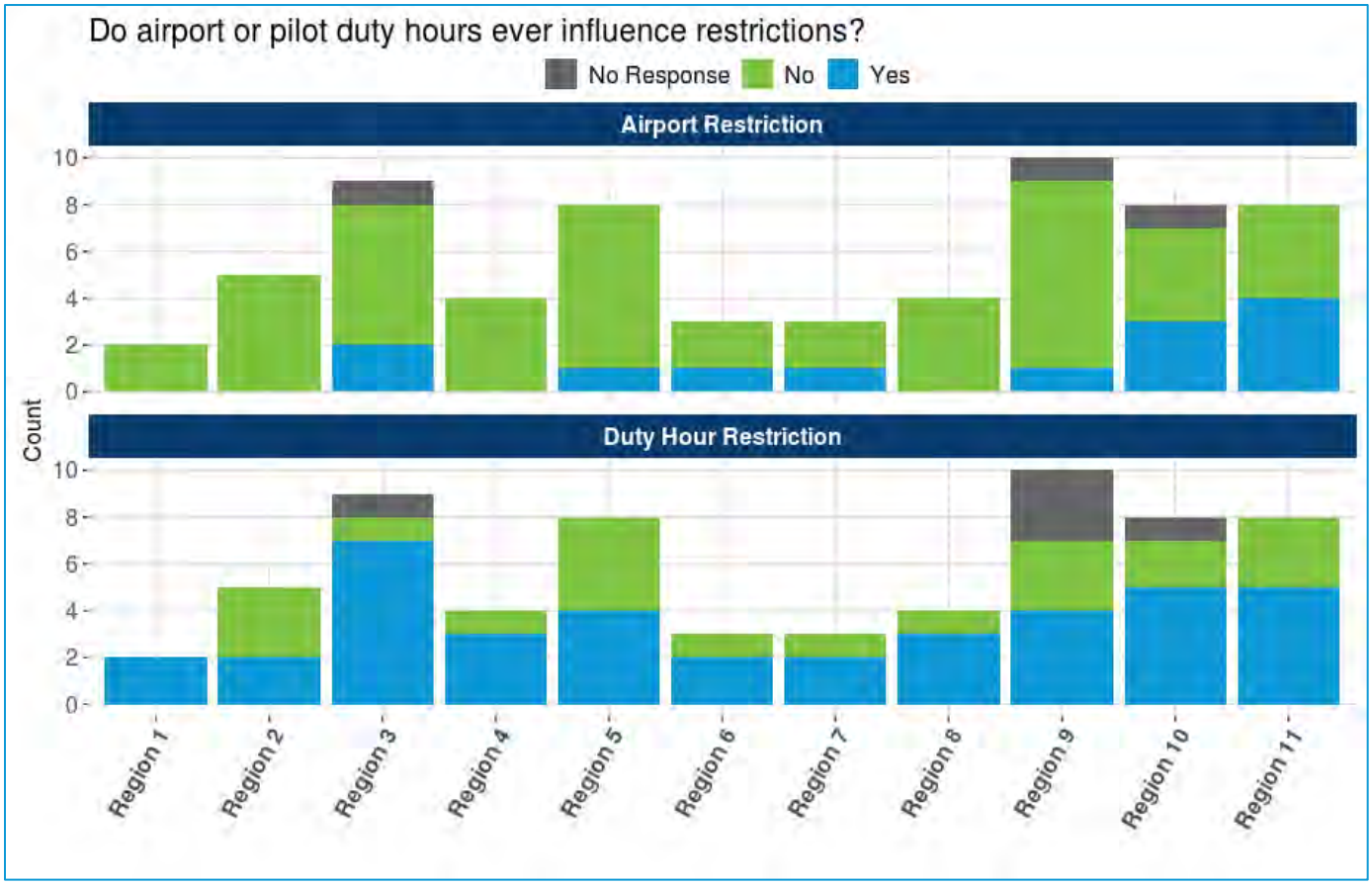
Selected comments from respondents:

- *"Rare, but charter company is expanding their fleet"*
- *"No planes/pilots are available on rare occasions"*
- *"Weather is always a factor. Large events in the state decrease the availability"*
- *"Always been able to find a plane but sometimes this causes delays"*
- *"Primarily during case reallocation with intra-op decline and time sensitive acceptance; several cases this year, at least one case this year when secondary charter choice at extreme expense for surgical team"*
- *"On rare occasions when a hospital plane not available, will charter"*
- *"Planes are ultimately located but there have been delays"*
- *"There has not been a time when we absolutely could not find a plane or team, but we have had delays"*
- *"Not unusual to delay OR for teams having trouble finding flight"*

Pilot duty hour restrictions: Pilot duty hour limitations are an additional variable that influences ability to fly organs/teams. OR delays could lead to need for additional teams to fly out to donor airports in the event that pilots time out.

Table 3. Do airport or pilot duty hour restrictions ever influence recovery?

	No	Yes	No Response
Airport restrictions	53 (74.6%)	14 (19.7%)	4 (5.6%)
Pilot duty hour restrictions	23 (32.4%)	42 (59.2%)	6 (8.5%)

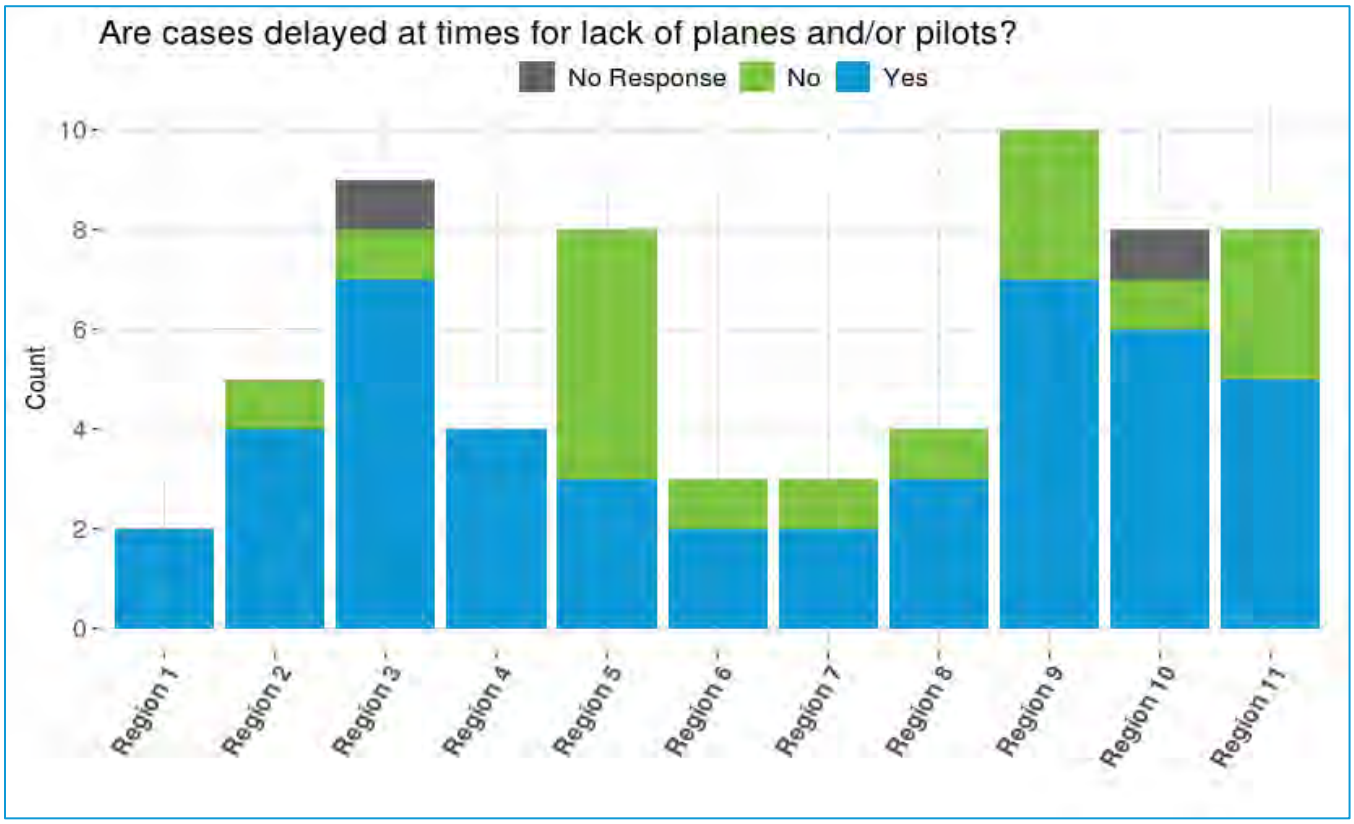


Selected comments from respondents:

- *"Pilot will "time out" if put on standby too soon or on the ground during organ recovery"*
- *Problems "due to pilot time restrictions"*
- *"…unable to distinguish source of unavailability (plane or pilot); may be pilot availability as rate limiting…pilot time out while on site has been an close call this year several times"*
- *"Sometimes need to delay the flight due to duty hours restrictions (relatively rare) or swap crews during procurement if duty hours are going to run out."*
- *"….pilots have timed out when flying very far - to the coasts to import organs…"*
- *"have had pilot time-out but not unable to find one"*
- *"pilots time out and sometimes needs another crew and one may not always be available"*
- *"Due to time out schedules of pilots, i.e. one pilot may time out in 2 hours, but the next pilot is not available for 5 hours"*
- *"…pilot timed out while waiting for recovery team-new pilots and plane had to be sent to recovery hospital to pick up team"*
- *"pilots/team times out frequently"*
- *"OR delay/bump resulted in pilot timing out....resulted in having to cancel recovery and delay 24hrs"*
- *"Seems to be happening more consistently"*
- *"never heard of this issue"*
- *"Case times adjusted due to pilot times"*
- *"If pilot availability or duty time is a concern we may strategically set the OR time based on those circumstances"*
- *"Can sometimes require additional plane when cases are delayed"*

- *"Experience a lot of time-out issues with pilots"*
- *"Typically because the recovery gets bumped due to trauma and pilots have to wait, gets bumped and have to fly in additional team"*
- *"definite impact on setting the OR time; safety concerns have led companies to be very strict about restriction"*
- *"Will flip teams when necessary and can add cost"*
- *Center "…has occasionally needed to secure a second plane/team when delays at donor site occurs or team times out"*
- *"Leads to delays in clamp times because pilot duty hours run out. NOT AN INSIGNIFANT PROBLEM! HAPPENS FREQUENTLY."*

Timing of donor OR times:



Selected comments from respondents:

- *"rarely, heart/lung teams will delay typically by 1-2hrs when planes take a while to find"*
- *"Prior to hiring broker in 2016, 45% of case were delayed due to flight arrangement problems"*
- *"Weather restrictions can be challenge"*
- *"The percent of cases delayed is very low"*
- *"Delays related to availability of surgeons (locally) and surgeons from outside teams (may be a surgeon or transportation issue)"*
- *"…Any time when aircraft are needed for use that are not our aircraft it takes additional time to get them into placed and can cause a delay. "*
- *"Need 5 hour heads up. Often leaves to delays. All charter companies need 5-6 hours of lead time. Some centers are demanding jets. Delays also occur because of lack of staff"*
- *"Usually, the delays are from teams to outside of the state. Especially heart and lung teams."*

- *"…when it is our donor, we can try to influence the timing of the cases in order to use our own plane…can go to OR sooner/later for weather. Also because we have our own plan we can get to donor hospitals faster and potentially get the unstable donor and utilize those organs"*
- *"Never had to turn down an organ but have had some delays"*
- *"Usually because Lung teams cannot find planes"*
- *"OR time regularly adjusted due to teams arriving from outside OPOs (OR start may not be delayed but more frequently setting of the OR time delayed based on flight availability)"*
- *"Delays are only due to surgical team availability"*
- *"Delays to start OR due to teams coming in"*
- *"…sometimes the delays are because the incoming team can't get a plane"*
- *"Delays in setting OR time. More often delays with last minute changes"*
- *"30% of cases experience some delay"*

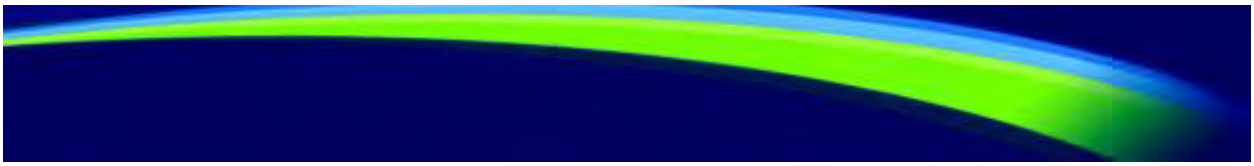
Issues to Consider: Respondents conveyed that flying teams for organ recovery influences timing of the donor OR. Issues raised included:

1. Donor instability with longer pre-recovery times
2. Potential loss of organs due to logistics (e.g. lung)
3. Influence of case duration on OPO staffing requirements (inability to staff other cases if still managing existing cases due to time delays)
4. Concerns about pilot duty hours once activated if flight does not occur in timely fashion
5. Concerns about need for simultaneous fly-outs with broader sharing
6. Potential revocation of authorization with longer case times
7. Increased hospital costs related to longer case times
8. Airplane/pilot availability issues due to local sporting events or concerts where all private planes are committed to others
9. Pilot duty hour restrictions leading to need for additional pilots/planes to be flown into donor airports
10. Weather influence (need for strong local backup in the event of weather events that preclude flying)

Limitations: Obvious limitations to this report include the somewhat "anecdotal" nature of the questionnaire and the knowledge level of the respondents. We attempted to reach leadership at the OPOs and transplant centers as is indicated above in order to lessen these concerns.

Conclusions: The Operations and Safety Committee's goal in developing and executing this questionnaire was to assist the relevant UNOS/OPTN committees in their work towards eliminating DSAs and Region as units of allocation. We believe that the issues related to increased air travel and potential OR delays and costs are important issues for the committees to consider and hope that our work will help this process.

Appendix D: Public Comment Analysis



Eliminate the Use of DSAs and Regions in Liver and Intestine Distribution

Liver and Intestine Distribution Using Distance from Donor Hospital
Version 2. Updated Nov 16, 2018

Elizabeth C. Miller

Eliminate the Use of DSAs and Regions in Liver and Intestine Distribution

Liver and Intestine Distribution Using Distance from Donor Hospital

Contents

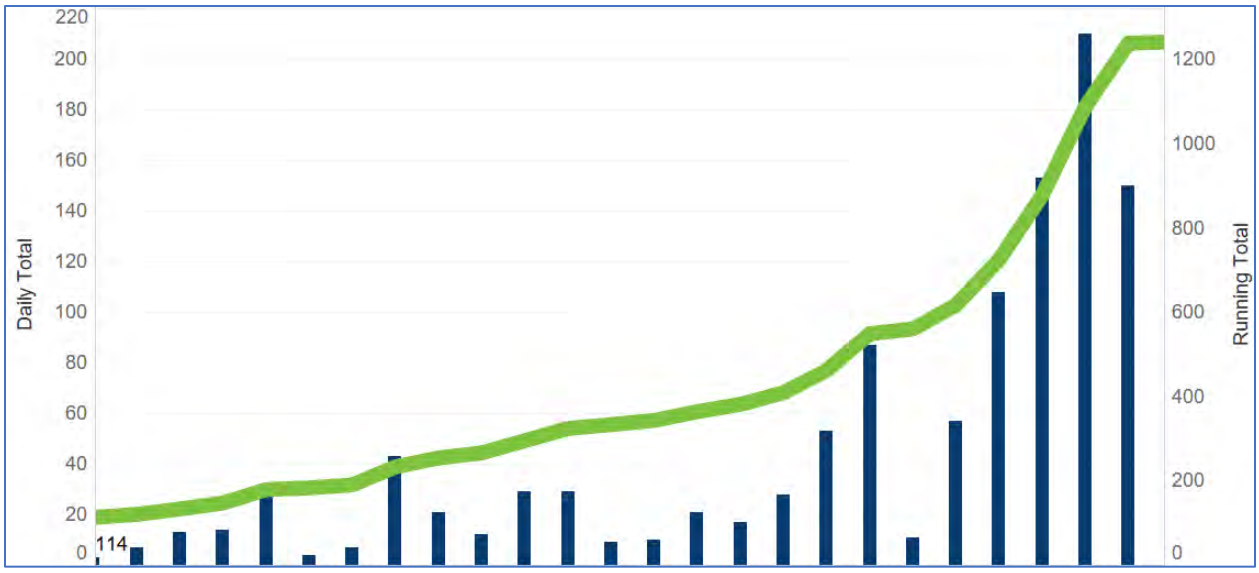
Process

The proposal was released from October 8, 2018 to November 1, 2018. Comments were collected and managed using REDCap electronic data capture tools hosted at UNOS.[2] All comments were posted to the OPTN website and available to the public throughout the publc comment period. During this period, staff and Committee leadership periodically shared updates on participation rates and themes observed from the comments submitted up to that point. On October 30, the Committee discussed the themes received to date. On November 1, the Committee received all of the comments and this written public comment analysis. As with most public comment proposals, the general themes did not change substantially after the first week of comment. Instead, additional comments illuminated different aspects of the major themes or showed changes in sentiment between different subpopulations that had not yet participated.

Participation

The purpose of public comment is to assure "that the perspectives and concerns of the general public are taken into account and addressed in policy proposals".[3] During the public comment period, there were 1,242 comments submitted. For comparison, the Liver Committee's 2016 distribution proposal received 1,064 comments and the 2017 distribution proposal received 647 comments.

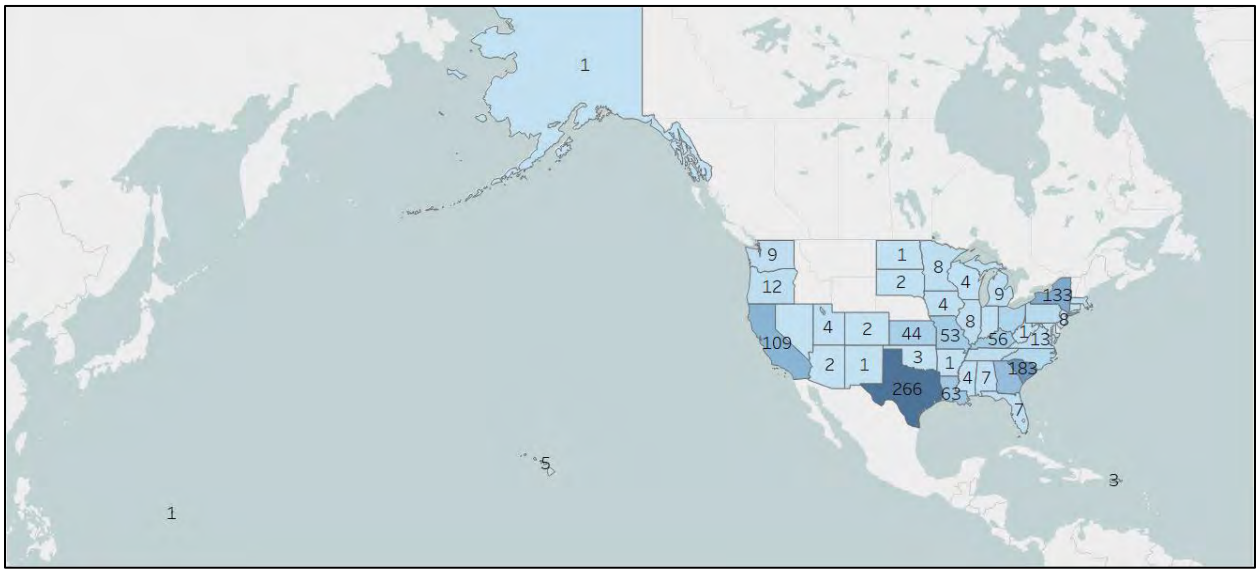
Figure 2: Participation by Time



[2] Paul A. Harris, Robert Taylor, Robert Thielke, Jonathon Payne, Nathaniel Gonzalez, Jose G. Conde, Research electronic data capture (REDCap) – A metadata-driven methodology and workflow process for providing translational research informatics support, J Biomed Inform. 2009 Apr;42(2):377-81.
[3] OPTN Bylaws, Appendix M: Definitions

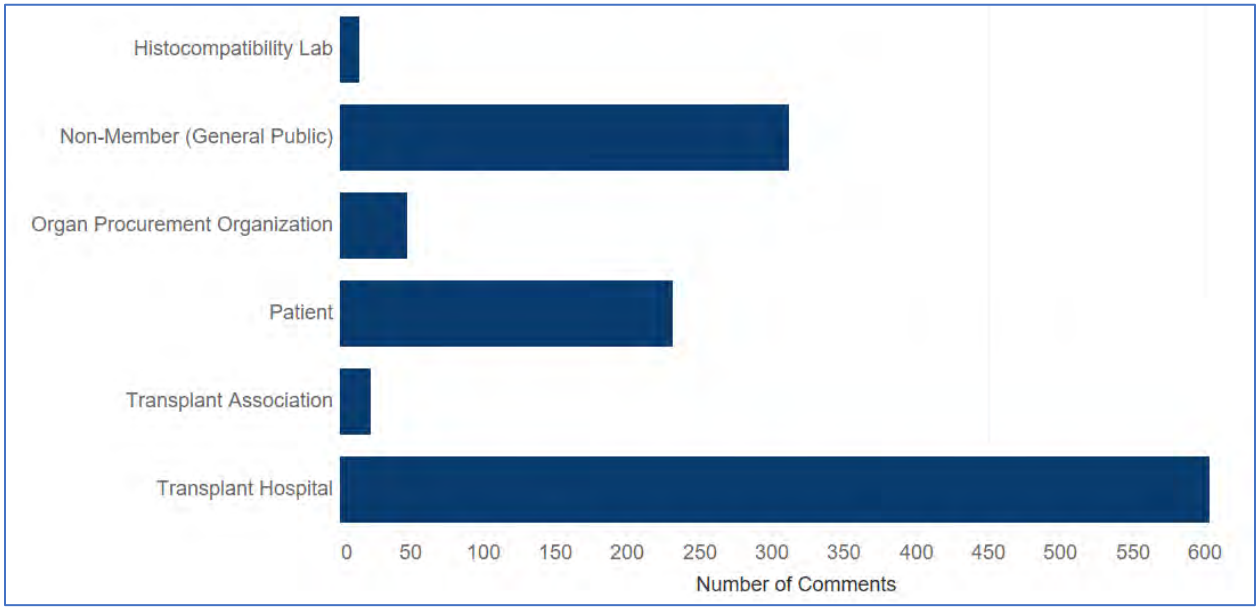
The comments were submitted from at least 41 states plus Guam and Puerto Rico.[4] A disproportionate number of the comments originated from Texas (n = 266), South Carolina (n =183), New York (n = 133), and California (n = 109). For this reason, it is important to evaluate the merits of each comment instead of utilizing the volume of individual comments as a national, public opinion survey.

Figure 3: Participation by Geography



The comments were submitted by multiple different types of members. The largest member type was transplant hospitals.

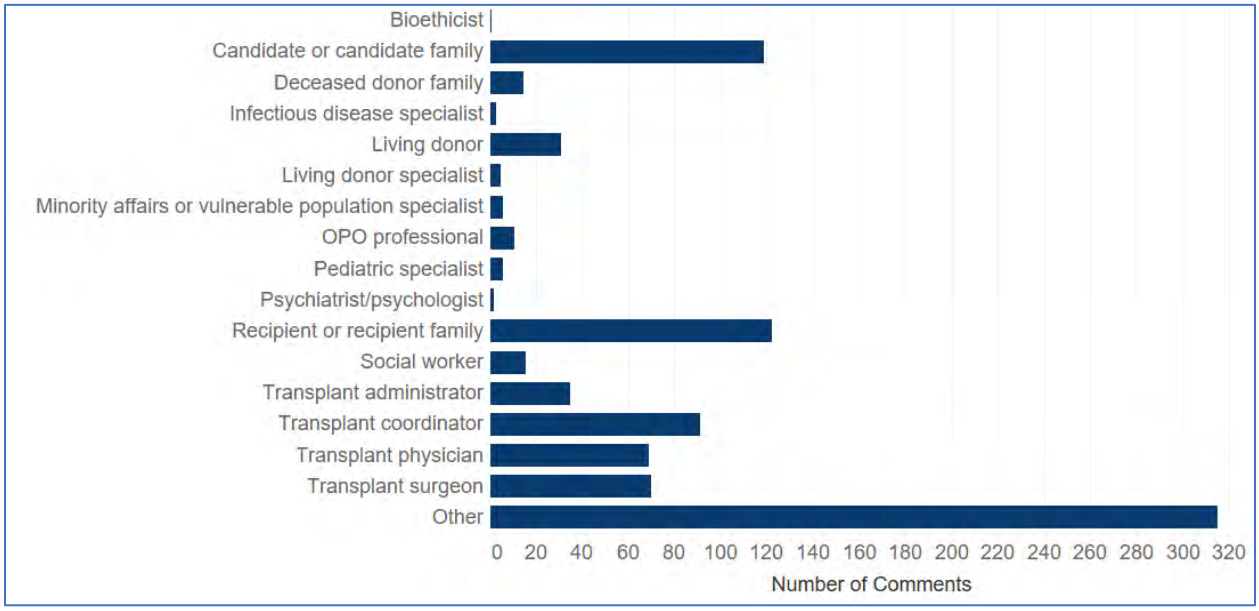
Figure 4: Participation by Member Type



[4] Not all respondents submitted their state of residence.

When asked for their relationship to transplantation, the largest category was “other.” For respondents that selected a relationship, the two largest categories were types of patients: candidate or candidate family; and recipient or recipient family.

Figure 5: Participation by Relationship to Transplant



Themes in Public Comment

Commenters covered many different topics. Policy decisions for the committee focused largely on the following themes:

1. Allocation Framework
2. Circle Sizes
3. Sharing Threshold
4. Blood Type Variance for Puerto Rico
5. Pediatric Allocation

For each theme listed above, options raised during public comment are described below.

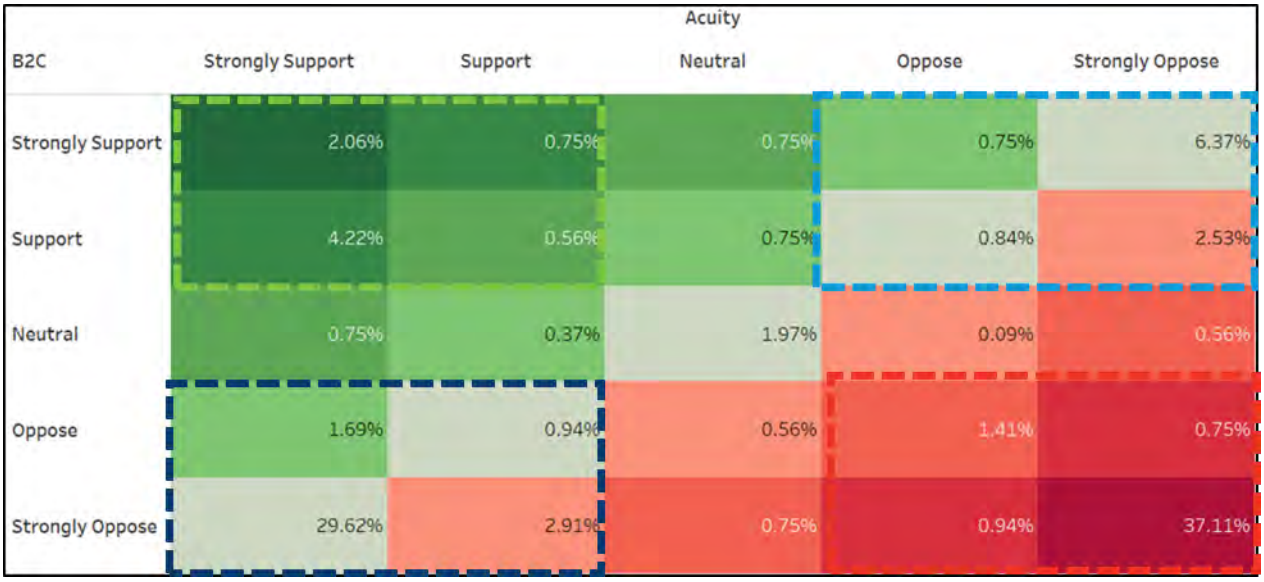
Allocation Framework

Options:

1. Broader 2 Circles (B2C) (Public comment proposal)
2. Acuity Circles
3. Population-based
4. State-based
5. National
6. No Change

Commenters were asked whether they supported or opposed the B2C model and whether they supported or opposed the acuity circles model. Commenters fell into one of 5 groups – those who opposed both models, neutral, those who supported both, those who supported B2C and oppose acuity, and those who supported acuity and opposed B2C. 35.15% supported acuity and opposed B2C. (The dark blue box below.) 10.50% supported B2C and opposed acuity circles. (The light blue box below.) 7.59% supported both models. (The light green box below.) 40.21% opposed both models. (The red box below.)

Figure 6: Comparison of Sentiment on Frameworks



There was some correlation between location of the responses and the preferences of the commenters. The Carolinas, Georgia, Florida, Kentucky, Pennsylvania, Missouri, and Iowa tended to oppose both models, while California, New York, Texas, Colorado, Wisconsin, and Nevada preferred the acuity circles, and Hawaii, Utah, Louisiana, Oregon, Indiana and South Dakota preferred B2C. Other states had more mixed responses.

Figure 7: Comparison of Sentiment on Frameworks by State

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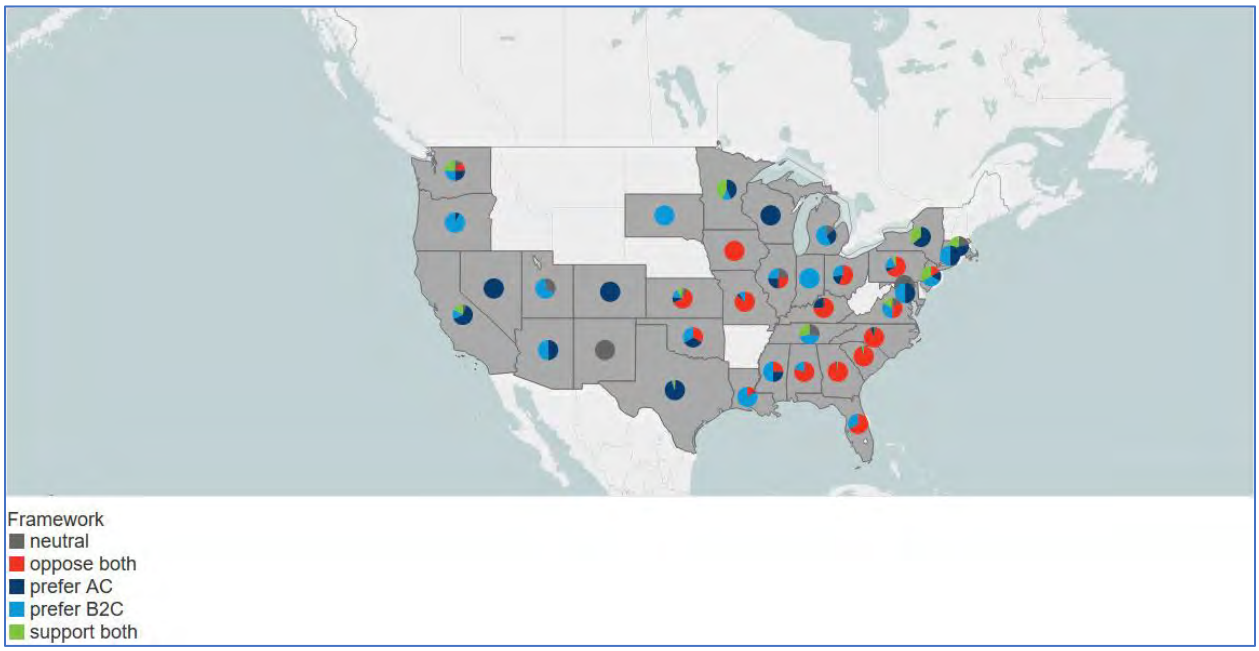
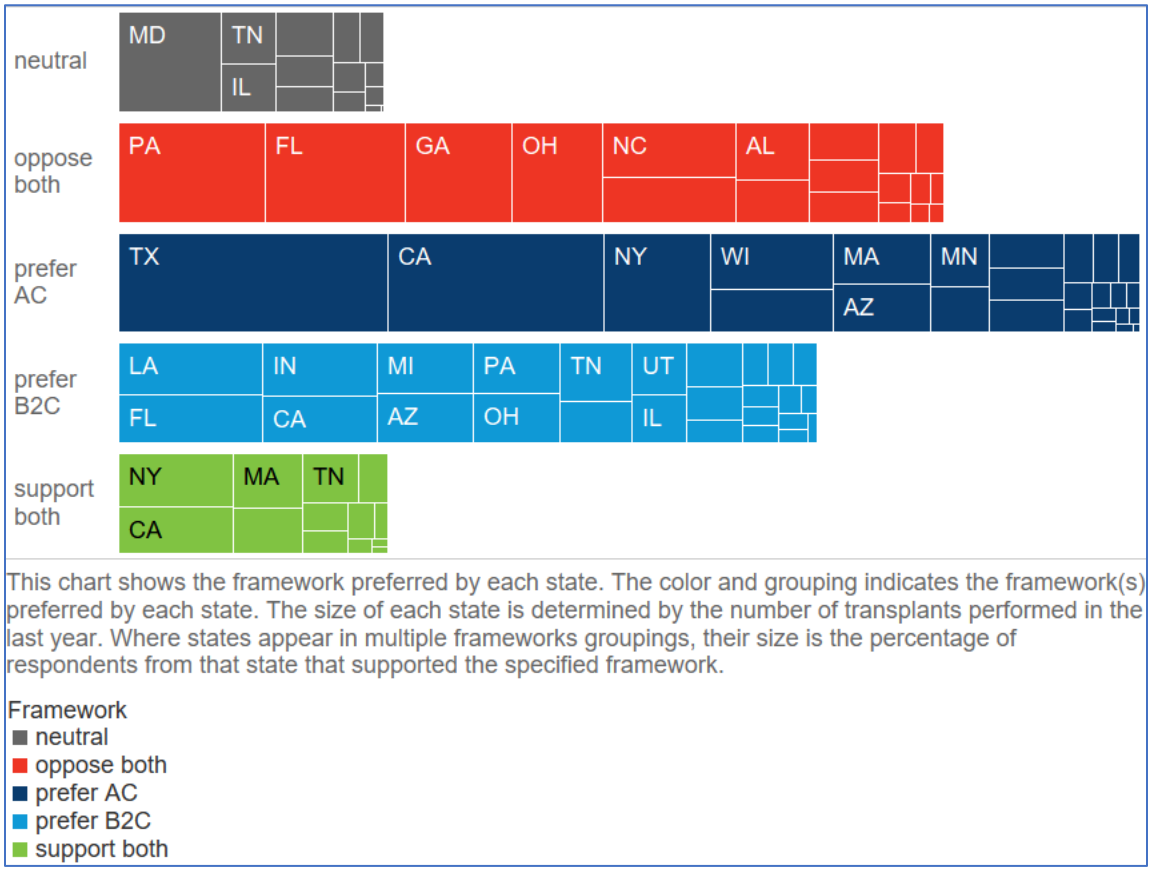


The next chart shows the preference by framework by each state – with each state weighted by their 2-year transplant volume. This shows a preference for acuity circles.

Figure 8: Feedback on Framework Weighted by State Transplant Volume



Option #1 – Broader 2 Circles (B2C)

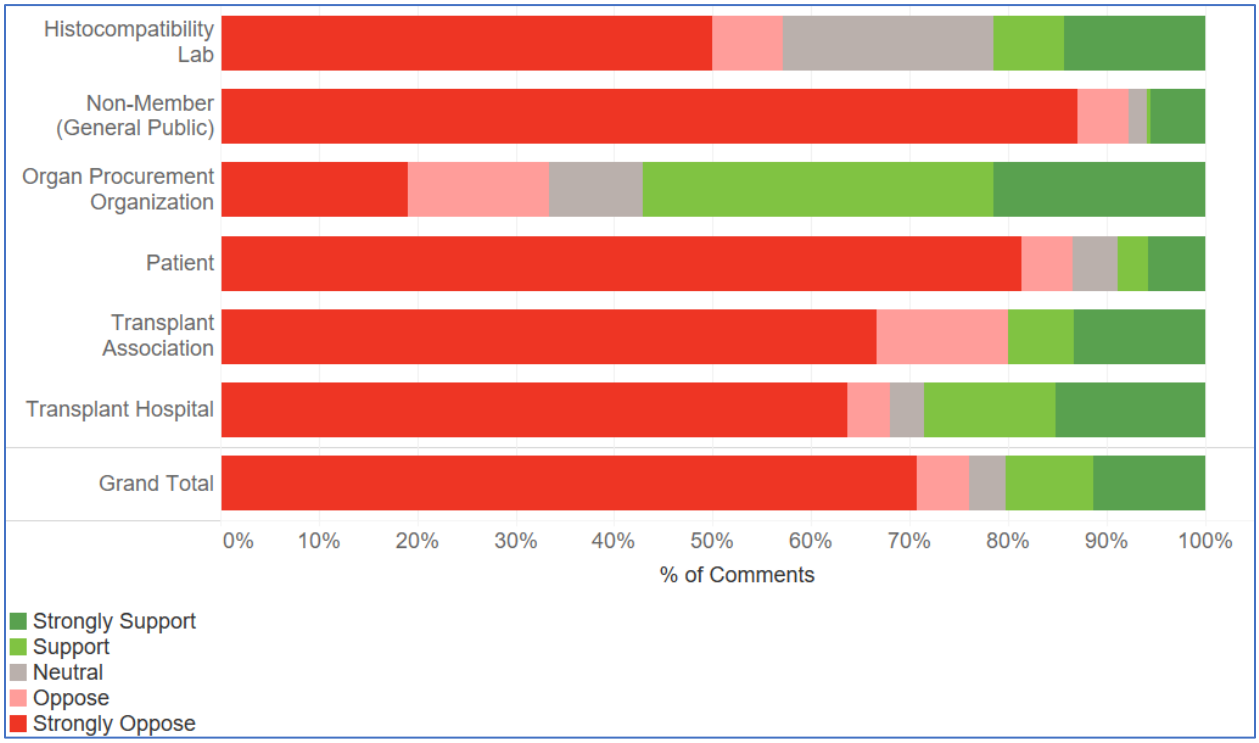
The current proposal uses the B2C allocation framework modeled by the SRTR.

Comments in Favor	Comments in Opposition
✓ Desire to minimize the amount of change compared to current system and Acuity Circles	× Lack of improvement in variance in median MELD at transplant over the December 2017 proposal for non-exception candidates.
✓ Less organs flying than Acuity Circles	× Greater focus on geographic proximity than Acuity Circles
	× Lack of a significant decrease in waitlist mortality compared to the acuity circles model.
	× The increase in flying was not defensible as a justification for geographically limiting organ allocation.
	× Several commenters indicated their belief that the B2C framework is not consistent with the OPTN Final Rule.

B2C reflects the policy language that the Committee proposes. The group that showed the most support for this option was OPOs. Less than 50% of any other group supported or strongly supported this

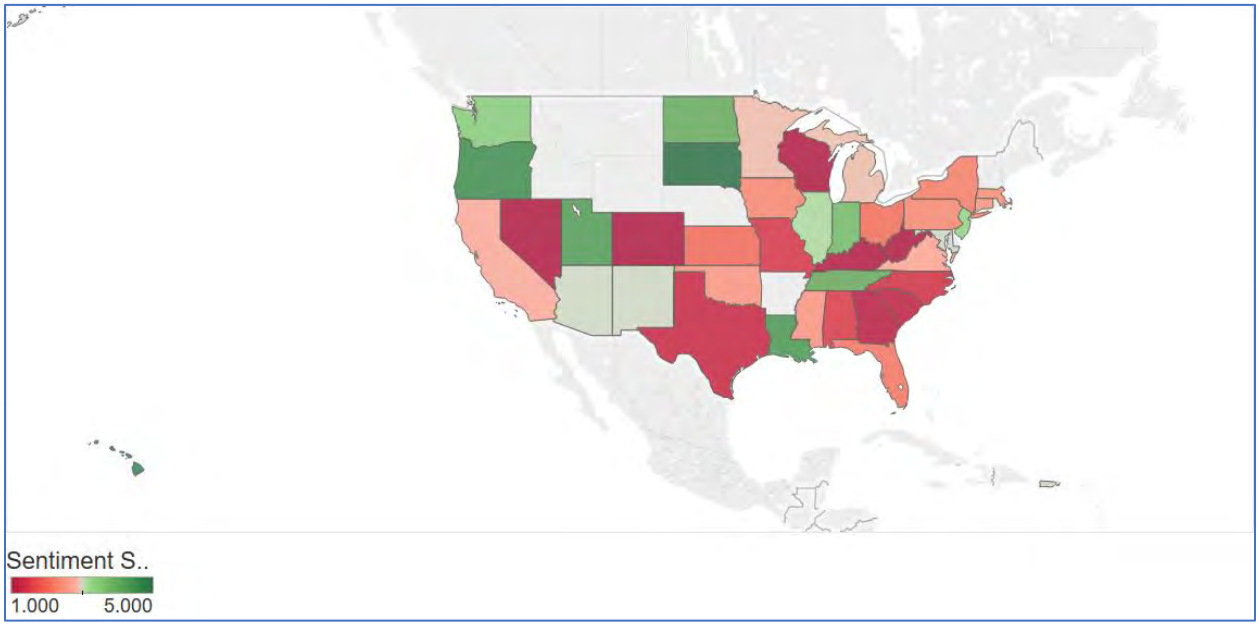
approach. The majority of every group except for OPOs and histocompatibility labs strongly opposed B2C.

Figure 9: Sentiment of B2C Framework by Member Type



The sentiment was divided between states, with the average sentiment of the commenters in each state resulting in about as many states generally in favor of B2C as generally opposed.

Figure 10: Sentiment of B2C Framework by State



Option #2 – Acuity Circles

This option is the acuity circles framework that was also modeled by the SRTR this year.

Comments in Favor	Comments in Opposition
✓ Improves the disparity in access more than B2C	× The increase in flying was not defensible as a justification for geographically limiting organ allocation.
✓ Greater focus on medical urgency than B2C	× Greater change, compared to current system and B2C
	× One commenter indicated their belief that the Acuty Circles framework is not consistent with the OPTN Final Rule.
	× More flying than B2C: concern with costs, outcomes, and discards
	× Concern that the framework does not sufficiently address access for patients by SES

Figure 11: Sentiment of Acuity Circles Framework by Member Type

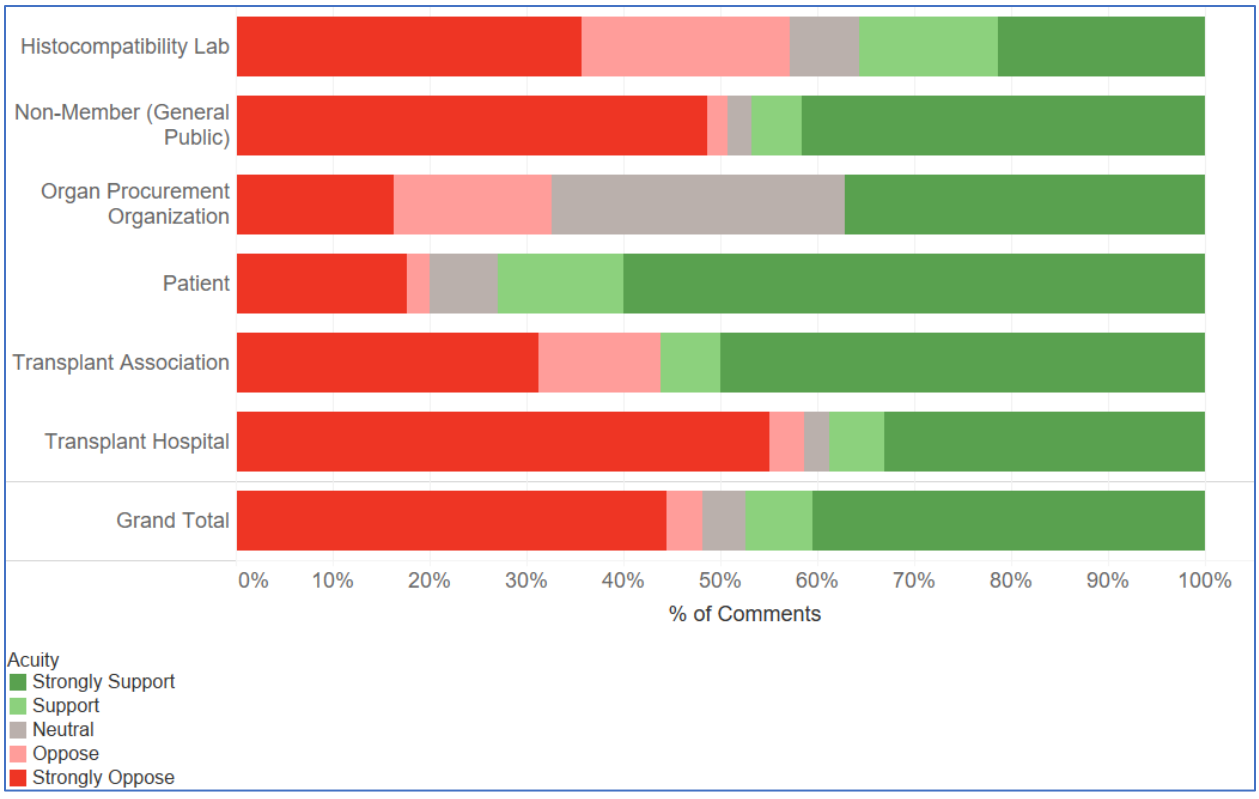
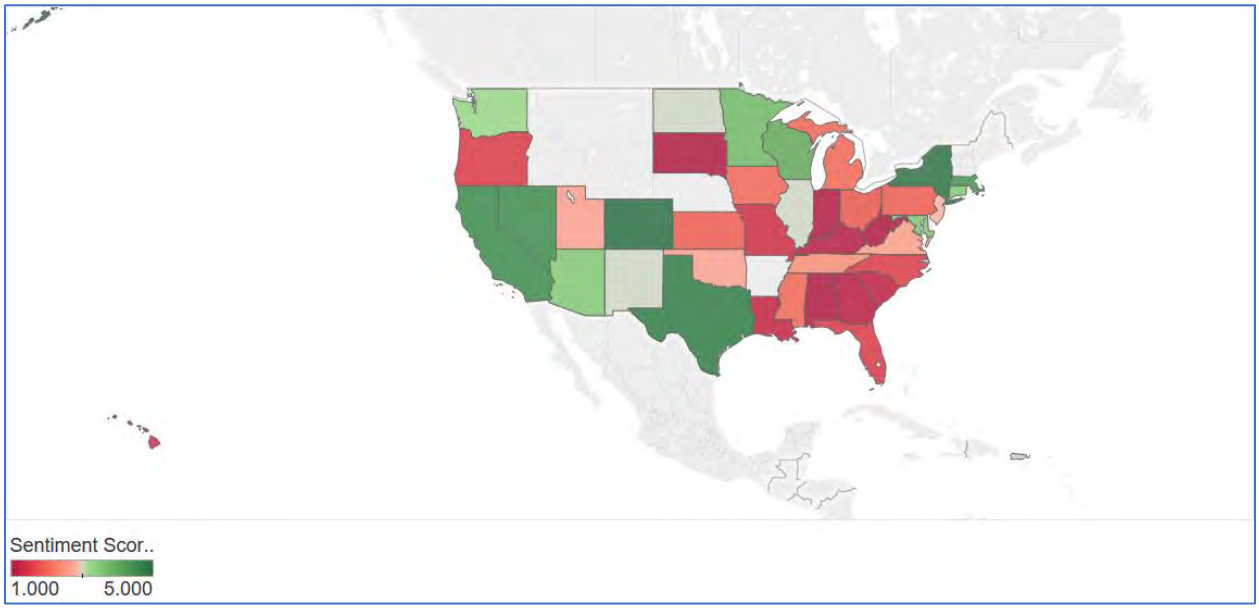


Figure 12: Sentiment of Acuity Circles Framework by State



Option #3 – Population-based

Some commenters requested a population-based framework, but did not provide additional information about the details of such a framework. The commenters were concerned with the areas of the country that have large areas of sparse population in between population centers.

Option #4 – State-based

Some commenters proposed a state-based allocation that would use the state as the first level of allocation. The commenters suggested that it would preserve access to transplant for candidates in areas of the country where there is a higher incidence of liver disease and mortality. Other commenters who supported state-based allocation suggested that they would not be willing to donate if their liver was not placed in their local area. [5]

Option #5 – National

The Attorney Generals of New York and California, and other commenters proposed a completely national system, with no geographic considerations. They contend that even the geographic boundaries used in the proposal continue to disadvantage some patients based on their listing location because there would still be areas of the country where the likelihood of death from liver disease is higher than others, even when the overall mortality risk is lower for that area.

Option #6 – No Change

Approximately a quarter of the commenters, including ASTS, did not support any change. These commenters include a group of centers that included Indiana University Health, The University of Kansas Health System, Vanderbilt, University Medical Center, and Washington University in St. Louis/Barnes-Jewish Hospital Transplant Center. The themes in their comments were:

[5] The Ad Hoc Geography Committee reviewed this concept and concluded that this was another type of pre-existing administrative boundary that was not designed for or optimized for allocation of organs, and would not The Liver Committee also discussed this topic and received advice from UNOS staff that a state based distribution model did not meet the requirements of the OPTN Final Rule.

- Concerns about the fact that a transplant hospital might have areas that are covered in water or are sparely populated within 150 nm
- Belief that it is more important to increase donation through methods like OPO performance goals and education for the general public than to change allocation
- Desire not to donate if their liver would not go to a local candidate
- Concerns that the process is moving too quickly
- Desire to prioritize offers to populations that have higher waitlist mortality rates
- Desire to prioritize offers to populations that have higher incidence of liver disease
- Desire to prioritize offers to populations that have less access to the waitlist
- Concerns about increased cold time
- Belief that MMaT is not appropriate way to measure disparity because MELD doesn't predict mortality risk
- Concerns about increased costs with additional travel
- Concerns that additional travel may result in additional discards
- Disbelief that there can be a decrease in transplant numbers and a simultaneous decrease in waitlist mortality
- Concerns that OPO performance is not a factor that is considered
- Belief that candidates can move to areas with more supply

Circle Sizes

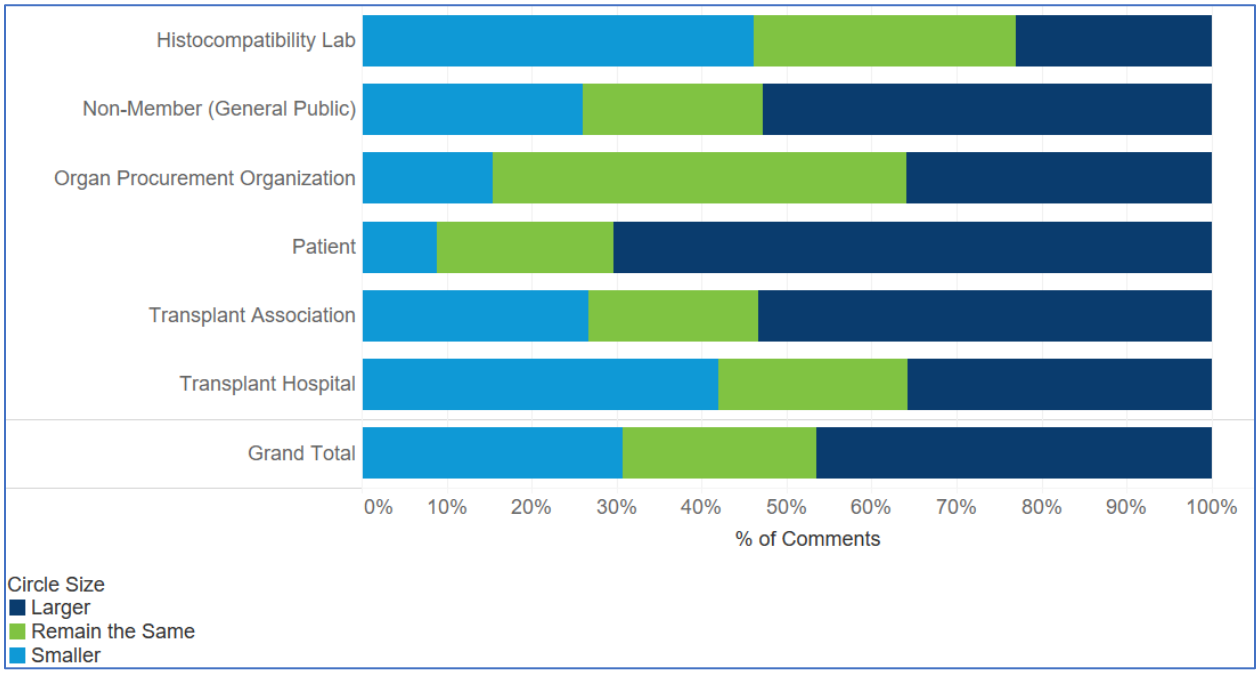
The committee specifically asked for feedback on the size of circles. The options provided were as proposed, smaller or larger. Several commenters provided additional text feedback on specific sizes or requesting a population-based circle.

Options:

1. 150/250/500 nautical miles (Public comment proposal)
2. Larger (such as 150/300/600)
3. Smaller
4. Population Based

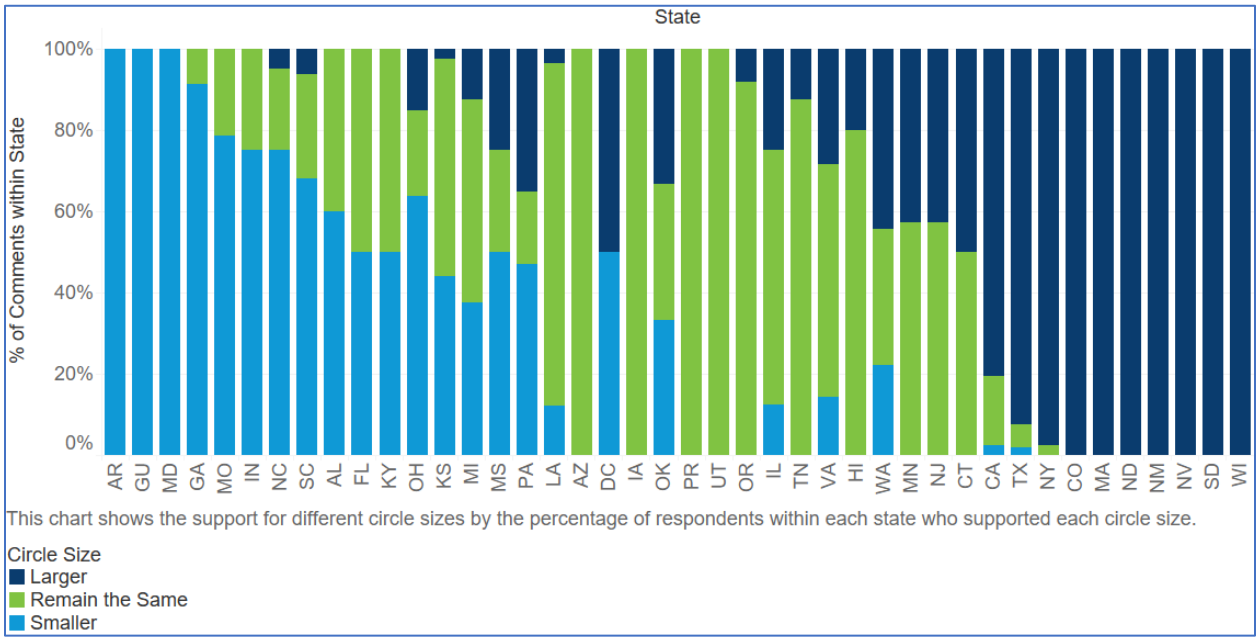
Several constituent groups were represented in public comment respondents. OPOs were the only constituent group that favored the committee's proposed circles sizes the most. No groups had 50% or more that in favor of smaller circles. Patients and general public commenters favored larger circles.

Figure 13: Feedback on Circle Sizes by Member Type



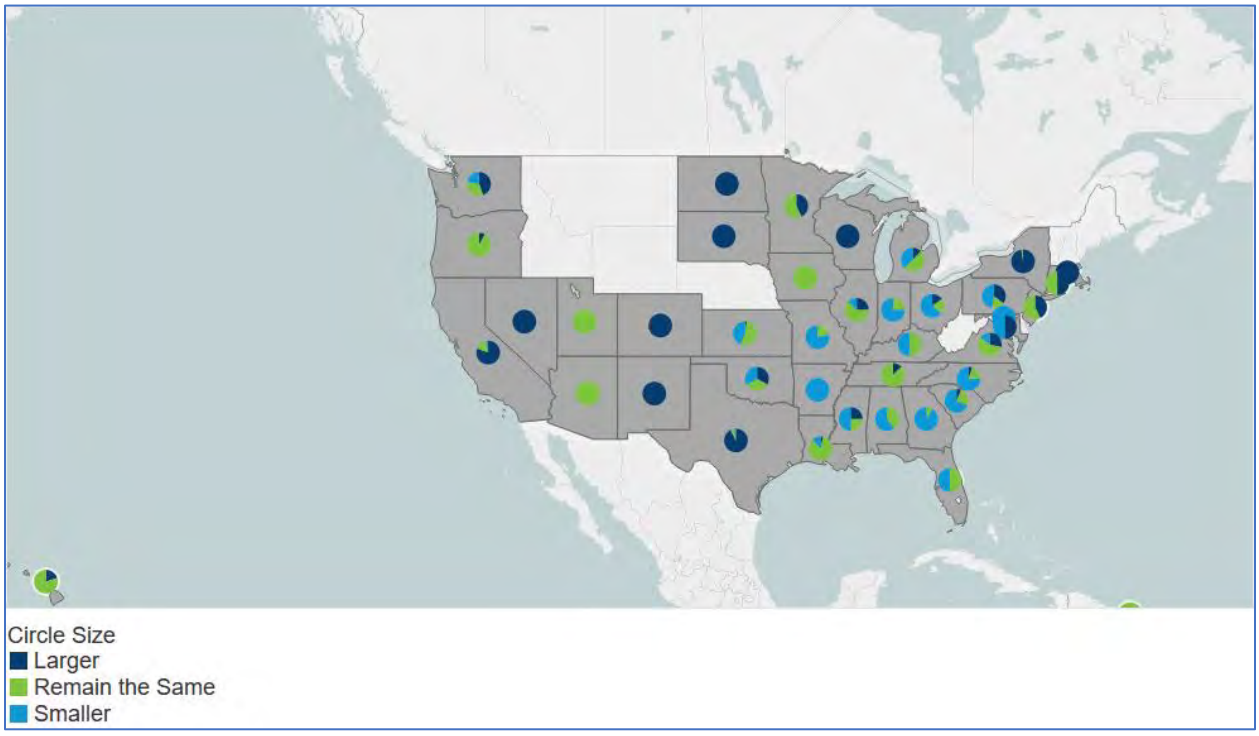
There were responses from most states. The next chart shows the preference for circle sizes within each state. Across the 50 states, there isn't a clear consensus for a circle size.

Figure 14: Feedback on Circle Sizes by State



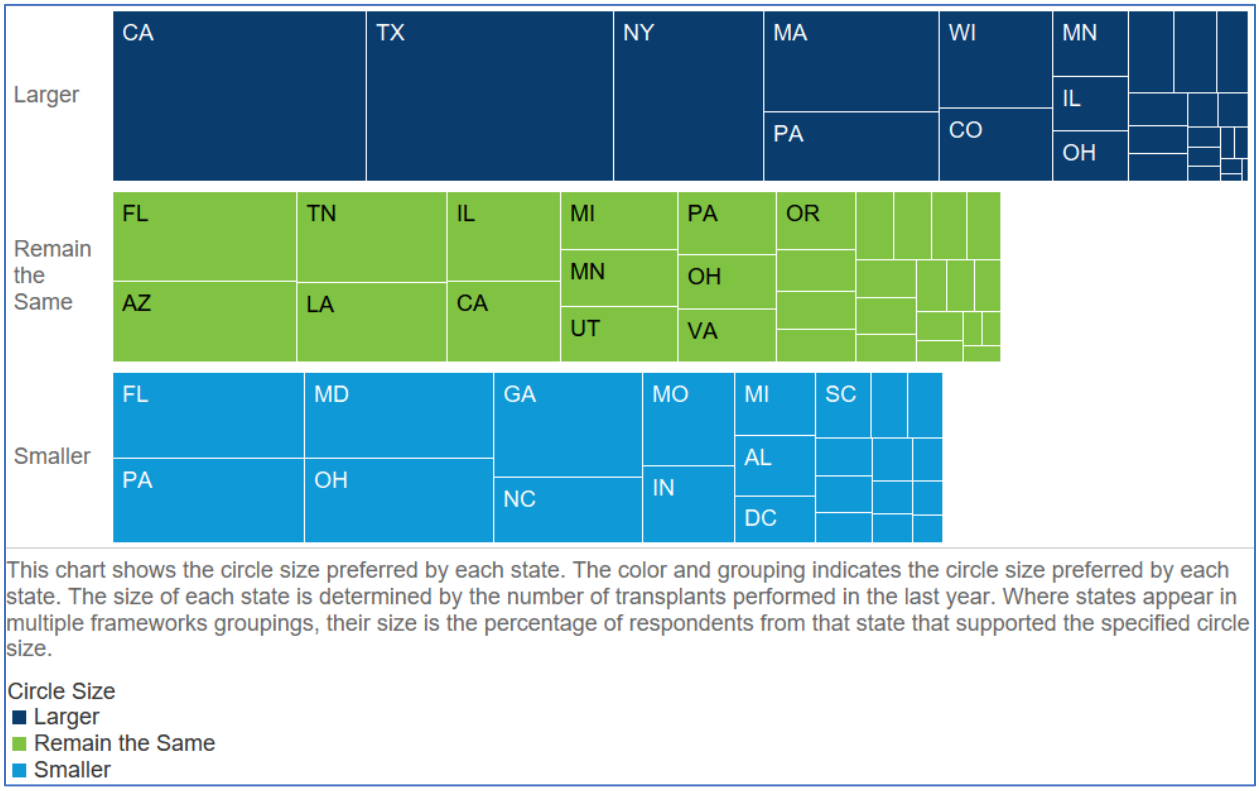
Looking at this on a map, there is a preference for smaller circle sizes in the mid-west and south-eastern states.

Figure 15: Feedback on Circle Sizes by State



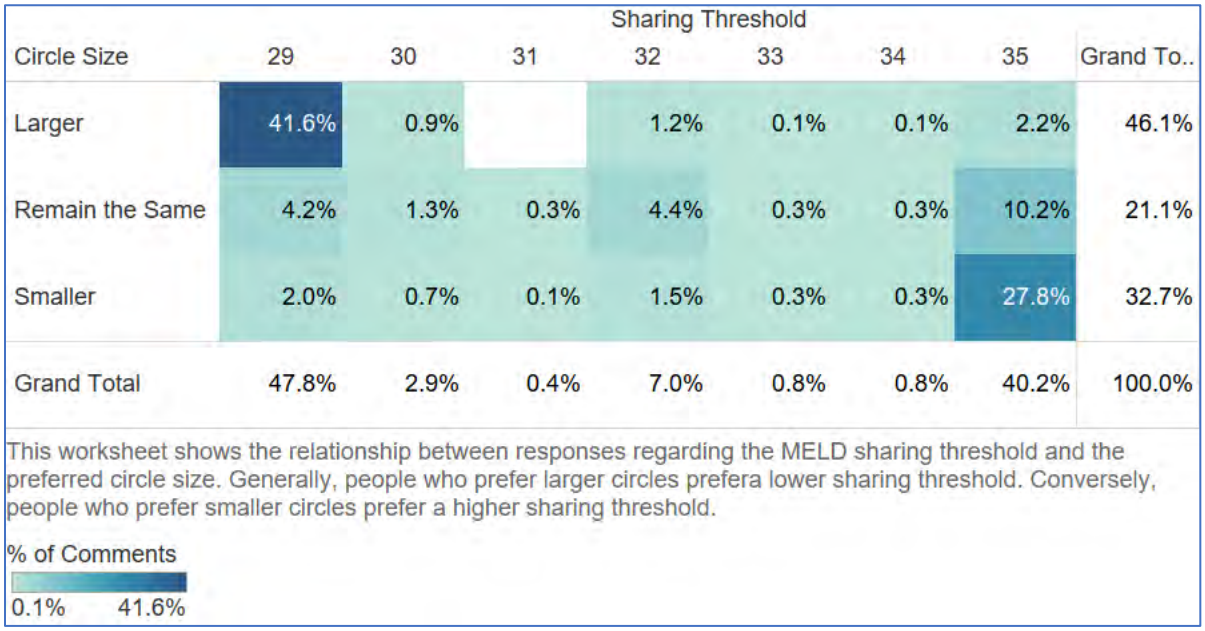
The next chart shows the preference for circle sizes by each state wth the comments weighted by the transplant volume within each state. Weighted this way, there shows more preference for larger distribution circles.

Figure 16: Feedback on Circles Sizes Weighted by State Transplant Volume



There appear to be trends in a commenter's feedback on circles size and their opinion on the distribution threshold. Commenters who favored larger circles tended to favor a lower threshold, and those who favored a smaller circle favored a higher threshold. This is not unexpected since a larger circle size and lower threshold both create broader distribution and a smaller circle and higher threshold result in less broad distribution and more travel. It does appear to show that most commenters either weight travel and logistics or variance and waitlist deaths more across the board.

Figure 17: Feedback Regarding MELD Threshold and Circle Size



	Sharing Threshold							
Circle Size	29	30	31	32	33	34	35	Grand To..
Larger	41.6%	0.9%		1.2%	0.1%	0.1%	2.2%	46.1%
Remain the Same	4.2%	1.3%	0.3%	4.4%	0.3%	0.3%	10.2%	21.1%
Smaller	2.0%	0.7%	0.1%	1.5%	0.3%	0.3%	27.8%	32.7%
Grand Total	47.8%	2.9%	0.4%	7.0%	0.8%	0.8%	40.2%	100.0%

Option #1 – 150/250/500 nautical miles

The current proposal uses circles of 150, 250 and 500 nm around the donor hospital as the units of allocation.

This option reflects the policy language that went out for public comment. Of the options included in the questionnaire, this had the second-most supporters.

Option #2 – Larger

The majority of commenters preferred circles larger than the proposed 150/250/500 nm.

Some commenters were concerned that the 150 nm circle was too small because their hospital would not be within the 150 nm circle of donor hospitals that are currently in the transplant hospital's DSA. Many suggested a circle of at least 250 or favored the 300/600 modeled with acuity circles, while others preferred 500 and 1000 nm. One commenter suggested a circle of 750 for MELD less than 35 and 1000 nm for MELD of 35 and higher. The specific alternatives proposed by commenters were:

5. 250/500 nm
6. 300/600 nm
7. 500/1000 nm
8. 750/1000 nm

Many of the commenters who responded in favor of larger circles provided written responses indicating a preference for modeling population-based circles (see option #4) and expressing concerns over the fact that the circle would include the ocean or another country for many hospitals. Additional comments mentioned that 150-nm circles would be smaller than many current DSA boundaries and would result in less access for certain patients. Others were concerned with maintaining access for areas of the country with high prevalence of liver disease.

Option #3 – Smaller

The least-preferred option of those on the form was circles that were smaller than 150/250/500 nm. One commenter specifically suggested a circle of 75 nm for the smallest unit of allocation.

The commenters that preferred this option were in the minority. The commenters who preferred this option also generally preferred a higher distribution threshold. Commenters were concerned with the increased costs and difficulty with logistics such as finding pilots with the increases in flying predicted in the models. Many of the commenters who supported smaller circles also were against all of the modeled options.

Option #4 – Population Based

In addition to the options above, some commenters wrote in with an additional suggestion. The committee received comments requesting consideration of population-based circles, including quite a few comments requesting that it be modeled before the committee decided on a solution. Several commenters believed that set distance circles would disadvantage areas where a circle would include water or another country or where there are large rural areas in between population centers. They hope that circles that adjust based on population would ensure access for those areas. This concept was supported by ASTS.

MELD Distribution Threshold

Options:

1. 32 (Public comment proposal)
2. 35
3. 29
4. 25
5. 15
6. None

Most of the commenters who expressed an opinion on the distribution threshold were transplant hospitals. There were more comments from New York on this question than from any other state.

Figure 18: Feedback on Distribution Threshold by Member Type

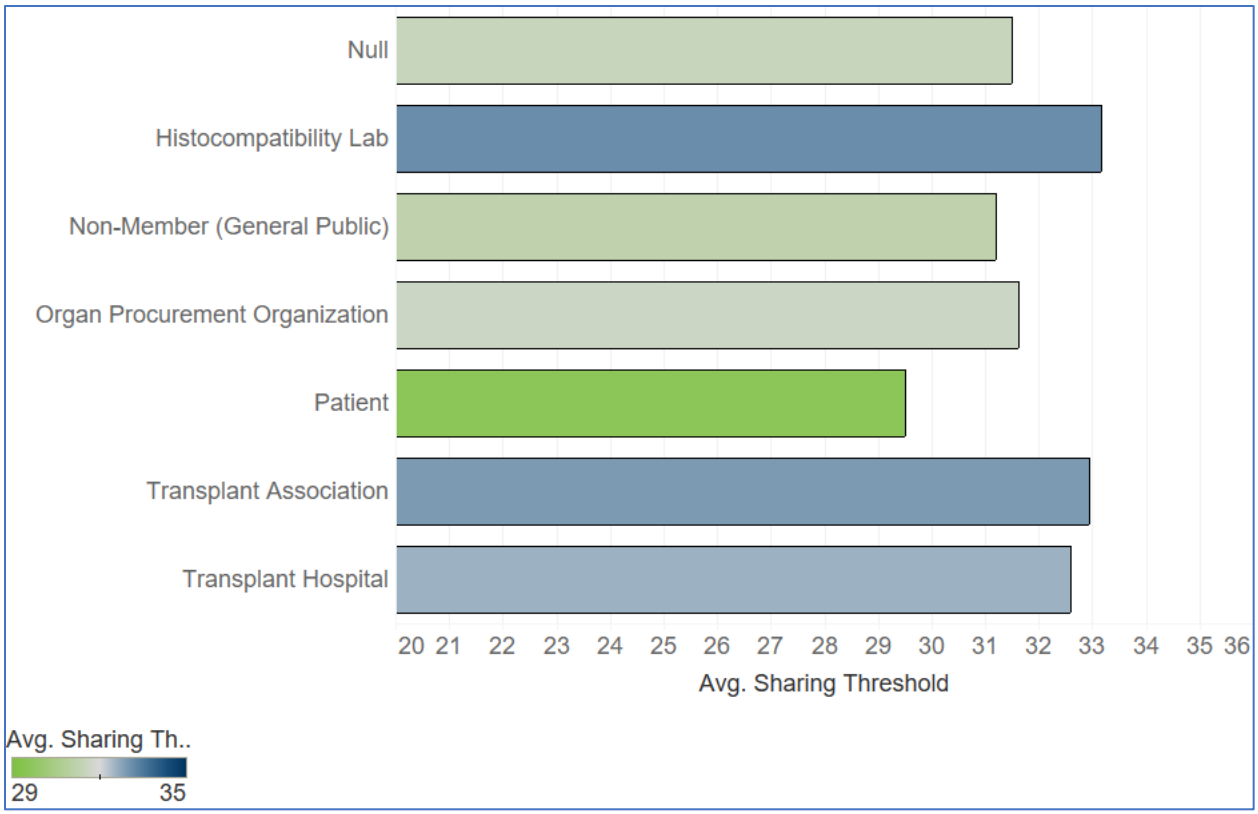
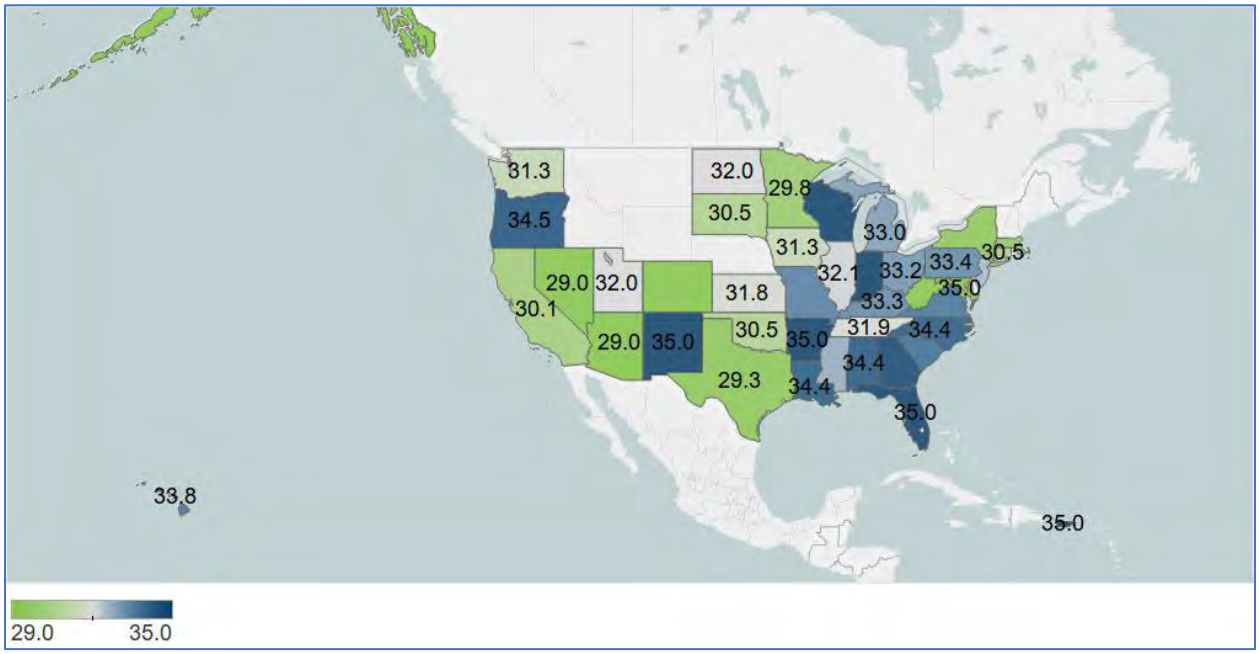


Figure 19: Feedback on Distribution Threshold by State



Option #1 – MELD/PELD of 32

The current proposal includes a MELD/PELD distribution threshold of 32. It allocates livers to candidates with a MELD or PELD of 32 or higher within 250 nm of the donor hospital before candidates with a MELD or PELD lower than 32 within 150 nm.

This option reflects the policy language that went out for public comment.

Roughly 10% of commenters preferred this distribution threshold.

Option #2 – MELD/PELD of 35

The SRTR also modeled B2C with a distribution threshold of 35, similar to Share 35. This option was largely preferred by commenters who also supported smaller circles. It was supported by approximately 24% of commenters. Many of these commenters also preferred to keep the allocation as close as possible to the version passed in December 2017.

Option #3 – MELD/PELD of 29

The majority of commenters preferred a distribution threshold of 29. This option was not modeled by the SRTR, but appeared to be a point at which the difference in mortality rates increased more dramatically.

Option #4 – MELD/PELD of 25

One commenter proposed a distribution threshold of 25, stating that it would decrease mortality rates.

Option #5 – MELD/PELD of 15 or lower

Several commenters proposed a distribution threshold of 15 in order to increase distribution and further reduce waitlist mortality and variance in median MELD at transplant. Some also asserted that they believed that any higher threshold was a violation of the Final Rule.

Option #6 – None

Several commenters suggested that there was no need for a distribution threshold at all.

ABO Variance

Options:

1. Only apply this variance to Hawaii (public comment proposal and current policy)
2. Apply this variance to both Hawaii and Puerto Rico

Option #1 – Only apply this variance to Hawaii

The current proposal does not include a variance for Puerto Rico, but does include one for Hawaii. For blood type O donors recovered in Hawaii, the variance changes the order of allocation to include any blood type recipients in the same classifications. This removes the priority for O and B candidates that would otherwise exist when allocating O donors and allows for allocation of O donors to A and AB candidates in Hawaii before national offers to O and B candidates.

This option reflects the current policy language and the proposal that went out for public comment.

Commenters who expressed an opinion on the variance all agreed that it should continue to apply to Hawaii. Those who thought it should not apply to Puerto Rico didn't believe the same logistical issues exist for traveling to the mainland from Puerto Rico that exist for Hawaii.

Option #2 – Apply the variance to both Hawaii and Puerto Rico

The other option that the committee sought feedback on in public comment was applying the same variance to O donors recovered in Puerto Rico as well.

Supporters of this option pointed to equity and assisting the population of Puerto Rico. Although most commenters did not take a stance on this question, those that did were fairly evenly split, with slightly more favoring extending the variance to Puerto Rico. Many commenters focused on the isolation of Puerto Rico without regard to their ABO population.

Pediatric Allocation

The current proposal allocates pediatric donor organs first within 500nm of the donor hospital and then nationally. It allocates these organs nationally to pediatric candidates before offering them to any adult MELD candidates.

This option reflects the policy language that went out for public comment.

The comments received regarding pediatric allocation either directly expressed support for this change or requested this kind of change. There were no comments opposed to the change.

Other Considerations

AOPO and others requested careful monitoring of organ wastage so that the policy could be quickly changed if the additional travel results in increased wastage of organs.

AOPO and the OPO Committee also requested additional enhancements to the functioning of DonorNet℠ to ensure efficient placement of organs, including transparency around offers and expedited placement.

Comments Received

Below are the regional and committee comments submitted during the public comment period.

Regional Comments[6]

Region 1

Region 1 (9 of 21 voting members submitted a vote online):

- *Broader 2-circle distribution: 0 strongly support, 3 support, 0 abstain/neutral, 3 oppose, 3 strongly oppose*
- *MELD sharing threshold recommendation: 1 for MELD 34, 1 for MELD 32, **6 for MELD 29**, 1 abstain*
- *Size of fixed distance circles recommendation: 1 for remain the same, 0 for smaller, **7 for larger**, 1 abstain*
- *Acuity circles: **6 strongly support**, 2 support, 0 abstain/neutral, 1 oppose, 0 strongly oppose*

Many on the call supported broader sharing and did not think either model presented by the committee would make significant changes to the current system. Of the two models presented, there was support for the Acuity Circle model as the best next step to successfully share more broadly. Those in favor of the acuity model are aware that there will need to be changes in the way the community procures and transports organs. There is no way to predict the change in cost, cold ischemic time or discards because there is no way to predict changes in behavior. If Broader Sharing 2 Circle is chosen, the most support voiced was for using a sharing threshold of 29. Those on the call supported allowing Hawaii to keep their variance, but did not see a need to expand the variance to include Puerto Rico.

Region 2

Region 2 (16 of 58 voting members submitted a vote online):

- *Broader 2-circle distribution: 4 strongly support, 4 support, 2 abstain/neutral, 2 oppose, 4 strongly oppose*
- *MELD sharing threshold recommendation: 1 for MELD of 29, 1 for MELD 30, 5 for MELD 32, **8 for MELD 35**, 1 abstain*
- *Size of fixed distance circles recommendation: 5 for remain the same, **7 for smaller**, 4 for larger, 0 abstain*
- *Acuity circles: 0 strongly support, **5 support**, 3 abstain/neutral, 4 oppose, 4 strongly oppose*

There is a concern about population density in relation to the size of sharing circles. With such high population density in the northeast, did the committee consider available resources such as hospital staff and the number airplanes? Smaller sharing circles would make more sense in areas of high population density.

There was a comment that in regards to pediatric patients, B2C seems to be the most favorable for that group.

Another commenter stated that the B2C model seems to be favorable to patients on the wait list while keeping costs down at the same time.

[6] Comments from the regions are approved by the Regional Councilor and are meant to express the overall sentiment of the participants on the regional webinar. They are not a transcript of the regional meeting nor do they reflect other comments submitted from the region.

Region 3

Region 3 (13 of 45 voting members submitted a vote online):

- *Broader 2-circle distribution: 0 strongly support, 4 support, 3 abstain/neutral, 4 oppose, 2 strongly oppose*
- *MELD sharing threshold recommendation: **6 for MELD of 35**, 3 for MELD 32, 4 abstain*
- *Size of fixed distance circles recommendation**: 7 for remain the same**, 2 for smaller, 4 abstain*
- *Acuity circles: 0 strongly support, 1 support, 2 abstain/neutral, 3 oppose, **7 strongly oppose***

While some members noted that it is important for the region to provide feedback and be involved in picking a policy that addresses the legal matters at hand, there were other members who shared the following concerns:

Flying increases in all regions but only some areas of the country will gain with this proposal. Some areas will be flying more, but they will increase the number of livers. However, members believe that region 3 will be flying more but will be losing livers. There will be no larger improvements for the overall system - flying will increase, logistics will become more challenging and burdensome, volume of overall livers transplanted will decrease. Region 3 will do less, but at a higher cost. Members also believe that the SRTR modeling uses older data to assess the "current" state of liver allocation and may affect the comparisons made to the modeled options in terms of the counts of waitlist deaths, waitlist mortality rates, and transplant volume.

There is concern that any of these proposals will jeopardize access for poor and minority patients. Opening the door to fixed circles and lowering the sharing MELD will worsen disparity for these groups and still does not help certain areas of the country such as California. There is a sense that the legal matters have created arbitrary time constraints and more information is needed. Costs need to be better examined before moving forward. Members felt that % flying is a surrogate of cost (mostly due to jet fuel), but there are other increased costs to consider as well. Putting the cost into dollars increased vs transplant gained or dollars increased vs MELD variance decreased would be more meaningful when evaluating the value of the proposal. Members would still like to see the state distribution idea modeled and considered before adopting a final policy.

Other feedback:

One member commented that they would prefer a sharing threshold of 29. This would increase access for sicker patients registered at transplant centers that are in cities on the coast and areas with higher population density.

One member commented that Puerto Rico is only a 2.5 hour flight and its distance from the mainland does not justify a variance.

There was a suggestion to prioritize re-transplants differently because they have a higher mortality rate.

Region 4

Region 4 (17/44 voting members submitted a vote online):

- *Broader 2-circle distribution: 4 strongly support, 3 support, 1abstain/neutral, 1 oppose, **8 strongly oppose***
- *MELD sharing threshold recommendation**: 8 for MELD of 29**, 1 for MELD 33, 4 for MELD 32, 4 for MELD 35*
- *Size of fixed distance circles recommendation: 5 for remain the same, 2 for smaller, **9 for larger***
- *Acuity circles: **7 strongly support**, 2 support, 3 abstain/neutral, 2 oppose, 3 strongly oppose*

Those attending the webinar were engaged and provided thoughtful feedback.

Some members commented that in Texas they are already flying 60-70% of the time to get livers and have a much larger distribution area than what is in the proposed policy. There was concern that the proposed model would disadvantage patients at centers near the coast where much of the circle will be over water. There was also concern that the B2C model would result in an increase in waiting list mortality in Texas.

Some on the webinar commented that any proposal should have very large circles (500 plus nm), and the sharing for MELD down to 25 to affect mortality for sick people and to increase access.

There was some support for the acuity models and for lowering the threshold for the B2C model to 25-26 because the mortality curve increases around that level. There was concern that transplanting candidates with higher MELDs would increase costs more than additional flying.

There was feedback that based on the data, centers in Texas and Oklahoma will have an increase in transplants under the B2C model.

There was concern that increasing the MELD threshold or reducing the circle size would limit access for patients at the VA hospitals since there are a very few across the country and veterans have to travel to one of these centers to get a transplant.

There was a comment that the modeling does not reflect disparity between supply and demand. This is influenced by OPO performance, center acceptance practices and activity of living donor programs. Centers need to consider maximizing resources and capabilities. Increasing the size of the circle is not the answer given the cost associated with flying. A cost analysis is needed to understand how changes will effect transplant centers.

Region 5

Region 5 (16 of 45 voting members submitted a vote online):

- *Broader 2-circle distribution: 3 strongly support, 4 support, 2 abstain/neutral, 2 oppose, 5 strongly oppose*
- *MELD sharing threshold recommendation: 2 for MELD of 35, 6 for MELD 32, 8 for MELD 29, 0 abstain*
- *Size of fixed distance circles recommendation: 6 for remain the same, 0 for smaller, 9 for larger, 1 abstain*
- *Acuity circles: 6 strongly support, 4 support, 3 abstain/neutral, 2 oppose, 1 strongly oppose*

One member commented that we should consider Acuity 300/600 since it has the most significant reduction of MELD/PELD at transplant.

Multiple members expressed they would have liked to have seen more modeling data including the impact of lowering the MELD threshold to 29 on the percent of transplants that would require flying, and the overall data for MELD thresholds lower than 32, with specific mention of 29 and 25.

One person asked who would absorb the increased transportation costs associated with larger nautical mile distances.

A member recommended phased approach with B2C-32 for 1 year and then B2C-29 phased in to allow for modeling and observation of behavior and modification of policy.

Multiple members voiced support for lower MELD thresholds including 29 (with 250/500nm), 25, and 24.

One member voiced that they feel that centers that do not share as much are underrepresented on the liver committee and that this proposal is not representative of them.

Region 6

Region 6 (23 of 80 voting members submitted a vote online). Draft comments

- *Broader 2-circle distribution: **17 strongly support**, 5 support, 0 abstain/neutral, 1 oppose, 0 strongly oppose*
- *MELD sharing threshold recommendation: 2 for MELD of 29, 3 for MELD 32, **18 for MELD 35***
- *Size of fixed distance circles recommendation: **21 for remain the same**, 1 for smaller, 1 for larger*
- *Acuity circles: 1 strongly support, 2 support, 1 abstain/neutral, 4 oppose, **15 strongly oppose***

The region expressed great concern over the lack of consideration for Alaskan donors. Since any donor in Alaska will be more than 500 nautical miles from a transplant center, those livers will go straight to national sharing. That is not an efficient means for liver allocation due to the distance to ship the organ and the increased cold ischemic time. One member proposed that transplant centers in the Pacific Northwest be included in a 500 nautical mile circle around the donor hospital in Alaska; that way those offers would not go straight to national offers and hopefully prevent unnecessary organ discards.

It was noted that in the B2C model it is concerning that there are sharp cliffs when it comes to allocation. A patient with a MELD of 16 that is 145 nautical miles from a donor will get a liver offer before a patient with a MELD of 31 that is 155 nautical miles from the donor.

A comment was made that the region will see an increase in the number of organs exported and they are concerned that waitlist mortality rates will increase because of that. It was also noted that the amount of flying will increase, adding an exorbitant amount to a transplant program's costs. With the increase in flying will there be enough planes?

Region 7

Region 7 (11 of 34 voting members submitted a vote online):

- *Broader 2-circle distribution: 2 strongly support, **4 support,** 1 abstain/neutral, 2 oppose, 2 strongly oppose*
- *MELD sharing threshold recommendation: 3 for MELD 29, **5 for MELD 32**, 3 for MELD 35*
- *Size of fixed distance circles recommendation: **6 for remain the same**, 4 for larger, 1 abstain*
- *Acuity circles: 3 strongly support, 2 support, 3 abstain/neutral, 1 oppose, 2 strongly oppose*

An OPO member commented that:

They understand there is a need for change before intervention comes from entities outside the transplant community such as Congress. Outside intervention would negatively affect the transplant community in general and especially donation. There was support expressed for the circle model which makes logical sense given the time constraints. It was noted that the changes to lung allocation caused a big shift in the export of lungs in the beginning, but now seems to be reaching an equilibrium in their area and noted that there is certainly benefit to transplanting patients who are sicker. Whichever solution is settled on for liver will be monitored and there will be data collected that can assess for unintended consequences such as traveling too much with too little benefit. The measure of median MELD is driven by several factors, but surgeon/transplant program preferences in organ acceptance can certainly drive this measure. Broader sharing could level out this factor by encouraging more conservative centers to become more aggressive and centers that are already aggressive due to lack of organ offers to receive more offers and reduce some of their risk.

One member noted that they preferred the acuity circles model. For the broader 2-circle distribution, this member thought that the MELD 32 may not be the right sharing threshold. Additionally, for the sickest patients, access should not be limited to 250 nautical miles.

Members like the policy's modeled effects on pediatrics and adolescents and believe it is an advancement for this population.

One member commented that Hawaii and Puerto Rico both warrant variances.

Region 8

Region 8 (5 of 31 voting members submitted a vote online):

- *Broader 2-circle distribution: 2 strongly support, **3 support**, 0 abstain/neutral, 0 oppose, 0 strongly oppose*
- *MELD sharing threshold recommendation: **4 for MELD of 35**, 1 for MELD 32*
- *Size of fixed distance circles recommendation**: 4 for remain the same**, 1 for smaller*
- *Acuity circles: 0 strongly support, 0 support, 2 abstain/neutral, 1 oppose, **2 strongly oppose***

Members are concerned about the increased amount of flying predicted with any of the SRTR models and the impact on cold ischemia time, discard rates, transplant rate, and costs. Members also believe that the SRTR modeling is not using the most up-to-date data. Additionally, there was a request to provide the modeling data on socioeconomics at a regional level to better understand impact and additional analysis is needed to know how this will impact rural areas. The timeline for addressing the legal matters is compressed and more analysis/information may be needed.

Members do not support lowering the MELD sharing threshold to 29 in the broader 2-circle model. There was some support for increasing the MELD sharing threshold from the proposed 32 to 35. It was noted that some city programs, like Denver, in region 8 are not going to be within even 500 nautical miles. There was also a comment that a state first distribution should be an option for consideration.

Members continue to voice concerns about access to care and access to the waiting list. Mortality on the waiting list still needs to be better addressed. Members urged UNOS and the OPTN to consider all aspects of the Final Rule and not just those that relate to geography.

Region 9

Region 9 (15 of 28 voting members submitted a vote online):

- *Broader 2-circle distribution: 0 strongly support, 2 support, 2 abstain/neutral, 1 oppose, **10 strongly oppose***
- *MELD sharing threshold recommendation: **12 for MELD of 29**, 1 for MELD 30, 0 for MELD 32, 1 for MELD 35*
- *Size of fixed distance circles recommendation: 0 for remain the same, 0 for smaller, **15 for larger**, 0 abstain*
- *Acuity circles: **13 strongly support**, 2 support, 0 abstain/neutral, 0 oppose, 0 strongly oppose*

Those who attended the call were engaged and provided thoughtful feedback.

There was overall support from those on the call for the acuity model and broader sharing. Many agreed that the acuity model minimizes geography and emphasizes acuity of illness. Some commented that based on the SRTR analysis, the acuity model decreases waitlist mortality and reflects a more efficient way of allocating livers and is the most fair nationally.

There was some support for not having any MELD thresholds for sharing since MELD stratifies patient at risk. In addition, data shows that MELD scores in the mid-20's have increased mortality on the waiting list. The lower the threshold, the more equity for patients.

There were comments that Region 9 has long tradition of believing in broad sharing and that livers should go to patients with highest severity scores and has regional sharing of livers this way for many years. Although not in the modelling, there will likely be substantial behavioral changes regarding utilization of organs as a result of changes in policy.

Some members commented that while there is increased cost to travel, cost savings by transplanting sicker patients earlier outweighs expense of travel. There won't be people sitting in ICUs with very high MELDs which takes a lot of resources.

There was a comment that MELD scores guide us to the sickest patients; there is no other situation in healthcare where geography directs access to therapy for your disease (e.g. chemo or insulin for diabetics). Transport time and how many organs are flown depends on factors such as traffic and time of day. There is no way to accurately predict this.

There was feedback that 150 mile circle will restrict sharing in NY and many areas of the country. 150 mile sharing circle is smaller than about 20% of current DSA and is too restrictive.

There was feedback that the community needs to step back and focus on basic principles of equity. Organs are a national resource – two people, equally as sick, should have equal access to get a transplant. There needs to be equity among transplant patients who really need organs and not among transplant hospitals and physicians. If you are sick, you should have access to these organs regardless of location.

Region 10

Region 10 (16 of 34 voting members submitted a vote online):

- Broader 2-circle distribution: 6 strongly support, **7 support**, 2 abstain/neutral, 0 oppose, 1 strongly oppose
- MELD sharing threshold recommendation: 1 for MELD of 30, 6 for MELD 32, 1 for MELD 33, 1 for MELD 34, **7 for MELD 35**, 0 abstain
- Size of fixed distance circles recommendation: 8 for remain the same, 8 for smaller, 0 abstain
- Acuity circles: 0 strongly support, 1 support, 2 abstain/neutral, 2 oppose, **10 strongly oppose**

Members in the region had concerns about geographic barriers and calculating distance from donor hospital from the transplant hospital and not place of candidate residence. Candidates who live in the western part of Michigan could potentially miss liver offers since they are listed at a transplant center in southeastern Michigan and that would increase the distance from a donor hospital on the other western side of Lake Michigan. They would also like to see that population density is considered by the committee before selecting one of the proposed models.

The comment was made that any changes made to liver allocation should be done in an iterative fashion since more changes will surely come with time. It would be sensible to make a more conservative change at this time, especially with changes in NLRB starting as well. The lawsuit has asked for DSA and region to be removed from liver allocation, and that should be the focus of any changes made to liver allocation. The group favored the B2C model and in general, favored 35 over 32 since the modeling showed minimal differences in the outcomes measured. There was concern over why 32 was favored by Liver and Intestinal Committee over 35 and how 29 will be advocated without any modeling.

There is concern that mortality rates will rise in the first year due to the volume of exception candidates. Many exception scores will be higher than the sharing threshold decided on for the new allocation system, so patients with MELD scores will be disadvantage compared to exception patients. Region 10 has roughly 10% of exception cases so will not be able to take advantage of this exception backlog.

Region 11

Region 11 (14 of 37 voting members submitted a vote online):

- *Broader 2-circle distribution: 3 strongly support, 1 support, 3 abstain/neutral, 2 oppose**, 5 strongly oppose***
- *MELD sharing threshold recommendation: 4 for MELD of 35, 1 for MELD of 34, 4 for MELD 32, 1 for MELD of 30, 4 abstain*
- *Size of fixed distance circles recommendation: **7 for remain the same**, 6 for smaller, 1 abstain*
- *Acuity circles: 1 strongly support, 1 support, 4 abstain/neutral, 0 oppose, **8 strongly oppose***

One member commented that the Final Rule has multiple principles, not just geography. This member also stated this is a disruptive change and asked how mortality and burden of disease are being considered in this proposal. He stated that this could potentially exacerbate the health of populations with disparities and that all patients with liver disease, not just the listed patients, should be considered. Another member agreed and added that the states with the lowest instances of liver disease (based on CDC data) stand to gain the most from this proposal and that every center in region 11 will do less transplants and they have the highest level of liver disease.

Another member commented that sharing livers between regions is the best thing about this proposal and distribution between borders is a good thing. He also expressed concern about the inefficiency of distance and increased flight times not being compliant with the Final Rule and is surprised about the staggering increases and associated costs. He recommended adjusting the distance and MELD thresholds to prevent “average livers” crisscrossing in the air.

One member shared that with the changes to exception points as a result of the NLRB, it is difficult to predict what scores will be for exception patients. This is especially true of pediatric patients, since PELD scores are higher than MELD scores, and most pediatric patients are transplanted with PELDs greater than 30. For this reason, a higher cap on exception scores should be considered to give more of a buffer and make sure these pediatric patients can get an exception score that will help them get offers.

There is concern that one of the drivers in variance in median MELD is the prevalence of exception patients and high exception scores in certain areas. Why didn’t the committee use laboratory MELD (and exclude exceptions) for the MMaT calculation?

Committee Comments

OPTN/UNOS Patient Affairs Committee

The OPTN/UNOS Patient Affairs Committee thanks the Liver & Intestinal Organ Committee for the opportunity to provide feedback on their proposal to eliminate DSA and Region from liver distribution. Unanimously, the PAC wholeheartedly supports a proposal that facilitates broader distribution of not just livers, but all organs, and thus minimizes the significance of geography in allocation. Although there was still some residual confusion about the use of concentric circles in light of the 3 frameworks recently out for public comment; a majority understood the constraints within which the Liver Committee had to make rapid changes. The PAC supports a solution that:

- Prioritizes the sickest candidates first
- Promotes utilization and mitigates discards
- Does not prolong the allocation process
- Considers recipient/graft outcomes

The PAC was evenly split regarding whether the Broader 2 Circle (B2C) or the Acuity-based Model was the better solution. Those favoring the B2C tended to also work in the transplant or OPO profession, or had other fiduciary experience, so were sensitized to cost concerns. This cohort felt this model balances equity in access and prioritizing the most urgent patients first while optimizing successful organ transplants, avoiding organ wastage and mitigating costs. These members emphasized concerns other transplant professionals have cited pertaining to cost increases. Members acknowledged that although beyond the OPTN's purview, reimbursement should be addressed with all payers, not just by CMS to justify and document that patients, even sicker ones receiving transplants sooner than those under the current allocation system, can return to healthier lifestyles and ultimately reduce their cost of care over an extended period of time. A few members felt the OPTN should broach this subject with third-party payers. However, the average patient has no knowledge of the fiscal impact these changes will have to programs (or OPOs), or the downstream financial effects. The PAC did acknowledge that if the cost increases were so significant that they caused a transplant program closure, this could impact access. In terms of circle size, the PAC continues to seek a firm recognition that the variable of concern is really time, not distance. Should this system be adopted, some members supported a MELD threshold of 29, based upon increased mortality risk of the other options. Other members supported a higher threshold, such as 32, which is what the OPTN Board of Directors approved in December 2017.

Those who supported the acuity model felt this system would provide a more equitable distribution of livers based upon Median MELD at Transplant (MMaT) and Waitlist Mortality Rates. From a patient perspective, and all things being equal, the PAC felt this model was more equitable and in line with the Final Rule. Ideally, neither cost nor geography would disadvantage candidates. They also debated whether outcomes would be better (transplanting sicker patients earlier, before they are too sick to be transplanted or die on the waiting list) or potentially negatively impacted (from the effects of potentially longer ischemic times, or transplanting sicker candidates).

There was mixed support for extending the Closed Variance for Allocation of Blood Type O Deceased Donor Livers in Hawaii to Puerto Rico (PR). Those who favored applying the variance to PR felt it was reasonable as the geographic challenges for these non-contiguous states were likely similar. In addition, there was some support for further extending a variance to Alaska and other areas in which there is not a transplant hospital w/in the 500 nautical mile circle (perhaps extending the allocation area to a slightly larger area, e.g. an additional 100 or 200 nautical miles). However, some members felt that PR was not in the same position as Hawaii, and was not at as much of a disadvantage. Others proposed revisiting this question as part of the post-implementation monitoring.

While not directly related to the proposal decision requested, the PAC emphasized education, not only for the transplant community, but particularly for the general public and patients. As the OPTN modifies the geographic distribution for the other organ systems, a proactive messaging strategy would be helpful to ensure public trust in the organ allocation system, promoting equity and fairness, and encouraging donation.

Finally, and not specific to this proposal, the PAC continues to encourage all OPTN committees to write policy proposals at a level an average candidate or recipient would understand. This is essential to more patients submitting feedback. A 79-page proposal written in "professional speak" intimidates and discourages members of the general public from commenting on these policy proposals. If the entire proposal cannot be written in plain language, we would advocate for an accompanying "layman's abstract" or summary.

PAC members asked the following questions, which were answered to the satisfaction of the group:

• Question: 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. The Liver Committee is proposing excluding these donors' from the calculation of MMaT and MPaT because the scores at transplant for these recipients tend to be outliers. Why?

> Answer: These are being excluded as these candidates are typically transplanted at a lower MMaT, and may disadvantage other patients if they were included in the system that calculates MMat and MPaT.

• Question: How exactly will the B2C vs Acuity model improve mortality rates on waitlists?

> Answer: The expected survival on the waitlist was calculated to have improved under these model because patients who would have been too sick to be transplant, or were at highest risk to die while waiting, will be transplanted.

• Question: How will split livers be allocated?

> Anaswer: Exactly as they are today.

• Question: What timeframe did the modelling cover?

> Answer: The modelling included transplants conducted over a year's time.

• Question: If the pediatric list is exhausted nationally, then would the offer come back to adult allocation and start over?

> Anaswer: Yes, the offers will be extended to adult candidates after pediatric candidates, as is done today.

• Question: If travel is restricted due to weather-related events, is there a contingency distribution model in place so discards do not occur due to weather related incidents? Would the organ then be allocated within a non-fly area 150 miles?

> Answer: There is not. Usually this is not an issue; it is rare that procurement teams can't get an organ to a potential recipient. Sometimes the patient can't travel. Teams typically have a robust back-up plan so organs do not go to waste.

• Question: What is the time table for implementation?

> A: The National Liver Review Board is expected to be implemented in the first quarter of 2019, and the allocation changes will take effect after that

OPTN/UNOS Minority Affairs Committee

On October 15, 2018 the Minority Affairs Committee (MAC) heard a presentation on the Liver Committee's proposed changes to geographic liver allocation. The MAC thanks the Liver Committee for its work on the proposal. The following questions were asked by MAC members and answered by the Liver Committee chair.

• Question: Does the SRTR modeling upon which the proposal is based show an impact on minority populations?

> o Answer: No, the modeling generally did not show positive or negative impact on minority populations compared to the current system. While ethnicity and gender were neutral compared to the current system, there was a slightly positive impact on pediatric liver candidates.

• Question: Could the proposed changes lead to livers being shipped significant distances before the liver surgeon assesses the organ, increasing discard rates?

- Answer: It is standard for liver surgeons to travel to procure the organs now, or use the local center that they have a relationship with to do so; therefore the surgeons would know at the time of procurement the liver quality and discard rates shouldn't be impacted.

• Question: What will be the impact with SLK?

- Answer: 250 nm (the size being considered by the Liver Committee) is smaller than most regions, although it would be a moving circle based on donor hospital. There is no indication there would be broader sharing of kidneys with SLK than what it is at the current time but the Committee will monitor closely.

• Question: Will the Liver Committee carefully consider rural, gender, race and other minority and socioeconomic populations in the post-implementation monitoring plan?

- Answer: Yes, consideration of these populations is critical and will be included in the post-implementation monitoring plan.

• Question: Did the Liver Committee consider the impact on waitlist mortality and costs?

- Answer: Yes – waitlist mortality for both the B2C and acuity circles would be slightly better than the current system and the 2017 Board approved option. Although assessing impact on costs can be difficult, the modeling did look at flying rates and there was an increase which indicates a potential increase in costs.

OPTN/UNOS Pancreas Transplantation Committee

On October 10th, 2018 the Pancreas Committee reviewed the Liver Committee's proposal to change geographic allocation. The Pancreas Committee thanks the Liver Committee for its efforts and for the opportunity to comment on its proposal. The following questions were asked by Pancreas Committee members and answered by the Liver Committee analyst:

• Question: How were the percentages of organs flown calculated?

- Answer: The SRTR based the LSAM estimate on distance, specifically, on the distance at which driving would switch to flying. There will be variation based on differences in population density in the country.

• Question: Will the changes result in a significant change in SLK transplants?

- Answer: There is not estimated to be a significant change in SLK transplants. The same qualifications will exist to be considered for an SLK transplant; it will not change the order in which an organ is offered according to geographic distribution.

• Question: What will be the effect on small liver programs – could some shut down because they do fewer transplants?

- Answer: There will be variation in how individual programs respond to the changes; some program volume may increase while other programs may see volume shrink. It is important to note that the modeling cannot account for changes in behavior that may result from changes in allocation.

OPTN/UNOS Transplant Coordinators Committee

The OPTN/UNOS Transplant Coordinator Committee (TCC) thanks the Liver & Intestinal Organ Committee for the opportunity to provide feedback on their proposal to eliminate DSA and Region from

liver distribution. The TCC reviewed the proposal and provided the following feedback, based on the questions the Liver Committee posed.

a. What MELD sharing threshold does the Committee recommend?

The TCC supports a MELD threshold of 29-31. On average, with a few exceptions, most programs are transplanting candidates with a MELD of around 29 or lower. Although this would mean more candidates would be in the catchment area, the group felt this would be more equitable.

b. Whether the sizes of the fixed distance circles should be larger, smaller, or remain the same.

The TCC did not explicitly respond to this question.

c. Whether the Committee prefers the broader 2-circle model or the acuity circles model.

The TCC supports the acuity model. The travel time increase seems acceptable in light of the impact on waitlist mortality. In other words, it appears many more lives would be saved with a marginal increase in travel time.

d. Do you support expanding Policy 9.11.B: Closed Variance for Allocation of Blood Type O Deceased Donor Livers in Hawaii to apply to Puerto Rico as well?

The TCC supports expanding the variance to Hawaii, as it stands that Puerto Rico likely faces similar challenges.

The TCC noted that as organ recovery centers proliferate, allocation based off of those locations will have to be addressed.

OPTN/UNOS Operations and Safety Committee

The Operations and Safety Committee discussed this proposal and offers the following responses: • The Committee supports the proposed size of the fixed distance circles. • The Committee supports the expansion of the Hawaii variance to Puerto Rico in order to mitigate the negative impact on candidates in Puerto Rico. The Committee agreed that variance would not change in the new allocation policies. • The Committee agreed there will be an increase in travel for liver allocations, which will impact costs for OPO and transplant centers. The Committee has acknowledged there is a current regional shortage of pilots and planes nationally, which may increase stress on procurement and organ transport logistics. The Committee acknowledges there is regional variability and propose further evaluation and data collection to help ensure that the safety of organ placement is as transparent and efficient as possible.

OPTN/UNOS Ethics Committee

The Ethics Committee reviewed the Liver Committee's proposal during the October 29 in-person meeting in Chicago, IL. The Ethics Committee appreciates the opportunity to comment, and the work that the Liver Committee has done in preparing this proposal. The Ethics Committee's comments centered on the difficulty of fully considering the implications of the Liver Committee's proposal given the limited time and lack of adequate justifications for their recommendation. Some suggested that cost and efficiency considerations do not supersede the importance of equity in changing geographic allocation. A couple of concerns were raised: 1. Inadequate ethical justification for proposed changes: The Committee was concerned that it could not adequately evaluate the Liver Committee's recommendations because the rationales for the two options (B2C, and acuity) were not provided in relation to other options. In particular, the differences between the B2C and acuity circle options were not adequately explained, nor was the justification for preferring B2C to acuity. The Liver Committee should clearly identify the rationale for selecting one option over another, as well as the relative impact of each considered option on equity and utility. 2. Concern for harming underserved, vulnerable populations: Many theories of distributive justice suggest that while a single policy cannot rectify existing inequalities, a policy ought not to exacerbate inequalities. The accelerated timeline under which the Liver Committee was required to make

changes to liver geographic allocation might have unintended consequences for vulnerable populations because the analyses may not have considered all potential outcomes. In particular, members expressed concern that rural patients could be adversely affected, and the Liver Committee should consider the potential impact to these and other patients when developing their recommendations. Efforts must be made to ensure that the perspectives of historically underrepresented groups and the vulnerable be included in allocation policies. The Liver Committee should also assess the projected impact of their recommendation on the potential closure of transplant programs serving rural areas and underserved populations. The Liver Committee should better explain the implications of supporting one solution over another. Ethics Committee members indicated that cost and efficiency should not drive a solution characterized by greater efficiency, and less equity. Ensuring equity means giving patients reasonable likelihood to access transplantation regardless of their geographic location.

OPTN/UNOS Organ Procurement Organization Committee

The OPO Committee discussed this proposal and offers the following responses:

• The Committee supports the proposed size of the fixed distance circles. The Committee acknowledged that there are differences in populations across the country, but for simplicity it is best to keep the distances the same until further evaluation of population density can be completed.

• The Committee supports the broader 2-circle model and recommend that the Liver Committee continue to evaluate this model based on the data.

• The Committee supports the expansion of the Hawaii variance to Puerto Rico in order to mitigate the negative impact on candidates in Puerto Rico with the proposed change from regions to fixed distance circles in organ allocation.

• The Committee agreed that there will be a budgetary impact for both the OPTN and OPO community. The Committee agreed that upgrades to DonorNet® are needed as broader distribution models are evaluated and implemented. This will help ensure that organ placement is transparent and efficient and could potentially provide important data for future efforts. The Committee also agreed that OPOs will have an increase in costs related to data collection, transportation, and logistical issues such as coordinating OR times.

Other Comments

Additional comments are posted online[7] and provided in an excel document.

[7] https://optn.transplant.hrsa.gov/governance/public-comment/liver-and-intestine-distribution-using-distance-from-donor-hospital/