EXECUTIVE SUMMARY
OF THE
OPTN/UNOS BOARD OF DIRECTORS MEETING
December 3-4, 2018
Irving, TX

Sue Dunn, RN, B.S.N., M.B.A, OPTN/UNOS President, called the meeting to order at 3:10 p.m. on December 3, 2018. A quorum was present, and 39 of the Board members attended in person or by electronic means of communications.

In the first order of business, the Board approved Valinda Jones as Patient & Donor Affairs Representative on the OPTN Board of Directors for a partial term expiring on June 30, 2019, to fill the vacancy created by the resignation of Willie Oler, Ed.D., effective immediately.

The Board also approved the appointment of Randee Bloom, Ph.D., M.B.A., RN, to the OPTN/UNOS Executive Committee.

Ms. Dunn presented the biannual Executive Committee report to the Board.

The Board approved several resolutions contained in the Consent Agenda in two votes. The subject of the individual resolutions approved in the Consent Agenda follows here:

1. The Board approved the minutes of the June 10-12, 2018 meeting of the Board of Directors held in Richmond, Virginia.
2. The Board approved changes to Bylaws D.10.A (Functional Inactivity) and D.10.B (Notification 1 Requirements for Transplant Program Functional Inactivity), regarding the definition of functionally inactive pancreas programs.
3. The Board approved the guidance document entitled “Guidance on Pediatric Transplant Recipient Transition and Transfer.”
4. The Board approved changes to Policies 2.2 (OPO Responsibilities), 4.3 (Requirements for Performing and Reporting HLA Typing), and 4.4 (Resolving Discrepant Donor and Recipient HLA Typing Results); and Bylaws C.2.D (OPO Affiliation), regarding the entry of HLA data.
5. The Board approved changes to Bylaws 1.1.B (Overview of the Voting Process); 1.3 (OPO Members); 1.3.A (OPO Member Requirements); 1.3.C (OPO Member Voting Privileges); Appendix B (Membership Requirements for Organ Procurement Organizations (OPOs)); and Appendix M (Definitions), regarding the extension of voting privileges to hospital-based organ procurement organizations.

The Board approved the slate of nominees for the election of members of the Board of Directors for the term beginning July 1, 2019.

Brian Shepard, UNOS CEO and OPTN Executive Director gave the Executive Director’s report to the Board.

Dr. David Reich, Treasurer, and Matt Lovetro, UNOS Director of Finance, gave a report of the Finance Committee and presented two recommended actions for consideration by the Board. Thereafter, the Board approved the revised 2019 OPTN Operating Budget, and the Board approved the transfer of $1,000,000 from the OPTN Primary Account to the OPTN Reserve Account.

Danyel Gooch, M.S.N., RN, CCTC, and Alex Tulchinsky, UNOS Chief Technology Officer, gave a report of the Information Technology Advisory Committee (ITAC).

The Board approved new policies and substantial changes to existing policies for the allocation of livers resulting in the elimination of the use of DSAs and Regions in liver distribution in a distribution framework known as “acuity circles.” Due to the complexity of the competing liver distribution proposals, the process the Board utilized to consider several proposed amendments, and the extensive discussion by the Board, a detailed description of the Board’s discussion regarding this proposal is appended to this Executive Summary as “Exhibit A.”

In the first order of business for the second day of the meeting, the Board approved the creation of new Bylaw Appendix K: Membership and Personnel Requirements for Islet Programs, as well as related changes to Bylaws to establish pancreatic islet program requirements. The Board amended the original proposal to clarify to require islet programs to either be located at a hospital that has a designated kidney, liver, or intestine transplant program, or to have an affiliation with pancreas, kidney, liver, or intestine transplant programs, and to require a pancreas, kidney, liver, or intestine transplant surgeon to be on site at the islet program.

The Board approved the following resolution regarding frameworks for the geographic distribution of organs:

> WHEREAS, that the Board of Directors, in order to promote efficiency, understanding, and clear communication, has determined that it is beneficial to have a single framework for allocation policy development; and
>
> WHEREAS, that within that framework, individual policy committees would retain the flexibility to make customizations appropriate to the clinical differences among organs; and
>
> WHEREAS, that the Ad Hoc Geography Committee recommends the Continuous Distribution allocation framework for its ability to appropriately integrate cold ischemic time, system costs, and candidates' medical urgency; Now, therefore be it
>
> RESOLVED, that the Board of Directors adopts the Continuous Distribution allocation framework as best suited for future OPTN organ allocation policies; and
>
> FURTHER RESOLVED, that the Board directs the organ-specific committees to move toward the Continuous Distribution allocation framework as they consider future amendments and improvements to their respective allocation policies.

Ryan Davies, MD, Chair of the Thoracic Organ Transplantation Committee, presented an update regarding lung allocation following the removal of the DSA as a unit of distribution in lung allocation policy in November 2017.

Nicole Turgeon, MD, Chair of the Kidney Transplantation Committee, presented an update on progress the Committee has made on eliminating the use of DSAs and Regions in kidney and pancreas distribution, in collaboration with the Pancreas Transplantation Committee.

The meeting adjourned at 12:22 pm on December 4, 2018.

OPTN | ORGAN PROCUREMENT AND TRANSPLANTATION NETWORK

Executive Summary of OPTN Approval of Policies to Eliminate the use of DSAs and Regions in Liver Allocation

December 13, 2018

The Organ Procurement and Transplantation Network (OPTN) Board of Directors (Board) met on December 3, 2018, in Dallas, Texas, and 41 members of the Board were present in person or virtually. Sue Dunn, OPTN President, presided over the meeting and the discussion of a Proposal to Eliminate the use of DSAs and Regions in Liver Allocation, which was developed by the OPTN Liver and Intestinal Organ Transplantation Committee.

On behalf of the United States Department of Health and Human Services (HHS), Christopher McLaughlin, Chief of the Organ Transplantation Branch of the Division of Transplantation, Healthcare Systems Bureau at HHS requested a written description of the Board's rationale for changes to the liver allocation system adopted at that meeting. Specifically, the OPTN was asked to describe the amendments considered, the votes taken, the data and materials considered, and the Board's justification for concluding that the policy as adopted best meets the requirements of the OPTN Final Rule. The request reiterated the directive from Health Resources and Services Administration (HRSA) Administrator George Sigounas, on behalf of HHS, "to consider and explain how any liver allocation policy approved by the OPTN satisfies the requirements of the OPTN Final Rule. If some form of geographic limitation is incorporated, the OPTN Board should provide its written rationale, together with supporting evidence, explaining how any such limitation is justified and required by 42 C.F.R. §121.8(a)(8), including concerning the size and shape of any geographic units selected. Because the OPTN Final Rule permits geographic limits based on transplant candidates' place of residence or listing only to the extent required by one of the factors described in 42 C.F.R. §121.8(a)(1)-(5), the OPTN Board should provide its rationale as to how any specific geographic unit of distribution is justified by one of those regulatory factors."1

On December 3, 2018, the Board considered a proposal by the Liver and Intestinal Transplantation Committee (Committee) to revise how livers are allocated. The Board approved the Committee's proposal with two amendments. The first amendment made minor clarifying changes to the Committee's proposal to more accurately reflect the Committee's intent.2 The second amendment was an amendment to the allocation sequences for adult donor allocation.3 This second amendment replaced the order of allocation

1 George Sigounas letter to Sue Dunn, OPTN President, July 31, 2018.
2 Results for the technical corrections amendment were 37 In Favor; 0 Oppose; 1 Abstain.
3 Results for the acuity circles amendment were 24 In Favor; 14 Oppose; 0 Abstain.

proposed by the Committee (Broader 2 Circles, or B2C) with another allocation framework modeled by the SRTR at the request of the Committee (Acuity Circles).

The Board approved the amended Acuity Circle framework proposal as the solution that best fulfilled the requirements of the OPTN Final Rule.

Public Feedback

The Committee met on October 1, 2018 to vote on a policy proposal to put out for special public comment. The Committee considered the Broader 2 Circles (B2C) model with a Model for End-Stage Liver Disease (MELD)/ Pediatric End-Stage Liver Disease (PELD) threshold of 32, the B2C model with a MELD/PELD threshold of 35, the B2C model with a MELD/PELD threshold of 29, and the Acuity Circles (AC) model. There was some support for all of these models; however, the largest number of committee members supported B2C with a MELD/PELD threshold of 32. Due to the split in opinion on the options, the Committee voted to send B2C with a MELD/PELD threshold of 32 out for public comment and asked for input on the other models.[4]

The special public comment period lasted from October 8, 2018 to November 1, 2018. During this time, the OPTN hosted a number of webinars to educate and solicit feedback from the general public and the transplant community. There was a webinar for each of the OPTN Regions, during which regional representatives provided feedback on the proposal. There were also two national educational webinars, one aimed at patients and one for transplant professionals. Additionally, UNOS staff or the chair of the Liver Committee presented the proposal to a number of the OPTN committees.

The Committee met in-person on November 2, 2018 after public comment closed to discuss the public comment feedback and decide which model to recommend to the Board. In response to public comment feedback, the Committee made several changes to the proposal. These changes included:

1. Changing the MELD threshold to 29 for liver allocation and simultaneous liver kidney (SLK) allocation
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 not take effect until at least 3 months after the implementation of the NLRB.[5]

At the conclusion of the meeting, the Committee voted to recommend the B2C model with a MELD/PELD threshold of 29, with the other changes noted above, to the Board for consideration.[6] Although there was a majority of the Committee in favor of B2C, the members of the Committee were divided. The Committee vote on whether to recommend B2C with a threshold of 29 or Acuity Circles was 9 in favor of Acuity Circles and 11 in favor of B2C.

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4 Meeting Summary for October 1, 2018 meeting, OPTN/UNOS Liver and Intestinal Organ Committee, https://optn.transplant.hrsa.gov/media/2731/20181001_liver_committee_minutes.pdf .

5 *Liver and Intestine Distribution Using Distance from Donor Hospital*, OPTN/UNOS Liver and Intestinal Transplantation Committee, October 2018, https://optn.transplant.hrsa.gov/media/2766/liver_boardreport_201812.pdf (accessed December 9, 2018).

6 Meeting Summary for November 2, 2018 meeting, OPTN/UNOS Liver and Intestinal Organ Committee, https://optn.transplant.hrsa.gov/members/committees/liver-and-intestine-committee/ .

On November 13, 2018, the Board Policy Group (BPG), a subset of the Board, convened to discuss the updated policy proposal and provide a recommendation about the proposal to the full Board. The purpose of the BPG was to examine the proposal in preparation for the Board meeting and decide whether to support the proposal. The BPG, reflecting the mixed opinion in the Liver Committee, was undecided on their support for the proposal and voted to put the proposal on the discussion agenda for the Board.

On November 26, 2018, the patient and donor affairs representatives to the Board convened to discuss the proposal and review a summary of the feedback provided by patients and donor families during public comment.

Meeting materials for the Board meeting were sent to members of the Board two weeks prior to meeting in accordance with contractual requirements and to allow time for Board members to review.

Members of the Board were asked to submit any amendments to the proposal that they would like considered prior to November 28, 2018 so that these proposed amendments could be organized and provided to all Board members in advance of the meeting and more thoughtfully considered.

The Board met in-person on December 3, 2018. At this meeting, Julie Heimbach, M.D., Chair of the Liver Committee, presented the proposal. The Board discussed the proposal for B2C as well as the amendments submitted.

Actions Considered

The Committee recommended the B2C policy to the Board.[7] Board members submitted the following potential amendments to that proposed policy for consideration by the Board:

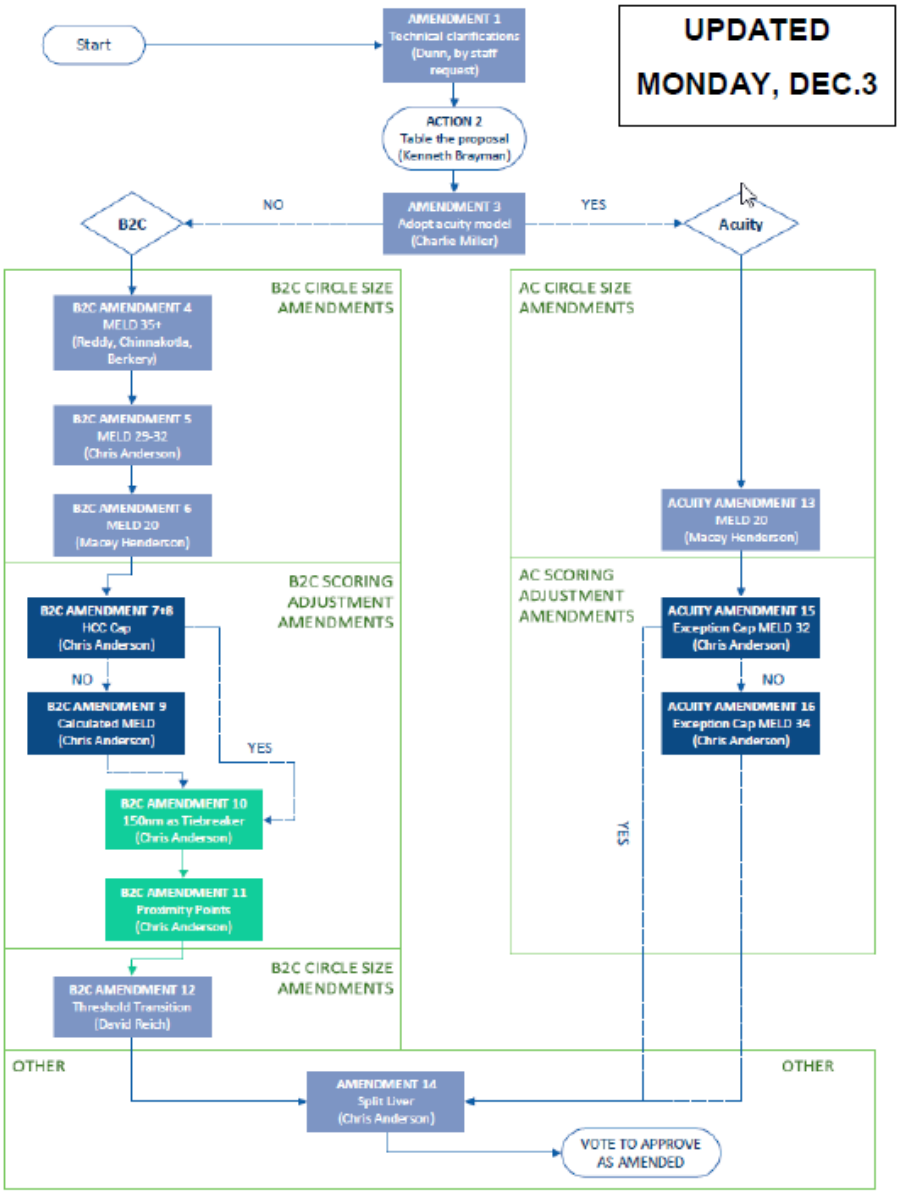
Amendment 1	An amendment to make technical clarifications to liver allocation tables.
Action 2	A motion to table the committee proposal.
Amendment 3	An amendment to utilize Acuity Circles for liver distribution.
Amendment 4	An amendment to add an additional classification for candidates with a MELD/PELD score of at least 35, to be allocated to 500nm.
Amendment 5	An amendment to replace classifications with a MELD/PELD of at least 29 with a MELD/PELD of at least 32.
Amendment 6	An amendment to replace classifications with a MELD/PELD of at least 15 with a MELD/PELD of at least 20.
Amendment 7	An amendment to institute a Hepatocellular Carcinoma (HCC) cap at a MELD/PELD score of 28.

7 *Liver and Intestine Distribution Using Distance from Donor Hospital*, OPTN/UNOS Liver and Intestinal Transplantation Committee, October 2018, https://optn.transplant.hrsa.gov/media/2766/liver_boardreport_201812.pdf (accessed December 9, 2018).

Amendment 8	An amendment to institute a Hepatocellular Carcinoma (HCC) cap at a MELD/PELD score of 31.
Amendment 9	An amendment to limit the initial 250 and 500 nm classifications to calculated MELD scores.
Amendment 10	An amendment to use the distance between transplant hospital and donor hospital as a sorting criteria among similar MELD/PELD scores.
Amendment 11	An amendment to award proximity points to candidates within 150 nm of the donor hospital.
Amendment 12	An amendment to transition the implementation of the liver distribution proposal.
Amendment 13	An amendment to replace classifications with a MELD/PELD of at least 15 with a MELD/PELD of at least 20.
Amendment 14	An amendment to expand the existing split liver variance.
Amendment 15	An amendment to institute an exception cap at a MELD/PELD score of 32
Amendment 16	An amendment to institute an exception cap at a MELD/PELD score of 34.

The actions were organized so that only the actions that remained relevant given prior decisions were discussed and voted on at the Board meeting. For instance, amendments to change the threshold used in the B2C model were not considered once the Board decided not to pursue the B2C model.

Figure 1: Amendments Flow Chart



The Board followed this order, which eliminated the need to discuss and vote on potential amendments 4-12. Therefore, the amendments discussed during the Board meeting were as follows:

Amendment 1: Technical Clarifications

Amendment 1 was a technical clarification to the liver allocation tables. The amendment clarified that the table titles refer to the donor hospital and not the donor residence, and it clarified the blood type allocation sequence. This amendment was relevant regardless of whether the Board pursued the B2C proposal or the Acuity Circles proposal, so the Board voted on this amendment first.

The Board voted as follows: 37 In Favor; 0 Oppose; 1 Abstain; therefore, the amendment was adopted.

Action 2: Table Current Proposal and Implement the December 2017 Liver Proposal

Action 2 was to table the current proposal and instead implement the allocation model that was approved by the Board at the December 2017 Board meeting. The sponsor of the amendment suggested that the proposal being discussed did not satisfy the OPTN Final Rule, relied on a data based on DSA (median MELD at transplant in the DSA as a measure of disparity), did not address Organ Procurement Organization (OPO) performance, did not properly consider socioeconomic disparities, and was rushed through the policy-making process.

Tabling the proposal and reverting to the 2017 liver allocation policy would entail great organizational risk and could take policy-making power out of the hands of the transplant community since that policy had already been determined to be improperly reliant on DSA and region in distribution.8 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."9 The OPTN agrees that the use of DSAs and regions currently used in liver allocation and in the December 2017 proposal was not the best proxy for efficiency, as discussed further in the Committee's briefing paper.10 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. 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."11 The letter contained a deadline for the Board to adopt a new liver allocation policy by its December 2018 meeting.

The Board voted as follows: 5 In Favor; 35 Oppose; 1 Abstain; therefore, the motion did not pass and the Board continued discussing the proposal.

Amendment 3: Adopt Acuity Circles Model

Amendment 3 was to adopt the Acuity Circles (AC) model instead of the B2C model. The sponsor of the amendment argued that the AC model better balanced geographic constraints while prioritizing the most urgent candidates, citing much of the same evidence the Committee considered when discussing the proposal. Further, the sponsor pointed out that the Committee vote on the proposal recommending B2C was very closely divided, with many members of the Committee supporting the AC model. Additional discussion of this amendment is included below under "**Board Justification**."

The Board voted as follows: 24 In Favor; 14 Oppose; 0 Abstain; therefore, the amendment was adopted. Practically, this also eliminated the need for the Board to discuss amendments 4-12 which only applied to the B2C model.

8George Sigounas, letter to Sue Dunn, OPTN President, July 31, 2018.
9 Ibid.
10 *Liver and Intestine Distribution Using Distance from Donor Hospital*, OPTN/UNOS Liver and Intestinal Transplantation Committee, October 2018, https://optn.transplant.hrsa.gov/media/2766/liver_boardreport_201812.pdf (accessed December 9, 2018), page 4 and Appendix A at page 103.
11 George Sigounas, letter to Sue Dunn, OPTN President, July 31, 2018.

Amendment 13: MELD 20

Amendment 13 was to replace the classifications for "MELD/PELD of at least 15" with "MELD/PELD of at least 20." This would broadly distribute livers to candidates with a MELD/PELD of at least 20 before distributing to candidates below MELD/PELD 20. The sponsor of the amendment stated that the MELD 15 threshold has historically been used as a cutoff because previous research showed that patients with a MELD score of 15 did not benefit from a transplant.12 However, the current MELD score incorporates patient's serum sodium and pre-transplant care for liver candidates has improved.13 Additionally, recent analysis has shown that the cutoff benefit for MELD sodium occurs at MELD 20 rather than at MELD 15.[14] By raising the threshold from MELD 15 to MELD 20, allocation would better reflect current scientific understanding.

The Chair of the Liver Committee noted that the article cited by the sponsor was published in November 2018 and therefore there has not been much time for the information to be evaluated, stating that it may be too soon for consideration. Additionally, such a component of the policy was not put out for public comment or part of the modeling request, so the impact of such a change could not be measured through these forums either. Specifically, it was unknown whether the impact of the change would be the same for pediatric candidates, especially those with a PELD score, which is calculated differently from MELD. The OPTN Final Rule states that allocation policies "shall be based on sound medical judgment." While the committees make adjustments to proposals following SRTR modeling and public comment, (ex. changing the threshold from 32 to 29), this amendment was outside of the concepts considered by the Committee and the public or the variables assessed by the SRTR modeling, and could raise questions of whether the Board based its decision on sound medical judgment.

The Board vote was as follows: 9 In Favor; 25 Oppose; 1 Abstain; therefore, the amendment did not pass.

Amendment 15: MELD 32 Exception Cap

Amendment 15 would set a cap at MELD 32 for exception candidates over the age of 18, except for candidates with Hepatic Artery Thrombosis (HAT). The intent of this amendment was to ensure that MELD scores are not artificially inflated and exception candidates do not inappropriately receive liver offers prior to sicker candidates.

The Chair of the Liver Committee stated that the National Liver Review Board (NLRB) will be implemented in January 2019. With the NLRB, there is no MELD elevator, which previously inflated exception scores by automatically increasing MELD scores for those candidates with exceptions at set time intervals, and scores will be assigned based on the median MELD at transplant within the candidate's DSA. Given these facts, the majority of the Committee did not think that the proposed cap was necessary.

12 Merion et al., "The Survival Benefit of Liver Transplantation." *The American Journal of Transplantation* 5, no. 2 (February 2005): 307-313 https://doi.org/10.1111/j.1600-6143.2004.00703.x.
13 Nagai et al., "Effects of Allocating Livers for Transplantation Based on Model for End-Stage Liver Disease-Sodium Scores on Patient Outcomes." *Gastroenterology* 155, no. 5 (November 2018): 1451-1462 https://doi.org/10.1053/j.gastro.2018.07.025
14 *Ibid.*

The sponsor agreed to withdraw this amendment after this discussion and the Board did not vote on it.

Amendment 14: Expand the Existing Split Liver Variance

Amendment 14 would create a new variance where centers would be permitted to split an allocated liver into segments, and transplant the first liver segment into the candidate for whom the organ was accepted, while transplanting the second liver segment to an additional candidate registered at their transplant program. In an existing variance, centers can choose to split a liver and utilize either the anatomic right lobe or the anatomic right tri-segment in the patient that the liver was allocated to and then use the anatomic left or the anatomic left lateral segment for another candidate at their center that appeared on the match run, or at a candidate at an affiliated pediatric center who appeared on the match run. The proposed amendment would allow centers to use any segment first and utilize the second segment for another candidate at their center, or an affiliated center.

After some discussion by the Board, the amendment was voluntarily withdrawn by the sponsor with the acknowledgement that the Liver Committee will discuss this issue and work to incorporate it into a related policy proposal that is going out for public comment in January 2019.

Vote to Approve the Policy as Amended

Following the consideration of these proposed amendments as described above, the Board voted on the proposal as amended (Acuity Circles): 30 In Favor; 7 Oppose; 2 Abstain; therefore, the amended proposal was adopted.

Data and Materials Considered

The members of the Board were provided with:

1. A briefing paper outlining the Committee's recommendation and rationale15
2. A summary analysis of public comments16
3. Each amendment submitted by a member of the Board17
4. A legal analysis with direction on how to evaluate the Committee's proposal and any amendments18
5. Presentations or remarks regarding the Committee's proposal19 and the amendments that were considered20
6. Principles of Geographic Distribution21

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15 *Liver and Intestine Distribution Using Distance from Donor Hospital*, OPTN/UNOS Liver and Intestinal Transplantation Committee, October 2018, https://optn.transplant.hrsa.gov/media/2766/liver_boardreport_201812.pdf (accessed December 9, 2018).
16 *Liver and Intestine Distribution Using Distance from Donor Hospital*, OPTN/UNOS Liver and Intestinal Transplantation Committee, October 2018, https://optn.transplant.hrsa.gov/media/2766/liver_boardreport_201812.pdf (accessed December 9, 2018), Appendix D at page 116 *et seq*.
17 OPTN Board of Directors, *Amendments Booklet* (Dallas: OPTN/UNOS, 2018).
18 OPTN Board of Directors, *Amendments Booklet* (Dallas: OPTN/UNOS, 2018), page 5.
19 Heimbach, Julie. "Liver and Intestine Distribution Using Distance from Donor Hospital" Committee Presentation, OPTN/UNOS Board Meeting, Dallas, December 3, 2018.
20 Miller, Charles, "Amendment 3: Replace the B2C 29 Model with the AC Model" Amendment Sponsor Remarks, OPTN/UNOS Board Meeting, Dallas, December 3, 2018.
21 *Frameworks for Organ Distribution*, OPTN/UNOS Ad Hoc Geography Committee, August 2018, https://optn.transplant.hrsa.gov/media/2762/geography_boardreport_201812.pdf (accessed December 13, 2018).

7. A letter from select members of the Committee supporting Acuity Circles22
8. All of the materials and education available to the general public23

Board Justification

The Board is responsible for adopting policies for the allocation of organs in accordance with the OPTN Final Rule.24 It requires that allocation policies "shall not be based on the candidate's place of residence or place of listing, except to the extent required by paragraph a, Sections 1 through 5 of [Section 121.8]."25 In other words, the Board must justify any use of the candidate's place of residence or listing as necessary to pursue one the following enumerated requirements for organ allocation policies:

> (1) Shall be based on sound medical judgment;
> (2) Shall seek to achieve the best use of donated organs;
> (3) Shall preserve the ability of a transplant program to decline an offer of an organ or not to use the organ for the potential recipient in accordance with §121.7(b)(4)(d) and (e);
> (4) Shall be specific for each organ type or combination of organ types to be transplanted into a transplant candidate;
> (5) Shall be designed to avoid wasting organs, to avoid futile transplants, to promote patient access to transplantation, and to promote the efficient management of organ placement26

In selecting the Acuity Circles model for liver allocation policy, the Board focused on the ability of the model to allocate to the candidates with the greatest need while distributing livers as broadly as possible.

1. Shall be based on sound medical judgment

In order for an allocation policy to be based on sound medical judgement, the policy must be supported by evidence, such as available data and modeling. The Committee considered several different forms of evidence; these included inferential modeling from the SRTR, descriptive data requests from UNOS research staff, published literature, and public comment. The metrics available to the Committee during their deliberations were also available to the Board, including variance in median MELD/PELD at transplant, percentage of organs flown, median travel time and distance, and waitlist mortality.27 The SRTR provided predictions regarding how each model was expected to impact these metrics and others; the impact of the Acuity Model is discussed below.28

While public opinion should not be the sole basis of any policy, public feedback is an important part of the policy development process, and the OPTN Final Rule requires the OPTN Board to "take into account the comments received in developing and adopting policies for implementation by the OPTN."29 The Committee considered the feedback provided in public comment and looked to the comments as a source for identifying themes in developing the policy, as well as input on how to balance the competing interests of efficiency and equitable access. The Committee modified the proposal in response to public feedback;

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22 Terry Box, Sander Florman, Sommer Gentry, John Goss, and Ryutaro Hirose to Brian Shepherd and Sue Dunn.
23 https://optn.transplant.hrsa.gov/governance/public-comment/liver-and-intestine-distribution-using-distance-from-donor-hospital/
24 42 C.F.R. §121.8.
25 42 C.F.R. §121.8(a)(8).
26 42 C.F.R. §121.8(a)
27 *Liver and Intestine Distribution Using Distance from Donor Hospital*, OPTN/UNOS Liver and Intestinal Transplantation Committee, October 2018, https://optn.transplant.hrsa.gov/media/2766/liver_boardreport_201812.pdf (accessed December 9, 2018), tables 3, 4 and 5 on pages 12-17.
28 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)
29 42 C.F.R §121.4(b)(1)

for further discussion, see the Briefing Paper.30 The Board discussions reflected similar conversations to those that the Committee undertook when evaluating the public comments.

The Board is composed of experts and stakeholders in the field of transplantation.31 The OPTN also solicited specialists in the field of liver transplant to serve on the Committee so it could rely on their expertise in the policy making process. The Board considered the expert opinions of the Committee members in the many aspects of the proposal and when evaluating the differences between the proposal as submitted by the Committee and the Acuity Circles amendment. Although the Committee voted in favor of B2C by a small margin, nearly half of the Committee members supported the Acuity Circles model, citing data, research, and their experience in practice.

The Acuity Circles model is based on the sound medical judgment of the Committee and the community, as it was proffered as a policy option, and the Board relied on this evidence and the Board's own expertise in adopting this model over B2C.

2. Shall seek to achieve the best use of donated organs

In seeking to achieve the best use of donated organs, the Board and committees consider whether policy will impact the number of transplants and waitlist mortality rate. While both models showed a slight reduction in the number of transplants overall, both showed an increased number of candidates transplanted with MELD scores of 35 or higher and pediatric candidates, and the reduction in the number of transplants was not statistically significant.32 While both models predicted an improvement for these candidate groups in terms of waitlist mortality rates under the current system, the Acuity Circles model showed an even lower waitlist mortality rate, particularly among patients listed with calculated MELD or PELD scores.33

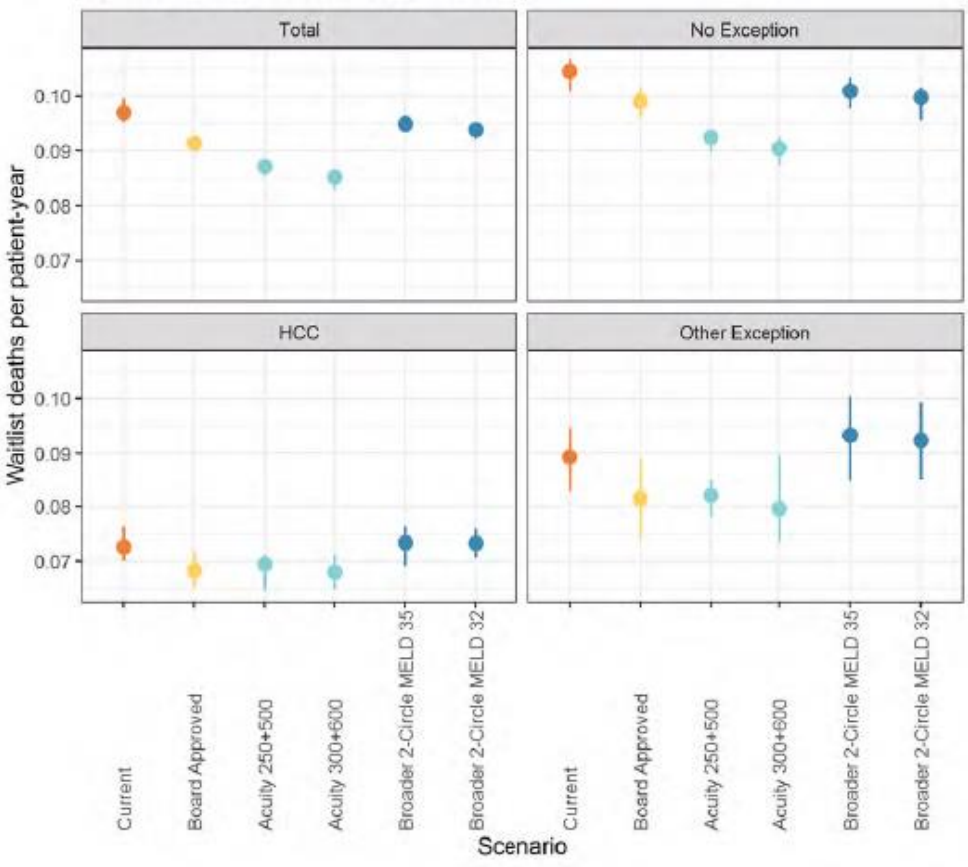
30 *Liver and Intestine Distribution Using Distance from Donor Hospital*, OPTN/UNOS Liver and Intestinal Organ Transplantation Committee, October 2018, https://optn.transplant.hrsa.gov/media/2766/liver_boardreport_201812.pdf (accessed December 9, 2018), pages

31 The OPTN Final Rule and OPTN Bylaws require that the Board of Directors be composed of approximately 50% transplant surgeons and physicians: at least 25% transplant candidates, recipients, donors and donor family members; non-physician transplant professionals, histocompatibility professionals, and non-transplant professionals with other areas of expertise. 42 C.F.R. §121.2(a); OPTN Bylaws Article II, 2.1.C. https://optn.transplant.hrsa.gov/media/1201/optn_bylaws.pdf (accessed December 13, 2018).

32 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 6.

33 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), figures 11-14.

Figure 2: Waitlist Deaths by Exception Status



The reduction of deaths on the waitlist was considered a measure of best use of transplanted organs, and was an influencing factor in the Board's ultimate decision to adopt the Acuity Circles model instead of the B2C model.

3. Shall preserve the ability of a transplant program to decline an offer of an organ or not to use the organ for the potential recipient

This policy proposal does not affect the ability of the transplant program to decline an organ.

4. Shall be specific for each organ type or combination of organ types to be transplanted into a transplant candidate

This proposal is specific in its treatment of liver allocation, liver-kidney allocation, intestine allocation and liver-intestine allocation to candidates on the wait list for the relevant organ.

5. Shall be designed to avoid wasting organs, to avoid futile transplants, to promote patient access to transplantation, and to promote the efficient management of organ placement

This component of the OPTN Final Rule requires the Board to strike a balance between seemingly conflicting goals: to promote patient access to transplantation, which may result in broader distribution systems, while also promoting the efficient management of organ placement, where local distribution is prioritized. Recognizing the value in both goals, the Board considered each in turn.

Designed to Avoid Wasting Organs

An organ is considered “wasted” when the organ is recovered from a donor but is not ultimately transplanted.34 It is a priority of the OPTN, in compliance with the Final Rule, to avoid wasting organs as much as is feasible. The data provided by the SRTR cannot predict the number of discards that may occur in a new allocation policy, which would be the most accurate measure of organ wastage. However, the Committee looked at the impact from the “Share 35” change to liver allocation policies, when greater numbers of organs were flown across the OPTN Regions, which resulted in an increase in the number of livers transplanted and no increase in the number of discarded organs, and felt it was rational to anticipate similar results under the Acuity Circles model.35 In fact, during that same period, there was in increase in the number of livers transplanted.36 Additionally, there is typically an inverse relationship between the number of organs transplanted and the number of organs recovered but not transplanted. Since the SRTR did not predict a substantial decrease in the number of organs transplanted, it is logical to infer that there will be no negative impact on the number of organs discarded.

Avoid Futile Transplants

A futile transplant occurs when the recipient of the organ experiences a negative outcome, such that the transplanted organ is not viable, shortly after receiving the transplant. In order to avoid futile transplants, the OPTN considers post-transplant survival rates, and the impact of travel time as it affects cold ischemic time and the organ’s ultimate viability. There is no predicted negative impact on post-transplant outcomes under the Acuity Circles model.37 The Board considered the Committee’s discussion of the ability of livers to handle 10 hours of cold ischemic time before there is a noticeable negative impact on post-transplant outcomes with most livers.38 While the broader distribution under the Acuity Circles model did predict an increase in travel time, the Board used its medical judgment to determine that the increase in travel time of a median of 12 minutes[39] was so minimal as not to result in a clinically significant impact the viability of the liver or the recipient’s likelihood of experiencing a higher risk of poorer post-transplant outcomes.

Promote Patient Access to Transplantation

Allocation policies that promote access to transplantation must offer organs as broadly as possible. The broader the allocation, the more opportunity candidates have to be offered an organ, regardless of their place of residency or listing, which results in a more equitable allocation policy. A primary goal of the recent changes to liver allocation policy is to achieve more equity in access to transplant for liver candidates already registered on the waiting list. A representative from HRSA reinforced at the Board meeting that it was appropriate for the Board to consider

34 Donor family members on the Board expressed a desire to change the way the OPTN refers to organs that are recovered and not transplanted and avoid the term “waste” as it places a negative label on a donor’s organ. However, here the term “wasted” is used because it is still included in the Final Rule.
35 *Liver and Intestine Distribution Using Distance from Donor Hospital*, OPTN/UNOS Liver and Intestinal Transplantation Committee, October 2018, https://optn.transplant.hrsa.gov/media/2766/liver_boardreport_201812.pdf (accessed December 9, 2018), page 21.
36 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.
37 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), figures 18-21.
38 Lee, Kwang-Woong, Christopher E. Simpkins, Robert A. Montgomery, Jayme E. Locke, Dorry L. Segev, and Warren R. Maley. "Factors Affecting Graft Survival After Liver Transplantation from Donation After Cardiac Death Donors." Transplantation 82, no. 12 (2006): 1683-688. doi:10.1097/01.tp.0000250936.73034.98.
39 The median transportation time for livers is modeled at 1.7 hours under the current system, and 1.9 hours under the acuity circles model. 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)

promoting access for candidates, as opposed to all patients, which would include patients not registered on the waiting list.

In order to situate candidates with similar priority levels so that they have a similar chance of allocation, the Board and Committee examined the variance in median MELD at transplant (MMaT) across the country. The goal is to have as little variance as possible, which would indicate that candidates with relatively similar levels of need are receiving organ offers at similar rates. While both proposed models predicted a significant reduction in variance of MMaT from the current policy and the December 2017 policy, the Acuity Circles model was predicted to have the lowest variance of the considered allocation policies at 4.33 (see Table 1 below). Although there are no modeling results for B2C with a MELD threshold of 29, it can be extrapolated from the modeling of thresholds of 35 and 32 that lowering the threshold to 29 would not make such a significant difference that it would reduce the variance more than Acuity Circles does. As such, the Board found that the Acuity Circles model performs better than the B2C model in terms of promoting patient access to transplant.

Table 1: Varaince in Median Allocation MELD/PELD at Transplant40

Scenario	Variance in MMaT
Current	9.97
2017 Board Approved	7.41
Acuity Circles	4.33
Broader 2-Circle MELD 35	6.74
Broader 2-Circle MELD 32	6.54

Efficient Management of Organ Placement

While striving towards broader distribution to increase candidate access to transplantation, the OPTN is also required to seek the efficient management of organ placement. Multiple factors contribute to whether organ placement is efficient, including cost and time of transportation for procurement; increased cost and time impacts the number of transplants a transplant hospital or center can perform.

The Board's discussion was consistent with conversations among Committee members and the public before the meeting, which began with the premise that a national framework for allocation would not be feasible if the system was to also be efficient because of the increased time and costs associated with travel and considering offers.41 As such, the Board recognized that some geographical considerations would be required to establish an efficient organ placement system. When considering procurement, the Board discussed how a broader allocation policy will increase the number of flights used in procurement, which was a cost and time concern considered by the Committee as well.[42] Though the decrease in costs to the healthcare system

40 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)
41 *Liver and Intestine Distribution Using Distance from Donor Hospital*, OPTN/UNOS Liver and Intestinal Transplantation Committee, October 2018, https://optn.transplant.hrsa.gov/media/2766/liver_boardreport_201812.pdf (accessed December 9, 2018)
42 *Liver and Intestine Distribution Using Distance from Donor Hospital*, OPTN/UNOS Liver and Intestinal Transplantation Committee, October 2018,

overall were considered as something that might mitigate the effects of the additional air travel, the Board ultimately placed more weight on the increases in costs related to organ placement, as required by the Final Rule, as opposed to the net costs to the entire transplantation and healthcare system, which would include factors such as shorter post-transplant ICU times.[43]

The Board adopted the fixed distance circle sizes recommended by the Committee, by which a circle around the organ donor hospital is applied equally to all candidates, and the distance is a reasonable proxy for differences in efficiency of placement. Adoption of the fixed distance circle sizes also achieved the goal of meeting the HRSA directive to eliminate the use of DSAs and regions, discussed above. The Committee recommended the distances of 150 nm, 250 nm, and 500 nm for the fixed circle sizes.44 The smallest circle, 150 nm, was chosen as the approximate maximum distance that most transplant surgeons were willing to drive rather than fly to recover the organ, representing a material change in cost and therefore impact on efficiency.45 The largest circle, 500nm, was selected based on data that show that 92% of livers are transplanted within 500 nm of the donor hospital, and the Board adopted the Committee's recommendation of prioritizing maintaining a candidate's current access to transplant as much as was feasible.46 The inner circle of 250 nm was selected to provide for variations in geography and logistics across the county, as there are some areas where a surgeon is willing to drive up to 250 nm to recover a liver.47 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. This balanced the efficiency of avoiding air travel and the variation of hospital and OPO practice. The selection of the specific distances is further discussed in the briefing paper from the Committee.[48]

> During its consideration of the Acuity Circles model, the Board sought the feedback of Organ Procurement Organization (OPO) professionals on the Board regarding procurement challenges. These members agreed that it is becoming increasingly difficult to obtain charter pilots to fly to procure organs at night, and that there are some delays in recovery times associated with increased flying that may impact donor families. However, they also agreed that their OPOs would be able to adjust and make the changes necessary to implement Acuity Circles. Any allocation policy adopted that distributes livers more broadly would increase cost, but the Board

https://optn.transplant.hrsa.gov/media/2766/liver_boardreport_201812.pdf (accessed December 9, 2018), pages 15-18.
43 *Liver and Intestine Distribution Using Distance from Donor Hospital*, OPTN/UNOS Liver and Intestinal Transplantation Committee, October 2018, https://optn.transplant.hrsa.gov/media/2766/liver_boardreport_201812.pdf (accessed December 9, 2018), page 17, referencing 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.
44 *Liver and Intestine Distribution Using Distance from Donor Hospital*, OPTN/UNOS Liver and Intestinal Transplantation Committee, October 2018, https://optn.transplant.hrsa.gov/media/2766/liver_boardreport_201812.pdf (accessed December 9, 2018), pages 23-27.
45 *Liver and Intestine Distribution Using Distance from Donor Hospital*, OPTN/UNOS Liver and Intestinal Transplantation Committee, October 2018, https://optn.transplant.hrsa.gov/media/2766/liver_boardreport_201812.pdf (accessed December 9, 2018), pages 23-27.
46 *Liver and Intestine Distribution Using Distance from Donor Hospital*, OPTN/UNOS Liver and Intestinal Transplantation Committee, October 2018, https://optn.transplant.hrsa.gov/media/2766/liver_boardreport_201812.pdf (accessed December 9, 2018), pages 23-27.
47 *Ibid*.
48 *Ibid.*

assessed the increased cost in the Acuity Circles model as one that was manageable given the increased access it also provides for the highest urgency candidates.

Additionally, the Board considered how the Acuity Circles model relates to the Continuous Distribution framework proposed by the Geography Committee, which framework was subsequently adopted by the Board.49 The Continuous Distribution framework is the goal for all organ allocation policies in the future, and the Board was cognizant of moving toward that goal with this proposal. The Board discussed the idea of incorporating a consideration of population in the circle sizes to account for the different logistical challenges faced in different areas of the county at some point in the future. The Acuity Circles model was designed as a way of providing some degree of adjustment for population50 and could be adapted to adjust for population under a continuous distribution framework more easily in the future than B2C.

The factors that showed the biggest differences between the two models were variance in MMaT, waitlist mortality, and percent of organs flown. In balancing these considerations, the Board placed more weight on reducing the variance in MMaT (promoting access to transplant) and the waitlist mortality (best use of organs), as these most directly impacted the candidates waiting for transplant. While the need for efficient placement of organs was sufficient to require that allocation consider the candidate's place of listing, the Board placed less weight on this factor, which drove the adoption of the amendment in favor of Acuity Circles.

Summary

In summary, the Board considered each of the requirements in the OPTN Final Rule when it chose the Acuity Circles model for the distribution of livers. It used multiple forms of evidence as part of its medical judgment. It reviewed predicted number of transplants and waitlist mortality rates when considering the best use of donated organs. It reviewed the variance in MMaT when considering patient access. It reviewed post-transplant outcomes and predicted travel times when considering futile transplants. And it reviewed the cost and time of procurement when considering the efficient management of organ placement.

49 *Frameworks for Organ Distribution*, OPTN/UNOS Ad Hoc Geography Committee, August 2018, https://optn.transplant.hrsa.gov/media/2762/geography_boardreport_201812.pdf (accessed December 13, 2018)
50 *Liver and Intestine Distribution Using Distance from Donor Hospital*, OPTN/UNOS Liver and Intestinal Transplantation Committee, October 2018, https://optn.transplant.hrsa.gov/media/2766/liver_boardreport_201812.pdf (accessed December 9, 2018), page 9.