



# MELD Exception Conversion

*Prepared by: Elizabeth Miller  
UNOS Policy & Community Relations Department*

## Contents

Executive Summary	2
What problem will this proposal address?	2
Why should you support this proposal?	2
How was this proposal developed?	2
What is the Committee proposing?	5
Delay implementation of NLRB so that there is no transition period.	5
Convert exception scores	5
Which populations are impacted by this proposal?	7
How does this proposal impact the OPTN Strategic Plan?	8
How does this proposal comply with the Final Rule?	8
How will the OPTN implement this proposal?	9
How will members implement this proposal?	9
Will this proposal require members to submit additional data?	10
How will members be evaluated for compliance with this proposal?	10
Conversion Plan	11
Appendix A: MELD Exception Score Transition public comment analysis	12



# MELD Exception Conversion

## Executive Summary

Liver allocation currently uses donor service areas and OPTN regions as units of distribution and liver model for end-stage liver disease (MELD) score exceptions are currently reviewed by regional review boards (RRB) using regional agreements. The OPTN Board of Directors (Board) approved changes that will use distance from the donor hospital as the geographic units for distribution. The Board also approved policy changes that will create a national liver review board (NLRB) and provide new guidance for the scores that should be assigned for the most common exceptions.

The Liver and Intestinal Transplantation Committee (Committee) originally requested that NLRB be implemented at least three months before allocation changes to allow time for all of the exceptions scores awarded under the RRB systems to expire so that only exceptions awarded under the NLRB system would be in place when the allocation changes took effect. However, unintended consequences of using the NLRB scores in the regional allocation system were identified, and a proposal was circulated for public comment that would solve this by using an alternate score during the transition period.

As a result of the comments received and because having 3 months between NLRB and adoption of Acuity circle model is no longer possible due to the need to go out for public comment, the Committee identified a better solution to the problems associated with using scores assigned under one system in the other allocation system. The Committee now recommends implementing NLRB and Acuity Circles allocation at the same time, and converting existing exception scores on the date of implementation.

## What problem will this proposal address?

Currently, both the allocation and exception review systems for livers use regions. Once NLRB and Acuity Circles allocation are implemented, both the allocation system and the system for awarding exception scores will be national systems that use relative distances to factor in geography. The Acuity Circles allocation system will use distance from the donor hospital as a factor in match run order. The NLRB will use the median MELD at transplant (MMaT) within 250 nautical miles (NM) of the listing hospital as a reference point when assigning exception scores. If scores assigned in the regional exception system are used in the national allocation system, candidates in one region may be unfairly advantaged or disadvantaged relative to candidates in another region but in the same geographical unit of distribution solely because their score was awarded by a different review board.

Further, if candidates are permitted to keep their exception scores until they expire, there will be some candidates with exception scores for the same diagnosis at the same transplant hospital that are higher or lower than one another at the same time, based on when the candidate's exception is due for extension. These differences will have the potential to affect candidate order on match runs even after all pre-NLRB exception scores have expired, because the time at score and higher is used to rank candidates within the same classification, blood type compatibility and MELD or pediatric model for end stage liver disease (PELD) score.

## Why should you support this proposal?

This recommended timing and conversion plan will place exceptions candidates on more even footing more quickly, and avoid creating a lasting change in candidate order on the match run that would not have occurred but for the transition.

## How was this proposal developed?

### *Background*

In December 2018, the Board approved a proposal from the Committee that changed allocation of livers to a system in which the geographic basis is distance from the donor hospital.<sup>1</sup> As part of the same proposal, the Board approved the use of median MELD at transplant within 250 NM (MMaT/250) of a candidate's listing hospital in scoring MELD exceptions.<sup>2</sup>

The Liver Committee originally requested a delay of three months in between implementation of the scoring changes and implementation of allocation changes. This would permit time for most exception candidates to transition to the new scoring methodology for exception scores according to the renewal schedules in policy. Following the Board meeting, the exception scoring changes were scheduled to be implemented on January 31, 2019, and the allocation changes were scheduled for April 30, 2019.

After realizing that one unintended consequence of the delayed implementation was that certain candidates would be disadvantaged during the transition period by the use of the NLRB exception system in the existing allocation system, the Committee proposed an adjustment to the implementation plan to align scoring during the transition period. If MMaT/250 was implemented while the current allocation system was in place, exception candidates that extended an exception or applied for a new exception at transplant hospitals within four affected DSAs where not all of the transplant hospitals in the DSA have the same MMaT/250 would consistently appear in lower classifications on the match run than candidates at another local transplant hospital in DSA-level allocation sequences.<sup>3</sup>

The Liver Committee's proposal was to use the median MELD at transplant in the DSA (MMaT/DSA) during the transition period. After determining that the change would require public comment, the Executive Committee amended the proposal to make the same change to transition scoring, but shorten the transition to approximately one month to allow time for a period of public comment. This was circulated for public comment January 31, 2019 through March 22, 2019.

### **Public Comment**

The Executive Committee sent out for public comment the solution of assigning exception scores relative to MMaT/DSA during the transition period.<sup>4</sup> This would have provided for an interim transition period during which the exception scores assigned under the RRB system would begin to phase out and new scores assigned relative to MMaT under the NLRB system would phase in. After approximately one month, with about one third of the exception scores transitioned to the new NLRB scoring, the allocation changes would take effect. Then, the OPTN computer system would automatically replace MMaT/DSA with MMaT/250 but keep each exception candidate's score that was assigned during the transition the same relative to MMaT. For instance, if a candidate received a score under NLRB transition scoring of MMaT/DSA minus 3, it would be automatically converted to MMaT/250 minus 3 on the day allocation changes take effect. However, a candidate that received a score approved by their Regional Review Board would retain that score for up to three months, until the exception was due for extension. This would have ensured aligned scores for the portion of the exception candidates who had exceptions reviewed by the NLRB from the first day of the new allocation system.

During the public comment period, comments were focused on the major themes of:

---

<sup>1</sup> OPTN Policy Notice *Liver and Intestine Distribution Using Distance from Donor Hospital*, Liver and Intestinal Transplantation Committee, January 2019, [https://optn.transplant.hrsa.gov/media/2788/liver\\_policynotice\\_201901.pdf](https://optn.transplant.hrsa.gov/media/2788/liver_policynotice_201901.pdf) (Accessed January 19, 2019).

<sup>2</sup> OPTN Policy Notice *Liver and Intestine Distribution Using Distance from Donor Hospital*, Liver and Intestinal Transplantation Committee, January 2019, [https://optn.transplant.hrsa.gov/media/2788/liver\\_policynotice\\_201901.pdf](https://optn.transplant.hrsa.gov/media/2788/liver_policynotice_201901.pdf) (Accessed January 19, 2019).

<sup>3</sup> OPTN Public Comment Proposal *MELD Exception Scores during NLRB Transition*, Executive Committee, January 2019, [https://optn.transplant.hrsa.gov/media/2840/liver\\_publiccomment\\_20190131\\_language.pdf](https://optn.transplant.hrsa.gov/media/2840/liver_publiccomment_20190131_language.pdf) (Accessed January 23, 2019).

<sup>4</sup> The Executive Committee initially supported this as proposed by the Liver Committee, with a three month transition that would allow for conversion of most of the exception candidates. Including time for public comment has caused a delay in implementation of the NLRB, and the transition period will now be approximately one month.

**1) Only using exception scores assigned under the NLRB system exception in Acuity Circles allocation**

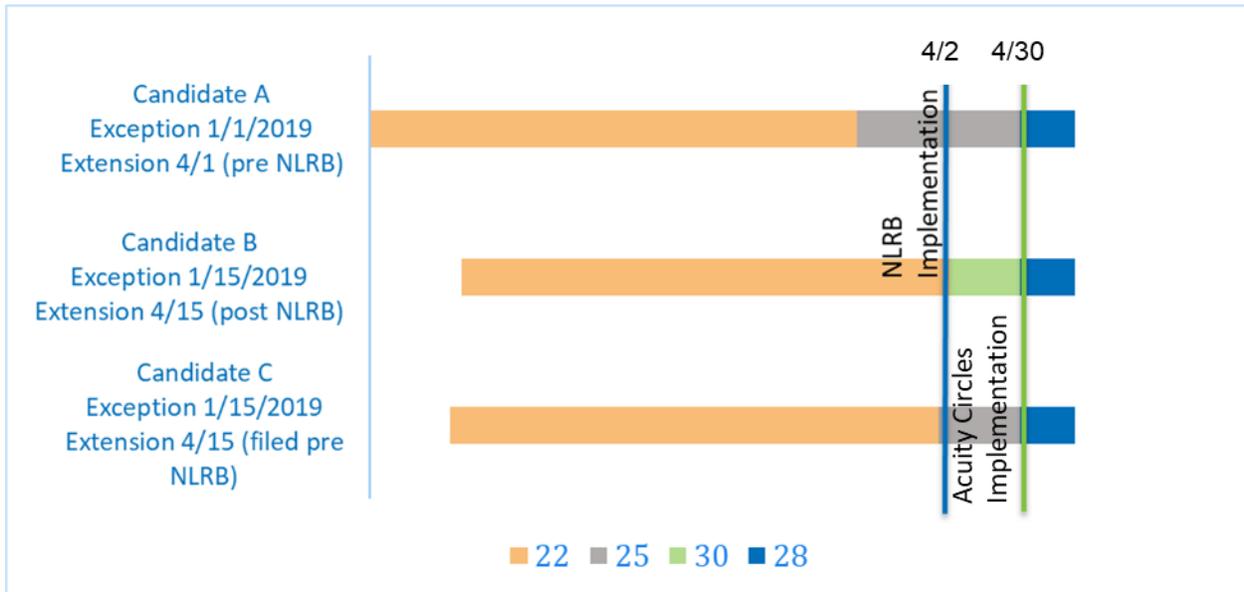
Several commenters objected to implementing Acuity Circles so soon after NLRB was implemented since most exception candidates would still have scores that were assigned under the RRB system at the time Acuity Circles was implemented. Some of the commenters were concerned that using the RRB-system scores in the Acuity Circles allocation system would potentially give greater advantage to exception candidates in certain regions with historically higher exception score trends. Several commenters requested that the timeline be adjusted to allow for a three month transition period as originally planned. Other commenters, including Region 10, requested that the NLRB re-review all exception scores before Acuity Circles takes effect.

**2) Ensuring that candidates with exceptions for the same diagnosis who have the same MMaT are ordered according to who has been waiting longest**

Several commenters expressed concerns that the plan proposed in public comment, assigning exception scores based on MMaT/DSA during the transition period would cause some candidates to be advantaged or disadvantaged depending on the time their exception or extension is approved during the transition. Because time at score and higher is used to order candidates within the same classification, blood type compatibility, and MELD/PELD score, this advantage or disadvantage could last well beyond the transition period, and affect the candidate's placement on all future match runs.

This problem is illustrated in the figure below. In this example, all three candidate are at the same hospital with the same diagnosis. Candidate A was the first to have an exception, Candidate C was second, and Candidate B was the last to get an exception. Candidates A and C were due for extension, and had their forms extended before NLRB took effect (on April 2, in this example). Candidate B was due for an extension the day after Candidate C, and his was approved by the NLRB. Since Candidates A and C were approved prior to the implementation of NLRB, their score is a 25, the next score under the current system. Since Candidate B was approved by the NLRB, his score is a 30, the MMaT-3 in his DSA. On April 30, Acuity Circles is implemented and all three candidates' exception scores are converted to 28, the MMaT-3 in their 250 NM circle. Now, solely because of the higher score awarded during the transition period, Candidate B will be ahead of Candidates A and C, even though Candidate B was the last of the three to receive the exception.

**Figure 1: Impact of using MMaT/DSA during a 1-month transition period**



### 3) Conversion feedback

The public comment proposal specifically solicited feedback on conversion of exception scores, especially related to the exceptions scores that are not easily mapped to a specific score under the NLRB system. In regional discussions, the idea of converting was discussed favorably, with emphasis placed on having all scores converted in some way when Acuity Circles is implemented. Region 10 voted on an amendment (8 strongly support, 7 support, 8 abstain/neutral) to convert and have the NLRB review all of the non-standard exceptions and assign each a new score individually. While the Committee was supportive of the idea of having the NLRB reviewers manually review each form, it would be logistically difficult. Each of the more than 1,000 non-standard exceptions would have to be reviewed by 5 of the approximately 110 reviewers<sup>5</sup> on the adult review boards. This would mean that the reviewers would each have an average of 45 forms each within a short period at the transition, in addition to normal reviews.

## What is the Committee proposing?

After considering the feedback provided in public comment, the Committee recommends a new plan for ensuring the fairest treatment of candidates possible during the implementation of these two projects.

### Delay implementation of NLRB so that there is no transition period.

The Committee recommends implementing NLRB and allocation changes simultaneously. This option addresses the specific problem that would be introduced by having the allocation using DSA and region while exception scores are based on a different geographic area. It also addresses the potential inequity associated with the example in *Figure 1* above. With the transition period removed, there is not a need to create an additional DSA-based scoring system to ensure equity while the allocation remains DSA and Region based. Additionally, implementing NLRB on April 30 (as the Committee is now recommending) instead of April 2 (as it would have been under the public comment plan) allows more time to notify and educate the community about the changes before implementation.

### Convert exception scores

Based on public comment feedback, the Committee also recommends converting most of the existing exception scores on the day NLRB and Acuity Circles are implemented. If the NLRB and allocation changes were implemented simultaneously, but there was no conversion of existing exception scores, some candidates would transition from their current RRB-system scores to MMaT-based scores under the new allocation system; this would result in some candidates receiving offers based on exception scores assigned under the old scoring system. The RRB system and associated exception scores were created to work in an allocation system based on DSAs and OPTN regions. They include regional agreements and regional review boards, both designed to address geographic variability in access to transplant and clinical practice. The NLRB and associated exception scoring system using MMaT/250 were designed to work with a system of allocation based on circles around the donor hospital. When scores assigned under one system are used in the other system, it creates the potential for unintended advantage or disadvantage to certain patients. The Committee recommends converting scores to avoid this result.

The Committee considered the most equitable way to convert existing scores. The Committee reviewed the types of exceptions that are currently in the system. The existing exception scores that would need to be converted can be grouped into three basic groups:

1. "Standard", policy-assigned scores that meet criteria and provide discrete data that enables identification (identified in green on the table below);
2. "Like standard" exception scores that are the same value as the standard, policy-assigned score for the candidate's diagnosis (identified in yellow on the table below<sup>6</sup>); and

---

<sup>5</sup> There will be approximately 110 adult HCC board reviewers, 110 adult other diagnosis board reviewers, and 55 pediatric board reviewers. OPTN data, February 11, 2019.

<sup>6</sup> These exception scores can be identified by the fact that they are equal to the score that would be assigned according to the schedule of scores for that diagnosis in policy. For complete schedules for each diagnosis, see *Appendix 1: Diagnosis Conversion Tables*.

3. “Non-standard” exception scores that cannot be easily mapped to a standard, policy-assigned score (identified by no highlight in the table below).

**Table 1: Snapshot of the Number of Exception Forms by Diagnosis on March 22, 2019<sup>7</sup>**

Diagnosis	Total # of unexpired forms	Approved Forms					Pending Approval Forms	
		# Auto approved by system	# Chair at Standard score	# RRB at Standard score	# Chair at Non-Scheduled score	# RRB at Non-Scheduled score	Standard Score	Non-Scheduled Score
Familial Amyloidosis	6		2	2		1	1	
HCC	1861	774		912		118	45	12
Hepatic Artery Thrombosis (HAT)	8	6			1	1		
Hepatopulmonary Syndrome	93		63	9	4	15	2	
Metabolic Disease	13	11		1				1
Other specify <sup>1</sup>	813	1			55	731		26
Portopulmonary Hypertension	45		28	6	4	7		
Primary Oxaluria	13		8	4		1		
<b>TOTAL</b>	<b>2852</b>	<b>822</b>	<b>101</b>	<b>934</b>	<b>64</b>	<b>874</b>	<b>48</b>	<b>39</b>

The Committee discussed the appropriate conversion for adult, adolescent and pediatric candidates.

The Committee recommends converting the standard and like standard groups by assigning the standard score listed in policy for the candidate’s diagnosis. For instance, if a candidate has an exception score of 30 and is on his 3<sup>rd</sup> HCC extension, the OPTN can identify him as a candidate who has a score that is the same as the policy-assigned standard score, and will convert that candidate’s exception score to the new policy-assigned score for the HCC candidates on their third extension (MMaT-3). The Committee is recommending conversion of the non-standard scores to the score assigned for most exceptions in the new system.

The result is that most adult candidates will have scores converted to MMaT-3, most adolescent candidates’ scores will be converted to MMaT, and most pediatric candidates’ scores will be converted to median PELD at transplant (MPaT).

In the RRB system, candidates with standard exceptions are assigned scores ranging from 22 to 40. Those exceptions that are assigned an exception score of 40 in the RRB system are also assigned a 40 in the NLRB system. Because the scores would be the same, the Committee chose not to include scores of 40 or higher in the conversion. Because exception scores of less than 22 are all awarded by the RRB and are lower than any standard exception score, the Committee also chose to exclude these scores from conversion.

After excluding the scores of 40 and higher, there was still one diagnosis that would be converted, but would not automatically receive a score of MMaT-3 (for adults, or MMaT/MPaT for adolescents or pediatrics) in the NLRB system. Primary Hyperoxaluria was recognized in the exception scoring as requiring a higher exception score. In both the RRB and NLRB systems, candidates with primary hyperoxaluria are awarded an exception score 3 points higher than other exceptions. The Committee recommends preserving this distinction, and converting candidates that either meet the criteria for primary

<sup>7</sup> OPTN data, accessed 3/22/2019 8:30am.

hyperoxaluria or were awarded the same score as if they did to a score of MMaT (for adults, or MMaT+3 for adolescents and MPaT+3 for pediatrics). This will keep their scores consistent with the NLRB scoring guidelines.

Applying all of these decisions, the Committee proposes converting exception scores according to the table below.

**Table 2: Score conversion plan**

Age	Diagnosis	Current exception score	Exception score after conversion
At least 18 at registration	Any	40	40
At least 18 at registration	Any (except primary hyperoxaluria)	22-39	MMaT-3
At least 18 at registration	Primary hyperoxaluria	22-39	MMaT
At least 18 at registration	Any	Less than 22	No change to score
At least 12, and less than 18 at registration	Any	40	40
At least 12, and less than 18 at registration	Any (except primary hyperoxaluria)	22-39	MMaT
At least 12, and less than 18 at registration	Primary hyperoxaluria	22-39	MMaT+3
At least 12, and less than 18 at registration	Any	Less than 22	No change to score
Less than 12	Any	40 or higher	No change to score
Less than 12	Any (except primary hyperoxaluria)	Less than 40	MPaT
Less than 12	Primary hyperoxaluria	Less than 40	MPaT+3

For any candidates that have submitted an exception form, but it has not yet been approved or denied by the RRB when NLRB is implemented, the same rules for conversion will apply as for the approved forms, and the pending form will be routed to the NLRB for approval.

## Which populations are impacted by this proposal?

As of March 18, 2019 there were 2,870 active approved or pending MELD/PELD exception forms. As shown in the table below, 1,488 adult exceptions and 23 adolescent exceptions are within the range of 22-39 that will be converted, and 80 pediatric exceptions are below 40 and will be converted. The remaining exceptions will not be converted.

**Table 3: Snapshot of Active Approved or Pending MELD and PELD Exception Forms by Candidate Age Group and Requested Score on March 18, 2019<sup>8</sup>**

Requested Score	Pediatric	Adolescent	Adult	Total
6	0	0	1,122	1,122
7-14	0	0	19	19
15-21	5	13	78	96
22-39	75	23	1,488	1,586
40	7	5	9	21
> 40	26	0	0	26
<b>Total</b>	113	41	2,716	2,870

## How does this proposal impact the OPTN Strategic Plan?

1. Increase the number of transplants: There is no impact to this goal.
2. Improve equity in access to transplants: This proposal will improve equity in access to transplants by ensuring that most liver candidates with exception scores have consistently-awarded scores at the time the new allocation sequence takes effect. It eliminates the period of transition in which some candidates would have scores assigned under an old system and others would have scores assigned under a new system.
3. Improve waitlisted patient, living donor, and transplant recipient outcomes: There is no impact to this goal.
4. Promote living donor and transplant recipient safety: There is no impact to this goal.
5. Promote the efficient management of the OPTN: There is no impact to this goal.

## How does this proposal comply with the Final Rule?

The Final Rule requires that 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 placement;...(8) Shall not be based on the candidate's place of residence or place of listing, except to the extent required by paragraphs (a)(1)-(5) of this section.”<sup>9</sup>

1. *Sound Medical Judgment:* The Committee proposes simultaneous implementation and conversion based on sound medical judgment. The materials provided include descriptive data concerning the impact of the proposed options.
2. *Best Use of Donated Organs:* The Committee believes that offering organs to the most medically urgent candidates first is the best use of donated livers. This policy seeks to make the best use of donated organs by granting similar access to exception candidates with the same diagnosis listed at the same time at the same hospital.
3. *Preserve Ability to Decline an Offer:* This does not affect the ability of a transplant program to decline an offer.
4. *Specific to Organ Type:* This is specific to an organ type. In this case, the proposed policy is specific to the allocation of deceased donor livers.
5. *Avoid Wasting Organs:* Organs are wasted when a transplantable organ is not transplanted. This policy would not result in any increase in organs that would not be transplanted.

<sup>8</sup> OPTN data, accessed March 18, 2019.

<sup>9</sup> 21 C.F.R. §121.8(a).

*Avoid Futile Transplants:* A futile transplant may occur if a recipient is transplanted with an organ that does not continue to function soon after transplantation. This proposed policy change does not incentivize futile transplants.

*Promote Patient Access to Transplantation:* This proposal promotes liver candidate access to transplant by ensuring that candidates requesting an exception score for the same degree of illness at the same time in the same first unit of allocation have the same MELD exception score.

*Promote Efficient Management of Organ Placement:* A proposal that reduces logistical complications associated with procuring an organ and transporting it from the donor to the candidate promotes efficient management of organ placement. This proposal would have no impact on the efficient management of organ placement. Candidates within the same area have similar logistical complications, and changing the order in which they appear is unlikely to affect efficient management of organ placement.

8. *Geographic Considerations:* A policy may be based in a candidate's residence or place of listing only to the extent required to achieve the considerations listed above. The proposed implementation timeline and conversion plan will not add any additional consideration of the candidate's place of listing.

The Final Rule provides for transition procedures to “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.”<sup>10,11</sup> The OPTN is proposing a transition, aimed at equalizing the impact of the transition on candidates.

The Final Rule requires that the Board “[p]rovide opportunity for the OPTN membership and other interested parties to comment on proposed policies and shall take into account the comments received in developing and adopting policies for implementation by the OPTN”.<sup>12</sup> The Committee is not recommending any change to policy, but the change to the implementation timeline and the conversion plan is in direct response to public comment received on the *MELD Exception Scores during NLRB Transition* public comment proposal.

## How will the OPTN implement this proposal?

The OPTN will publish an updated MMaT/250 two weeks before the implementation of NLRB and Acuity Circles. The NLRB policy and processes will be implemented on the same day as the Acuity Circles allocation changes. Current approved and pending exception scores will be converted. This proposal is not expected to change the planned implementation date of April 30, 2019 for the remainder of *Liver and Intestine Distribution Using Distance from Donor Hospital*.

## How will members implement this proposal?

In order to ensure efficient review of exception forms as the RRB is replaced by the NLRB, liver transplant programs are asked to avoid submitting new exception applications or extensions during the week of April 23-30 unless necessary. This will allow the RRB to review as many of the exceptions submitted prior to the NLRB as possible, and will minimize the number of exception forms submitted in the RRB system that must be reviewed by the NLRB.

---

<sup>10</sup> 21 C.F.R. 121.8(d)

<sup>11</sup> The provision for creating transition protections was reiterated in the letter from Administrator Sigounas, which stated, “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 (sic) 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 to refine, modify, and improve any OPTN liver policy.” George Sigounas, letter to Sue Dunn, OPTN President, July 31, 2018.

<sup>12</sup> 42 C.F.R. 121.4(b)(1).

**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?**

This will not change the current routine monitoring of members.

## Conversion Plan

1 **RESOLVED**, upon implementation of the *Liver and Intestine Distribution Using Distance from*  
 2 *Donor Hospital* proposal (hereafter “Acuity Circles”), adopted by the OPTN Board of Directors on  
 3 December 3, 2018, liver transplant candidates will be converted as follows:

4  
 5 **Candidates will be categorized into three age categories:**

- 6 1. **Adult candidates:** Candidates ages 18 or older at the time of registration.  
 7  
 8 2. **Adolescent candidates:** Candidates who will be 12 years or older at the time of implementation of  
 9 Acuity Circles and were registered prior to the age of 18.  
 10  
 11 3. **Pediatric PELD candidates:** Candidates who will be under the age of 12 years old at the time of  
 12 implementation of Acuity Circles.

13  
 14 ***FURTHER RESOLVED***, candidates with current approved or pending MELD or PELD exception  
 15 scores and extensions for diagnoses of Primary Hyperoxaluria at the time of implementation of  
 16 Acuity Circles will have their scores converted as follows:

17  
 18 **Table C-1: Conversion of MELD or PELD Exceptions and Extensions for candidates with a diagnosis**  
 19 **of Primary Hyperoxaluria upon implementation of Acuity Circles**

<b><i>If candidate is</i></b>	<b><i>And their current exception score is</i></b>	<b><i>Then the candidate’s exception score will be equal to:</i></b>
<i>Adult, Adolescent, or Pediatric PELD</i>	<i>40 and above</i>	<i>Their existing score; no conversion</i>
<i>Adult</i>	<i>22-39</i>	<i>MMaT</i>
<i>Adolescent</i>	<i>22-39</i>	<i>MMaT+3</i>
<i>Adult and Adolescent</i>	<i>21 and below</i>	<i>their existing score; no conversion</i>
<i>Pediatric PELD</i>	<i>39 and below</i>	<i>MPaT+3</i>

20  
 21 ***FURTHER RESOLVED***, candidates with current approved or pending MELD or PELD exception  
 22 scores and extensions for diagnoses other than Primary Hyperoxaluria at the time of  
 23 implementation of Acuity Circles will have their scores converted as follows:

24  
 25 **Table C-2: Conversion of MELD or PELD Exceptions and Extensions for candidates with diagnoses**  
 26 **other than Primary Hyperoxaluria upon implementation of Acuity Circles**

<b><i>If candidate is</i></b>	<b><i>And their current exception score is</i></b>	<b><i>Then the candidate’s exception score will be equal to:</i></b>
<i>Adult, Adolescent, or Pediatric PELD</i>	<i>40 and above</i>	<i>Their existing score; no conversion</i>
<i>Adult</i>	<i>22-39</i>	<i>MMaT-3</i>
<i>Adolescent</i>	<i>22-39</i>	<i>MMaT</i>
<i>Adult and Adolescent</i>	<i>21 and below</i>	<i>Their existing score; no conversion</i>
<i>Pediatric PELD</i>	<i>39 and below</i>	<i>MPaT</i>

# Appendix A: MELD Exception Score Transition

*MELD Exception Scores during NLRB Transition*

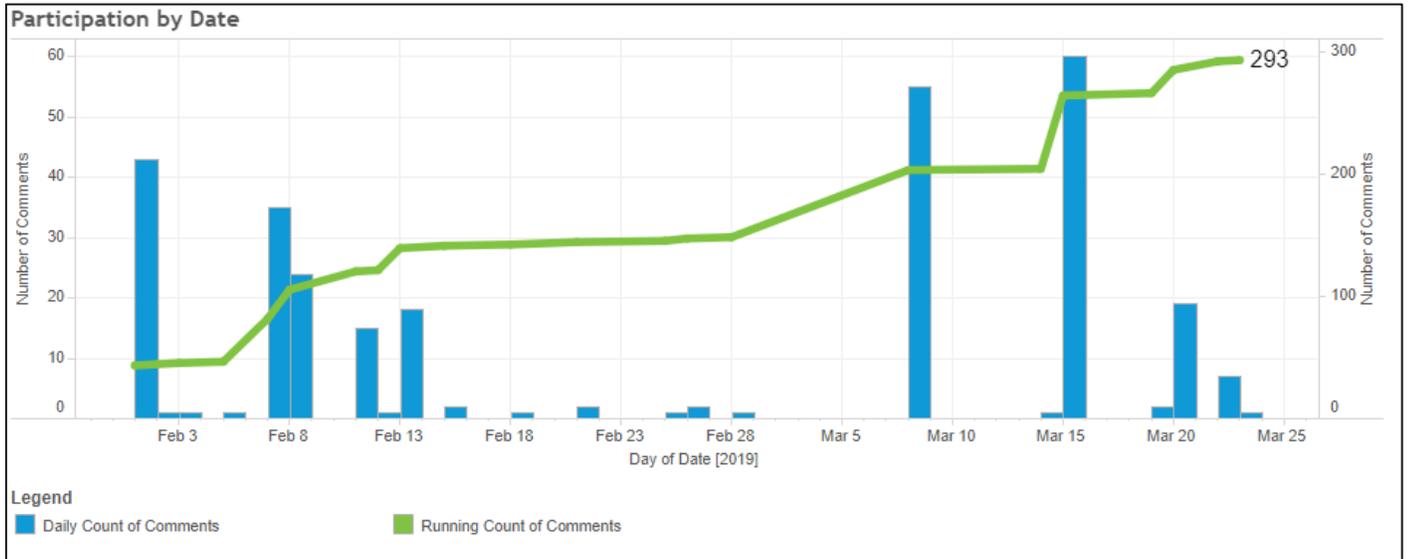
## Contents

Participation	2
Sentiment	5
Themes in Public Comment	8
Comments Received	9
Regional Comments	9
Organizations	11
Individual Comments	12

# Participation

The proposal was released from January 31, 2019 to March 22, 2019. During that time, it received 293 comments.

Figure 1: Total Comments Received



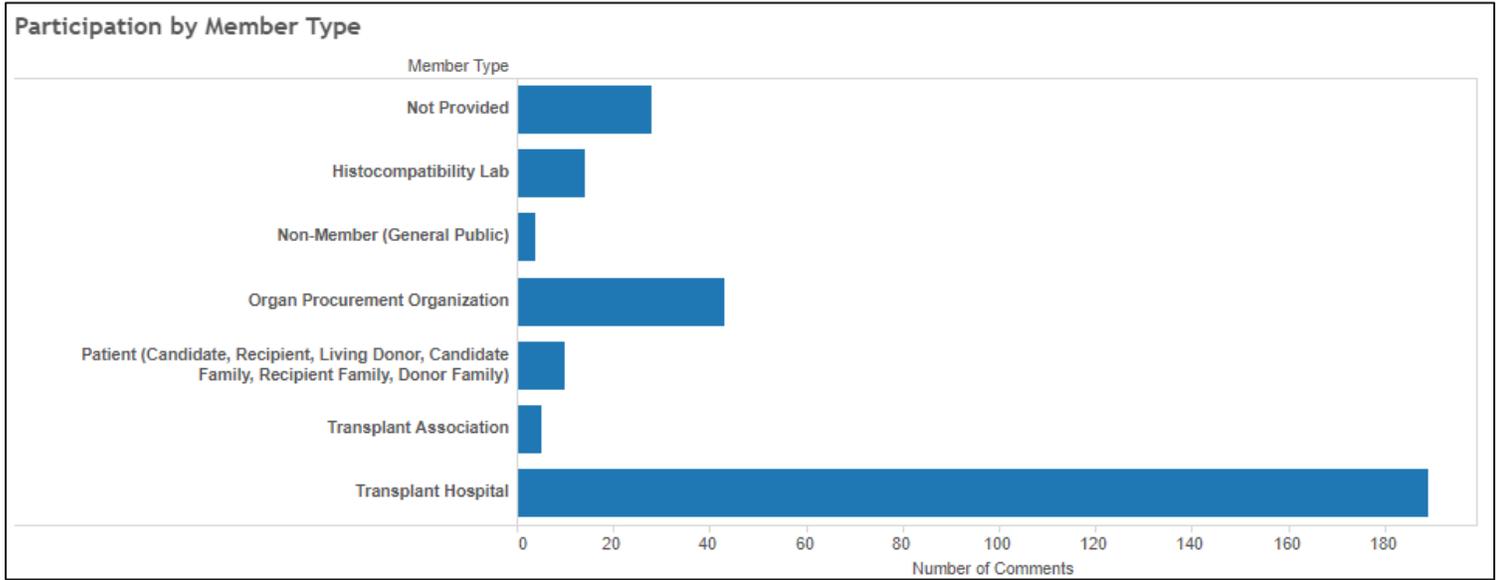
In total, 30 comments were submitted for posting on the OPTN website and 263 votes were submitted at regional meetings.<sup>13</sup>

<sup>13</sup> Each vote at a regional meeting was counted as one comment.



The comments were submitted by multiple different member types.

**Figure 3: Types of Commenters**

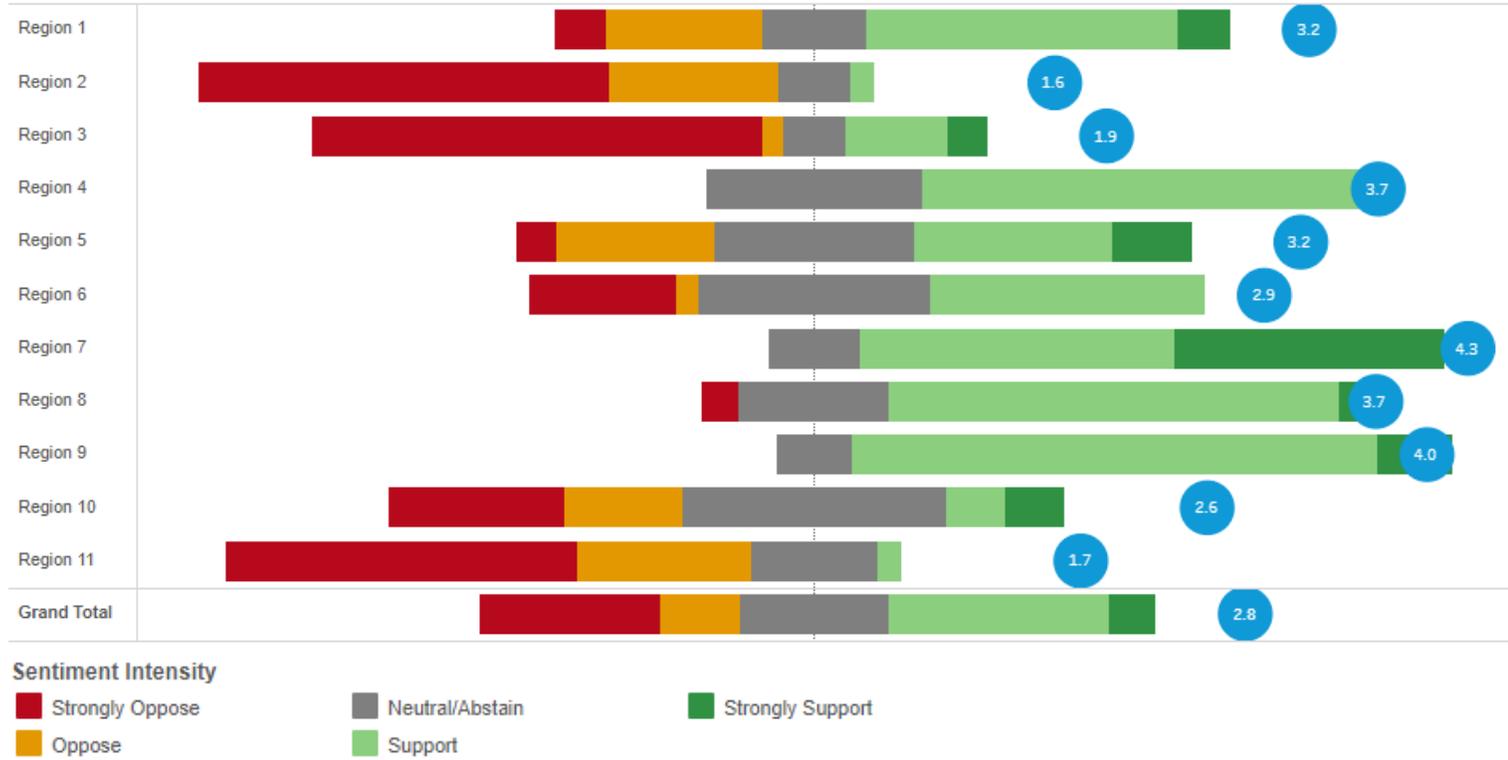


# Sentiment

There were 263 votes submitted at the 11 regional meetings. Sentiment varied by region with an overall sentiment score of 2.8 out of 5.

**Figure 4: Regional Sentiment**

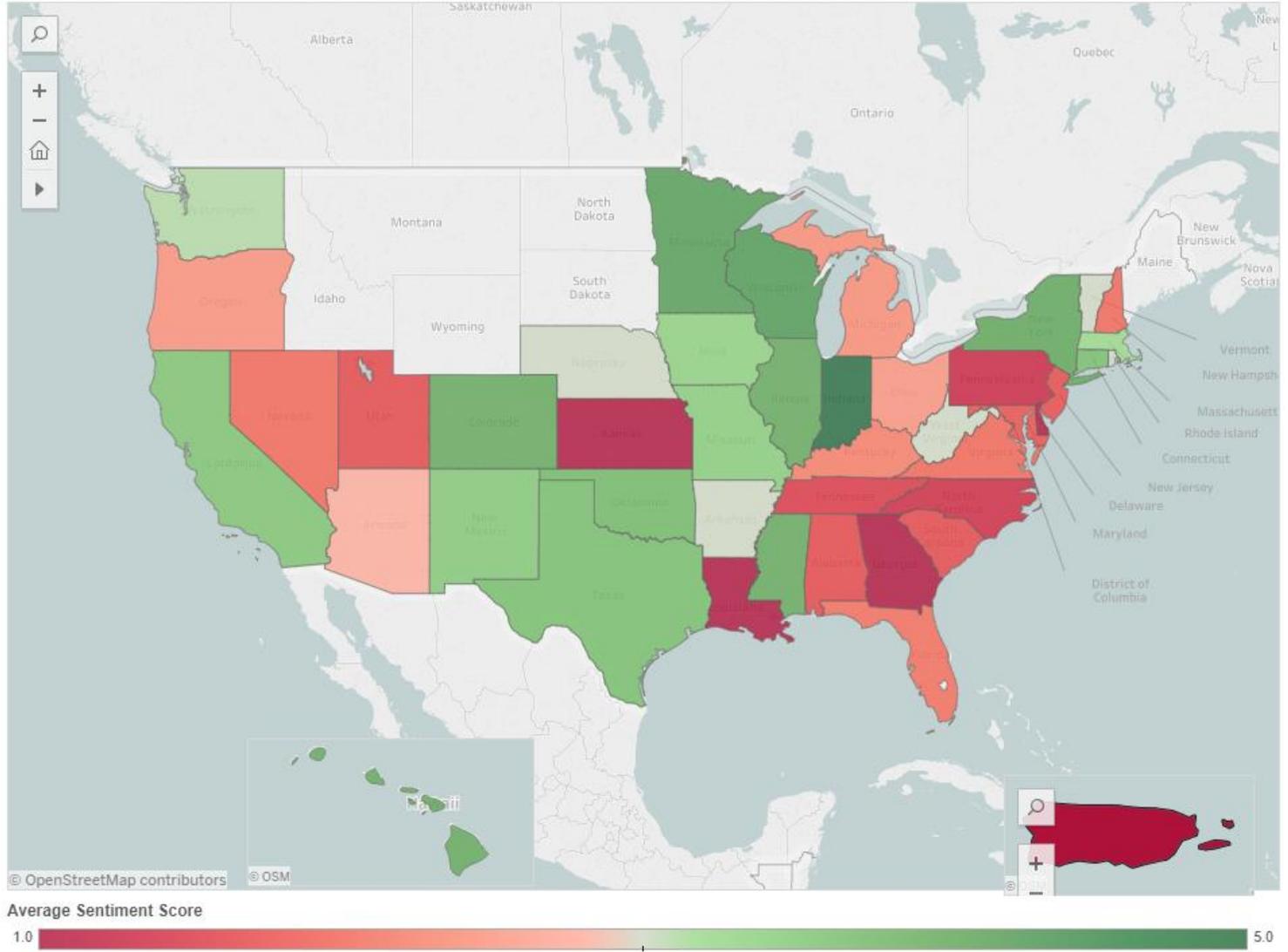
## Sentiment at Regional Meetings



There was variation in sentiment by state. States in the southeastern part of the country were generally more opposed to the proposal than states in other regions.

Figure 5: Sentiment by State

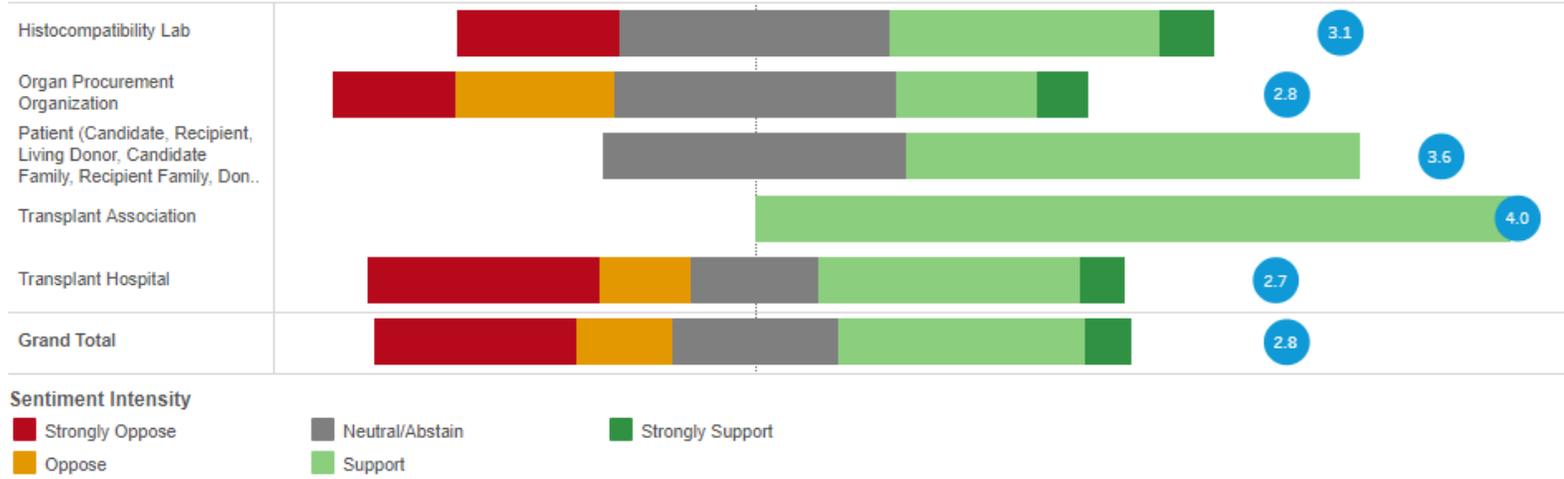
MELD Exception Scores During NLRB Transition



Sentiment also varied by member type. Histocompatibility labs, organ procurement organizations, and transplant hospitals all had mixed opinions, while patients and transplant associations had generally favorable opinions. The overall sentiment score across member types was 2.8 out of 5.

Figure 6: Sentiment by Member Type

Sentiment by Member Type



## Themes in Public Comment

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

- **Only using exception scores assigned under the NLRB system exception in Acuity Circles allocation**  
Several commenters objected to implementing Acuity Circles so soon after NLRB was implemented since most exception candidates would still have scores that were assigned under the RRB system at the time Acuity Circles was implemented. Some of the commenters were concerned that using the RRB-system scores in the Acuity Circles allocation system would potentially give greater advantage to exception candidates in certain regions with historically higher exception score trends. Several commenters requested that the timeline be adjusted to allow for a three month transition period as originally planned. Other commenters, including Region 10, requested that the NLRB re-review all exception scores before Acuity Circles takes effect.
- **Ensuring that candidates with exceptions for the same diagnosis who have the same MMaT are ordered according to who has been waiting longest**  
Several commenters expressed concerns that the plan proposed in public comment, assigning exception scores based on MMaT/DSA during the transition period would cause some candidates to be advantaged or disadvantaged depending on the time their exception or extension is approved during the transition. Because time at score and higher is used to order candidates within the same classification, blood type compatibility, and MELD/PELD score, this advantage or disadvantage could last well beyond the transition period, and affect the candidate's placement on all future match runs.
- **Conversion options**  
Some commenters expressed support for converting exception scores prior to implementation of the NLRB. There were also comments about the way the NLRB will work after NLRB and Acuity Circles are implemented. These comments were not addressed as part of this implementation plan, but the Committee will consider them as feedback about the system as the impact of the changes from NLRB is evaluated. These comments include the following concepts:
  - Exception scores should be based on a national MMaT or as broad a geographic area as possible
  - Policy is too complicated and has too many acronyms
  - Status 1A and 1B patients should be included in the MPaT calculation. Status 1A patients should be given a PELD of 76 and Status 1B patients should be given a PELD of 50 in the calculation of national MPaT.
  - MMaT calculation should be based on lab MELD not allocation MELD
  - NLRB has not been properly modelled
  - There is room for refinement of the MELD calculation
  - The OPTN Should focus on OPO behavior, transplant center practices, and organ donation rates

## Comments Received

Below are the individual comments submitted during the public comment period. They are organized by type (region, organization, individual).

### Regional Comments<sup>15</sup>

#### Region 1

Region 1 vote: 1 strongly support, 6 support, 2 neutral/abstain, 3 oppose, 1 strongly oppose

***Region 1 Comments:***

***No comments.***

#### Region 2

Region 2 vote: 0 strongly support, 1 support, 3 neutral/abstain, 7 oppose, 17 strongly oppose

***Region 2 Comments:***

The members in Region 2 were united in their dislike of the proposed changes. If MMaT is to be based on DSA in the interim period, they will lose out on livers to other nearby areas because their MMaT scores are lower than other nearby DSAs. They felt that in order to make the system as fair as possible across the nation either acuity circle distribution implementation should be delayed so that there is a three month window between NLRB implementation and acuity circle implementation so that all exception scores are renewed under the new system. The other option they put forward would be to take a systematic approach to reviewing the two-thirds of exceptions that are standard and semi-standard. For the remaining one-third of exceptions, which are non-standard, the NLRB would need to manually review those cases in the one month transition period. The region is aware that would put a heavy burden on the NLRB to review a large number of cases in a short period of time; however, since this would only be a one-time influx of reviews, it is manageable. They suggested a triage approach that the highest non-standard exception cases be reviewed first and then work down from there.

#### Region 3

Region 3 vote: 2 strongly support, 5 support, 3 neutral/abstain, 1 oppose, 22 strongly oppose  
Amendment to convert all scores using a National Median MELD at Transplant on the day of implementation and continue the use of the National Median MELD at Transplant moving forward: 20 strongly support, 3 support, 5 neutral/abstain, 0 oppose, 3 strongly oppose  
Motion from the floor for message that region 3 supports the liver committee proposal passed by the board in December, 2017: 14 strongly support, 6 support, 5 neutral/abstain, 2 oppose, 1 strongly oppose

***Region 3 Comments:***

The region voiced strong support for a national median MELD score at transplant since we will be using NLRB. They believe using a national score would help equalize scores and more quickly equalize median Meld at transplant throughout the country. It was also recommended that exception scores should be evaluated, particularly the "other" exceptions to help reduce variance in exception scores. The region also voiced concern the state based allocation system never got equal consideration or vetting despite it achieving the same goals as AC or B2C.

#### Region 4

Region 4 vote: 0 strongly support, 15 support, 7 neutral/abstain, 0 oppose, 0 strongly oppose

***Region 4 Comments:***

No comments.

---

<sup>15</sup> Comments from the regions are approved by the Regional Councillor and are meant to express the overall sentiment of the region. They are not a transcript of the regional meeting; therefore, they may not include every comment expressed at the meeting.

## Region 5

Region 5 vote: 4 strongly support, 10 support, 10 neutral/abstain, 8 oppose, 2 strongly oppose

*Region 5 Comments:*

Why 250 nm was selected was questioned as it inadvertently causes a disparity for exception candidates. MELD should reflect a local environment and access should be differentiated for various exceptions.

## Region 6

Region 6 vote: 0 strongly support, 13 support, 11 neutral/abstain, 1 oppose, 7 strongly oppose

*Region 6 Comments:*

A member commented the outlined timeline seems unrealistic for success.

## Region 7

Region 7 vote: 6 strongly support, 7 support, 2 neutral/abstain, 0 oppose, 0 strongly oppose

*Region 7 comments:*

No comments.

## Region 8

Region 8 vote: 1 strongly support, 12 support, 4 neutral/abstain, 0 oppose, 1 strongly oppose

*Region 8 comments:*

No comments.

## Region 9

Region 9 vote: 2 strongly support, 14 support, 2 neutral/abstain, 0 oppose, 0 strongly oppose.

*Region 9 comments:*

No comments.

## Region 10

Region 10 vote: 2 strongly support, 2 support, 9 neutral/abstain, 4 oppose, 6 strongly oppose  
Amendment to review non-standard exceptions during one month transition period: 8 strongly support, 7 support, 8 neutral/abstain, 0 oppose, 0 strongly oppose

*Region 10 comments:*

The members of Region 10 were not in favor of the proposal. As mentioned during the Liver Committee Update, the region would like to there to be a national MMaT at time of acuity circle implementation instead of using MMaT/250NM. One member stated that they would be in favor of delaying the allocation changes so that there would still be the three month interval between NLRB implementation and acuity circle implementation. If that is not an option, the region supported the idea of reviewing all non-standard exception cases during the one month transition period, so that when acuity circles are implemented every patient has a MMaT/250NM. The region voted on the proposal as written which showed opposition to the proposal. They then voted on the proposal with the amendment that all non-standard exceptions be reviewed during the one month transition period between NLRB and acuity circle implementations.

## Region 11

Region 11 vote: 0 strongly support, 1 support, 5 neutral/abstain, 7 oppose, 14 strongly oppose  
Amendment to use National MMaT for the transition and the new allocation system: 13 strongly support, 7 support, 5 neutral/abstain, 0 oppose, 0 strongly oppose

*Region 11 Comments:*

The region has concerns that candidates with the same disease for the same donor liver will have different scores. It was noted that candidates that transition to the new scoring system in April may temporarily have a lower MELD score despite having a longer waiting time. Using median MELD at transplant (MMaT) for the DSA is generally problematic. An example was given of 2 cities in the same state that are within 150 miles of each other but have different MMaT. The

region recommends using the national median MELD at transplant for the transition period and the new liver distribution policy.

## Organizations

We received comments from five organizations.

### **Beth Israel Deaconess Medical Center**

We are supportive of the policy of the MLRB but the following are our concerns: The policy needs to have some further consideration into the timing of implementation of the MMaT. Due to the fact that patients can keep their MELD score until the next extension but then must have a MELD score equivalent to MMaT-3, it is possible that some patients who have been listed with MELD exception score and whose extension is due soon, could be disadvantaged as they may show up on match run lower than patients who have been listed for shorter period of time but have had an extension in their exception just prior to Jan 31. For example: a patient with a MELD extension on Jan 29 would increase to a score of 34 until April 29th, yet a patient who is already on 34 with a MELD extension after Jan 29 would drop to a MELD score equivalent to MMaT-3 which could be lower than 34. This is a disadvantage to the patient who is supposed to have a high priority.

### **The American Society of Transplantation (AST)**

The American Society of Transplantation opposes the timing of the implementation of the MELD Exception Score During NLRB Transition proposal – which is a month before the acuity circle allocation system, as this shorter lag between the two implementations is projected to create disparity in patient access. The original intention was to provide a 3-month lag between the NLRB and the new acuity circle allocation system to ensure a uniform review of MELD exceptions by the NLRB, as well as to provide sufficient time between the implementation of two major policies. Furthermore, the 3-month lag would have protected against new disparities that this newest proposal would yield. Until MELD exceptions are standardized, it will be unjust to allocate over wide geographic areas- but the current proposal entails an approximately 2-month period during which livers will be allocated to patients with MELD exceptions that won't have cycled through the NLRB. In certain parts of the USA, this will likely siphon large volumes of livers from one area to another for an unfair reason. For example, the median allocation MELD in the NYRT DSA is 34, while it is 30-31 in the PADV DSA. So, patients granted exceptions based on the MMAT-3 in the NYRT DSA will receive 31 points, while those in PADV will receive 27-28. However, once acuity circles are implemented, donors in PADV will be 'local' (based on 150NM circles) to recipients in NYRT, and therefore patients in NYRT who received exceptions during the period will have higher scores for the same disease as patients in their 'local' area (PADV), thereby creating a disparity based on geography. This will be a direct result of only having 1 month between this revised NLRB exception policy and acuity circles. We offer several potential solutions that we believe would be strong alternatives: 1. at the same time acuity circles are implemented, reset all exception points to the MMAT-3 for the 250NM circles, as proposed, rather than leave those given exception points based on their MMAT in the DSA with a potential advantage, or 2. delay the implementation of the new allocation policy by two months. The latter option offers two major advantages: 1) it prevents the creation of new geographic disparities by having the 1-month period described above; and 2) it provides sufficient time to adjust to the new NLRB system, which will help to mitigate logistical, technical, or other issues that could occur with the initiation of two major policies in rapid succession. Keeping the 3-month delay will also be honoring the initial belief of the Liver Committee and the OPTN/UNOS Board that spacing out two major policy changes is best for the system operations and for patient care.

### **The American Society of Transplant Surgeons (ASTS)**

The American Society of Transplant Surgeons (ASTS) abstains on the OPTN/UNOS proposal to establish a MMaT exceptions score methodology aligned with DSA-based allocation for a one-month period when the NLRB is active, and the new allocation system starts on April 30, 2019 as this decision will have no long term impact. For the future, the ASTS strongly urges UNOS to

apply NLRB MELD exceptions to the largest geographic area possible to allow for equalization of MELD exceptions that would parallel the equalization of MMaT expected with the new allocation, in as close to real time as possible. The timeline for implementation and equalization of MMaT and exception scores should be as short as possible. ASTS promotes the principle that patients in the same sharing area should have equivalent exception points.

### **American Society for Histocompatibility and Immunogenetics (ASHI)**

The American Society for Histocompatibility and Immunogenetics (ASHI) supports this proposal to ensure that affected liver patients are not disadvantaged during a transition period.

### **Society for Pediatric Liver Transplantation**

The pediatric liver transplant community represented by the Society for Pediatric Liver Transplantation (SPLIT) supports this policy in so far as the national MPaT will be applied only to those individuals with Standard Exception Requests but has concerns on the following points: 1) The calculation of national MPaT excludes large populations of pediatric recipients in its calculation, namely patients who are transplanted at Status 1A or 1B. We suggest that there be an assigned score of 50 for children transplanted at 1B and 76 for those transplanted at 1A to allow for more accurate calculations. 2) The language to account for liver/intestine exception candidates should be made more clear- all of these candidates are at high MELD/PELD scores, and they also have a high mortality rate, and will be evaluated on an individual case-by-case basis by the Pediatric NLRB. 3) This policy change seems unnecessarily complicated to be implemented for just 1 month, and may have unintended consequences and stress upon recipients and their families on the waitlist.

## **Individual Comments**

We received comments from 14 individuals.

### **Anonymous**

If the National review board cannot be implemented on time it's better to push everything back just a few months to get it right. The uncertainty is hard in patients and their doctors. Stick with the original plan of implementing the national review board then do the allocation change 90 days later as planned. Changing too much too soon make it more difficult to pinpoint a problem if one arises.

### **Anonymous**

You use too many acronyms. You have MMaT which I discovered meant "Median MELD at transplant" Your acronyms have acronyms. Here I am, a general lay person who knows someone is going to become a living donor for a friend of hers and the process intrigued me enough to read about the statistics, etc and you use so many acronyms I don't have a clue what you are talking about. Aaand there went my interest.....(Not really but for the vast majority that would be true.)

### **Malay Shah**

What's the point in moving forward with any proposal of any kind? The organizations and institutions that regulate and support transplant have proven themselves to be incapable of directing any meaningful, thoughtful and beneficial policy of any kind. Rather than focusing any efforts into improving organ donation and identifying real healthcare disparities, efforts have been taken to only propose and pass policy as dictated by HHS and litigation. Rather than asking for public comment to this proposal, I feel that at this point, it would be more prudent to ask administrators and lawyers what they most appropriate steps would be. Clearly, the advice of stakeholders and experts in the field are not valued and not accepted.

### **Maribel Carr**

In order to be transparent and avoid yet another pitfall, what exactly is the MMaT/DSA for each of the 52 liver donation service areas, and especially for the identified outliers' DSAs?

### **Kenneth Andreoni**

My opposition to this suggestion is simply that patient's illness is more fairly based on LAB MELD, and not allocation MELD. It is impossible to foresee how using Allocation MELD instead of LAB MELD will harm acutely ill patients by giving less ill patients with exception points too much relative access to organs. We must be clear in separating LAB from ALLOCATION MELD when we discuss Mean MELD at Transplant issues.

### **Anonymous**

The premise of the liver allocation change was to remove DSA as an element of allocation. As different centers have different practices (and different MELD at txp), it seems that exception points should be specific for the center and not the DSA centers. Each liver center should have their median MELD at txp be an internal standard for exception points.

### **Seth Karp**

As we move to a national distribution system, MELD - 3 will lead to a patients with the same disease competing for the same liver at a different MELD scores depending solely on where they live. This move to a national system for MELD exceptions has not been adequately modeled and the impact on various communities has not been adequately addressed.

### **Grace Gagne**

My dear husband of 50 yrs, passed away while waiting for liver and kidney transplants, from the NASH. He was Denied his transplant at Mayo-Jacksonville, FL, due to being malnourished. He could not even tolerate supplements thru NJ tube. (He had lost approx 65 lbs from Apr -Dec 2018!) He was also on a transplant list at Mass Gen Hospital, Boston. Tho, MGH tried desperately to nourish him, he lost his battle on Dec 29th. I know of several other patients who also have been denied a liver transplant, due to being malnourished. I suggest, if nourishment is detrimental in the survival of liver and other transplants, Nourishment should become an important equation of the MELD Formula. How do I get involved in this endeavor? Gigi Gagne

### **Melanie Best**

RE: Request for Grandfathering of Current Perihilar Cholangiocarcinoma Patients under the Current UNOS Liver Allocation Formula Dear Members of the UNOS Executive Committee: On the advice of UNOS' Patient Services department, I am submitting this urgent request for grandfathering under the current liver allocation formula of me and other perihilar cholangiocarcinoma patients on the UNOS wait list who underwent adjuvant radiation/brachytherapy on our bile ducts while the current allocation formula was in effect and with the understanding this formula would govern the allocation of livers to us. I realize the comments you are accepting on this website do not specifically pertain to my request, but Patient Services suggested this avenue as the most expeditious route to present my urgent appeal to you. As a patient with a MELD exception score on the UNOS list for liver transplant, I will be unfairly disadvantaged by the new liver-allocation formula being adopted by UNOS. Irrespective of UNOS' motivations for changing the formula going forward, without a grandfather remedy for people like me who have had their bile ducts irreparably damaged in the course of our pre-transplant radiation therapy, great harm will unnecessarily be done to us. I am in the Mayo Clinic's liver transplant program, having been diagnosed in May 2018 with de novo perihilar cholangiocarcinoma and undergone the pre-transplant radiation and chemo therapy treatments per Mayo's cholangiocarcinoma protocol in July and August of 2018 at Mayo's Rochester, MN, facilities. That treatment protocol includes brachytherapy in the bile ducts, which necessitates a liver transplant as the final stage of treatment since, subsequent to this therapy, my existing liver

cannot be restored to proper functioning. I entered this treatment program assured that, under the UNOS allocation formula, I would be certain within a reasonable period to rise to the maximum possible MELD score and the top of the wait list. The new UNOS formula, by assigning a fixed, MMAT-3 score to exception patients like me, increases the risk that I will experience metastasis and/or life-threatening cholangitis from ongoing ERCP procedures while I wait indefinitely for a donor liver. Unlike wait-list patients who do not have perihilar cholangiocarcinoma, under the metastasis and cholangitis scenarios I would become ineligible for transplant; therefore, to make an appeal to get a liver at that point would be moot and quite possibly the result would be my death. By keeping perihilar cholangiocarcinoma patients who started treatment under the previous UNOS formula permanently below the median MELD score, the new UNOS formula creates a terrifying future for me and others in my situation in which we will wait indefinitely, maybe forever, for transplant. Given this situation, which affects a finite subset of patients on the UNOS wait list, I am urgently requesting that UNOS remedy this problem by grandfathering the perihilar cholangiocarcinoma patients who, in good faith, entered this bile duct-altering radiation/brachytherapy treatment protocol under the old UNOS allocation formula, to enable us to be prioritized for transplant according to that formula. Such grandfathering is the compassionate and ethical course of action and is in your power to effectuate. Thank you so much for considering my request, Melanie S. Best

### **Timothy Marcum**

I am on the liver transplant list at Vanderbilt University, in Nashville, TN. and Mayo Clinic, in Jacksonville, FL. My blood MELD would be 18, but I have Pulmonary Hypertension and Hepatopulmonary Syndrome. With my extra points, I Meld score is 27. I am on 25 liters of oxygen and they had to order me a special regulator to get me to 25. I have been going up about 2 liters per oxygen per month, but they tell me that I cannot go any higher than 25. If the exceptional points program is changed and my points are rolled back, I will die before I get a liver transplant. Once I get the liver transplant, they say that I will be able to come off the oxygen.

### **Lance Stein**

There are serious issues from a logistical and practical standpoint with all of the "unchecked" changes that have been proposed the last few years. The MMaT vary because transplant center behaviors vary. Standardize nationally how centers manage, list, and transplant patients. Not the outcome. The main problem with MMaT is that it is falsely elevated for the vast majority of programs, especially in the NE and West given the wonton use of MELD exceptions. MMaT should only be calculated using median lab MELD at transplant, not median transplanted MELD at transplant. Median transplanted MELD incorporating exceptions are unfairly elevated in some regions/states more than others. Patients will continue to be harmed and will die in greater numbers in some regions until transplant center behaviors, exceptions, OPOs, are all standardized across the country. These current changes including this one will only serve to regionally shift those who will be harmed. Shame on you all.

### **Randee Bloom**

In light of the challenge put forth, I appreciate the consideration of an individualized review of non-standard exception scores during the one month (or longer) transition period. Additionally, a means to reach a calculated equally devised MELD score, such as median lab MELD, applied nationally appears to offer the balance and transparency we seek for all stakeholders.

### **Anonymous**

I am writing in strong opposition not only to stated MELD exception scores during NLRB Transition, but to the proposed transition to overhaul the entire organ allocation system as a response to the legal action taken by an individual who did not receive the scarce "GIFT" of life through organ donation. This sets a dangerous legal and moral precedent. There are over 110,000 individuals on the waiting list, hoping to be allocated an organ. There will be roughly some 36,000 recipients of that life-saving gift in the coming year. This leaves approximately

74,000 individuals who will not. 74,000 individuals who will cling to life on dialysis or by whatever means possible. And there will be many who die. It should also be noted that, as proposed, the movement toward a new allocation system will not increase the number of those transplanted. It will merely shuffle the deck for those who are, based on geography. The issue at hand, is not where people are geographically located. It is the fact that there are not enough organs to go around. As we review geography, related to organ donation, this, too, is not a perfect system. Organ donations happen as a function of location of death, proximity to services, organ registration, and other systematic influences such as healthcare, medicare and so on. There are many forces impacting organ donation, before the process of matching even begins. Further, organs are not a commodity, they are a gift. However, the allocation system attempts to view them as a commodity, with a shelf life, and without cost of movement, nor risk to those moving them. I am disappointed that those who are attempting to change the system, are not operating from the shared viewpoint that organs are a gift, and have limited scope in terms of their ability to move, and immensely high cost and risks associated with their movement. Further, it stands to bear that organs which are forced to move longer distances could result in higher discard rates, which has been shown to occur already with changes in lung allocation. The proposal can be seen as irresponsible, through the viewpoint that actually fewer organs could be transplanted as a result of strains on the system. As a result, one death + one lawsuit could lead to many more deaths on the wait list. One not need look far for an example of a similar case. A lawsuit meant to discredit the organ donation and allocation system, as the result of individual grievances has resulted in the lowest organ donation rates in 20 years in Germany. Many more people who need organs (over 10,000 waiting in that country) will not receive organs as a result. Germany still has too few organ donors after scandal (Disclaimer, this is a link to a third party website for informational purposes) <https://www.thelocal.de/20161103/germany-still-has-too-few-organ-donors-after-scandal> Organ donor numbers in Germany fall to lowest level in 20 years (Disclaimer, this is a link to a third party website for informational purposes) <https://www.thelocal.de/20180115/organ-donor-numbers-fall-to-lowest-level-in-20-years> It is my view that those in the organ donation space have one responsibility. To increase the number of organs available to those in need. Any activity to shuffle the deck for those who receive the gift, especially while adding immense potential cost and adding risk to both patients and healthcare providers, is, in my opinion, an exercise in futility. Instead, let's calculate the proposed spend and utilize those funds to increase the number of people who can come off dialysis, to get transplants, and live healthy, productive lives. We can always make tweaks and do our best to increase transparency in the process along the way.

## **Will Chapman**

It should be alarming that we are having a public comment on something that will affect 1-month of the initial NLRB implementation, but ignoring what will happen immediately thereafter for at least the next several years under the combination of the NLRB and the new AC plan, assuming this goes into effect. I agree with the idea that sharing for exception points should be equal in any exception region based on the patients disease condition. This was the whole idea of changing exception scoring, but the NLRB was not designed to be used with a 500-mile sharing plan. Under the new plan (starting on May 1), exception score listed recipients within the 500 NM (1150 ground mile diameter) circle for a given donor will be assigned median MELD at transplant (MMAT) minus 3 based on the MMAT in a 250 NM radius around the recipient's transplant center and compared with other patients in the 500 NM circle around the donor. Thus, if the recipient is from an area with historically elevated exception MELD scores, they will automatically be assigned higher MELD scores than other patients in the 500 NM circle with the same disease condition, and this will take YEARS to correct. Here are the specific issues that ALL should be VERY concerned about: There will be a 12 month inclusion of old (regional (RRB)) data included in the new NLRB...this lagging data will (falsely) elevate the scores in high exception areas compared to the rest of the country for the same conditions. We are moving to 500 nautical mile radius (1150 ground mile diameter) circles for sharing, yet using 250 NM circles for determining MMAT. This does not make sense...the circles for MMAT should be the same as the circles for sharing. It is not fair that Pittsburgh will have patients who will be significantly disadvantaged

compared to NY for the same disease condition, in the same sharing area. It is not fair that Hartford and New Haven will be significantly disadvantaged compared to Boston for the same disease condition, in the same sharing area. The system we will switch to will vastly over prioritize areas that have had inflated MELD scores. The Liver Intestine Committee requested SRTR to model the effects of the new NLRB proposal, but were told that SRTR had too many competing interests to conduct this assessment. Why would we be concerned about this issue for the 1-month of continued DSA-based sharing, but NOT concerned about the path forward on the 500 NM circle plan? We appear to be headed to a new plan that will over-prioritize regions of the country that have been much more liberal with granting of exception scores and who have been at a very inflated exception score level. We have been working under the assumption that the NLRB would be implemented at least 3 (preferably 6) months prior to any allocation change, for the last several years, however at the last minute, UNOS has informed us that the new policies would be implemented almost simultaneously. We have been working under the assumption that "broad sharing" would only apply for laboratory MELD, not exception scores, yet at the last minute, the policy changed to include exception MELD patients. This was never the plan.....until the last minute change. For all of the above reasons, confidence in the UNOS process is at a low point, and faith in our current system is heavily compromised. As an aside, only four liver programs would be affected for the upcoming 1-month period of NLRB use under the current DSA plan (basis of current comment period), amongst the approximately 150 liver programs in the US.