

## Public Comment Proposal

# MELD Exception Scores during NLRB Transition

*OPTN/UNOS Executive Committee*

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

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# MELD Exception Scores during NLRB Transition

*Affected Policies:* 9.4.D Calculation of Median MELD or PELD at Transplant  
*Sponsoring Committee:* Executive Committee  
*Public Comment Date:* January 31-March 22, 2019

## Executive Summary

Liver allocation currently uses donor service areas (DSAs) and OPTN regions as units of distribution. That will change when recently approved allocation changes are implemented (targeted for April 30, 2019). The National Liver Review Board (NLRB) was to be implemented on January 31, 2019, but that plan was delayed because unintended consequences were identified in the plan to base the model for end stage liver disease (MELD) exception scores on median MELD at transplant within 250 NM of the transplant hospital (MMaT/250). Because the MMaT/250 for transplant programs within the same DSA can vary, similarly situated candidates at different hospitals within a DSA can have different scores, and would consistently appear lower or higher than one another on every match run while allocation is still based on DSA and region. The OPTN is now soliciting comments on a policy change that would apply only with respect to the calculation of exception scores to address this issue. This transition policy would be in effect for a brief period after the public comment period (scheduled to end March 22, 2019) and before implementation of the revised allocation policy (targeted for April 30, 2019).

In an attempt to address this situation, the OPTN Executive Committee approved the OPTN Liver Committee's proposed temporary solution: using the median MELD at transplant in the DSA (MMaT/DSA) instead of MMaT/250 during the period between implementation of the NLRB and implementation of liver allocation changes (hereafter, "transition period"). This transition period will be interim, and will expire upon the implementation of liver allocation changes (targeted for April 30, 2019). The goal of this approach is to better align the calculation of exception scores with the current allocation system during the transition period.

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

The Committee requests feedback on the proposed temporary solution of using the MMaT/DSA instead of MMaT/250 during the transition period. In addition to feedback on the proposed solution, the Committee welcomes comment on the other options considered by the committee as well as whether to convert exception scores that were granted by Regional Review Boards (RRB) but will expire after the implementation of the new allocation system (see pages 5-6). The Executive Committee may reconsider these alternate solutions for this proposal.

## What problem will this proposal address?

Upon the implementation of NLRB, MMaT will be used to calculate exception scores for candidates. As part of the Board-adopted proposal in December of 2018, MMaT is set to be calculated based on a 250 nautical mile radius from the transplant candidate's hospital. This calculation was tied to a unit of allocation in the new allocation system – 250 nautical miles from the donor hospital. However, preliminary data recently reviewed by the Liver Committee showed assigning exception scores relative to MMaT/250 while DSAs are still in use for allocation results in certain similarly situated candidates at different hospitals within a DSA receiving different exception scores, and consistently appearing lower or higher than one another on every match run. Though this is a temporary problem, only existing during the transition period, the Executive Committee seeks the feedback of the community on whether to address this problem for the short transition period, and if so, how.

## Why should you support this proposal?

This proposal will reduce the disparate impact on some exception candidates in the same DSA during the transition period.

## How was this proposal developed?

### *Development of underlying proposal*

In 2017, two proposals from the OPTN/UNOS Liver and Intestinal Organ Transplantation Committee (Liver Committee) were approved by the Board. The first proposal, originally approved in June 2017, created the NLRB and changed exception scoring to be based on MMaT/DSA.<sup>1</sup> The second was approved in December 2017 and changed allocation of livers to allocation by DSA and region, with some consideration for distance between donor hospital and transplant hospital.<sup>2</sup>

Before either of those proposals was implemented, the Board directed the Liver Committee to propose revisions to policy that included providing OPTN Final Rule compliant replacements for the use of Region and DSA in liver allocation and the use of DSA in the median MELD or pediatric end-stage liver disease (PELD) at transplant scoring for exception patients.<sup>3</sup>

After reviewing the OPTN's determination that the "disparate sizes, shapes, and populations of DSAs as drawn today are not rationally determined in a manner that can be consistently applied equally for all candidates,"<sup>4</sup> the Health Resources and Services Administration (HRSA) Administrator (Administrator) sent a letter to the OPTN on July 31, 2018, stating that "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."<sup>5</sup> The letter contained a deadline for the Board to adopt a new liver allocation policy by its December 2018 meeting. Additionally, the Administrator explained that "[t]he OPTN may also implement transition patient protections. See 42 CFR § 121.8(d)(1) (providing that when the OPTN revises organ allocation policies, it shall consider whether to adopt transition procedures that would treat people on the waiting list and await transplantation prior to the adoption or effective date of the revised policies no less favorably than they would have been treated under the previous policies)."<sup>6</sup>

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<sup>1</sup> *Proposal to Establish a National Liver Review Board*, OPTN/UNOS Liver and Intestinal Transplantation Committee, June 2017, [https://optn.transplant.hrsa.gov/media/2176/liver\\_boardreport\\_nlrp\\_201706.pdf](https://optn.transplant.hrsa.gov/media/2176/liver_boardreport_nlrp_201706.pdf) (accessed January 20, 2019).

<sup>2</sup> *Enhancing Liver Distribution*, OPTN/UNOS Liver and Intestinal Transplantation Committee, December 2017, [https://optn.transplant.hrsa.gov/media/2329/liver\\_boardreport\\_201712.pdf](https://optn.transplant.hrsa.gov/media/2329/liver_boardreport_201712.pdf) (accessed January 20, 2019).

<sup>3</sup> Yolanda Becker, OPTN President, letter to the OPTN Liver and Intestinal Organ Transplant Committee, June 25, 2018.

<sup>4</sup> Yolanda Becker, OPTN President, letter to Administrator Sigounas, June 25, 2018.

<sup>5</sup> George Sigounas, letter to Sue Dunn, OPTN President, July 31, 2018.

<sup>6</sup> *Ibid.*

The Liver Committee proposed using distances of 150NM, 250NM, and 500NM between donor hospital and transplant hospital instead of DSA and region for liver allocation. It also proposed using MMat/250 from the transplant candidates' hospital as the basis for exception scores. 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 many exception candidates to transition to the new scoring methodology for exception candidates according to the renewal schedules in policy. At the December 2018 Board meeting, the Board approved both of these changes, as well as the time between implementation.<sup>7</sup> 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 the Board's December 2018 meeting, in preparation for implementation of scoring changes, the Liver Committee reviewed a report of MMat/250 for each liver transplant program.<sup>8</sup> Within this cohort, the report showed four DSAs where the liver transplant programs within the same DSA do not have the same MMat/250 (**Table 1**).<sup>9</sup> In one DSA, there is a single transplant program that has a MMat/250 one point below all of the others in the DSA. In another, there is a single transplant program that has a MMat/250 two points above all of the others in the DSA. In one DSA, there are two transplant programs two points higher than the other two transplant programs. In the final DSA, there are four transplant programs with the same MMat/250, one that is a point higher, and another that is a point lower.

**Table 1: DSAs in which MMat within 250NM of Liver Transplant Programs differs by Transplant Program<sup>10</sup>**

DSA Code	Transplant Hospital Code	MMaT
<b>MAOB</b>	CTYN	30
	MABI	31
	MACH	31
	MALC	31
	MAMG	31
	MAUM	32
<b>LAOP</b>	LACH	27
	LAOF	27
	LATU	27
	LAWK	29
<b>TXSB</b>	TXJS	30
	TXCM	31
	TXMC	31
	TXSP	31
	TXTX	31
<b>MNOP</b>	MNMC	30
	MNSM	30
	MNUM	32
	SDMK	32

If MMat/250 is implemented during the transition period, exception candidates that extend an exception or apply for a new exception at some of the affected transplant hospitals within these four DSAs will

<sup>7</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>8</sup> OPTN/UNOS Liver Committee meeting January 17, 2019.

<sup>9</sup> Ibid.

<sup>10</sup> OPTN/UNOS Descriptive Data Request. "NLRB: Median Transplant Scores to be Implemented." Prepared for Liver and Intestinal Transplantation Committee Conference Call, January 17, 2018.

consistently appear in lower classifications on the match run than those candidates at another transplant hospital in DSA-level allocation sequences.<sup>11</sup>

The Liver Committee proposed an adjustment to the implementation plan to align scoring during the transition period. The Liver Committee's proposal was to use the MMaT/DSA during the transition period. The Executive Committee considered the Liver Committee's proposal on January 25, 2019. At that time, the Executive Committee was of the opinion that it could be enacted without soliciting public comment prior to implementation. Therefore, the Executive Committee approved this proposal for implementation<sup>12</sup>. On January 30, 2019, the Administrator informed the OPTN by letter that "HRSA views the transition policy approved January 25, 2019, as a policy change that should be subject to additional public comment before it is implemented."<sup>13</sup>

In light of the letter from the Administrator, the OPTN reconsidered the options available to solve the problem of exception scores that were not aligned with allocation during the transition period. On January 30, 2019, the Executive Committee repealed the January 25, 2019 approval in order to solicit public comment on the proposal prior to a final determination.<sup>14</sup> In light of the new information about the need for public comment<sup>15</sup>, the OPTN proposes that exception scores be assigned relative to MMaT/DSA during the transition period, and that the transition period be shortened to approximately a month to permit time for public comment, which is outlined further below, under *What is the Committee Proposing?*. The options the OPTN considered are discussed below.

### ***Other options considered***

The OPTN considered several different options to resolve this issue. The Executive Committee welcomes comment on these options and may reconsider these options following public comment.

#### **1) Leave MMaT/250 during the transition period. (2018 Board approved)**

This option would implement the entire NLRB system immediately, including assigning exception scores based on MMaT/250. It would have the advantage of being easy to explain and would not require any policy change. It also would result in more similar scores among transplant hospitals in a single region compared to MMaT/DSA. This option was already approved by the Board, has already been out for public comment, and has been communicated to members.

#### **2) National MMaT during the transition period.**

The OPTN considered using the national MMaT during the transition period, since it would be unaffected by the distribution unit. However, the purpose of using a localized MMaT was to factor in the differences in the ability to access transplant across the country. A score based on a national

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<sup>11</sup> Beginning on the day the new exception scoring takes effect, candidates will be assigned exception scores based on MMaT when they apply for a new exception or extend existing exceptions. Since exception scores are valid for a period of up to 3 months, candidates who already have existing exception scores on the day NLRB takes effect will not all change to MMaT-based exception scores at the same time. Some will request a new exception or extend an existing exception in the first week, while others may not need to do so until months later. During this transition period, there will be some candidates with exception scores based on the current exception scoring and others based on MMaT. Early in the transition period, there will be more candidates with scores assigned under the current system, and at the end of the transition period, most exception candidates will have scores based on MMaT. During this time, even with this change, there will be similarly situated candidates who have different exception scores, potentially at the same transplant hospital. This particular difference in scores is unavoidable during the transition, and is part of the reason the Liver Committee previously requested that the scoring changes take effect at least three months before the implementation of allocation changes. This proposal does not change the fact that there will be some candidates with old scores and some candidates with new scores during the transition period.

<sup>12</sup> OPTN/UNOS Executive Committee meeting, January 25, 2019.

<sup>13</sup> George Sigounas, letter to Sue Dunn, January 30, 2019.

<sup>14</sup> OPTN/UNOS Executive Committee meeting, January 30, 2019.

<sup>15</sup> 42 CFR 121.4(b)(1) provides that the OPTN must "[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.

MMA<sub>T</sub> would not grant the same chance of transplant to candidates in areas where the local MMA<sub>T</sub> is high that it would in areas with a lower local MMA<sub>T</sub>.

**3) Manually adjust MMA<sub>T</sub> for the affected transplant hospitals.**

The OPTN considered using a different score in place of MMA<sub>T</sub>/250 only for candidates at the 10 affected transplant hospitals in the four affected DSAs. This could either involve assigning all of the candidates in a DSA the highest MMA<sub>T</sub>/250 within the DSA or the lowest MMA<sub>T</sub>/250 in the DSA. This would solve the problem of assigning different exception scores to similar candidates during the transition period, but would create a fractured system that could be difficult to explain to members and candidates.

**4) Delay implementation of NLRB so that there is no transition period.**

The OPTN considered implementing NLRB and allocation changes simultaneously. This option would address the specific problem of allocation using DSA while scores are based on a different geographic area.

If the transition period was eliminated, candidates would transition from their current scores to MMA<sub>T</sub>-based scores under the new allocation sequence; 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 RRBs, both designed to address geographic variability in access to transplant and clinical practice. The use of MMA<sub>T</sub>/250 by the NLRB and associated exception scoring system 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 disadvantage to certain patients. The OPTN wanted to avoid this result, so it considered options for converting exception scores if there was a simultaneous implementation of NLRB and allocation changes.

While most of the existing exception scores could be relatively easily converted by assigning the standard score listed in policy for the candidate's diagnosis, approximately 1/3 of the exception scores are not so easily converted. This other group is comprised of candidates with exception scores that cannot be readily tied to a standard score. For these, the OPTN considered not converting these scores, expiring the exception scores early, or creating a method of converting based on the regional median transplant scores. The OPTN would like public comment on whether non-standard RRB-generated exception scores should be converted, and by what method.

## What is the Committee proposing?

### MMA<sub>T</sub>/DSA during the transition period

The Executive Committee supports assigning exception scores relative to MMA<sub>T</sub>/DSA during the transition period.<sup>16</sup> This would provide 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 MMA<sub>T</sub> under the NLRB system would phase in. Once approximately a third of the scores have transitioned, after approximately one month, the allocation changes would take effect. Then, the OPTN computer system would automatically replace MMA<sub>T</sub>/DSA with MMA<sub>T</sub>/250 and keep each exception candidate's score that was assigned during the transition the same relative to MMA<sub>T</sub>. For instance, if a candidate received a score under NLRB transition scoring of MMA<sub>T</sub>/DSA minus 3, it would be automatically converted to MMA<sub>T</sub>/250 minus 3 on the day allocation changes take effect. This would ensure aligned scores for this portion of the exception candidates from the first day of the new allocation system.

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<sup>16</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.

The Executive Committee supports this transition plan because the MMat based exception scoring would align with the unit of allocation during the transition period. When it was proposed in the DSA and region system in 2017, it was proposed as MMat/DSA, and then when it was amended in 2018 for the nautical mile circle based allocation system, the NLRB scoring was changed to MMat/250. Reverting to MMat/DSA for the transition period (in which the NLRB exists in and DSAs and regionals are used as units of distribution in the allocation system) would maintain this alignment because both exception scores and allocation would use DSA during the short transition period. Although the transition period will no longer be long enough to allow rollover of most of the existing exception scores, a transition period of approximately one month still allows for transition of approximately a third of the existing exception candidates prior to the new allocation system being implemented and allows for some time in between implementation of NLRB and allocation so that there is time to allow the community to adjust to the revised processes related to submission and review of exception forms.

In order for similarly situated liver transplant candidates within the same DSA to receive similar offers during the transition period, the OPTN proposes using MMat/DSA on initial implementation of the scoring changes, and MMat/250 only when the allocation changes are also implemented.

## Which populations are impacted by this proposal?

There were a total of 1221 candidates on the liver waiting list on January 25, 2019 with a MELD exception, 181 (15%) of which are in the four affected DSAs.<sup>17</sup> Of those candidates, approximately 1/3 would be expected to be due for an extension of their exception score during the transition period.<sup>18</sup> This subset of these candidates requiring extensions during this transition period and any candidates that might apply for a MELD exception in these DSAs will experience more equal access to transplant during the transition period. This is the population directly targeted by this proposal.

Because MMat/DSA would be used for all exception scores awarded during the transition period, candidates at transplant hospitals outside of the four affected DSAs who are awarded exception scores during the transition period may also be impacted because they may experience an additional change in their exception score. Of the 145 active liver transplant programs in the country with MELD score candidates:

- 62 (43%) have the same MMat, whether calculated as MMat/DSA or MMat/250.
- 83 (57%) will have a different MMat/250 than MMat/DSA.

This means that, if this proposal is approved, individual candidates' exception scores assigned during the transition period are likely to change when the transition period ends. Because the MMat/DSA scores will only be used during the transition period, some of these candidates will see their scores change when allocation changes are implemented and their scores are converted from MMat/DSA to MMat/250.

Most of the liver transplants (approximately 63%) under current allocation take place within the DSA. Another approximately 31% of transplanted organs are accepted and transplanted within the region.<sup>19</sup> In some regions, there may be more variation in scores between DSAs during the transition period if this proposal is adopted. Changing to MMat/DSA scores in the same region for the transition period could impact a portion of the 31% of organs allocated within the region, but outside of the DSA during the transition period.

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<sup>17</sup> There were 14 MELD exception candidates in LAOP, 69 in MAOB, 63 in MNOP, and 35 in TXSB currently waiting on January 25, 2019. This count represents an approximate number of exception candidates on the liver waitlist on a given day. OPTN data.

<sup>18</sup> Exception scores must be renewed every 3 months. If the transition period is approximately one month, it can be assumed that approximately 1/3 of the existing exception scores will come due for renewal in that time.

<sup>19</sup> In 2016, 63% of liver transplants were from donors in the DSA, 30.6% were from within the region, and 6.4% were from within the nation. In 2017, 62.5% were from donors in the DSA, 32.3% were from within the region, and 5.4% were from within the nation. In 2018, 63.2% were from donors in the DSA, 31% were from within the region, and 5.7% were from within the nation. OPTN data.

Because candidates under the age of 12 will be awarded exception pediatric model for end-stage liver disease (PELD) scores based on the national median PELD at transplant (MPaT), they will not be directly impacted by this proposal. There is a slight change to the calculation of MPaT proposed, to exclude organs recovered outside of the region instead of outside 500NM during the transition period to align with the allocation units and the intent of excluding nationally allocated livers.

## 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 for some liver candidates by ensuring that candidates with MELD exceptions granted at the same time for the same diagnosis in the same DSA will have the same access to livers allocated at the DSA level during the transition period. This proposal may also reduce equity in access to transplant among similarly situated candidates in different DSAs within a region during the transition period.
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>20</sup>

1. *Sound Medical Judgment:* The Committee proposes the transition period 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 in the same DSA by assigning them an equal MELD exception score during the transition period, while livers are still allocated based on DSA.
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.  
*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

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<sup>20</sup> 21 C.F.R. §121.8(a).

during the transition period. This achieves more equity in access to transplant for these liver candidates during this transition period.

*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 DSA 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. This proposal seeks to reduce the geographic considerations in the placement of livers during the interim transition period that is expected to end on April 30, 2019 with the implementation of allocation changes. Using MMaT/DSA will tie exception scores to the first allocation unit while the first unit of allocation is still DSA. Although geography will be considered, it is required in order to promote access to transplant for similarly situated exception candidates, because it will treat candidates at all of the hospitals in the DSA the same, instead of treating candidates differently based on individual listing program. Doing so therefore also adheres strictly to the Final Rule, which specifically cites the candidate's "place of listing" as a geographic constraint to avoid. Using MMaT/DSA as a temporary geographic limitation is also required to ensure the best use of the organ, offering organs to the sickest candidates first. Additionally, the temporary use of MMaT/DSA during the approximately one month transition period conforms to the requirement to use geography "only to the extent required," and shall expire upon the implementation of allocation changes.

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>21,22</sup> The OPTN is proposing a transition, aimed at equalizing the impact of the transition on candidates within the same DSA. Currently, liver candidates are awarded exception scores based on their disease severity and regional agreements. Therefore, similar candidates with exception scores in the same DSA or the same region can expect to be awarded similar exception scores. This proposal would create a transition provision that would ensure that similar candidates in the same DSA are awarded similar exception scores.

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>23</sup> The letter from the Administrator provided clarification that this is a "policy change that should be subject to additional public comment before it is implemented."<sup>24</sup> Given that this change to exception scoring for the transition period requires a change to policy, the OPTN proposes this solution for consideration during public comment.

## How will the OPTN implement this proposal?

This proposal will require calculation of the MMaT for each DSA during the transition period, in addition to the recalculation of MMaT/250 to convert existing MMaT based exception scores upon implementation and programming of the new allocation policy (including distribution based on nautical mile distances) in UNet<sup>SM</sup>. It will require rapid communication to members to explain the change to the policy and the impact

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

<sup>22</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>23</sup> 42 C.F.R. 121.4(b)(1).

<sup>24</sup> George Sigounas, letter to Sue Dunn, January 30, 2019.

on patients whose scores may be different. The expected timeline for implementation of the National Liver Review Board has been adjusted to allow for public comment on this proposal. 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?**

If this proposal is approved, transplant hospitals may need to review their MMat/DSA and MMat/250 and evaluate whether they need to educate their patients about any changes in score they may experience. Some exception candidates will experience two score changes within an approximately one month period. Candidates who apply for a new exception or an extension of an exception score after implementation of NLRB and prior to the implementation of allocation changes will be awarded a new MMat/DSA score during the transition period, and then that score will be converted to a MMat/250 based score on the day that allocation changes are implemented (targeted April 30, 2019).

## **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.

## Policy or Bylaws Language

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

### 9.4 MELD or PELD Score Exceptions

#### 9.4.D Calculation of Median MELD or PELD at Transplant

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

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

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

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

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

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

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

*Effective pending notice to OPTN members and implementation of the National Liver Review Board, and shall expire upon the implementation of the Liver and Intestine Distribution Using Distance from Donor Hospital proposal, adopted by OPTN/UNOS Board of Directors December 3, 2018 and subsequent notice to OPTN members.*

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