

*Public Comment Proposal*

**Calculate Median MELD at Transplant  
around Donor Hospital and Update  
Sorting within Liver Allocation**

*OPTN Liver and Intestinal Organ Transplantation Committee*

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# Calculate Median MELD at Transplant around Donor Hospital and Update Sorting within Liver Allocation

## *Affected Policies:*

*Policy 1.2: Definitions*

*Policy 9.4.A: MELD or PELD Score Exception Requests*

*Policy 9.4.C.ii: Other MELD or PELD Score Exception Extensions*

*Policy 9.4.D: Calculation of Median MELD or PELD at Transplant*

*Policy 9.4.E: MELD or PELD Exception Scores Relative to Median MELD or PELD at Transplant*

*Policy 9.5: Specific Standardized MELD or PELD Score Exceptions*

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

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

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

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

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

*Policy 9.5.I.vii Extension of HCC Exceptions*

*Policy 9.6.A: Waiting Time for Liver Candidates*

*Policy 9.8: Liver Allocation, Classifications and Rankings*

*Policy 9.8.D: Sorting Within Each Classification*

## *Affected Guidelines:*

*National Liver Review Board Operational Guidelines*

## *Sponsoring Committee:*

*Liver and Intestinal Organ Transplantation*

## *Public Comment Period:*

*January 21, 2021 – March 23, 2021*

## Executive Summary

On February 4, 2020, the use of donation service areas (DSAs) and OPTN Regions was removed from liver allocation with the implementation of the Acuity Circles (AC) allocation policy, which is a series of

concentric circles around the donor hospital.<sup>1</sup> When the AC policy was implemented, the geographic basis for the calculation of the median model for end-stage liver disease (MELD) at transplant (MMaT) was changed. The MMaT is used to assign MELD exception scores for liver transplant candidates whose medical urgency for transplant is not appropriately represented by their calculated MELD score. Under the AC policy, the MMaT score for each transplant program is based on a subset of transplants performed within 250 nautical miles (NM) of the transplant program. This calculation provides higher exception scores to candidates listed at transplant programs with a higher MMaT, where a higher MELD score is needed to access transplant. However, it also means that two exception candidates with the same exception diagnosis listed at different transplant programs, may receive different MELD exception scores. When two transplant programs with different MMaT scores are in close geographic proximity, MELD exception candidates listed at the two programs will be included on many of the same match runs with different MELD exception scores, despite having the same exception diagnosis and urgency for transplantation.

This proposal intends to increase equity by utilizing an MMaT calculated around each donor hospital instead of the transplant program to assign exception scores. Under this proposal, every donor hospital would have a calculated MMaT and all exception candidates on a match run based at a specific donor hospital would have an exception score relative to the MMaT for that donor hospital.

This update to the MMaT calculation necessitates a change to the order in which candidates are sorted within liver allocation classifications. Currently, within an allocation classification, liver candidates are sorted by MELD or pediatric end-stage liver disease (PELD) score, blood type compatibility, and then waiting time at score or higher. Under the proposed MMaT calculation, exception scores will fluctuate based on the location of the donor, so exception candidates are no longer able to be sorted based on time at score or higher. This proposal changes how liver candidates are sorted so that after MELD or PELD score and blood type compatibility, candidates with a calculated MELD or PELD will be ranked ahead of exception candidates. Subsequently, candidates with a calculated MELD or PELD score will be ranked by time at score or higher while exception candidates will be ranked by time since submission of earliest approved exception.

This proposal intends to improve equity in access to individual donor offers for exception candidates and better align the geographic units used in the calculation of MMaT with the geographic units used in liver allocation.

The OPTN Liver and Intestinal Organ Transplantation Committee is seeking public comment feedback on the proposed changes described above.

The Committee submits the following proposal for public comment under the authority of the OPTN Final Rule, which states “The OPTN Board of Directors shall be responsible for developing...policies for the equitable allocation for cadaveric organs.”<sup>2</sup>

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<sup>1</sup> *Liver and Intestine Distribution Using Distance from Donor Hospital*, OPTN Liver and Intestinal Organ Transplantation Committee, December 2018, Available at <https://optn.transplant.hrsa.gov/>

<sup>2</sup> 42 CFR §121.4(a)

## Background

When being listed for a liver transplant, candidates receive a calculated MELD or PELD score, which is based on a combination of the candidate's clinical lab values.<sup>3</sup> These scores are designed to reflect the probability of death on the waitlist within a 3-month period, with higher scores indicating a higher probability of mortality and increased urgency for transplant. Candidates who are less than 12 years old receive a PELD score, while candidates who are at least 12 years old receive a MELD score. Candidates that are particularly urgent are assigned status 1A or 1B priority. When a transplant program believes that a candidate's calculated MELD or PELD score does not accurately reflect the candidate's medical urgency, they may request a score exception.

Under the National Liver Review Board (NLRB), which was implemented on May 14, 2019, most liver candidates with a MELD score exception are assigned a score relative to the MMaT for the area around the transplant program where they are listed.<sup>4,5</sup> Liver candidates with a PELD score exception are assigned a score relative to the median PELD at transplant (MPaT) for the nation. Prior to the NLRB, exception scores were not assigned relative to MMaT or MPaT. Instead, MELD or PELD exception candidates received a set score that increased with longer waiting time. The use of MMaT was designed to assign exception scores that appropriately rank exception candidates relative to other exception candidates and candidates with a calculated MELD score in the area where they are listed.

Before the AC policy, MMaT scores were calculated based on the DSA of the transplant program. All transplant programs within a DSA had the same MMaT. However, when the AC policy was implemented, which removed the use of DSAs and OPTN Regions from liver allocation policy, the geographic basis for the MMaT calculation was changed from the DSA to 250 NM around each candidate's transplant program.

When developing the AC policy, the Committee considered a number of options for replacing the use of DSA in the MMaT calculation, including a national MMaT and circles sizes of 150 NM, 250 NM, and 500 NM around each transplant program. The Committee ultimately decided that using a 250 NM circle around the transplant program was most appropriate because it would include a larger and more stable cohort than 150 NM, but was more reflective of MELD scores in the area around a transplant program than 500 NM. The Committee did not support a national MMaT because it fails to account for variation in MMaT across the nation.<sup>6</sup>

The Committee acknowledged that basing the MMaT calculation on the area around the transplant program, while basing allocation on the location of the donor hospital, would cause exception candidates on the same match run to have different exception scores.<sup>7</sup> However, the Committee felt that calculating MMaT based on the area around the transplant program would best approximate the pool of candidates with whom a candidate would compete for donor offers and the variation between

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<sup>3</sup> The calculation for the MELD and PELD scores can be found in OPTN Policy, Available at <https://optn.transplant.hrsa.gov/>.

<sup>4</sup> *Proposal to Establish a National Liver Review Board*, OPTN Liver and Intestinal Organ Transplantation Committee, June 2017, Available at <https://optn.transplant.hrsa.gov/>

<sup>5</sup> Candidates with a MELD exception score of 40 and HCC candidates on their six month delay are not assigned an exception score relative to the MMaT.

<sup>6</sup> *Liver and Intestine Distribution Using Distance from Donor Hospital*, OPTN Liver and Intestinal Organ Transplantation Committee, December 2018, Available at <https://optn.transplant.hrsa.gov/>

<sup>7</sup> Ibid.

transplant programs would even out over time.<sup>8</sup> Nonetheless, transplant programs in close geographic proximity have similar access to the same donor hospitals and if one transplant program has a higher MMaT, exception candidates at that program will be ranked higher than exception candidates at the nearby transplant program on many match runs.

For example, under the current system, transplant programs in Chicago, IL have an MMaT of 27. The transplant programs in Milwaukee, WI, which is 70 NM from Chicago, IL, have an MMaT of 28.<sup>9</sup> The higher MMaT in Milwaukee reflects the fact that a higher MELD score is typically needed to access transplantation in that area. However, for matches run at donor hospitals in close proximity to both Milwaukee and Chicago, the exception candidates listed in Chicago will be ranked lower than the exception candidates listed in Milwaukee, despite having the same exception diagnosis. Because most exception candidates are provided a score of MMaT-3, they typically appear on match runs together, essentially creating a block of exception candidates at a certain MELD or PELD score. This situation exists wherever there are two transplant programs with different MMaT scores in close geographic proximity.

Despite the fact that transplant programs in close geographic proximity can have different MMaT scores, causing exception candidates to appear on many of the same match runs with different exception scores, every transplant program has access to different donor hospitals. For example, organ offers for matches run at a donor hospital in Indianapolis will typically be offered to candidates listed at transplant programs in Chicago, which is within 150 NM of Indianapolis, before being offered to candidates listed at transplant programs in Milwaukee, which is more than 150 NM from Indianapolis. Therefore, it is important to note that while candidates at the programs in Milwaukee and Chicago appear within the same allocation classification for many donor hospitals due to their close proximity, there are donor hospitals where candidates in Chicago appear higher on the match run.

To address the fact that exception candidates at transplant programs within close geographic proximity can have different assigned exception scores, the Committee is proposing a change to the MMaT calculation to instead be based on the area around the donor hospital and all exception candidates would be assigned an exception score relative to the MMaT of the donor hospital where the match is run. The Committee is proposing this change based on member feedback after implementation of the AC policy that highlighted the situation described above and advocated for the concept of calculating the MMaT based on the donor hospital. The Committee reviewed and considered this feedback in the development of this proposal.

Under the proposed MMaT calculation, candidates' exception scores will not be known prior to the match being executed because the scores will be based on the MMaT of the donor hospital where the match is being run. Therefore, candidates with a MELD exception will not be able to be sorted based on time at current score or higher score and the proposal also includes changes to how candidates are sorted within allocation classifications.

## Purpose

The purpose of this proposal is to increase equity in access to individual donor offers for MELD exception candidates listed at different transplant programs and better align the geographic units used in the calculation of MMaT with the geographic units used in liver allocation.

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<sup>8</sup> Ibid.

<sup>9</sup> These MMaT scores are current as of the drafting of this document on December 10, 2020.

The Committee puts forth this proposal to address the situation described above based on initial experience with the NLRB and AC policy. The Committee reviewed and discussed post-AC implementation data and noted that the data represented just a small time period and was impacted by the COVID-19 pandemic. Despite a lack of quantitative analysis showing a disparity, the Committee determined that the situation described above warrants a change and the proposal increases equity in access to specific donor offers.<sup>10</sup>

The Committee submits the following proposal for public comment under the authority of the OPTN Final Rule, which states “The OPTN Board of Directors shall be responsible for developing...policies for the equitable allocation for cadaveric organs.”<sup>11</sup>

## Overview of Proposal

The proposal alters a number of components of liver allocation. The subsequent sections provide further detail on the proposed changes.

### Median MELD at Transplant around the Donor Hospital

The Committee is proposing to change the MMaT calculation to be based around the donor hospital as opposed to the transplant program. While this is a significant change in the MMaT calculation, many of the underlying principles in the MMaT calculation are remaining the same.

The MMaT for each transplant program 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 NM of the candidate's listing hospital in a 365 day period, excluding recipients who were transplanted with livers from living donors, donation after circulatory death (DCD) livers, or livers from donors at donor hospitals more than 500 NM away from the transplant hospital. Candidates who were status 1A or 1B at the time of transplant are excluded from the calculation as well. The 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 MPaT calculation also excludes recipients who were transplanted with livers from living donors, donation after circulatory death (DCD) livers, livers from donors at donor hospitals more than 500 NM away from the transplant hospital and candidates who were status 1A or 1B at the time of transplant. The MMaT and MPaT are both updated twice a year.

The Committee discussed the following decision points in developing the proposal.

#### *Initial Circle Size*

The first question the Committee considered in developing MMaT around the donor hospital was what initial circle size should be used in the calculation. They considered 150 NM, 250 NM, and 500 NM

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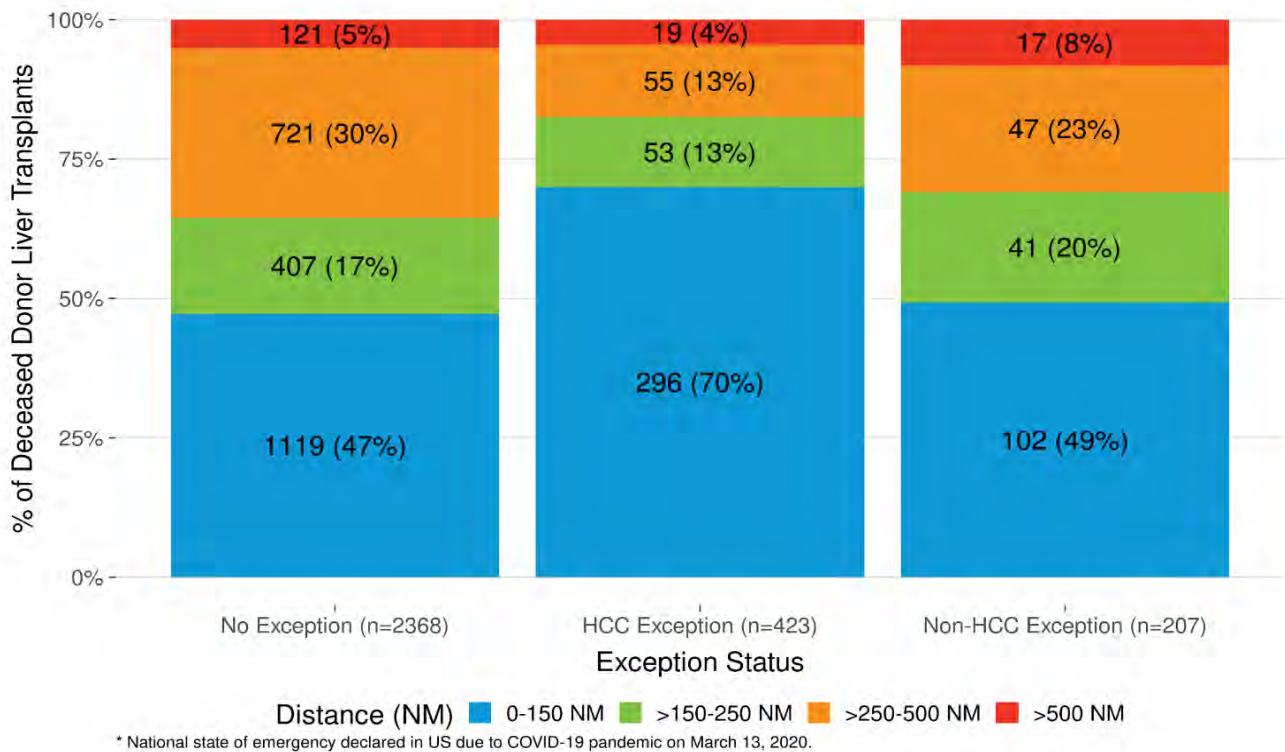
<sup>10</sup> See OPTN Liver and Intestinal Organ Transplantation Committee meeting summary, October 22, 2020. Available at <https://optn.transplant.hrsa.gov/>

<sup>11</sup> 42 CFR §121.4(a)

options and ultimately determined that utilizing a 150 NM circle around the donor hospital best reflects the MELD score needed to access transplant in the area around the donor hospital.<sup>12</sup>

**Figure 1** shows that, since the implementation of the AC policy, the majority of exception candidates have been transplanted with organs from donors within 150 NM of the donor hospital. For candidates with an HCC exception, the proportion of transplants that were performed within 150 NM of the donor hospital is even higher (70%), while for non-HCC exceptions, it is 49%. Based on this information, the Committee agreed that it was most important to accurately calculate the MMaT for the 150 NM area around the donor hospital in order to reflect proximate access to transplant and appropriately rank exception candidates and candidates with a calculated MELD score within the 150 NM circle.

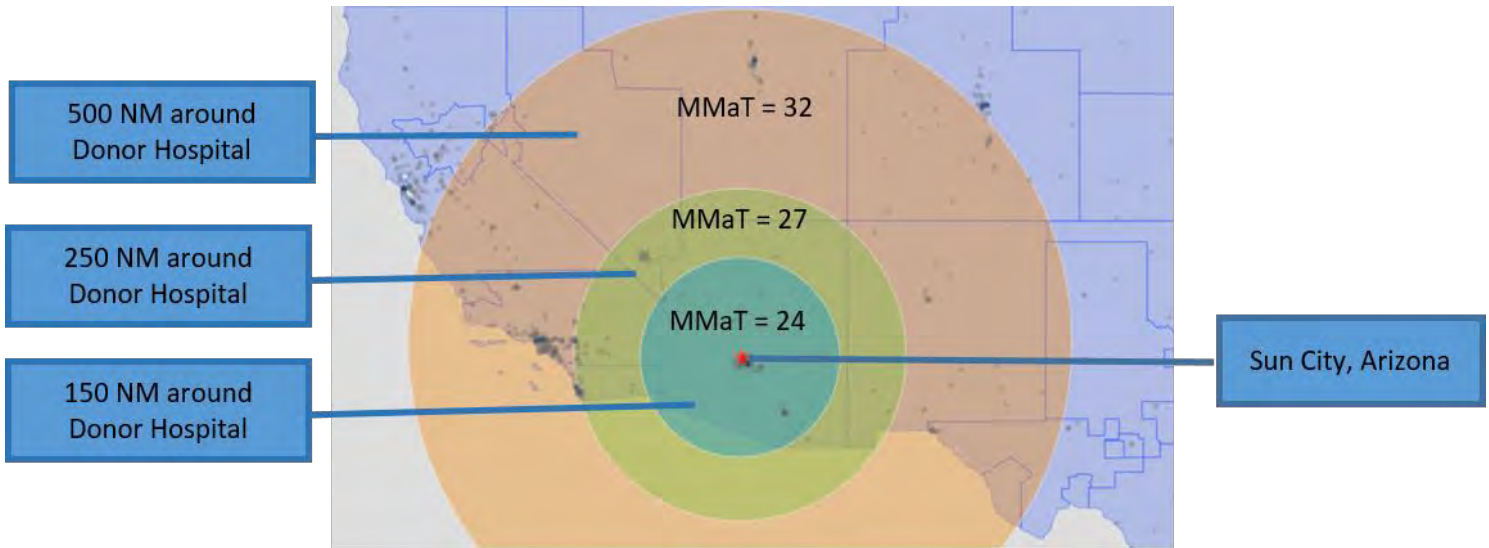
**Figure 1: Deceased Donor, Liver-Alone Transplants by Exception Status and Distance from Donor Hospital to Transplant Program, during 2/4/2020-8/4/2020**



To highlight the Committee’s decision, **Figure 2** below depicts an example of the proposed approach for a donor based in Sun City, Arizona.

<sup>12</sup> See OPTN Liver and Intestinal Organ Transplantation Committee meeting summary, October 22, 2020. Available at <https://optn.transplant.hrsa.gov/>

Figure 2: Donor Example in Sun City, Arizona



In this sample scenario, the MMaT within 150 NM around the donor hospital is 24, within 250 NM, it is 27, and within 500 NM, it is 32. For reference, the current MMaT for the transplant programs in Phoenix, AZ is 23. The MMaT for the transplant programs in Phoenix, AZ is instructive as it shows the MELD score that a candidate typically needs in order to be transplanted in the area.

If the MMaT around the donor hospital utilized a 250 NM circle, exception candidates on a match run for a donor in Sun City, AZ would be provided exception scores relative to an MMaT of 27. The Committee felt that utilizing a 250 NM circle would inappropriately rank exception candidates relative to candidates with a calculated MELD or PELD score in the 150 NM area around the donor hospital, which is the first geographic unit of allocation used for candidates with a MELD score.<sup>13</sup> If exception candidates were provided an exception score relative to an MMaT of 27, they would be ranked relatively highly compared to the candidates with a calculated MELD registered at transplant programs in the area around the donor hospital, where the MMaT is 23. The Committee felt it was most important to align the MMaT calculation with the initial geographic unit of allocation because this is where most exception candidates are transplanted.<sup>14</sup> The Committee used the same rationale to rule out the use of a 500 NM circle.

The Committee did note that utilizing either a 250 NM circle or 500 NM would have some benefits. Primarily, a 250 NM circle would attenuate some of the differences between high MELD and low MELD areas that are in close proximity. This is also seen in the Sun City, AZ example. As noted above, using a 150 NM circle around the donor in Sun City, AZ means that all exception candidates on the match run are provided an exception score relative to 24. This works well for the transplant programs in Phoenix, AZ, but exception candidates in San Diego, CA are ranked relatively lowly compared to candidates with a calculated MELD or PELD in that area, where the MMaT is 32. If a 250 NM circle were utilized, the MMaT would be 27, which is less aligned with the MMaT in the area immediately around Sun City, AZ but more

<sup>13</sup> Candidates listed as status 1A or 1B within 500 NM of a donor hospital are offered the liver before any MELD or PELD candidates within 150 NM.

<sup>14</sup> See OPTN Liver and Intestinal Organ Transplantation Committee meeting summary, October 22, 2020. Available at <https://optn.transplant.hrsa.gov/>



aligned with the MMaT in southern California. Utilizing a 250 NM circle may attenuate some of the differences in MMaT between areas. However, it is more likely that the liver is accepted for an exception candidate within 150 NM of the donor hospital, than 250 NM.

The Committee also noted that both a 250 NM and 500 NM circle would reduce variability in MMaT scores across the nation. However, the Committee remained in agreement that it was more important to ensure MMaT reflected the MELD score needed to appropriately access transplant within 150 NM of the donor hospital, as this is the first geographic unit used in allocation for MELD candidates and post-AC data shows that the majority of exception candidates are transplanted with livers from donor hospitals within 150 NM of the transplant program.<sup>15</sup>

The Committee is seeking public comment feedback on if a 150 NM circle should be used to calculate the MMaT for donor hospitals or if a different circle size should be utilized.

### *MMaT Calculation Cohort Size*

The Committee then considered what minimum cohort size of previous transplants should be required to calculate the MMaT for each donor hospital and how to ensure that such a cohort is available for all donor hospitals. The Committee is proposing that the minimum cohort needed to calculate an MMaT should be two transplant programs and ten qualifying transplants.<sup>16</sup> If there are not at least two transplant programs and ten qualifying transplants within 150 NM of a donor hospital, the geographic area used to calculate MMaT will increase in 50 NM increments until the minimum cohort threshold is met.

In current policy, there must be at least ten transplants within 250 NM in a prior 365 day period to calculate MMaT for a transplant program. When discussing the minimum cohort size needed to calculate the MMaT for each donor hospital, the Committee agreed that there was no reason to deviate from the ten transplant minimum. This number ensures that there is a sufficiently large cohort of recent transplants to calculate MMaT. However, the Committee also determined that it is important to ensure that the MMaT for a particular donor hospital is not based on transplants performed at only one transplant program. Therefore, in addition to the ten transplant minimum, the Committee is proposing that there must also be at least two transplant programs included in the MMaT calculation for each donor hospital. This will ensure that the transplant behavior of a single transplant program does not dictate the MMaT for a donor hospital, and therefore determine the exception scores for all MELD exception candidates on that match run. The Committee intends to continue to utilize a prior 365 day cohort in the MMaT calculation.

The Committee is also proposing that if a transplant program has not performed a transplant that is included in the MMaT calculation, the program is not counted in the two program threshold. This ensures that a transplant program that has only performed pediatric transplants or living donor transplants, and therefore is not contributing to the MMaT calculation, is not included in the cohort threshold. If such a program were included, there is the possibility that the MMaT for a donor hospital would be based on transplants performed at only one transplant program.<sup>17</sup>

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<sup>15</sup> Ibid.

<sup>16</sup> Qualifying transplants is defined as those transplants included in the MMaT calculation. Additional details are provided in subsequent sections of the proposal.

<sup>17</sup> See OPTN Liver and Intestinal Organ Transplantation Committee meeting summary, October 22, 2020. Available at <https://optn.transplant.hrsa.gov/>

The Committee is seeking public comment feedback on the minimum number of transplant programs and minimum number of transplants needed to calculate MMaT, as well as the use of only transplant programs that have performed a qualifying transplant.

When discussing the minimum cohort size needed to calculate the MMaT for each donor hospital, the Committee was aware that not every donor hospital would have two transplant programs and ten transplants performed within 150 NM. Under the current MMaT calculation, if there have not been ten transplants within 250 NM of a transplant program, the cohort timeframe is extended back to be based on 730 days. This works because the MMaT calculation for a transplant program can be based on the transplants performed at that program. However, there are donor hospitals where there simply are no transplant programs within 150 NM. As such, extending the cohort back in time would serve no purpose.

To address this, the Committee is proposing that when the minimum cohort is not met within 150 NM around a donor hospital, the geographic basis for the calculation increases in 50 NM increments until the minimum cohort size is satisfied. Increasing the circle size in 50 NM increments ensures that the minimum cohort size is met, while not expanding the geographic basis for the MMaT calculation beyond what is necessary.

When initially discussing how to handle donor hospitals without two transplant programs and ten transplants within 150 NM, the Committee considered increasing the circle size to align with the geographic units used in the allocation sequences (150 NM, 250 NM, 500 NM, and national). However, the Committee noted that aligning the MMaT calculation circles with the allocation circles was not necessary and that increasing in 50 NM increments created a more appropriate approach. By increasing in smaller increments, the MMaT for the donor hospital is more likely to reflect access to transplant in the area closer to the donor hospital, which is the Committee's intent.

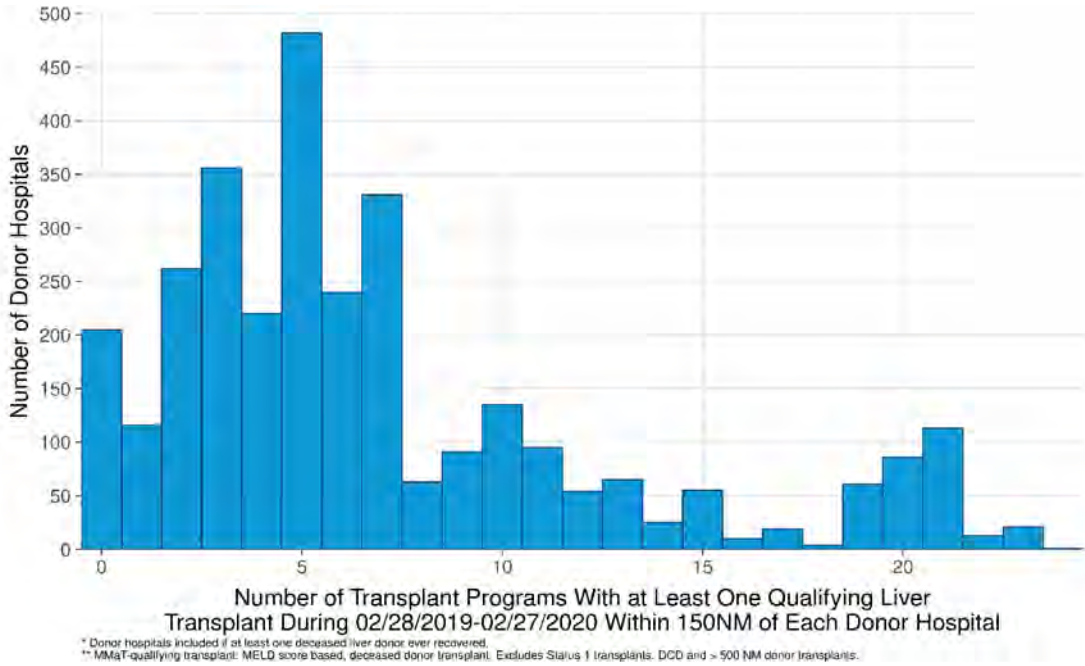
The Committee is seeking public comment feedback on the plan to increase the geographic basis used to calculate MMaT by 50 NM increments when the minimum cohort size is not met.

The Committee reviewed data on the number of liver transplant programs within 150 NM of each donor hospital with at least one MMaT-qualifying transplant. As seen in **Figure 3**, only 318 donor hospitals out of 3,213 had less than two transplant programs within 150 NM. This means that for 90% of donor hospitals, MMaT will be calculated based on a 150 NM circle, assuming that there have been at least ten transplants. The Committee considered this data when determining the minimum cohort size, as it would be impractical to choose an initial circle size that was rarely large enough to meet the minimum cohort threshold.<sup>18</sup>

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<sup>18</sup> Ibid.

**Figure 3: Number of Liver Transplant Programs within 150 NM of Each Donor Hospital with at Least One MMaT-Qualifying Transplant during 2/28/2019-2/27/2020**



### *MMaT Exclusions, Update Schedule, and Cohort Timeframe*

In the current calculation for MMaT, recipients who are transplanted with livers from living donors, DCD donors, and donors at donor hospitals more than 500 NM from the recipient’s transplant program are excluded. The calculation also does not include recipients who were listed as status 1A or 1B at the time of transplant. Living donor recipients do not typically receive transplants based their MELD score, and are often recipients of directed donation. Livers from DCD donors and from donors more than 500 NM from the recipient’s transplant program tend to be transplanted into candidates lower on the match run with lower MELD scores. These transplants are considered to be more aggressive transplants. The Committee agreed that the same exclusions should remain for the MMaT around the donor hospital, as including these transplants may disincentivize the use of these organs.

In addition, the current MMaT calculation is updated twice a year based on a cohort from a prior 365 day period. The Committee felt that the same timeframe and update schedule were appropriate, as these two aspects of the current MMaT calculation work well and there is no reason to change either aspect of policy.

The Committee is seeking public comment feedback on the MMaT calculation exclusions, update schedule and cohort timeframe.

### *Donor Hospitals in Hawaii, Puerto Rico, and Alaska*

The Committee is proposing that donor hospitals in Hawaii and Puerto Rico do not need to meet the two transplant program threshold due to their geographic isolation. The Committee discussed if donor hospitals in Alaska warranted unique consideration and determined that no additional changes were needed. While all three locations are geographically isolated from the contiguous U.S., there are liver

transplant programs located in both Hawaii and Puerto Rico. There is currently no liver transplant program located in Alaska.

In the AC policy, livers from non-DCD donors who are between ages 18 and 69 are allocated to all candidates with a MELD or PELD of 15 or higher within 500 NM of the donor hospital before being offered to more urgent candidates across the nation. In Hawaii and Puerto Rico, this means that livers from donors at donor hospitals on the two islands are offered to all candidates with a MELD or PELD down to 15 on each respective island before being offered to any candidates in the contiguous U.S. Because of this, the Committee agreed that it was appropriate to take additional measures to ensure that the MMaT for donor hospitals on the islands accurately represented the MELD score needed to access transplant on each respective island. This is complicated, however, by the two transplant program minimum cohort threshold. For donor hospitals in Hawaii, if two transplant programs were required to be included in the MMaT calculation, the calculation would include the transplant program in Hawaii and the closest transplant program in the contiguous U.S., which is in San Francisco, CA. In Puerto Rico, the MMaT calculation would include the transplant program in Puerto Rico and the closest transplant program in Miami, FL.

The inclusion of transplants performed at transplant programs in San Francisco, CA and Miami, FL would increase the MMaT at donor hospitals in Hawaii and Puerto Rico respectively such that exception candidates listed on match runs for donors in Hawaii and Puerto Rico would be inappropriately advantaged relative to candidates with a calculated MELD or PELD score.<sup>19</sup> This difference is particularly important in Hawaii and Puerto Rico because, as previously mentioned, most donors on the two islands are offered to most candidates on the respective islands before being offered more broadly.

As a result, the proposal includes a provision that does not require the donor hospitals in Puerto Rico or Hawaii to meet the two transplant program minimum threshold. The MMaT for donor hospitals in Hawaii and Puerto Rico must include at least ten transplants in a prior 365 day period. If there are not ten qualifying transplants, in the previous 365 days, the time period will be extended to a total of 730 days. In addition, there are donor hospitals in Hawaii that are more than 150 NM from the transplant program on the island. As a result, the initial circle size used to calculate MMaT for donor hospitals in Hawaii and Puerto Rico is 250 NM. This ensures that donor hospitals in Hawaii and Puerto Rico have MMaT scores that still include a sufficiently large cohort of transplants but remain reflective of access to transplant on the islands and that exception candidates are appropriately ranked relative to candidates with a calculated MELD or PELD score.

The Committee discussed whether Alaska required similar consideration. Under the AC policy, donors that become available in Alaska are considered to be located at the Seattle-Tacoma Airport (Sea-Tac) for purposes of allocation. This is because there is no liver transplant program in Alaska and all donors are routed through Sea-Tac. The Committee wanted to ensure that the MMaT calculation reflected the MMaT in the Seattle, WA area. However, because the Committee decided to increase the geographic area used to calculate MMaT in 50 NM increments, for donor hospitals in Alaska, the circle will get progressively larger until it reaches Seattle. Therefore, no special consideration is needed for donor hospitals in Alaska.

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<sup>19</sup> As of the drafting of this document, the MMaT for the transplant program in Hawaii is 22. In San Francisco, the MMaT is 30. The MMaT for the transplant program in Puerto Rico is 18. In Miami, the MMaT is 26.

The Committee is seeking public comment feedback on the proposal to calculate MMaT at donor hospitals in Hawaii and Puerto Rico. The Committee is also seeking public comment feedback on the proposal to calculate MMaT for donor hospitals in Alaska.

### *Median PELD at Transplant*

In current policy, the MPaT is calculated based on the median of the PELD scores of liver recipients who were less than 12 years old at the time of transplant across the nation.<sup>20</sup> MPaT is calculated using a national cohort because there are fewer PELD transplants performed and these recipients are typically transplanted at higher PELD scores.<sup>21</sup> Because MPaT is calculated using a national cohort and all PELD exceptions are assigned relative to the national MPaT, there is no disparity between PELD exception candidates, similar to what exists for MELD exception candidates. Therefore, the proposal does not change how MPaT is calculated.

The Committee is seeking public comment feedback on if there should be any corresponding changes to the MPaT calculation.

## Sorting within Liver Allocation

Within each allocation classification, liver candidates are sorted in the following order:

1. MELD or PELD score
2. Blood type compatibility (identical, compatible, then incompatible)
3. Waiting time at the current or higher MELD or PELD score (highest to lowest)
4. Time since submission of initial approved MELD or PELD exception request (highest to lowest)
5. Total waiting time (highest to lowest)

This means that when ranking candidates within an allocation classification, candidates with the highest MELD or PELD score in that classification appear first on the match run. Within the same MELD or PELD score, candidates are then ranked based on blood type compatibility, with blood type identical candidates being ranked ahead of blood type compatible candidates, who are ranked ahead of blood type incompatible candidates. Within the same blood type compatibility, candidates are then ranked based on time at current MELD or PELD score or higher MELD or PELD score. If multiple candidates of the same MELD or PELD score have the same blood type compatibility and time at score or higher, they are then ranked by time since submission of initial approved exception. And if all else is equal, the candidates are then sorted by total waiting time.

The use of MMaT around the donor hospital requires that the way in which candidates are sorted within allocation classifications be changed. By using MMaT around the donor hospital, MELD exception scores for exception candidates will fluctuate based on the MMaT of the donor hospital and will only be known once the match is run. If one donor hospital has an MMaT of 30, most MELD exception candidates on that match run will have an exception score of 27. However, the same exception candidate could be on a match run based at a donor hospital where the MMaT is 27 on the same day, and therefore have an

<sup>20</sup> The MPaT calculation also excludes status 1A/1B recipients and recipients who are transplanted with livers from living donors, DCD donors, and donors at donor hospitals more than 500 NM from the recipient's transplant program.

<sup>21</sup> *Liver and Intestine Distribution Using Distance from Donor Hospital*, OPTN Liver and Intestinal Organ Transplantation Committee, December 2018, Available at <https://optn.transplant.hrsa.gov/>

exception score of 24. MELD exception candidates will no longer have a constant MELD exception score and their specific score will only be known for a match run once the match is executed. Due to the variability in MELD exception scores based on the MMaT of the donor hospital, it is impossible to capture time at current score or higher score for MELD exception candidates.

To address this issue, the Committee is proposing that MELD or PELD exception candidates be ranked by time since submission of earliest approved MELD or PELD exception request while candidates with a calculated MELD or PELD score be ranked by time at current calculated MELD or PELD score or higher calculated MELD or PELD score. Further, the Committee is proposing that within the same MELD or PELD score and blood type compatibility, candidates with a calculated MELD or PELD score be ranked ahead of candidates with a MELD or PELD exception score.

In developing the proposal, the Committee first determined that exception candidates with the same MELD or PELD score and blood type compatibility should be ranked relative to each other based on time since submission of earliest approved exception. This sorting method already exists in policy and ranks exception candidates who have had an exception for a longer period of time ahead of exception candidates who have had an exception for a shorter period of time, when MELD or PELD is equal and blood type compatibility is the same. Similarly, the Committee agreed that candidates with a calculated MELD or PELD score should be ranked by time at current calculated score or higher calculated score, as this sorting method already exists in policy and it is appropriate to rank calculated MELD or PELD candidates based on time at score or higher, when MELD or PELD score and blood type compatibility are equal.

The Committee reviewed sample scenarios where exception candidates were sorted based on time since submission of earliest approved exception and calculated MELD or PELD candidates were sorted based on time at current calculated score or higher, without any further distinction between exception and calculated MELD or PELD candidates. In these scenarios, the Committee realized that the two proposed methods for counting waiting time disproportionately advantaged exception candidates.

In most cases, exception requests are submitted for exception candidates around the time they are registered and active on the waitlist, meaning that the use of time since submission of earliest approved exception was, more or less, giving exception candidates waiting time since they were added to the waitlist. However, for most calculated MELD or PELD candidates, their time at calculated score or higher was dictated by the laboratory update schedule. In the standard candidate trajectory, where a candidate's MELD or PELD score increases the longer he or she is on the waitlist, candidates were typically only receiving time since the last time their laboratory values were updated.<sup>22</sup> Therefore, in most of the sample scenarios, exception candidates were being ranked ahead of candidates with a calculated MELD or PELD score when the candidates had the same MELD or PELD score and blood type compatibility.

To address this concern, the Committee is proposing the addition of a new level of sorting after blood type compatibility that ranks candidates with a calculated MELD or PELD score ahead of candidates with a MELD or PELD exception score. It is important to reiterate that candidates with a calculated MELD or PELD score will be ranked ahead of exception candidates only when MELD or PELD score and blood type compatibility are the same. An exception candidate with a higher MELD or PELD will still be ranked above a calculated MELD or PELD candidate with a lower score. **Figure 4** below depicts the proposed

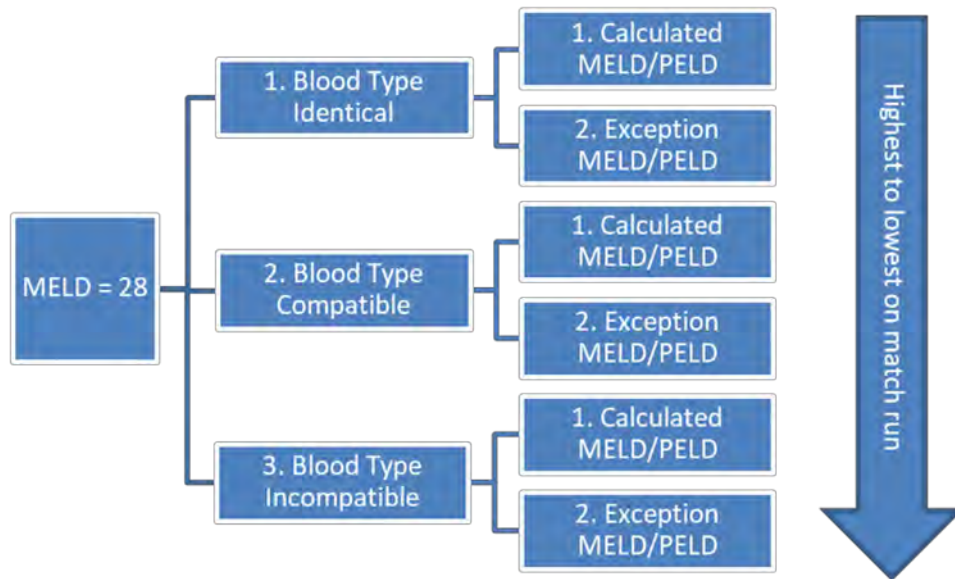
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<sup>22</sup> The laboratory update schedule is described in OPTN Policy which is available at <https://optn.transplant.hrsa.gov/>

sorting algorithm beginning with a MELD or PELD score of 28. As a reminder, within each allocation classification, liver candidates are sorted in the following order:

1. MELD or PELD score
2. Blood type compatibility (identical, compatible, then incompatible)
3. Waiting time at the current or higher MELD or PELD score (highest to lowest)
4. Time since submission of initial approved MELD or PELD exception request (highest to lowest)
5. Total waiting time (highest to lowest)

**Figure 4: Sorting within Allocation Classifications**



Ranking calculated MELD or PELD candidates ahead of exception MELD or PELD candidates of the same MELD or PELD score and blood type compatibility is based on the clinical experience of the Committee and the published literature, which shows that candidates with a MELD or PELD exception score have historically had better waitlist outcomes than candidates with a calculated MELD or PELD score.

Previously published literature has shown that candidates with a MELD or PELD exception, specifically those candidates with an exception for HCC, experienced better waitlist outcomes compared to non-HCC candidates, including: lower waitlist dropout rates at 12 months (11.5% for HCC candidates compared to 17.7% for non-HCC candidates) and higher likelihood of transplant at 90 days and lower likelihood of death at 90 days than non-HCC candidates with the same calculated MELD score as the HCC exception score.<sup>23,24</sup> Additional research showed that the risk of waitlist removal for HCC candidates remained stable at increasing MELD scores and was significantly lower than non-HCC candidates at similar MELD scores.<sup>25</sup> Overall, previous research has consistently shown that candidates with an HCC

<sup>23</sup> K. Washburn et al., "Hepatocellular Carcinoma Patients Are Advantaged in the Current Liver Transplant Allocation System," *American Journal of Transplantation* 10, no. 7 (May 10, 2010): 1643–48, <https://doi.org/10.1111/j.1600-6143.2010.03127.x>.

<sup>24</sup> A. B. Massie et al., "MELD Exceptions and Rates of Waiting List Outcomes," *American Journal of Transplantation* 11, no. 11 (September 15, 2011): 2362–71, <https://doi.org/10.1111/j.1600-6143.2011.03735.x>.

<sup>25</sup> David Goldberg et al., "Increasing Disparity in Waitlist Mortality Rates with Increased Model for End-Stage Liver Disease Scores for Candidates with Hepatocellular Carcinoma versus Candidates without Hepatocellular Carcinoma," *Liver Transplantation* 18, no. 4 (March 29, 2012): 434–43, <https://doi.org/10.1002/lt.23394>.

exception have lower mean days on the waiting list, higher transplantation rates, and lower waiting list death rates.<sup>26</sup>

These analyses predate a number of liver allocation policy changes that were designed to equalize waitlist outcomes between HCC and non-HCC candidates. First, in 2015, the HCC “cap and delay” policy was implemented, which instituted a six-month delay in MELD exception score assignment for HCC candidates and capped HCC exception scores at 34.<sup>27,28</sup> Published research suggests that these policy changes did increase equity between HCC and non-HCC candidates, with some advantage for HCC candidates remaining.<sup>29</sup> It is also necessary to note that this research is primarily restricted to HCC exceptions, which accounted for 76% of all exception request forms in the first six months of AC, but there are other diagnoses for which candidates receive exceptions.<sup>30</sup>

Also, the NLRB and AC policies significantly changed how exceptions scores are assigned and how exception candidates are prioritized. There has been no quantitative analysis conducted after implementation of these two policies that show the impact on HCC and non-HCC waitlist outcomes due to the lack of appropriate follow-up time.

The Committee also cited their medical judgement to support the ranking of candidates with a calculated MELD or PELD score ahead of exception candidates of the same MELD or PELD score and blood type compatibility. In their medical experience, the Committee agreed that, on average, a candidate with a calculated MELD or PELD is more medically urgent than a candidate that has a MELD or PELD score exception.<sup>31</sup>

The Committee considered a proposal to weight waiting time differently for exception and calculated MELD or PELD candidates that would provide priority for candidates with a calculated MELD or PELD but still included a pathway for exception candidates to gain priority with longer waiting time. The Committee felt that this would be too complicated and it would be difficult to determine the proper weighting coefficient.<sup>32</sup>

The Committee is seeking public comment feedback on the proposed sorting approach, specifically on the ranking of candidates with a calculated MELD or PELD score ahead of exception candidates of the same MELD or PELD score and blood type compatibility.

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<sup>26</sup> Patrick Grant Northup et al., “Excess Mortality on the Liver Transplant Waiting List: Unintended Policy Consequences and Model for End-Stage Liver Disease (MELD) Inflation,” *Hepatology* 61, no. 1 (October 29, 2014): 285–91, <https://doi.org/10.1002/hep.27283>.

<sup>27</sup> *Proposal to Delay HCC Exception Score Assignment*, OPTN Liver and Intestinal Organ Transplantation Committee, November 2014

<sup>28</sup> *Proposal to Cap the HCC Exception Score at 34*, OPTN Liver and Intestinal Organ Transplantation Committee, November 2014

<sup>29</sup> Tanveen Ishaque et al., “Liver Transplantation and Waitlist Mortality for HCC and Non-HCC Candidates Following the 2015 HCC Exception Policy Change,” *American Journal of Transplantation* 19, no. 2 (November 9, 2018): 564–72, <https://doi.org/10.1111/ajt.15144>.

<sup>30</sup> OPTN Descriptive Data Request. “Out-of-the-Gate Monitoring of Liver and Intestine Acuity Circles Allocation, 6 Month Report Removal of DSA and Region as Units of Allocation” Prepared for the OPTN Liver and Intestinal Organ Transplantation Committee, October 22, 2020

<sup>31</sup> See Acuity Circles Subcommittee meeting summary, August 12, 2020. Available at <https://optn.transplant.hrsa.gov/>

<sup>32</sup> See Acuity Circles Subcommittee meeting summary, August 26, 2020. Available at <https://optn.transplant.hrsa.gov/>



## Additional Changes

The Committee is seeking feedback on a number of additional changes that are part of the proposal.

### *Approved vs. Assigned*

In current policy, if the NLRB fails to make a decision on an initial exception or exception extension request within 21 days of the day of submission, the candidate is assigned the requested score. There is no clear distinction in OPTN policy between exception requests that are reviewed and *approved* by the NLRB and those requests where the NLRB failed to make a decision and the candidate is *assigned* the requested score.

Included in this proposal are a number of clarifications to make policy more consistent in the distinction between approved and assigned exceptions.

The primary change to note as part of these clarifications relates to HCC exceptions. Currently, candidates with an approved or assigned HCC exception can be automatically approved for an HCC extension, even if the initial exception request is not automatically approved, as long as the candidate meets standardized extension criteria. The current policy states that only candidates with an approved exception can receive these automatic extensions. However, HCC candidates with an assigned exception are eligible to have extensions automatically approved because the distinction between approved and assigned exceptions has not previously been made. The Committee's concern is that candidates with an assigned exception will have subsequent extensions automatically approved and the case will never be appropriately reviewed. By distinguishing between approved and assigned exceptions throughout policy, only HCC candidates with an approved exception will be able to have subsequent extensions automatically approved, which is the Committee's intent.<sup>33</sup>

The Committee is seeking public comment feedback on the distinction between approved versus assigned exceptions in policy.

### *Minimum Exception Score*

In developing the MMaT around the donor hospital proposal, the Committee recognized that there is the possibility for a donor hospital to have an MMaT score below 18. This is significant because livers from non-DCD donors between the ages 18 and 69 are allocated to candidates down to MELD or PELD 15 in the area around the donor hospital before being offered to more medically urgent candidates across the nation. If a donor hospital were to have an MMaT score equal to 17, most MELD exception candidates on the match run would have an exception score equal to MELD 14, meaning that the liver would be offered to all candidates with a MELD or PELD score of 15 or higher across the nation before being offered to a MELD exception candidate located in closer geographic proximity to the donor hospital.

This is not a new concern, as current policy includes a minimum exception score of 15 for candidates with a standardized exception. However, the concern is compounded by the fact that transplant programs will not be aware of the MMaT score at every donor hospital, so they cannot alter scores

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<sup>33</sup> See OPTN Liver and Intestinal Organ Transplantation Committee meeting summary, November 6, 2020. Available at <https://optn.transplant.hrsa.gov/>

based on a specific MMaT. Therefore, the Committee is proposing to extend the minimum exception score of 15 to include all MELD or PELD exceptions, both standardized and non-standardized.

This requires a change to the current policy for exception candidates on the six-month HCC delay. Currently, HCC candidates on their initial exception or first extension are provided an exception score of six, which is lower than proposed minimum score of 15. Under the proposed policy, transplant programs will still apply for exceptions for these candidates but instead of receiving a score of six, they will appear on match runs with their calculated MELD score. For HCC candidates that do not meet standardized criteria, transplant programs will be able to request an exception that correlates to the six month delay. For both standardized and non-standardized HCC exceptions, the candidates will have exceptions and will be accruing time since earliest approved exception request.

The Committee is seeking public comment feedback on the minimum exception score and if there is any reason to request a score lower than 15.

### *Requesting an Adjustment, not a Specific Score*

Currently, transplant programs request a specific score for MELD or PELD exception candidates. For example, if the MMaT at a transplant program is 30, the program would submit a request for MELD 27 to align with MMaT-3.

With this proposal, MMaT will fluctuate based on the MMaT of the donor hospital. Transplant programs will no longer be able to request a specific exception score, as MMaT and, consequently exception scores, will change with each donor hospital. As a result, transplant programs will need to request an adjustment of a certain amount of points higher or lower than MMaT or MPaT, instead of specific scores. This change in the system will impact PELD exception requests, even though the MPaT calculation is not changing.

The Committee noted that transplant programs should still be able to specifically request exceptions for MELD or PELD 40 and above as these candidates are particularly urgent and a transplant program would only request such a high score of a specific purpose. As a result, in the proposal, transplant programs will be able to request a specific score if the score is for MELD 40 or PELD 40 and higher. These exception scores are not tied to MMaT or MPaT and will not change based on the donor hospital or an updated MPaT.

The Committee is seeking public feedback on requesting score adjustments as opposed to specific scores and if that change will be feasible for transplant programs.

### *New Donor Hospitals*

In 2019, there was an average of 3.5 new donor hospitals added to UNet<sup>SM</sup> each month. This does not include adjustments to the exact location of donor hospitals already in the system. For both new donor hospitals and updates to the location of an already-existing donor hospital, UNet will have the ability to automatically calculate an MMaT prior to the initiation of any liver match run. The MMaT for existing donor hospitals will still be updated twice each year as outlined in policy. The cohort used for new donor hospitals will align with the most recent bi-annual update to all MMaT scores.

## NOTA and Final Rule Analysis

The Committee submits the proposed changes to liver allocation policy for Board consideration under the authority of the OPTN Final Rule, which states “The OPTN Board of Directors shall be responsible for developing...policies for the equitable allocation for cadaveric organs.”<sup>34</sup> The Final Rule requires that when developing policies for the equitable allocation of cadaveric organs, such policies must be developed “in accordance with §121.8,” which 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.”

This proposal:

- **Is based on sound medical judgment**<sup>35</sup> because it is an evidenced-based change relying on the following evidence:
  - Published literature showing that candidates with a calculated MELD or PELD score have historically worse waitlist outcomes than candidates with a MELD or PELD exception. Specifically, previously published literature has shown that candidates with an HCC exception have lower waitlist dropout rates at 12 months (11.5% for HCC candidates compared to 17.7% for non-HCC candidates) and higher likelihood of transplant at 90 days and lower likelihood of death at 90 days than non-HCC candidates with the same calculated MELD score as the HCC exception score.<sup>36,37</sup> Additional research has shown that the risk of waitlist removal for HCC candidates remained stable at increasing MELD scores and was significantly lower than non-HCC candidates at similar MELD scores.<sup>38</sup>
  - The Committee also cited their medical judgement that, on average, a candidate with a calculated MELD or PELD is more medically urgent than a candidate that has a MELD or PELD score exception.<sup>39</sup>
- **Seeks to achieve the best use of donated organs**<sup>40</sup> by ensuring organs are allocated and transplanted according to medical urgency.
  - This proposal seeks to achieve the best use of donated organs by ensuring that liver transplant candidates with a MELD or PELD exception are appropriately ranked relative to other exception candidates and candidates with a calculated MELD or PELD score.

<sup>34</sup> 42 CFR §121.4(a).

<sup>35</sup> 42 CFR §121.8(a)(1).

<sup>36</sup> K. Washburn et al., “Hepatocellular Carcinoma Patients Are Advantaged in the Current Liver Transplant Allocation System,” *American Journal of Transplantation* 10, no. 7 (May 10, 2010): 1643–48, <https://doi.org/10.1111/j.1600-6143.2010.03127.x>.

<sup>37</sup> A. B. Massie et al., “MELD Exceptions and Rates of Waiting List Outcomes,” *American Journal of Transplantation* 11, no. 11 (September 15, 2011): 2362–71, <https://doi.org/10.1111/j.1600-6143.2011.03735.x>.

<sup>38</sup> David Goldberg et al., “Increasing Disparity in Waitlist Mortality Rates with Increased Model for End-Stage Liver Disease Scores for Candidates with Hepatocellular Carcinoma versus Candidates without Hepatocellular Carcinoma,” *Liver Transplantation* 18, no. 4 (March 29, 2012): 434–43, <https://doi.org/10.1002/lt.23394>.

<sup>39</sup> See Acuity Circles Subcommittee meeting summary, August 12, 2020. Available at <https://optn.transplant.hrsa.gov/>

<sup>40</sup> 42 CFR §121.8(a)(2).

- The proposed changes to sorting within liver allocation classifications will further ensure that the most medically urgent candidates are appropriately prioritized for transplant and may decrease waitlist mortality for candidates with a calculated MELD or PELD score as they will be ranked ahead of candidates with a MELD or PELD exception score of the same blood type compatibility and allocation MELD or PELD score.
- **Is designed to...promote patient access to transplantation<sup>41</sup> by giving similarly situated candidates equitable opportunities to receive an organ offer.**
  - This proposal is designed to promote patient access to transplantation by providing more equitable access to specific donor offers for liver transplant candidates with a MELD or PELD exception registered at different transplant programs.
  - The proposal also provides more equitable access to transplant for candidates with a calculated MELD or PELD score compared to candidates with a MELD or PELD exception score.

This proposal mitigates the effect of the candidate’s place of residence or place of listing, because the proposal is designed to provide MELD exception scores based on transplants performed in the area around the donor hospital. All exception candidates on a match run will be provided an exception score relative to the same MMaT regardless of where they are listed. This proposal does not impact the use of distance between the donor hospital and transplant program already utilized in liver allocation policy. The change to sorting within liver allocation classifications is not based on a candidate’s place of listing or place of residence.

This proposal also preserves the ability of a transplant program to decline an offer or not use the organ for a potential recipient,<sup>42</sup> and it is specific to an organ type, in this case livers.<sup>43</sup>

Although the proposal outlined in this briefing paper addresses certain aspects of the Final Rule listed above, the Committee does not expect impacts on the following aspects of the Final Rule:

- Shall be designed to avoid wasting organs, to avoid futile transplants, ... and to promote the efficient management of organ placement;

## Implementation Considerations

### Member and OPTN Operations

This proposal will need to be programmed and the implementation timeframe will be based on the specific programming requirements.

The Final Rule requires the OPTN to “consider whether to adopt transition procedures” whenever organ allocation policies are revised.<sup>44</sup> The Committee discussed two transitional procedures as part of the proposal. First, the Committee discussed what cohort for calculating MMaT should be used upon implementation – the cohort used for the previous MMaT update or an updated cohort that aligns with the implementation date. The Committee determined that when the proposal is implemented, the cohort used to calculate the MMaT for each donor hospital should be based on the date the proposal is

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<sup>41</sup> Id.

<sup>42</sup> 42 CFR §121.8(a)(3).

<sup>43</sup> 42 CFR §121.8(a)(4).

<sup>44</sup> 42 CFR §121.8(d).

implemented, not the date that the last MMaT and MPaT update was calculated. When the proposal is implemented, MELD exception scores will be converted from the specific score requested based on the MMaT of the transplant program, to the score relative to the MMaT of donor hospitals. For example, if a candidate has an MELD exception score of 27 that is three points below that MMaT of the transplant program, that score will be converted to be MMaT-3 and will change with each donor hospital. This does not include candidates who have a MELD or PELD exception of 40 or higher. These exception scores are not tied to MMaT or MPaT.

Second, the system does not currently distinguish between time spent at a higher exception or higher calculated score. In this proposal, candidates with a calculated MELD or PELD score are sorted by time at current calculated MELD or PELD score or a higher calculated MELD or PELD score. Time spent at a higher exception score is not included. However, upon implementation, there will be candidates with a calculated MELD or PELD score whose time at current score or higher includes time at a higher exception MELD or PELD score that was accrued prior to implementation. The Committee decided that it was not necessary to distinguish between time at a higher exception MELD or PELD score or time at a higher calculated MELD or PELD score that was accrued prior to implementation. These candidates will be able to keep the time accrued at the higher exception score, but after implementation, time will be restricted to just time at calculated scores. This decision ensures that candidates with a calculated MELD or PELD score who accrued time at a higher exception score are treated no less favorably than under the previous policy because they will keep the previously accrued time at a higher exception score whereas candidates after implementation will only accrue time at a higher lab score.

### *Operations affecting Histocompatibility Laboratories*

There is no expected operational impact on histocompatibility laboratories.

### *Operations affecting Organ Procurement Organizations*

There is no expected operational impact on OPOs.

### *Operations affecting Transplant Hospitals*

The primary operational impact on transplant hospitals involves the updated MMaT calculation being based around the donor hospital. Candidates with an exception will no longer have a static exception score relative to the MMaT of the transplant program where he or she is registered. Instead, exception candidates will have a MELD or PELD score adjustment. For PELD candidates, this adjustment will still be relative to the national MPaT. For MELD candidates, the adjustment will be relative to the MMaT of the donor hospital where a match is being run. This means that MELD exception scores will fluctuate based on the MMaT of the donor hospital and the specific score will not be known until the match is run.

Transplant program staff will need to be prepared to inform exception candidates that they do not have a specific exception score, but an exception relative to the MMaT or MPaT.

### *Operations affecting the OPTN*

The proposed changes will need to be programmed into UNet. The OPTN will continue to be responsible for updating the MMaT score on a bi-annual basis. The OPTN will distribute a policy notice to inform members of all approved policy changes following final Board action (Board consideration of the final proposal is currently planned for June 2021), and system notices will be used to communicate when

system changes are scheduled and these policy changes will be implemented. The OPTN will also create educational materials to support these proposed changes.

## Potential Impact on Select Patient Populations

This proposal has the potential to impact a number of select patient populations. The Committee decided not to model the proposal as the Liver Simulate Allocation Model (LSAM) cannot periodically update the MMaT during a multi-year simulation run. An LSAM simulation would be based on prior acceptance behavior and would not be able to show specific changes to waitlist outcomes due to the nature of the proposal. Based on this information, the proposed changes are unlikely to show an impact on waitlist metrics in the LSAM and the Committee decided that modeling would not be useful.<sup>45</sup>

It is probable that candidates with a MELD or PELD exception may see lower access to transplant, as they will be ranked behind candidates with a calculated MELD or PELD score who have the same MELD or PELD score and blood type compatibility. The extent of this impact was not quantified.

It is known that a large portion of pediatric candidates are transplanted with an exception.<sup>46</sup> The OPTN Pediatric Transplantation Committee has expressed concern that the ranking of candidates with a calculated MELD or PELD ahead of MELD or PELD exception candidates of the same MELD or PELD score and blood type compatibility could disproportionately impact pediatric candidates, especially for non-DCD donors age 18-69. This proposal does not impact the priority that pediatric candidates have in allocation policy for pediatric and adolescent donors. The specific impact of the proposal on pediatric candidates was not quantified.

## Projected Fiscal Impact

### *Projected Impact on Histocompatibility Laboratories*

There is no expected fiscal impact for histocompatibility laboratories.

### *Projected Impact on Organ Procurement Organizations*

There is no expected fiscal impact for OPOs.

### *Projected Impact on Transplant Hospitals*

There should be minimal or no fiscal impact to hospitals.

### *Projected Impact on the OPTN*

Preliminary estimates indicate that this would be an enterprise effort, as over 6,100 hours may be needed for IT programming, communication, and ongoing monitoring. This is estimated to be a larger

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<sup>45</sup> See OPTN Liver and Intestinal Organ Transplantation Committee meeting summary, October 22, 2020. Available at <https://optn.transplant.hrsa.gov/>

<sup>46</sup> In the first six months after implementation of the AC policy, 36.4% of pediatric candidates age 0-11 years were transplanted with an exception. In the same timeframe, 55% of pediatric candidates age 12-17 years were transplanted with an exception. For adult candidates (age 18 and higher), only 19.9% of transplant recipients had an exception.

effort than the *Liver and Intestine Distribution Using Distance from Donor Hospital* (estimated at 4,470 hours) that was approved by the Board in 2018.<sup>47</sup>

## Post-implementation Monitoring

### Member Compliance

The Final Rule requires that allocation policies “include appropriate procedures to promote and review compliance including, to the extent appropriate, prospective and retrospective reviews of each transplant program's application of the policies to patients listed or proposed to be listed at the program.”<sup>48</sup>

The proposed language will not change the current routine monitoring of OPTN members because these policy changes address candidates’ exception score values and candidate sorting on the match run.

### Policy Evaluation

The Final Rule requires that allocation policies “be reviewed periodically and revised as appropriate.”<sup>49</sup> To assess the effect of these changes to the calculation of median MELD at transplant, the UNOS Research Department will analyze a number of relevant outputs in a pre vs. post analysis. Such analyses will be performed at approximately 6 months, 1 year, and 2 years post-implementation. National results will be provided and some analyses will be stratified by various geographic units, specialty board type (i.e., Adult HCC, Adult Other Diagnosis, and Pediatric), and other features as appropriate.

Questions of interest:

- Are non-exception and exception transplant candidates ranked with one another appropriately?
- Do exception candidates across the country have more equitable access to transplant, compared to one another?

Relevant analyses:

- Waiting list dropout rates, defined as removal due to death or too sick to transplant, by exception type (no exception, HCC exception, non-HCC exception)
- Waiting list transplant rates by exception type
- Count and percent of the waiting list by exception type
- Distribution of score adjustment requested for MELD or PELD exception requests
- Count and percent of MELD or PELD exception requests approved
- Count and percent of deceased donor transplant recipients by exception type
- Distribution of allocation MELD or PELD score or status at transplant by exception type
- Other metrics deemed relevant and necessary to the evaluation of the policy by the Liver and Intestinal Transplantation Committee at time of analysis

<sup>47</sup> *Liver and Intestine Distribution Using Distance from Donor Hospital*, OPTN Liver and Intestinal Organ Transplantation Committee, December 2018, Available at <https://optn.transplant.hrsa.gov/>

<sup>48</sup> 42 CFR §121.8(a)(7).

<sup>49</sup> 42 CFR §121.8(a)(6).

## Conclusion

This proposal improves equity in access to individual donor offers for exception candidates and better aligns the geographic units used in the calculation of MMaT with the geographic units used in liver allocation. In this proposal, MMaT will be calculated for every donor hospital and exception candidates will all be assigned an exception score relative to the MMaT for the donor hospital where the donor is located. In addition, the proposal changes how candidates are sorted within liver allocation classifications. When MELD or PELD score and blood type compatibility are equal, candidates with a calculated MELD or PELD score will be ranked ahead of candidates with a MELD or PELD exception. Candidates with a calculated MELD or PELD score will then be sorted by time at current calculated score or higher calculated score. Exception candidates will be sorted based on time since submission of earliest approved or assigned exception request.



## Policy and Guidelines Language

Proposed new language is underlined (example) and language that is proposed for removal is struck through (~~example~~). Heading numbers, table and figure captions, and cross-references affected by the numbering of these policies will be updated as necessary.

### 1 National Liver Review Board Operational Guidelines

#### 2 1. Overview

3  
4 The purpose of the National Liver Review Board (NLRB) is to provide fair, equitable, and prompt peer  
5 review of exceptional candidates whose medical urgency is not accurately reflected by the calculated  
6 MELD or PELD score. The NLRB will base decisions on policy, the guidance documents, and in cases which  
7 lack specific guidance, the medical urgency of the candidate as compared to other candidates with the  
8 same MELD or PELD score adjustment or specific MELD or PELD score.

9 The NLRB is comprised of specialty boards, including:

- 10 • Adult Hepatocellular Carcinoma (HCC)
- 11 • Adult Other Diagnosis
- 12 • Pediatrics, which reviews requests made on behalf of any candidate registered prior to  
13 turning 18 years old and adults with certain pediatric diagnoses

14  
15 The immediate past-Chair of the Liver and Intestinal Organ Transplantation Committee serves as the  
16 Chair of the NLRB for a two year term.

#### 18 1.2 Definitions

19 The definitions that follow are used to define terms specific to the OPTN Policies.

## 20 A

#### 21 **Active candidate**

22 A candidate on the waiting list who is currently suitable for transplantation and eligible to receive organ  
23 offers.

#### 24 **Agent**

25 A person legally authorized to act on behalf of another person.

#### 26 **Allocation MELD or PELD Score**

27 The highest exception or calculated MELD or PELD score available to the candidate at the time of the  
28 match run for a liver or liver-intestine according to Policy. Allocation MELD or PELD score includes liver-  
29 intestine points.

#### 30 **Alternative allocation system**

31 A type of variance that allows members who are permitted to join the variance to allocate organs  
32 differently than the OPTN Policies.

33 **Alternative local unit (ALU)**

34 A type of variance that creates a distinct geographic area for organ procurement and distribution.

35 **Alternative point assignment system**

36 A type of variance that allows members who are permitted to join the variance to assign points for  
37 organ allocation differently than required by the OPTN Policies.

38 **Antigen mismatch**

39 An antigen mismatch occurs when an identified deceased or living donor antigen is not recognized as  
40 equivalent to the recipient’s own antigens. In cases where a donor or candidate only has one antigen  
41 identified at a human leukocyte antigen (HLA) locus (A, B, or DR), the antigens are considered to be  
42 identical at that locus.

43

44 **Approved MELD or PELD Exception**

45 A MELD or PELD exception or exception extension that met standardized criteria in OPTN policy or was  
46 reviewed and approved by the NLRB

47

48 **Assigned MELD or PELD Exception**

49 A MELD or PELD exception or exception extension where the NLRB failed to make a decision within 21  
50 days of the date of submission of the request and the candidate was assigned the requested score.

51 **Authorization**

52 The act of granting permission for a specific act. This is sometimes called consent, which is not to be  
53 confused with informed consent.

54 **M**

55 **Match**

56 A donor and the donor’s matched candidate. This includes deceased, living, and KPD donors.

57

58 **~~Match MELD or PELD Score~~**

59 ~~The MELD or PELD score available to the candidate at the time of the match for a deceased donor liver~~  
60 ~~or liver intestine.~~

61

62 **Policy 9: Allocation of Livers and Liver-Intestines**

63

64 **9.4 MELD or PELD Score Exceptions**

65 If a candidate’s transplant program believes that a candidate’s current MELD or PELD score does not  
66 appropriately reflect the candidate’s medical urgency for transplant, the transplant program may submit  
67 a MELD or PELD score exception request to the National Liver Review Board (NLRB).

68

69 **9.4.A MELD or PELD Score Exception Requests**

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

71

- 72 1. A request for a ~~specific MELD or PELD score either~~:

- 73 a. An adjustment of a certain amount of points higher or lower than MMaT or  
 74 MPaT or  
 75 b. A specific MELD or PELD score of 40 or higher  
 76 2. A justification of how the medical criteria supports that the candidate has a higher  
 77 MELD or PELD score  
 78 3. An explanation of how the candidate's current condition is comparable to that of other  
 79 candidates with that MELD or PELD score  
 80 2. A justification that outlines how a candidate's medical condition warrants an exception  
 81 and the specific score being requested.  
 82

83 ~~Approved MELD or PELD exception scores~~ are valid for 90 days from the date the exception is  
 84 approved or assigned.  
 85  
 86

### 87 **9.4.C MELD or PELD Score Exception Extensions**

#### 88 **9.4.C.ii Other MELD or PELD Score Exception Extensions**

89  
 90 A candidate's approved or assigned exception will be maintained if the transplant  
 91 hospital program enters a MELD or PELD Exception Score Extension Request before  
 92 the due date, even if the NLRB does not act before the due date. If the extension  
 93 request is denied or if no MELD or PELD Exception Score Extension Request is  
 94 submitted before the due date, then the candidate will be assigned the calculated  
 95 MELD or PELD score based on the most recent reported laboratory values.  
 96

97 Each approved or assigned MELD or PELD exception extension is valid for an  
 98 additional 90 days beginning from the day that the previous exception or extension  
 99 expired.  
 100

### 101 **9.4.D Calculation of Median MELD or PELD at Transplant**

102 ~~Median MELD at transplant (MMaT) is calculated by using the median of the MELD scores at the~~  
 103 ~~time of transplant of all recipients at least 12 years old who were transplanted at hospitals~~  
 104 ~~within 250 nautical miles of the candidate's listing hospital in a prior 365 day period.~~  
 105

106 ~~Median PELD at transplant (MPaT) is calculated by using the median of the PELD scores at the~~  
 107 ~~time of transplant of all recipients less than 12 years old in the nation.~~  
 108

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

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

113  
 114 ~~The OPTN will recalculate the MMaT and MPaT twice a year based on an updated cohort. The~~  
 115 ~~updated cohort will include transplants over a prior 365 day period. If there have been fewer~~  
 116 ~~than 10 qualifying transplants within 250 nautical miles of a transplant hospital in the cohort,~~  
 117 ~~the MMaT will be calculated based on a total of a 730 day period.~~  
 118

119 For each donor hospital, the OPTN will calculate the MMaT based on a cohort of recipients  
 120 transplanted at programs at or within 150 nautical miles of the donor hospital in a prior 365 day  
 121 period. If there are either less than two active liver transplant programs or less than 10  
 122 qualifying transplants within 150 nautical miles of the donor hospital, the geographic area used  
 123 to calculate the MMaT will increase in 50 nautical mile increments until two active liver  
 124 transplant programs and 10 qualifying transplants are included in the MMaT cohort.

125  
 126 The MMaT is calculated by using the median of the MELD scores at the time of transplant of all  
 127 recipients within the geographic area defined above that are at least 12 years old at the time of  
 128 transplant. Recipients are excluded who are either of the following:

- 129 1. Transplanted with livers from living donors, DCD donors, or donors from donor hospitals  
 130 more than 500 nautical miles away from the recipient's transplant program or
- 131 2. Status 1A or 1B at the time of transplant.

132  
 133 If a transplant program has not performed at least one transplant included in the MMaT  
 134 calculation, the program is not included in the MMaT cohort.

135  
 136 If there are less than 10 qualifying transplants within 250 nautical miles of a donor hospital in  
 137 Hawaii or Puerto Rico, the MMaT will be calculated based on a total of 730 days. There does not  
 138 need to be two transplant programs within 250 nautical miles of donor hospitals in Hawaii or  
 139 Puerto Rico.

140  
 141 Median PELD at transplant (MPaT) is calculated by using the median of the PELD scores at the  
 142 time of transplant of all recipients less than 12 years old at the time of transplant in the nation.  
 143 Recipients are excluded who are either of the following:

- 144 1. Transplanted with livers from living donors, DCD donors, or donors from donor hospitals  
 145 more than 500 nautical miles away from the recipient's transplant program or
- 146 2. Status 1A or 1B at the time of transplant.

147  
 148 The OPTN will recalculate the MMaT and MPaT twice a year based on an updated cohort. The  
 149 updated cohort will include transplants over a prior 365 day period.

#### 150 **9.4.E: MELD or PELD Exception Scores Relative to Median MELD or PELD at Transplant**

151  
 152 A match run will provide MELD exception candidates on the match run a MELD exception score  
 153 relative to the MMaT for the donor hospital. PELD exception candidates are provided a PELD  
 154 exception score relative to the MPaT for the nation. If a candidate's exception score relative to  
 155 MMaT or MPaT would be lower than 15, the candidate's exception score will be 15.

156  
 157 ~~Exceptions scores will be updated to reflect changes in MMaT or MPaT each time the MMaT or~~  
 158 ~~MPaT is recalculated.~~ The following exception scores are not awarded relative to MMaT or  
 159 MPaT and will not be updated:

- 160 1. Exception scores of 40 or higher awarded by the NLRB according to *Policy 9.4.A: MELD or*  
 161 *PELD Score Exception Requests*
- 162 2. Any exception awarded according to *Policy 9.5.D: Requirements for Hepatic Artery*  
 163 *Thrombosis (HAT) MELD or PELD Score Exceptions*

- 164 3. Exceptions awarded to candidates less than 18 years old at time of registration according to  
 165 *Policy 9.5.I: Requirements for Hepatocellular Carcinoma (HCC) MELD or PELD Score*  
 166 *Exceptions*  
 167 4. ~~Initial exceptions and first extensions awarded to candidates at least 18 at time of~~  
 168 ~~registration according to *Policy 9.5.I: Requirements for Hepatocellular Carcinoma (HCC)*~~  
 169 ~~*MELD or PELD Score Exceptions*~~

170  
171

## 172 9.5 Specific Standardized MELD or PELD Score Exceptions

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

- 176
- 177 • Cholangiocarcinoma (CCA), according to *Policy 9.5.A: Requirements for Cholangiocarcinoma*  
 178 *MELD or PELD Score Exceptions*
  - 179 • Cystic fibrosis, according to *Policy 9.5.B: Requirements for Cystic Fibrosis MELD or PELD*  
 180 *Score Exceptions*
  - 181 • Familial amyloid polyneuropathy, according to *Policy 9.5.C: Requirements for Familial*  
 182 *Amyloid Polyneuropathy (FAP) MELD or PELD Score Exceptions*
  - 183 • Hepatic artery thrombosis, according to *Policy 9.5.D: Requirements for Hepatic Artery*  
 184 *Thrombosis (HAT) MELD or PELD Score Exceptions*
  - 185 • Hepatopulmonary syndrome, according to *Policy 9.5.E: Requirements for Hepatopulmonary*  
 186 *Syndrome (HPS) MELD or PELD Score Exceptions*
  - 187 • Metabolic disease, according to *Policy 9.5.F: Requirements for Metabolic Disease MELD or*  
 188 *PELD Score Exceptions*
  - 189 • Portopulmonary hypertension, according to *Policy 9.5.G: Requirements for Portopulmonary*  
 190 *Hypertension MELD or PELD Score Exceptions*
  - 191 • Primary hyperoxaluria, according to *Policy 9.5.H: Requirements for Primary Hyperoxaluria*  
 192 *MELD or PELD Score Exceptions*
  - 193 • Hepatocellular carcinoma, according to *Policy 9.5.I: Requirements for Hepatocellular*  
 194 *Carcinoma (HCC) MELD or PELD Score Exceptions*

195  
 196 ~~If a candidate's exception score based on the score assignments relative to MMaT or MPaT in this~~  
 197 ~~section would be lower than 15, the candidate's exception score will be 15.~~

198

### 199 9.5.A Requirements for Cholangiocarcinoma (CCA) MELD or PELD Score 200 Exceptions

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

203

- 204 1. Submits a written protocol for patient care to the Liver and Intestinal Organ Transplantation  
 205 Committee that must include *all* of the following:
- 206 • Candidate selection criteria
  - 207 • Administration of neoadjuvant therapy before transplantation

- 208 • Operative staging to exclude any patient with regional hepatic lymph node metastases,
- 209 intrahepatic metastases, or extrahepatic disease
- 210 • Any data requested by the Liver and Intestinal Organ Transplantation Committee
- 211
- 212 2. Documents that the candidate meets the diagnostic criteria for hilar CCA with a malignant
- 213 appearing stricture on cholangiography and at least *one* of the following:
- 214 • Biopsy or cytology results demonstrating malignancy
- 215 • Carbohydrate antigen 19-9 greater than 100 U/mL in absence of cholangitis
- 216 • Aneuploidy

217  
218 The tumor must be considered un-resectable because of technical considerations or

219 underlying liver disease.

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

232  
233 A candidate who meets the requirements for a standardized MELD or PELD score exception will

234 ~~be assigned~~ receive a score according to *Table 9-2* below.

235  
236 **Table 9-2: CCA Exception Scores**

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

237  
238 In order to be approved for an extension of this MELD or PELD score exception, transplant

239 ~~hospitals~~ programs must submit an exception extension request according to *Policy 9.4.C: MELD*

240 *or PELD Score Exception Extensions*, and provide cross-sectional imaging studies of the chest and

241 abdomen that exclude intrahepatic and extrahepatic metastases. These required imaging

242 studies must have been completed within 30 days prior to the submission of the extension

243 request.

### 244 **9.5.B Requirements for Cystic Fibrosis (CF) MELD or PELD Score Exceptions**

246 A candidate will receive a MELD or PELD score exception for cystic fibrosis if the candidate's

247 diagnosis has been confirmed by genetic analysis, and the candidate has a forced expiratory

248 volume at one second (FEV1) below 40 percent of predicted FEV1 within 30 days prior to  
 249 submission of the initial exception request.

250  
 251 A candidate who meets the requirements for a standardized MELD or PELD score exception will  
 252 ~~be assigned~~ receive a score according to *Table 9-3* below.

**Table 9-3: Cystic Fibrosis Exception Scores**

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

255  
 256 In order to be approved for an extension of this MELD or PELD score exception, transplant  
 257 ~~hospitals~~ programs must submit an exception extension request according to *Policy 9.4.C: MELD*  
 258 *or PELD Score Exception Extensions*.

259  
 260 **9.5.C Requirements for Familial Amyloid Polyneuropathy (FAP) MELD or PELD**  
 261 **Score Exceptions**

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

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

272  
 273 A candidate who meets the requirements for a standardized MELD or PELD score exception will  
 274 ~~be assigned~~ receive a score according to *Table 9-4* below.

**Table 9-4: FAP Exception Scores**

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

277  
 278 In order to be approved for an extension of this MELD or PELD score exception, transplant  
 279 ~~hospitals~~ programs must submit an exception extension request according to *Policy 9.4.C: MELD*  
 280 *or PELD Score Exception Extensions* and meet one of the following criteria:

- 281 1. An echocardiogram that shows that the candidate has an ejection fraction greater than  
 282 40 percent within the last 120 days

2. Registered and active on the waiting list for a heart transplant at that hospital

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

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

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

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

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

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

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

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

Table 9-5: HPS Exception Scores

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

In order to be approved for an extension of this MELD or PELD score exception, transplant ~~hospitals~~ programs must submit an exception extension request according to *Policy 9.4.C: MELD or PELD Score Exception Extensions*, with evidence that the candidate's PaO<sub>2</sub> remained at less than 60 mmHg on room air within the 30 days prior to submission of the extension request.

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

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



322  
323  
324  
325  
326

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

**Table 9-6: Metabolic Disease Exception Scores**

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

327  
328  
329  
330  
331  
332  
333  
334  
335  
336  
337

If the candidate does not receive a transplant within 30 days of being registered with the exception score, then the candidate’s transplant physician may register the candidate as a status 1B.

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

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

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344  
345  
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350

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

1. Document via heart catheterization initial mean pulmonary arterial pressure (MPAP) level greater than or equal to 35 mmHg and initial pulmonary vascular resistance (PVR) level greater than or equal to 240 dynes\*sec/cm<sup>5</sup> (or greater than or equal to 3 Wood units (WU)). These values must be from the same test date.
2. Other causes of pulmonary hypertension have been assessed and determined to not be a significant contributing factor
3. Initial transpulmonary gradient to correct for volume overload
4. Documentation of treatment
5. Document via heart catheterization within 90 days prior to submission of the initial exception either of the following:
  - Post-treatment MPAP less than 35 mmHg and post-treatment PVR less than 400 dynes\*sec/cm<sup>5</sup> (or less than 5 Wood units (WU)). These values must be from the same test date.
  - Post-treatment MPAP greater than or equal to 35 mmHg and less than 45 mmHg and post-treatment PVR less than 240 dynes\*sec/cm<sup>5</sup> (or less than 3 Wood units (WU)). These values must be from the same test date.
6. Documentation of portal hypertension at the time of initial exception

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352  
353  
354  
355  
356  
357  
358  
359  
360  
361

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

362

**Table 9-7: Portopulmonary Hypertension Exception Scores**

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

363

364

365

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374

In order to be approved for an extension of this MELD or PELD score exception, transplant hospitals programs must submit an exception extension request according to *Policy 9.4.C: MELD or PELD Score Exception Extensions* with evidence of a heart catheterization since the last exception or extension request that confirms either of the following:

- MPAP less than 35 mmHg and PVR less than 400 dynes\*sec/cm<sup>5</sup> (or less than 5 Wood units (WU)). These values must be from the same test date.
- MPAP greater than or equal to 35 mmHg and less than 45 mmHg and PVR less than 240 dynes\*sec/cm<sup>5</sup> (or less than 3 Wood units (WU)). These values must be from the same test date.

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

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

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

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

**Table 9-8: Primary Hyperoxaluria Scores**

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

390

391

392

393

394

395

In order to be approved for an extension of this MELD or PELD score exception, transplant hospitals programs must submit an exception extension request according to *Policy 9.4.C: MELD or PELD Score Exception Extensions* with evidence that the candidate is registered on the waiting list for a kidney transplant at that hospital.

396 **9.5.I Requirements for Hepatocellular Carcinoma (HCC) MELD or PELD Score**  
 397 **Exceptions**

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

398  
 399 **9.5.I.vii Extensions of HCC Exceptions**

400 A candidate with an approved exception for HCC is eligible for automatic approval of  
 401 an extension if the transplant program enters a MELD or PELD Exception Score  
 402 Extension Request that contains the following:

- 403  
 404 1. Documentation of the tumor using a CT or MRI  
 405 2. The type of treatment if the number of tumors decreased since the last request  
 406 3. The candidate's alpha-fetoprotein (AFP) level  
 407

408 The candidate's exception extension will then be automatically approved unless *any*  
 409 of the following occurs:

- 410  
 411 • The candidate's lesions progress beyond T2 criteria, according to 9.5.I.ii: *Eligible*  
 412 *Candidates Definition of T2 Lesions*  
 413 • The candidate's alpha-fetoprotein (AFP) level was less than or equal to 1,000  
 414 ng/mL on the initial request but subsequently rises above 1,000 ng/mL  
 415 • The candidate's AFP level was greater than 1,000 ng/mL, the AFP level falls  
 416 below 500 ng/mL after treatment but before the initial request, then the AFP  
 417 level subsequently rises to greater than or equal to 500 ng/mL  
 418 • The candidate's tumors have been resected since the previous request  
 419 • The program requests a score different from the scores assigned in Table 9-10.  
 420

421 When a transplant program submits either an initial exception request or the first  
 422 extension request for a liver candidate at least 18 years old at the time of  
 423 registration ~~submits an initial request or the first extension request~~ that meets the  
 424 requirements for a standardized MELD score exception, the candidate will ~~receive a~~  
 425 ~~MELD score of 6, and appear on the match run according to that exception score or~~  
 426 ~~the calculated MELD score, whichever is higher.~~

427  
 428 A candidate who meets these requirements for a MELD or PELD score exception for  
 429 HCC will ~~be assigned~~ receive a score according to *Table 9-10* below.  
 430

431

Table 9-10: HCC Exception Scores

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

432

## 433 9.6 Waiting Time

### 434 9.6.A Waiting Time for Liver Candidates

435 Liver transplant candidates on the waiting list accrue waiting time within status 1A or 1B or any  
436 assigned MELD or PELD score.

437

438 A candidate's waiting time at a MELD or PELD score equals the sum of *all* the following:

439

- 440 1. ~~Waiting time at current MELD or PELD score~~
- 441 2. ~~Previous waiting time accrued during an earlier period at current MELD or PELD score~~
- 442 3. ~~Previous total waiting time accrued at any MELD or PELD score higher than the current~~  
443 ~~MELD or PELD score~~
- 444 4. ~~Previous total waiting time accrued at status 1A and status 1B~~

445 Status 1A or 1B candidates will receive waiting time points based on their waiting time in that  
446 status, according to *Policy 9.7.A: Points for Waiting Time*. Status 1A candidates begin accruing  
447 waiting time at status 1A upon submission of the earliest *Liver Status 1A or 1B Justification Form*  
448 for status 1A. Status 1B candidates begin accruing waiting time at status 1B upon submission of  
449 the earliest *Liver Status 1A or 1B Justification Form* for status 1B.

450

451 Candidates with a MELD or PELD score begin accruing waiting time when the candidate is first  
452 registered as an active liver candidate on the waiting list.

453

454 Allocation MELD or PELD score waiting time is accrued as follows:

- 455 • If the candidate's allocation MELD or PELD score is a calculated MELD or PELD score,  
456 then allocation MELD or PELD score waiting time includes all waiting time at current or  
457 higher calculated MELD or PELD score. Waiting time at current or higher calculated  
458 MELD or PELD score includes *all* of the following:
  - 459 1. Waiting time at current calculated MELD or PELD score
  - 460 2. Previous waiting time accrued during an earlier period at current calculated  
461 MELD or PELD score
  - 462 3. Previous total waiting time accrued at any calculated MELD or PELD score higher  
463 than the current calculated MELD or PELD score
  - 464 4. Previous total waiting time accrued at status 1A and status 1B
- 465 • If the candidate's allocation MELD or PELD score is an exception MELD or PELD score,  
466 then allocation MELD or PELD score waiting time equals time since submission of  
467 earliest approved or assigned MELD or PELD exception request.

468

469

## 9.8 Liver Allocation, Classifications, and Rankings

470

Unless otherwise stated, all mentions of MELD or PELD in this section reference a candidate's ~~match~~ allocation MELD or PELD score.

471

472

473

### 9.8.D Sorting Within Each Classification

474

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

475

476

1. Total waiting time and blood type compatibility points (highest to lowest), according to *Policy 9.7: Liver Allocation Points*

477

478

2. Total waiting time at status 1A (highest to lowest)

479

480

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

481

482

1. Total waiting time and blood type compatibility points (highest to lowest), according to *Policy 9.7: Liver Allocation Points*

483

484

2. Total waiting time at status 1B (highest to lowest)

485

486

Within each MELD or PELD score allocation classification, all candidates are sorted in the following order:

487

488

489

1. Allocation MELD or PELD score (highest to lowest)

490

~~2. Identical blood types, compatible blood types, then incompatible blood types~~

491

~~3. Waiting time at the current or higher MELD or PELD score (highest to lowest)~~

492

~~4. Time since submission of initial approved MELD or PELD exception request (highest to lowest)~~

493

494

2. Blood type compatibility (identical, compatible, then incompatible)

495

3. Allocation MELD or PELD score type (calculated then exception)

496

4. Allocation MELD or PELD score waiting time (highest to lowest)

497

5. Total waiting time (highest to lowest)