

Briefing to the OPTN Board of Directors on

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 9.5: Specific Standardized MELD or PELD Score Exceptions

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

Policy 9.5.B: Requirements for Cystic Fibrosis (CF) MELD or PELD Score Exceptions

Policy 9.5.C: Requirements for Familial Amyloid Polyneuropathy (FAP) MELD or PELD Score Exceptions

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

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

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

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

Board of Directors Date:

June 14, 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.¹ 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. The Committee selected this method to provide clarity to patients, who would be assigned a single MELD score based on their listing program. However, it also means that two exception candidates with the same exception diagnosis listed at different transplant programs may receive different MELD exception scores.

Under this proposal, MMaT would be calculated around the donor hospital instead of the transplant program. 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 it is no longer practical to sort exception candidates 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 registered on the waitlist before turning 18 are ranked ahead of candidates registered on the waitlist candidates after turning 18. The sorting of pediatric candidates ahead of adult candidates of the same MELD or PELD and blood type compatibility is a post-public comment change made in response to feedback submitted throughout the public comment period. Candidates with a calculated MELD or PELD score will be ranked ahead of candidates with an exception score, when MELD or PELD score, blood type compatibility, and age category at time of registration (adult or pediatric) is the same. Candidates with a calculated MELD or PELD score will then be sorted based on time at score or higher while exception candidates will be sorted by time since submission of earliest approved exception.

This proposal intends to better align the geographic units used in the calculation of MMaT with the geographic units used in liver allocation.

The proposal to calculate MMaT around the donor hospital was generally supported throughout public comment. There was some opposition to the originally proposed changes to sorting within classifications. Specifically, the community was concerned with the proposed sorting of candidates with a calculated MELD or PELD ahead of candidates with an exception MELD or PELD with the same MELD or PELD score and blood type compatibility. The OPTN Liver and Intestinal Organ Transplantation Committee (the Committee) has updated the proposal to address these concerns.

¹ *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/>

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.² 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.^{3,4} 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.⁵

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.⁶ However, 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 transplant programs

² The calculation for the MELD and PELD scores can be found in OPTN Policy, Available at <https://optn.transplant.hrsa.gov/>.

³ *Proposal to Establish a National Liver Review Board*, OPTN Liver and Intestinal Organ Transplantation Committee, June 2017, Available at <https://optn.transplant.hrsa.gov/>

⁴ 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.

⁵ *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/>

⁶ *Ibid.*

would even out over time.⁷ 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 28.⁸ 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 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 no longer 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 better align the geographic units used in the calculation of MMaT with the geographic units used in liver allocation, as well as to improve access for pediatric candidates.

⁷ Ibid.

⁸ These MMaT scores are current as of the drafting of this document on April 13, 2021.

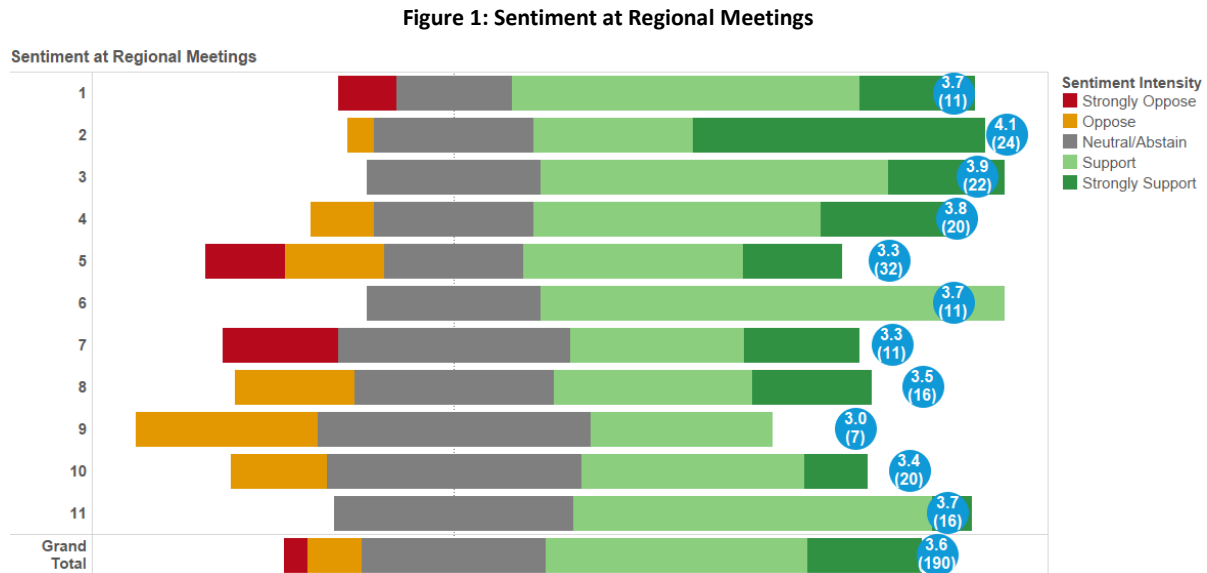
The Committee puts forth this proposal to address the situation described above based on initial experience with the NLRB and AC policy. The Committee reviewed and discussed post-AC implementation data and noted that the data represented a small time period and was impacted by the COVID-19 pandemic. Despite a lack of quantitative analysis showing a disparity, the Committee determined that the situation described above warrants a change.⁹

Sentiment from Public Comment

The proposal was out for public comment from January 21, 2021 to March 23, 2021. The proposal was presented at 11 regional meetings and received additional feedback on the OPTN website. The proposal was presented to the OPTN Pediatric Transplantation Committee and the OPTN Transplant Coordinators Committee.

Most comments supported the proposal to calculate MMaT around the donor hospital, but some concerns were raised regarding the proposed changes to sorting candidates of the same MELD or PELD score and blood type compatibility.

In all regions besides Region 9, the proposal received more votes in support or strong support than votes in opposition or strong opposition.¹⁰ Public comment sentiment from each of the 11 OPTN regions is shown in **Figure 1**.¹¹

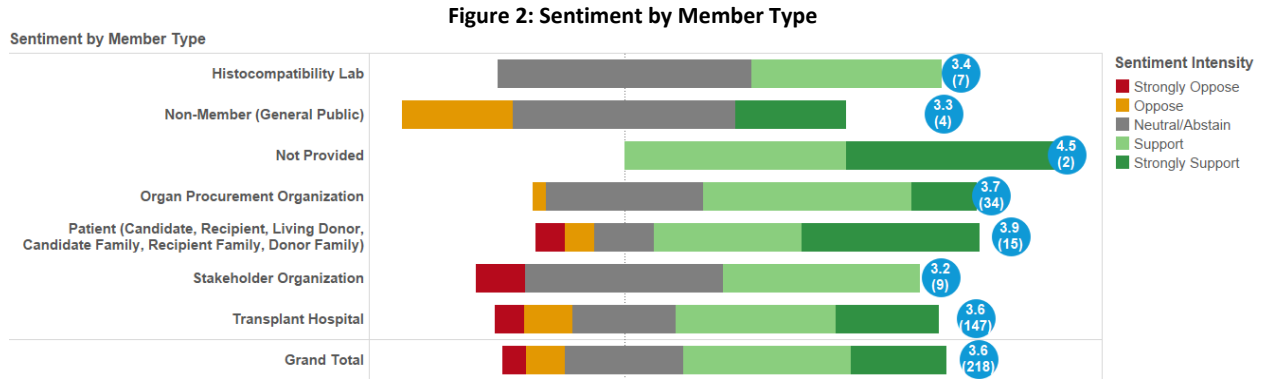


⁹ See OPTN Liver and Intestinal Organ Transplantation Committee meeting summary, October 22, 2020. Available at <https://optn.transplant.hrsa.gov/>

¹⁰ In Region 9 the vote was as follows: 0 strongly support, 2 support, 3 neutral/abstain, 2 oppose, 0 strongly oppose

¹¹ This chart shows the sentiment for the public comment proposal. Sentiment is reported by the participant using a 5-point Likert scale (1-5 representing Strongly Oppose to Strongly Support). Sentiment for regional meetings only includes attendees at that regional meeting. Region 6 uses the average score for each institution. The circles after each bar indicate the average sentiment score and the number of participants is in the parentheses

Public comment sentiment by member type is below in **Figure 2**.¹²



A number of transplant societies and organizations provided feedback on the proposal throughout public comment, including the American Society of Transplant (AST), the American Society of Transplant Surgeons (ASTS), the Society for Pediatric Liver Transplantation (SPLIT), the Association of Organ Procurement Organizations (AOPO), NATCO, the Global Liver Institute (GLI), and the North American Society for Pediatric Gastroenterology, Hepatology, and Nutrition (NASPGHAN).

The AST supported the use of MMaT around the donor hospital, but expressed concerns about the impact of the proposed sorting option on pediatric candidates and exception candidates more generally. The AST also noted that the AC policy has only been in place for a short period of time, much of which has been during the COVID-19 pandemic, and the true impact of AC has not yet been seen.

The ASTS generally supported the proposal but expressed a number of concerns including the impact on exception candidates and incorporating additional complexity into the liver allocation system. The ASTS also suggested capping MMaT-3 exception scores at 28, using a 250 NM circle to calculate MMaT around the donor hospital, calculating MMaT on a more frequent basis, not making a distinction between approved and assigned exceptions, and determining the MELD-Na equivalent of MELD 15. The ASTS recommended that candidates be sorted in the following order: candidates with a calculated PELD score, candidates with a calculated MELD score, candidates with a PELD exception, and finally candidates with a MELD exception.

The main theme throughout public comment was that sorting candidates with a calculated MELD or PELD ahead of candidates with a MELD or PELD exception score, when MELD or PELD score and blood type compatibility are equal, would disproportionately impact pediatric candidates, particularly adolescent candidates, and decrease their ability to access transplant when competing with adult candidates. This concern was discussed at seven of the OPTN Regional meetings and was noted in 19 of the 40 public comments submitted on the OPTN website.¹³ The Committee reviewed data to understand the magnitude of the concern, and decided to include a post-public comment change to sort pediatric

¹² This chart shows the sentiment for the public comment proposal. Sentiment is reported by the participant using a 5-point Likert scale (1-5 representing Strongly Oppose to Strongly Support). Sentiment by member type includes all comments regardless of source (regional meeting, committee meeting, online, fax, etc.) The circles after each bar indicate the average sentiment score and the number of participants is in the parentheses.

¹³ The concern was not noted at the Region 3, 9, 10, and 11 meetings. All public comments submitted on the proposal are available at <https://optn.transplant.hrsa.gov/>.

candidates (candidates registered prior to turning 18) ahead of adult candidates (candidates registered after turning 18) of the same MELD or PELD score and blood type compatibility.¹⁴ This post-public comment change is described in further detail in the Proposal for Board Consideration section below.

Other common themes in public comment included a lack of post-AC data to show a quantified disparity in access to transplant and no Liver Simulation Allocation Model (LSAM) modeling to understand impact of the change on waitlist metrics. Comments also noted that there has not been enough time under the AC system to allow for MMaT to equalize across the nation and the proposal is complicated and will be especially difficult to explain to candidates and their caregivers.

Proposal for Board Consideration

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 the same.

Currently, 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

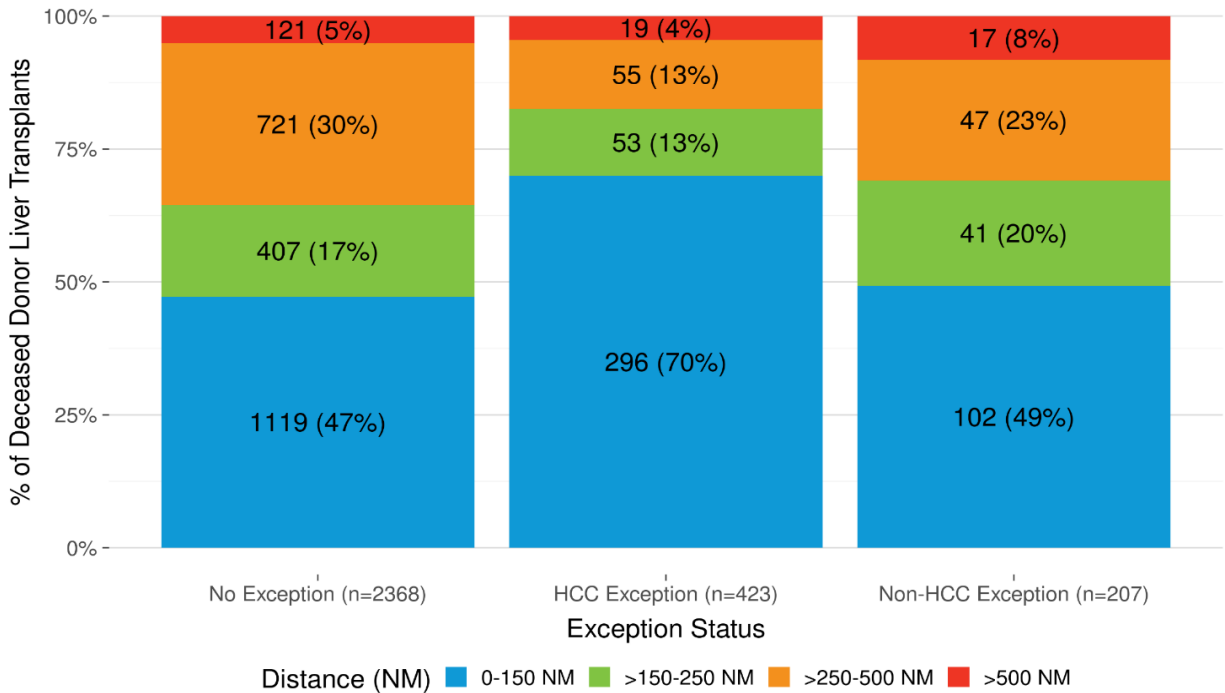
The first question the Committee considered in developing MMaT around the donor hospital was what initial circle size should be used in the calculation. They considered 150 NM, 250 NM, and 500 NM options and ultimately determined that utilizing a 150 NM circle around the donor hospital best reflects the MELD score needed to access transplant in the area around the donor hospital.¹⁵

¹⁴ See OPTN Liver and Intestinal Organ Transplantation Committee meeting summary, April 2, 2021. Available at <https://optn.transplant.hrsa.gov/>

¹⁵ See OPTN Liver and Intestinal Organ Transplantation Committee meeting summary, October 22, 2020. Available at <https://optn.transplant.hrsa.gov/>

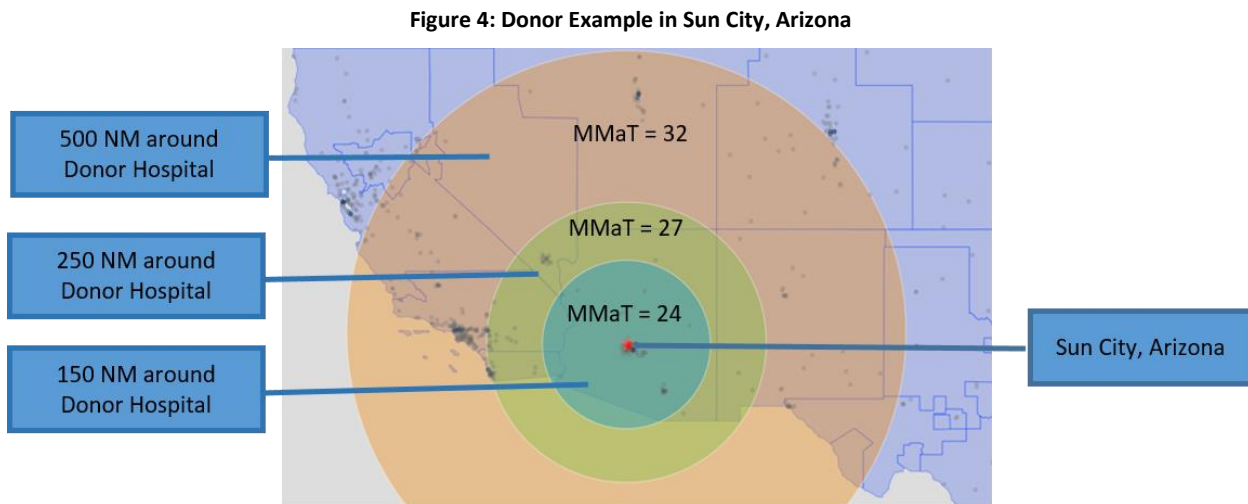
Figure 3 shows that, since the implementation of the AC policy, the majority of exception candidates have been transplanted with organs from donors within 150 NM of the donor hospital. For candidates with an HCC exception, the proportion of transplants that were performed within 150 NM of the donor hospital is 70%, while for non-HCC exceptions, it is 49%. Based on this information, it is 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.¹⁶

Figure 3: Deceased Donor, Liver-Alone Transplants by Exception Status and Distance from Donor Hospital to Transplant Program, during 2/4/2020-8/4/2020



¹⁶ See OPTN Liver and Intestinal Organ Transplantation Committee meeting summary, October 22, 2020. Available at <https://optn.transplant.hrsa.gov/>

To highlight the Committee's decision, **Figure 4** depicts an example of the proposed approach for a donor based 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 25. 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 access transplant 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, with most exception candidates therefore having a score equal to MELD 24 (MMaT-3). 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 25. 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.^{17,18} The Committee agreed 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.¹⁹ The Committee used the same rationale to rule out the use of a 500 NM circle.²⁰

Utilizing either a 250 NM or 500 NM circle would have some benefits. Primarily, a larger circle would attenuate some of the differences between high MELD and low MELD areas that are in close proximity. This can also be 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 candidates registered at transplant programs in Phoenix, AZ, but exception candidates in San Diego, CA are ranked relatively lowly compared to candidates with a

¹⁷ 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.

¹⁸ See OPTN Liver and Intestinal Organ Transplantation Committee meeting summary, October 22, 2020. Available at <https://optn.transplant.hrsa.gov/>

¹⁹ Ibid.

²⁰ Ibid.

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 aligned with the MMaT in southern California. In addition, basing the MMaT calculation on either a 250 NM or 500 NM circle would reduce variability in MMaT scores across the nation. However, it is more important to ensure MMaT reflects the MELD score needed to 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.²¹

The use of a 150 NM circle as the initial circle size for calculating the MMaT around the donor hospital was supported throughout public comment. The ASTS and Region 10 supported using a 250 NM circle but the Committee agreed with the original rationale for using a 150 NM circle and did not change this aspect of the proposal in response to public comment.

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.²² 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. There is no reason to deviate from the ten transplant minimum, as this number ensures that there is a sufficiently large cohort of recent transplants to calculate MMaT. However, it is important to ensure that the MMaT for a particular donor hospital is not based on transplants performed at a single 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 proposed policy will 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 PELD 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.²³

²¹ Ibid.

²² Qualifying transplants is defined as those transplants included in the MMaT calculation. Additional details are provided in subsequent sections of the proposal.

²³ See OPTN Liver and Intestinal Organ Transplantation Committee meeting summary, October 22, 2020. Available at <https://optn.transplant.hrsa.gov/>

This aspect of the proposal was supported throughout the public comment period and no changes were made to the minimum cohort size needed to calculate MMaT for a donor hospital.

When discussing the minimum cohort size needed to calculate the MMaT for each donor hospital, the Committee recognized 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 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 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).²⁴ However, aligning the MMaT calculation circles with the allocation circles is not necessary and increasing in 50 NM increments creates 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.²⁵

To support their decision, 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 5**, 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.²⁶

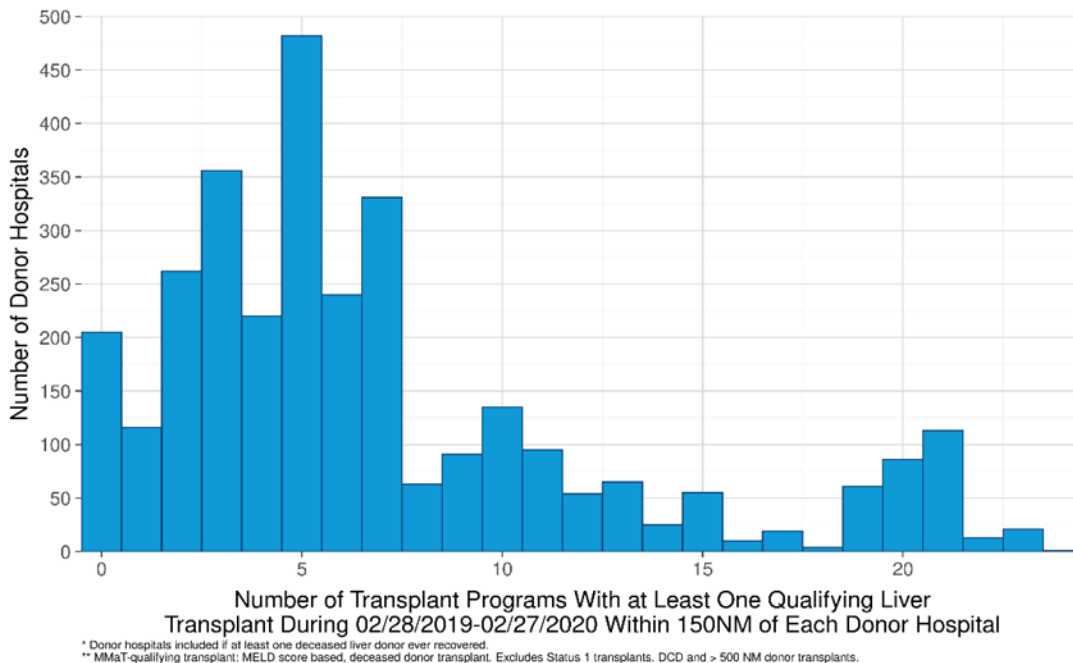
This part of the proposal was supported throughout public comment and no post-public comment changes were made.

²⁴ Ibid.

²⁵ Ibid.

²⁶ Ibid.

Figure 5: 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 around the transplant program, 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 same exclusions remain for the MMaT around the donor hospital, as including these transplants may disincentivize the use of these organs.²⁷

In addition, the current MMaT calculation is updated twice a year based on a cohort from a prior 365 day period. The same timeframe and update schedule remain appropriate, as these two aspects of the current MMaT calculation work well and there is no reason to deviate from the current process.²⁸

These parts of the proposal were supported throughout public comment. The ASTS suggested updating the MMaT scores every three months. However, the Committee agreed that this would be too short of a

²⁷ See OPTN Liver and Intestinal Organ Transplantation Committee meeting summary, October 22, 2020. Available at <https://optn.transplant.hrsa.gov/>

²⁸ Ibid.

timeframe as exception requests are extended every 90 days and updating the MMaT more frequently would lead to a lack of stability for candidates with a MELD or PELD exception.²⁹

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 described above. 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.³⁰ 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.

²⁹ See OPTN Liver and Intestinal Organ Transplantation Committee meeting summary, April 2, 2021. Available at <https://optn.transplant.hrsa.gov/>

³⁰ As of the drafting of this document, the MMaT for the transplant program in Hawaii is 23. In San Francisco, the MMaT is 33. The MMaT for the transplant program in Puerto Rico is 20. In Miami, the MMaT is 26.

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 the MMaT calculation reflects the MMaT in the Seattle, WA area. However, because the proposal increases 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.³¹

These aspects of the proposal were supported throughout public comment and no post-public comment changes were made.

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.³² MPaT is calculated using a national cohort because there fewer PELD transplants performed and these recipients are typically transplanted at higher PELD scores.³³ 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 alter how MPaT is calculated. This was not changed as a result of public comment feedback.

Sorting within Liver Allocation

Within each allocation classification, liver candidates are currently 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)

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 will fluctuate based on the MMaT of the donor hospital and will only be known once the match is run. If

³¹ See OPTN Liver and Intestinal Organ Transplantation Committee meeting summary, October 22, 2020. Available at <https://optn.transplant.hrsa.gov/>

³² 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.

³³ *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/>

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 exception score of 24. MELD exception candidates will no longer have a set 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. The proposal also sorts pediatric candidates ahead of adult candidates of the same MELD or PELD score and blood type compatibility, as well as candidates with a calculated MELD or PELD score ahead of candidates with an exception MELD or PELD score when MELD or PELD score, blood type compatibility, and age category (pediatric or adult) are the same.

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.³⁴ 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, blood type compatibility is the same, and age category is consistent. Similarly, the Committee determined 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, and age category at time of registration are equal.³⁵

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, it became evident that the two different 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.³⁶ Therefore, in most of the sample scenarios, exception candidates were being ranked ahead of candidates with a

³⁴ See OPTN Liver and Intestinal Organ Transplantation Committee meeting summary, August 7, 2020. Available at <https://optn.transplant.hrsa.gov/>

³⁵ Ibid.

³⁶ The laboratory update schedule is described in OPTN Policy which is available at <https://optn.transplant.hrsa.gov/>

calculated MELD or PELD score when the candidates had the same MELD or PELD score and blood type compatibility.³⁷

In the proposal that was released for public comment, the Committee proposed 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. This aspect of the proposal received significant public comment feedback, particularly from the pediatric community, who was concerned that the proposed sorting option would decrease pediatric access to adult donor offers. In fact, the proposal was presented to the OPTN Pediatric Committee prior to public comment and their concerns were noted in the public comment proposal.³⁸ In response to this feedback, the Committee has changed the proposal to sort pediatric candidates ahead of adult candidates after MELD or PELD score and blood type compatibility, while subsequently sorting candidates with a calculated MELD or PELD ahead of candidates with a MELD or PELD exception.

Post-Public Comment Changes to Address Impact on Pediatric Candidates

To address the concern raised in public comment, the Committee is proposing an additional level of sorting that will sort candidates registered on the waitlist before turning 18 ahead of candidates registered on the waitlist after turning 18, after MELD and PELD score and blood type compatibility and before sorting lab candidates ahead of exception candidates.

The original proposal to rank candidates with a calculated MELD or PELD score ahead of candidates with a MELD or PELD exception score of the same MELD or PELD score and blood type compatibility was supported by the clinical opinion of the Committee and the published literature which showed 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.^{39,40,41, 42}

However, these analyses predate a number of liver allocation policy changes that were designed to equalize waitlist outcomes between HCC and non-HCC candidates and research suggests that the policy changes have increased equity between HCC and non-HCC candidates, with some advantage for HCC

³⁷ See OPTN Liver and Intestinal Organ Transplantation Committee meeting summary, August 7, 2020. Available at <https://optn.transplant.hrsa.gov/>

³⁸ *Calculate Median MELD at Transplant around the Donor Hospital and Update Sorting within Liver Allocation*, OPTN Liver and Intestinal Organ Transplantation Committee, January 2021, Available at <https://optn.transplant.hrsa.gov/>

³⁹ 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>.

⁴⁰ 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>.

⁴¹ 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>.

⁴² 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>.

candidates remaining.^{43,44,45} It is also important to note that the 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.⁴⁶ More importantly, the available evidence is restricted to adult candidates and does not examine the difference in waitlist outcomes for pediatric candidates with a calculated MELD or PELD compared to pediatric candidates with a MELD or PELD exception score.

Public comment feedback was clear that the research cited in the original proposal did not include data on pediatric candidates and that there is no evidence to show that pediatric candidates with a MELD or PELD exception score are at a lower risk of waitlist mortality than adult candidates with a calculated MELD or PELD. More so, comments noted that the current PELD score has been shown to underestimate waitlist mortality in pediatric candidates and more than 40% of pediatric candidates require an exception score to reflect their true risk of waitlist mortality.^{47, 48} There was also a common concern that any reduction in pediatric access to adult donor offers could decrease the number of split liver opportunities, which in turn may result in fewer transplants being performed.

As a result of this feedback and a review of post-AC data, the Committee has changed the proposal to include another level of sorting that will rank pediatric candidates ahead of adult candidates of the same MELD or PELD score and blood type compatibility before sorting based on exception or calculated MELD or PELD score.

To inform the decision to make a post-public comment change to the sorting aspect of the proposal, the Committee reviewed updated data to better understand the potential impact on pediatric candidate access to adult donor offers.⁴⁹ This data showed that since the implementation of AC, 16.9% (n=55) of pediatric recipients age 0-11 and 33.3% (n=39) of adolescent recipients age 12-17 were transplanted with an adult donor. The Committee reviewed snapshots of the waitlist at given points in time, which showed that at higher MELD or PELD scores (greater than or equal to 29) a larger proportion of pediatric candidates were listed with an exception, while a larger number of adults were listed with calculated MELD or PELD scores, meaning that a large proportion of pediatric candidates (those with a MELD or PELD exception) would be ranked behind a large proportion of adult candidates (those with a calculated MELD or PELD score) at a given MELD or PELD score and with the same blood type compatibility. There is no strong evidence to show that pediatric candidates with a MELD or PELD exception experience better waitlist outcomes, like adults with a MELD or PELD score exception, when compared to

⁴³ *Proposal to Delay HCC Exception Score Assignment*, OPTN Liver and Intestinal Organ Transplantation Committee, November 2014

⁴⁴ *Proposal to Cap the HCC Exception Score at 34*, OPTN Liver and Intestinal Organ Transplantation Committee, November 2014

⁴⁵ 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>.

⁴⁶ 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

⁴⁷ Hsu, Evelyn, et al. "Improving the Predictive Ability of the Pediatric End-Stage Liver Disease Score for Young Children Awaiting Liver Transplant." *American Journal of Transplantation*, vol. 21, no. 1, 2020, pp. 222–228., doi:10.1111/ajt.15925.

⁴⁸ Braun, H. J., E. R. Perito, J. L. Dodge, S. Rhee, and J. P. Roberts. "Nonstandard Exception Requests Impact Outcomes for Pediatric Liver Transplant Candidates." *American Journal of Transplantation* 16, no. 11 (2016): 3181-191. doi:10.1111/ajt.13879.

⁴⁹ The data was presented to the Committee during their meeting on April 2, 2021. The entire report is included in the appendix. The pre-policy cohort is defined as 2/3/2019-2/3/2020. The post-policy cohort is defined as 2/4/2020-2/3/2021.

candidates with a calculated MELD or PELD score. Based on this information, the Committee agreed that the originally proposed sorting scenario had the potential to negatively impact pediatric candidate access to adult donor offers and a post-public comment change was needed.⁵⁰

Having reached the conclusion that the original proposal had the potential to decrease pediatric access to adult donor offers, the Committee reviewed three potential post-public comment changes to address the concern.⁵¹ The three options are listed below. The Committee ultimately decided to move forward with option three.

Table 1: Post-Public Comment Options

Option 1	Option 2	Option 3
After MELD/PELD and blood type compatibility, change sorting to:	After MELD/PELD and blood type compatibility, change sorting to:	After MELD/PELD and blood type compatibility, change sorting to:
<ol style="list-style-type: none"> 1. Pediatric exception candidates 2. Lab candidates (pediatric and adults) 3. Adult exception candidates 	<ol style="list-style-type: none"> 1. Pediatric exception candidates 2. Pediatric lab candidates 3. Adult lab candidates 4. Adult exception candidates 	<ol style="list-style-type: none"> 1. Pediatric lab candidates 2. Pediatric exception candidates 3. Adult lab candidates 4. Adult exception candidates

In each of the options considered, candidates with a MELD or PELD exception score and candidates with a calculated MELD or PELD score are still sorted separately. This differentiation is needed because the waiting time for these candidates is calculated differently (time since submission of earliest approved exception versus time at score or higher), and sorting them together would lead to incongruity.

The Committee decided to move forward with the third option because it addresses the concern raised throughout public comment by prioritizing pediatric candidates ahead of adult candidates of the same MELD or PELD and blood type compatibility. It also maintains the same pattern of sorting candidates with a calculated MELD or PELD score ahead of candidates with a MELD or PELD exception score between pediatric and adult candidates. In reviewing the snapshots of the waitlist, there were fewer pediatric candidates with calculated MELD or PELD scores greater than or equal to MELD or PELD 29 than pediatric candidates with a MELD or PELD exception score greater than or equal to 29. Therefore, it is appropriate to put the pediatric candidates with a calculated MELD or PELD score ahead of pediatric candidates with a MELD or PELD exception score so that the pediatric candidates with a calculated MELD or PELD score are not ranked behind a block of pediatric candidates with a MELD or PELD exception score.⁵² The Pediatric Committee reviewed the same data and potential post-public comment changes and supported option three as well.⁵³

⁵⁰ See OPTN Liver and Intestinal Organ Transplantation Committee meeting summary, April 2, 2021. Available at <https://optn.transplant.hrsa.gov/>

⁵¹ See OPTN Liver and Intestinal Organ Transplantation Committee meeting summary, April 2, 2021. Available at <https://optn.transplant.hrsa.gov/>

⁵² Ibid.

⁵³ See OPTN Pediatric Transplantation Committee meeting summary, March 30, 2020. Available at <https://optn.transplant.hrsa.gov/>

In discussing the proposed post-public comment change to sort pediatric candidates ahead of adult candidates of the same MELD or PELD score and blood type compatibility, the Committee noted that pediatric candidates are a vulnerable population and additional priority is justified based on the specific needs of these candidates.⁵⁴ This is in alignment with the *Ethical Principles of Pediatric Organ Allocation*.⁵⁵

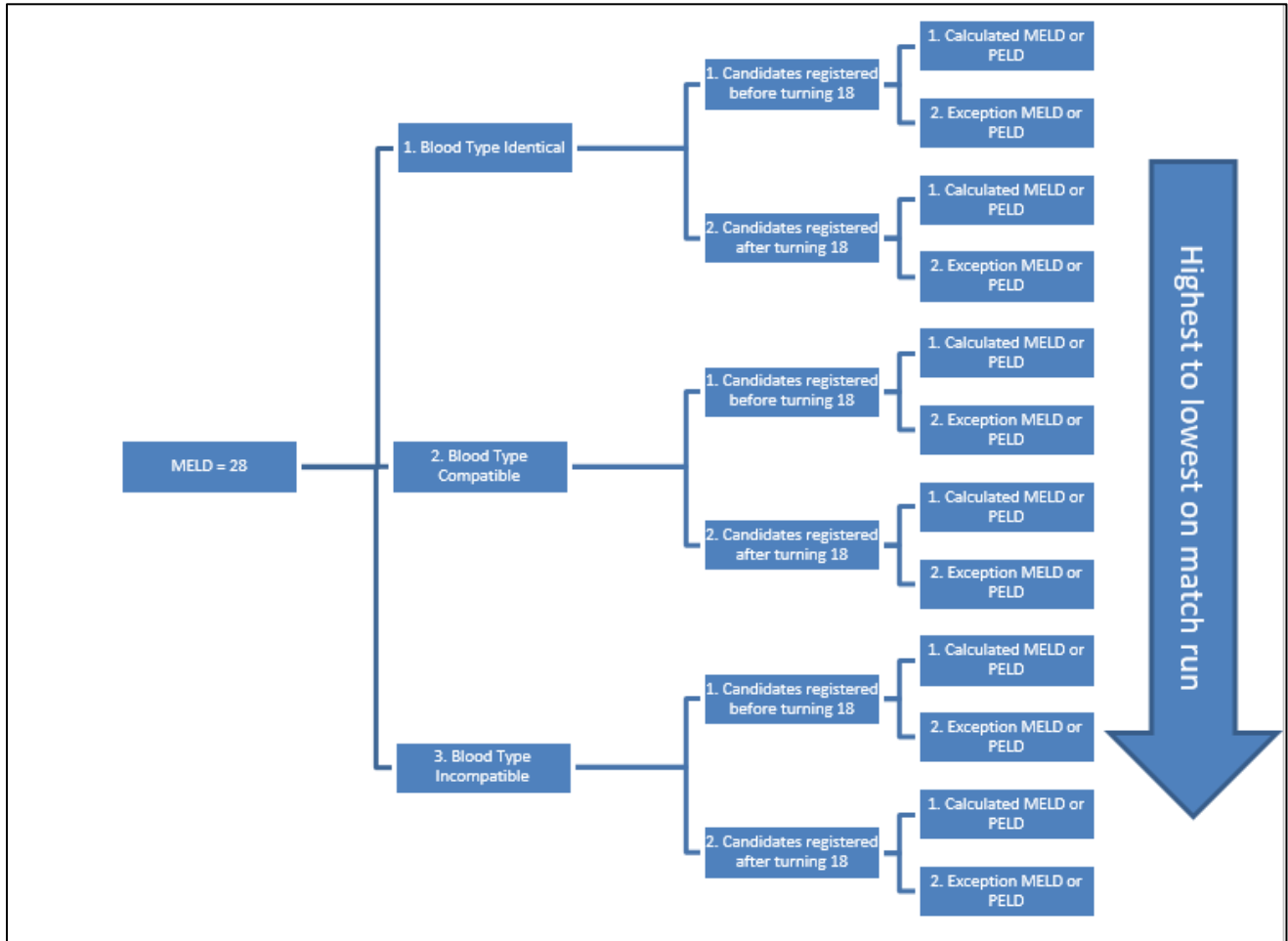
Figure 6 below depicts the proposed sorting algorithm beginning with a MELD or PELD score of 28. As a reminder, within each allocation classification, liver candidates would be sorted in the following order:

1. MELD or PELD score
2. Blood type compatibility (identical, compatible, then incompatible)
3. Age at time of registration on the liver waitlist (less than 18 years old followed by 18 years or older)
4. MELD or PELD score type (calculated then exception)
5. Waiting time:
 - a. For candidates with a calculated MELD or PELD: Time at the current or higher MELD or PELD score (highest to lowest)
 - b. For candidates with a MELD or PELD score exception: Time since submission of initial approved MELD or PELD exception request (highest to lowest)
6. Total waiting time (highest to lowest)

⁵⁴ See OPTN Liver and Intestinal Organ Transplantation Committee meeting summary, April 2, 2021. Available at <https://optn.transplant.hrsa.gov/>

⁵⁵ The Ethical Principles of Pediatric Organ Allocation are available at <https://optn.transplant.hrsa.gov/>

Figure 6: Sorting within Allocation Classifications



Additional Changes

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 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.⁵⁶

The Committee reviewed public comment feedback on this topic and elected to not make any post-public comment changes.

Minimum Exception Score

There is the possibility for a donor hospital to have an MMaT score below 18.⁵⁷ 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 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.

This change was supported throughout public comment and no post-public comment updates were made.

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.

⁵⁶ See OPTN Liver and Intestinal Organ Transplantation Committee meeting summary, November 6, 2020. Available at <https://optn.transplant.hrsa.gov/>

⁵⁷ See OPTN Liver and Intestinal Organ Transplantation Committee meeting summary, October 22, 2020. Available at <https://optn.transplant.hrsa.gov/>

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 update 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 for a specific purpose.⁵⁸ 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.

Throughout public comment, members noted that this aspect of the proposal would be difficult to explain to patients, candidates, and their caregivers. Candidates are accustomed to having a set MELD exception score. With this proposal, MELD exception scores will fluctuate with each match run, which could cause confusion in an already complex system. The Committee reviewed these concerns and agreed that the changes will need to be accompanied by adequate communication and education but determined that no post-public comment changes are needed as a result of this feedback.

New Donor Hospitals

In 2019, there was an average of 3.5 new donor hospitals added to UNetSM 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.

Clarification of Waiting Time

Upon further review of the proposed changes to policy language, it was necessary to clarify that the waiting time calculations specific to candidates with a calculated MELD or PELD and candidates with an exception score do not impact current policy regarding accrual of total waiting time while at an inactive status.⁵⁹

OPTN Policy 3.6.A states that liver candidates do not accrue waiting time while at an inactive status. Intestine candidates can accrue up to 30 days of waiting time while inactive. In the proposed policy language, candidates with a MELD or PELD exception score will be sorted based on time since submission of the earliest approved exception. This form of waiting time for exception candidates includes any time spent at an inactive status, which matches what is currently programmed.

⁵⁸ See OPTN Liver and Intestinal Organ Transplantation Committee meeting summary, November 6, 2020. Available at <https://optn.transplant.hrsa.gov/>

⁵⁹ See OPTN Liver and Intestinal Organ Transplantation Committee meeting summary, May 7, 2021. Available at <https://optn.transplant.hrsa.gov/>

Candidates with a calculated MELD or PELD score will be sorted based on time at current score or higher score. This form of waiting time does not include time at an inactive status. This matches what is currently programmed.

The Committee agreed that a post-public comment addition to the policy language was warranted to ensure these distinctions were clear.⁶⁰ The new language does not change to original intent of the proposal that was released for public comment.⁶¹

Liver-Intestine Candidates

Further clarification was needed in the policy language on the impact of the proposed changes on liver-intestine candidates.⁶² As a result, the updated language includes a number of post-public comment changes to ensure that the policy clearly delineates the effect on liver-intestine candidates.

Policy 9.1.F states adult liver-intestine candidates will receive a 10% increase in their MELD score while liver-intestine candidates under the age of 18 will receive 23 additional points to the MELD or PELD score. The updated language makes it more clear that liver-intestine points are included in time at current calculated score or higher calculated score. Liver-intestine points are included in time at score or higher in the current system and the Committee did not intend to change this as part of the proposal.

In addition, the updated language clarifies that liver-intestine candidates, whose allocation score is based on a calculated MELD or PELD score, should be considered as a calculated score for the purposes of sorting within classifications. If a liver-intestine candidate has an exception score that is higher than their calculated score plus liver-intestine points at the time of the match run, they will be considered an exception candidate.

These clarifications to the policy language do not change the Committee's original intent and are only meant to ensure the policy language is as unambiguous as possible.⁶³

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."⁶⁴ 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

⁶⁰ Ibid.

⁶¹ Ibid.

⁶² Ibid.

⁶³ Ibid.

⁶⁴ 42 CFR §121.4(a).

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 judgment⁶⁵** because it is an evidenced-based change relying on the following evidence:
 - Published literature showing that adult candidates with a calculated MELD score have historically worse waitlist outcomes than adult candidates with a MELD exception. Specifically, previously published literature has shown that adult 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 adult candidates with the same calculated MELD score as the HCC exception score.^{66,67} 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.⁶⁸
 - The Committee also cited their medical judgement and experience that, on average, an adult candidate with a calculated MELD presents is more medically urgent than an adult candidate that has a MELD or PELD score exception.⁶⁹
- **Seeks to achieve the best use of donated organs⁷⁰ 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.
 - The proposed changes to sorting within liver allocation classifications will further ensure that the most medically urgent candidates are appropriately prioritized for transplant.
- **Is designed to...promote patient access to transplantation⁷¹ by** giving similarly situated candidates equitable opportunities to receive an organ offer and improving access to transplant for pediatric candidates.
 - The proposal prioritizes pediatric candidates ahead of adult candidates of the same MELD or PELD score and blood type compatibility. This will increase access to transplant for pediatric candidates, an important, vulnerable population that NOTA requires the OPTN to “(M) recognize the differences in health and in organ transplantation issues between children and adults throughout the system and adopt criteria, policies, and procedures that address the unique health care needs of children.” The Committee recognized that pediatric candidates, especially adolescents, require access to adult

⁶⁵ 42 CFR §121.8(a)(1).

⁶⁶ 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>.

⁶⁷ 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>.

⁶⁸ 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>.

⁶⁹ See Acuity Circles Subcommittee meeting summary, August 12, 2020. Available at <https://optn.transplant.hrsa.gov/>

⁷⁰ 42 CFR §121.8(a)(2).

⁷¹ Id.

donor offers and altered the proposal to ensure pediatric candidates are provided sufficient access to these donor offers.⁷²

- Is “not...based on the candidate's place of residence or place of listing, except to the extent required by”⁷³ other factors in §121.8(a), because this proposal mitigates the effect of the candidate’s place of residence or place of listing by providing 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. Accounting for the candidate’s place of residence or place of listing in the way this proposal is designed is therefore required to promote access for similarly situated candidates.

This proposal also preserves the ability of a transplant program to decline an offer or not use the organ for a potential recipient,⁷⁴ and it is specific to an organ type, in this case livers.⁷⁵

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;

Alignment with OPTN Strategic Plan⁷⁶

Improve equity in access to transplants: This proposal will better align the geographic units used in the calculation of MMaT with the geographic units used in liver allocation.

Implementation Considerations

Member and OPTN Operations

This proposal will require changes to the UNet system and the implementation timeframe will be based on the specific requirements.

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.

⁷² See OPTN Liver and Intestinal Organ Transplantation Committee meeting summary, April 2, 2021. Available at <https://optn.transplant.hrsa.gov/>

⁷³ 42 CFR §121.8(a)(8).

⁷⁴ 42 CFR §121.8(a)(3).

⁷⁵ 42 CFR §121.8(a)(4).

⁷⁶ For more information on the goals of the OPTN Strategic Plan, visit <https://optn.transplant.hrsa.gov/governance/strategic-plan/>.

Operations affecting Transplant Hospitals

The primary operational impact on transplant hospitals involves the MMaT calculation being based around the donor hospital. Candidates with an exception will no longer have a set 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 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 applied to 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 if needed.

Potential Impact on Select Patient Populations

This proposal has the potential to impact a number of specific patient populations. The Committee decided not to model the proposal as the 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.⁷⁷

The Final Rule requires the OPTN to “consider whether to adopt transition procedures that would treat people on the waiting list and awaiting transplantation prior to the adoption or effective date of the revised policies no less favorably than they would have been treated under the previous policies” whenever organ allocation policies are revised.⁷⁸ The Committee acknowledged that there would potentially be candidates treated less favorably under the new policy, as their priority on the match run may shift due to the additional priority assigned to pediatric candidates, the additional priority assigned to calculated MELD or PELD candidates as compared to exception MELD or PELD candidates, and the use of MMaT around the donor hospital instead of MMaT around the transplant program.

First, adult candidates may see a slight decrease in access to donor offers due to the prioritization of pediatric candidates of the same MELD or PELD score and blood type compatibility. This decrease may be more noticeable for female candidates and candidates of small stature, as pediatric candidates may

⁷⁷ See OPTN Liver and Intestinal Organ Transplantation Committee meeting summary, October 22, 2020. Available at <https://optn.transplant.hrsa.gov/>

⁷⁸ 42 CFR §121.8(d).

receive livers from smaller adult donors.⁷⁹ However, the number of pediatric candidates at a given MELD or PELD score is relatively low compared to the number of adult candidates and any potential decrease in access to adult donor offers would be small and the benefit of greater access for pediatric candidates outweighed the small impact on adults.⁸⁰ Therefore, the Committee does not recommend any specific transition procedures pursuant to this particular policy change.

It is also likely that candidates with a MELD or PELD exception score 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, blood type compatibility, and are in the same age group (pediatric or adult). The extent of this impact was not quantified but was hypothesized to be small by the Committee. The Committee therefore does not recommend any specific transition procedures pursuant to this particular policy change.

Candidates with a MELD or PELD exception score in a high MELD area may also see decreased access to transplant as a result of this proposal. Under the MMaT around the transplant program system, these candidates are assigned higher exception scores due to being registered at a transplant program with a high MMaT. This proposal is intended to increase equity by assigning exception scores relative to the same MMaT on a match run. The Committee therefore does not recommend any specific transition procedures pursuant to this particular policy change.

The Committee discussed one transitional procedure as part of the proposal. Currently, the system does not distinguish between time spent at a higher exception or higher calculated score. In the 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.⁸¹ 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 accrued at calculated scores, including liver-intestine points. 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.

Projected Fiscal Impact

Projected Impact on Histocompatibility Laboratories

There is no expected fiscal impact for histocompatibility laboratories.

⁷⁹ See OPTN Liver and Intestinal Organ Transplantation Committee meeting summary, April 2, 2021. Available at <https://optn.transplant.hrsa.gov/>

⁸⁰ Ibid.

⁸¹ See OPTN Liver and Intestinal Organ Transplantation Committee meeting summary, April 14, 2020. Available at <https://optn.transplant.hrsa.gov/>

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

A significant development effort was facilitated by Policy and Community Relations, including frequent committee and subcommittee meetings, as well as internal team meetings to ensure alignment across IT, Research, and other internal stakeholders.

An Enterprise IT implementation effort, estimated at 7,700 hours, involves updating the calculation of the MMaT score based upon the revised requirements; updating and testing submission of liver exception requests; and updating and testing the liver allocation system to determine the allocation MELD of PELD score, allocation waiting time, and sorting of candidates. A Small Research implementation effort includes updates to analysis datasets and OPTN website data, and a Very Small Professional Education effort will update existing educational offerings.

Approximately 100 hours of ongoing monitoring from Research is anticipated in order to create evaluation reports and to update MMaT values twice a year. Communications anticipates 40 hours per year following implementation to promote training and education.

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.”⁸²

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.”⁸³ 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), age group (i.e., <2, 2-11, 12-17, 18+ years old), and other features as appropriate.

⁸² 42 CFR §121.8(a)(7).

⁸³ 42 CFR §121.8(a)(6).

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
- Distribution of transplant recipients by donor age and recipient age
- Other metrics deemed relevant and necessary to the evaluation of the policy by the Liver and Intestinal Transplantation Committee at time of analysis

Conclusion

This proposal 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 registered on the liver waitlist before turning 18 will be ranked ahead of candidates registered on the liver waitlist after turning 18. Subsequently, candidates with a calculated MELD or PELD score will be sorted 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 Language

1 **RESOLVED**, that the creation of *Policy 9.4.E: MELD or PELD Exception Scores Relative to Median MELD*
 2 *or PELD at Transplant*, as well as changes to *Policies 1.2: Definitions, 9.4.A: MELD or PELD Score*
 3 *Exception Requests, 9.4.C.ii: Other MELD or PELD Score Exception Extensions, 9.4.D: Calculation of*
 4 *Median MELD or PELD at Transplant, 9.5: Specific Standardized MELD or PELD Score Exceptions, 9.5.A:*
 5 *Requirements for Cholangiocarcinoma (CCA) MELD or PELD Score Exceptions, 9.5.B: Requirements for*
 6 *Cystic Fibrosis (CF) MELD or PELD Score Exceptions, 9.5.C: Requirements for Familial Amyloid*
 7 *Polyneuropathy (FAP) MELD or PELD Score Exceptions, 9.5.D: Requirements for Hepatic Artery*
 8 *Thrombosis (HAT) MELD or PELD Score Exceptions, 9.5.E: Requirements for Hepatopulmonary*
 9 *Syndrome (HPS) MELD or PELD Score Exceptions, 9.5.F: Requirements for Metabolic Disease MELD or*
 10 *PELD Score Exceptions, 9.5.G: Requirements for Portopulmonary Hypertension MELD or PELD Score*
 11 *Exceptions, 9.5.H Requirements for Primary Hyperoxaluria MELD or PELD Score Exceptions, 9.5.I:*
 12 *Requirements for Hepatocellular Carcinoma (HCC) MELD or PELD Score Exceptions, 9.5.I.vii Extension*
 13 *of HCC Exceptions, 9.6.A: Waiting Time for Liver Candidates, 9.8: Liver Allocation, Classifications and*
 14 *Rankings, 9.8.D: Sorting Within Each Classification*, as set forth below, are hereby approved, effective
 15 pending implementation and notice to OPTN members.

16
 17 **FURTHER RESOLVED**, that for the purposes of calculating time at current score or higher score for each
 18 candidate registration with a calculated MELD or PELD score, time at current score or higher score
 19 shall include any time accrued prior to the implementation date of this proposal at a higher MELD or
 20 PELD score, including MELD or PELD exception scores and liver-intestine points.

21
 22 **FURTHER RESOLVED**, that changes to the National Liver Review Board Operational Guidelines, as set
 23 forth below, are hereby approved, effective pending implementation and notice to OPTN members.

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.

24 1.2 Definitions

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

26 A

27 **Allocation MELD or PELD Score**

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

31 32 **Approved MELD or PELD Exception**

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

35

36 **Assigned MELD or PELD Exception**

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

39 **M**

40 **Match MELD or PELD Score**

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

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

46 **9.4 MELD or PELD Score Exceptions**

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

51 **9.4.A MELD or PELD Score Exception Requests**

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

- 53
- 54 1. ~~A request for a specific MELD or PELD score either:~~
 - 55 a. An adjustment of a certain amount of points higher or lower than MMat or
 56 MPaT or
 - 57 b. A specific MELD or PELD score of 40 or higher
 - 58 2. ~~A justification of how the medical criteria supports that the candidate has a higher~~
 59 ~~MELD or PELD score~~
 - 60 3. ~~An explanation of how the candidate's current condition is comparable to that of other~~
 61 ~~candidates with that MELD or PELD score~~
 - 62 2. A justification that outlines how a candidate's medical condition warrants an exception
 63 and the specific score being requested.

64

65 ~~Approved MELD or PELD exceptions scores~~ are valid for 90 days from the date the exception is
 66 approved or assigned.

68 **9.4.C MELD or PELD Score Exception Extensions**

69 **9.4.C.ii Other MELD or PELD Score Exception Extensions**

70 A candidate's approved or assigned exception will be maintained if the transplant
 71 ~~hospital program~~ enters a MELD or PELD Exception Score Extension Request before the
 72 due date, even if the NLRB does not act before the due date. If the extension request is
 73 denied or if no MELD or PELD Exception Score Extension Request is submitted before

74 the due date, then the candidate will be assigned the calculated MELD or PELD score
75 based on the most recent reported laboratory values.

76
77 Each approved or assigned MELD or PELD exception extension is valid for an additional
78 90 days beginning from the day that the previous exception or extension expired.
79

80 **9.4.D Calculation of Median MELD or PELD at Transplant**

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

84
85 ~~Median PELD at transplant (MPaT) is calculated by using the median of the PELD scores at the~~
86 ~~time of transplant of all recipients less than 12 years old in the nation.~~

87
88 ~~The MMaT and MPaT calculations exclude recipients who are either of the following:~~

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

92
93 ~~The OPTN will recalculate the MMaT and MPaT twice a year based on an updated cohort. The~~
94 ~~updated cohort will include transplants over a prior 365 day period. If there have been fewer~~
95 ~~than 10 qualifying transplants within 250 nautical miles of a transplant hospital in the cohort,~~
96 ~~the MMaT will be calculated based on a total of a 730 day period.~~

97
98 For each donor hospital, the OPTN will calculate the MMaT based on a cohort of recipients
99 transplanted at programs at or within 150 nautical miles of the donor hospital in a prior 365 day
100 period. If there are either less than two active liver transplant programs or less than 10
101 qualifying transplants within 150 nautical miles of the donor hospital, the geographic area used
102 to calculate the MMaT will increase in 50 nautical mile increments until two active liver
103 transplant programs and 10 qualifying transplants are included in the MMaT cohort.

104
105 The MMaT is calculated by using the median of the MELD scores at the time of transplant of all
106 recipients within the geographic area defined above that are at least 12 years old at the time of
107 transplant. Recipients are excluded who are either of the following:

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

111
112 If a transplant program has not performed at least one transplant included in the MMaT
113 calculation, the program is not included in the MMaT cohort.

114
115 If there are less than 10 qualifying transplants within 250 nautical miles of a donor hospital in
116 Hawaii or Puerto Rico, the MMaT will be calculated based on a total of 730 days. There does not
117 need to be two transplant programs within 250 nautical miles of donor hospitals in Hawaii or
118 Puerto Rico.

119

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

122 Recipients are excluded who are either of the following:

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

126

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

129

130 **9.4.E: MELD or PELD Exception Scores Relative to Median MELD or PELD at Transplant**

131 A match run will provide MELD exception candidates on the match run a MELD exception score
132 relative to the MMaT for the donor hospital. PELD exception candidates are provided a PELD
133 exception score relative to the MPaT for the nation. If a candidate's exception score relative to
134 MMaT or MPaT would be lower than 15, the candidate's exception score will be 15.

135

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

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

149

150 **9.5 Specific Standardized MELD or PELD Score Exceptions**

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

154

- 155 • Cholangiocarcinoma (CCA), according to *Policy 9.5.A: Requirements for Cholangiocarcinoma*
156 *MELD or PELD Score Exceptions*
- 157 • Cystic fibrosis, according to *Policy 9.5.B: Requirements for Cystic Fibrosis MELD or PELD*
158 *Score Exceptions*
- 159 • Familial amyloid polyneuropathy, according to *Policy 9.5.C: Requirements for Familial*
160 *Amyloid Polyneuropathy (FAP) MELD or PELD Score Exceptions*
- 161 • Hepatic artery thrombosis, according to *Policy 9.5.D: Requirements for Hepatic Artery*
162 *Thrombosis (HAT) MELD or PELD Score Exceptions*
- 163 • Hepatopulmonary syndrome, according to *Policy 9.5.E: Requirements for Hepatopulmonary*
164 *Syndrome (HPS) MELD or PELD Score Exceptions*
- 165 • Metabolic disease, according to *Policy 9.5.F: Requirements for Metabolic Disease MELD or*

166 *PELD Score Exceptions*

- 167 • Portopulmonary hypertension, according to *Policy 9.5.G: Requirements for Portopulmonary*
- 168 *Hypertension MELD or PELD Score Exceptions*
- 169 • Primary hyperoxaluria, according to *Policy 9.5.H: Requirements for Primary Hyperoxaluria*
- 170 *MELD or PELD Score Exceptions*
- 171 • Hepatocellular carcinoma, according to *Policy 9.5.I: Requirements for Hepatocellular*
- 172 *Carcinoma (HCC) MELD or PELD Score Exceptions*

173

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

176

177 **9.5.A Requirements for Cholangiocarcinoma (CCA) MELD or PELD Score** 178 **Exceptions**

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

181

182 1. Submits a written protocol for patient care to the Liver and Intestinal Organ Transplantation
 183 Committee that must include *all* of the following:

184

- 184 • Candidate selection criteria
- 185 • Administration of neoadjuvant therapy before transplantation
- 186 • Operative staging to exclude any patient with regional hepatic lymph node metastases,
 187 intrahepatic metastases, or extrahepatic disease
- 188 • Any data requested by the Liver and Intestinal Organ Transplantation Committee

189

190 2. Documents that the candidate meets the diagnostic criteria for hilar CCA with a malignant
 191 appearing stricture on cholangiography and at least *one* of the following:

192

- 192 • Biopsy or cytology results demonstrating malignancy
- 193 • Carbohydrate antigen 19-9 greater than 100 U/mL in absence of cholangitis
- 194 • Aneuploidy

195

196 The tumor must be considered un-resectable because of technical considerations or
 197 underlying liver disease.

198 3. Submits cross-sectional imaging studies. If cross-sectional imaging studies demonstrate a
 199 mass, the mass must be single and less than three cm.

200

201 4. Documents the exclusion of intrahepatic and extrahepatic metastases by cross-sectional
 202 imaging studies of the chest and abdomen within 90 days prior to submission of the initial
 exception request.

203

204 5. Assesses regional hepatic lymph node involvement and peritoneal metastases by operative
 205 staging after completion of neoadjuvant therapy and before liver transplantation.
 206 Endoscopic ultrasound-guided aspiration of regional hepatic lymph nodes may be advisable
 to exclude patients with obvious metastases before neo-adjuvant therapy is initiated.

207

208 6. Transperitoneal aspiration or biopsy of the primary tumor (either by endoscopic ultrasound,
 209 operative or percutaneous approaches) must be avoided because of the high risk of tumor
 seeding associated with these procedures.

210

211 A candidate who meets the requirements for a standardized MELD or PELD score exception will
 212 ~~be assigned~~ receive a score according to *Table 9-2* below.

213
 214

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

215
 216 In order to be approved for an extension of this MELD or PELD score exception, transplant
 217 ~~hospital~~ programs must submit an exception extension request according to *Policy 9.4.C: MELD*
 218 *or PELD Score Exception Extensions*, and provide cross-sectional imaging studies of the chest and
 219 abdomen that exclude intrahepatic and extrahepatic metastases. These required imaging
 220 studies must have been completed within 30 days prior to the submission of the extension
 221 request.

222
 223

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

224 A candidate will receive a MELD or PELD score exception for cystic fibrosis if the candidate’s
 225 diagnosis has been confirmed by genetic analysis, and the candidate has a forced expiratory
 226 volume at one second (FEV1) below 40 percent of predicted FEV1 within 30 days prior to
 227 submission of the initial exception request.

228
 229 A candidate who meets the requirements for a standardized MELD or PELD score exception will
 230 ~~be assigned~~ receive a score according to *Table 9-3* below.

231
 232

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

233
 234 In order to be approved for an extension of this MELD or PELD score exception, transplant
 235 ~~hospital~~ programs must submit an exception extension request according to *Policy 9.4.C: MELD*
 236 *or PELD Score Exception Extensions*.

237
 238

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

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

242
 243
 244

1. Either that the candidate is also registered and active on the waiting list for a heart transplant at that transplant hospital, or has an echocardiogram performed within 30

- 245 days prior to submission of the initial exception request showing the candidate has an
 246 ejection fraction greater than 40 percent.
- 247 2. That the candidate can walk without assistance.
 - 248 3. That a transthyretin (TTR) gene mutation has been confirmed.
 - 249 4. A biopsy-proven amyloid.

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 9-4* below.

253
 254 **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

255
 256 In order to be approved for an extension of this MELD or PELD score exception, transplant
 257 hospital programs must submit an exception extension request according to *Policy 9.4.C: MELD*
 258 *or PELD Score Exception Extensions* and meet one of the following criteria:

- 259 1. An echocardiogram that shows that the candidate has an ejection fraction greater than
 260 40 percent within the last 120 days
- 261 2. Registered and active on the waiting list for a heart transplant at that hospital

262
 263 **9.5.D Requirements for Hepatic Artery Thrombosis (HAT) MELD or PELD Score**
 264 **Exceptions**

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

268
 269 Candidates who meet these requirements will receive a MELD score of 40.

270
 271 In order to be approved for an extension of this MELD score exception, transplant hospital
 272 programs must submit an exception extension request according to *Policy 9.4.C: MELD or PELD*
 273 *Score Exception Extensions*.

274
 275 **9.5.E Requirements for Hepatopulmonary Syndrome (HPS) MELD or PELD Score**
 276 **Exceptions**

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

- 279 1. Ascites, varices, splenomegaly, or thrombocytopenia.
- 280 2. A shunt, shown by either contrast echocardiogram or lung scan.
- 281 3. PaO₂ less than 60 mmHg on room air within 30 days prior to submission of the initial
 282 exception request.
- 283 4. No clinically significant underlying primary pulmonary disease.

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289

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

290
291
292
293
294
295
296

In order to be approved for an extension of this MELD or PELD score exception, transplant hospital 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 PaO₂ 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

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302
303
304

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.

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

305
306
307
308
309
310
311
312
313

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 hospital 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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320

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)

- 321 level greater than or equal to 240 dynes*sec/cm⁵ (or greater than or equal to 3 Wood
 322 units (WU)). These values must be from the same test date.
 323 2. Other causes of pulmonary hypertension have been assessed and determined to not be
 324 a significant contributing factor
 325 3. Initial transpulmonary gradient to correct for volume overload
 326 4. Documentation of treatment
 327 5. Document via heart catheterization within 90 days prior to submission of the initial
 328 exception either of the following:
- 329 • Post-treatment MPAP less than 35 mmHg and post-treatment PVR less than 400
 330 dynes*sec/cm⁵ (or less than 5 Wood units (WU)). These values must be from the
 331 same test date.
 - 332 • Post-treatment MPAP greater than or equal to 35 mmHg and less than 45
 333 mmHg and post-treatment PVR less than 240 dynes*sec/cm⁵ (or less than 3
 334 Wood units (WU)). These values must be from the same test date.
- 335 6. Documentation of portal hypertension at the time of initial exception
 336

337 A candidate who meets the requirements for a standardized MELD or PELD score exception will
 338 ~~be assigned~~ receive a score according to *Table 9-7* below.
 339

340 **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

341
 342 In order to be approved for an extension of this MELD or PELD score exception, transplant
 343 ~~hospitals~~ programs must submit an exception extension request according to *Policy 9.4.C: MELD*
 344 *or PELD Score Exception Extensions* with evidence of a heart catheterization since the last
 345 exception or extension request that confirms either of the following:

- 346 • MPAP less than 35 mmHg and PVR less than 400 dynes*sec/cm⁵ (or less than 5 Wood
 347 units (WU)). These values must be from the same test date.
- 348 • MPAP greater than or equal to 35 mmHg and less than 45 mmHg and PVR less than 240
 349 dynes*sec/cm⁵ (or less than 3 Wood units (WU)). These values must be from the same
 350 test date.

351
 352 **9.5.H Requirements for Primary Hyperoxaluria MELD or PELD Score Exceptions**

353 A candidate will receive a MELD or PELD score exception for primary hyperoxaluria if the
 354 candidate's transplant ~~hospital~~ program submits evidence of all of the following:
 355

- 356 1. The liver candidate is registered on the waiting list for a kidney transplant at that transplant
 357 hospital
- 358 2. Alanine glyoxylate aminotransferase (AGT) deficiency proven by liver biopsy using sample
 359 analysis or genetic analysis

- 360 3. Estimated glomerular filtration rate (eGFR) by six variable Modification of Diet in Renal
 361 Disease formula (MDRD6), or glomerular filtration rate (GFR) measured by iothalamate or
 362 iohexol, is less than or equal to 25 mL/min on 2 occasions at least 42 days apart
 363

364 A candidate who meets the requirements for a standardized MELD or PELD score exception will
 365 be assigned receive an exception score according to *Table 9-8* below.
 366

367 **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

368 In order to be approved for an extension of this MELD or PELD score exception, transplant
 369 hospital programs must submit an exception extension request according to Policy 9.4.C: MELD
 370 or PELD Score Exception Extensions with evidence that the candidate is registered on the
 371 waiting list for a kidney transplant at that hospital.
 372
 373

374 **9.5.I Requirements for Hepatocellular Carcinoma (HCC) MELD or PELD Score**
 375 **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*.

376 **9.5.I.vii Extensions of HCC Exceptions**

377 A candidate with an approved exception for HCC is eligible for automatic approval of
 378 an extension if the transplant program enters a MELD or PELD Exception Score
 379 Extension Request that contains the following:
 380

- 381 1. Documentation of the tumor using a CT or MRI
- 382 2. The type of treatment if the number of tumors decreased since the last request
- 383 3. The candidate’s alpha-fetoprotein (AFP) level

384
 385 The candidate’s exception extension will then be automatically approved unless *any*
 386 of the following occurs:
 387

- 388 • The candidate’s lesions progress beyond T2 criteria, according to 9.5.I.ii: *Eligible*
 389 *Candidates Definition of T2 Lesions*
- 390 • The candidate’s alpha-fetoprotein (AFP) level was less than or equal to 1,000
 391 ng/mL on the initial request but subsequently rises above 1,000 ng/mL
- 392 • The candidate’s AFP level was greater than 1,000 ng/mL, the AFP level falls
 393 below 500 ng/mL after treatment but before the initial request, then the AFP
 394 level subsequently rises to greater than or equal to 500 ng/mL
- 395 • The candidate’s tumors have been resected since the previous request

- The program requests a score different from the scores assigned in Table 9-10.

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

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

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	6 <u>Calculated MELD</u>
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

9.6 Waiting Time

9.6.A Waiting Time for Liver Candidates

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

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

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

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

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

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

- 433
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- 449
- If the candidate’s allocation MELD or PELD score is based on a calculated MELD or PELD score, then allocation MELD or PELD score waiting time includes all waiting time at current or higher calculated MELD or PELD score, including liver-intestine points. Waiting time at current or higher calculated MELD or PELD score includes *all* of the following:
 1. Waiting time at current calculated MELD or PELD score, including liver-intestine points
 2. Previous waiting time accrued during an earlier period at current calculated MELD or PELD score, including liver-intestine points
 3. Previous total waiting time accrued at any calculated MELD or PELD score higher than the current calculated MELD or PELD score, including liver intestine points
 4. Previous total waiting time accrued at status 1A and status 1B
 - If the candidate’s allocation MELD or PELD score is an exception MELD or PELD score, then allocation MELD or PELD score waiting time equals time since submission of earliest approved or assigned MELD or PELD exception request, including time at an inactive status.

450 9.8 Liver Allocation, Classifications, and Rankings

451 Unless otherwise stated, all mentions of MELD or PELD in this section reference a candidate’s

452 ~~match~~ allocation MELD or PELD score.

453 9.8.D Sorting Within Each Classification

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

- 455
- 456
- 457
- 458
- 459
- 460
1. Total waiting time and blood type compatibility points (highest to lowest), according to *Policy 9.7: Liver Allocation Points*
 2. Total waiting time at status 1A (highest to lowest)

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

- 462
- 463
- 464
- 465
- 466
1. Total waiting time and blood type compatibility points (highest to lowest), according to *Policy 9.7: Liver Allocation Points*
 2. Total waiting time at status 1B (highest to lowest)

467 Within each MELD or PELD score allocation classification, all candidates are sorted in the

468 following order:

- 469
- 470
- 471
- 472
- 473
- 474
- 475
- 476
- 477
1. Allocation MELD or PELD score (highest to lowest)
 2. ~~Identical blood types, compatible blood types, then incompatible blood types~~
 3. ~~Waiting time at the current or higher MELD or PELD score (highest to lowest)~~
 4. ~~Time since submission of initial approved MELD or PELD exception request (highest to lowest)~~
 2. Blood type compatibility (identical, compatible, then incompatible)
 3. Age at time of registration on the liver waitlist (less than 18 years old followed by 18 years or older)

- 478 4. Allocation MELD or PELD score type (calculated, including liver-intestine points, then
- 479 exception)
- 480 5. Allocation MELD or PELD score waiting time (highest to lowest)
- 481 6. Total waiting time (highest to lowest)

1 Guidelines Changes

2 National Liver Review Board Operational Guidelines

3 1. Overview

4

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

10 The NLRB is comprised of specialty boards, including:

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

15

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

18

19

#

Appendix

The following data was presented to the Pediatric Committee on March 30 and the Liver Committee on April 2 to inform the decision to make a post-public comment change to the proposal to address concerns about the impact on pediatric candidate access to adult donor offers.^{84,85}

The cohorts include deceased donor liver transplants (liver-alone and liver multi-organ) during pre- and post- acuity circles policy eras.⁸⁶ The pre-policy era is defined as 2/3/2019-2/3/2020. The post-policy era is defined as 2/4/2020-2/3/2021.

Figure 7: Deceased Donor Liver Transplants by Recipient Age, Donor Age, and Era

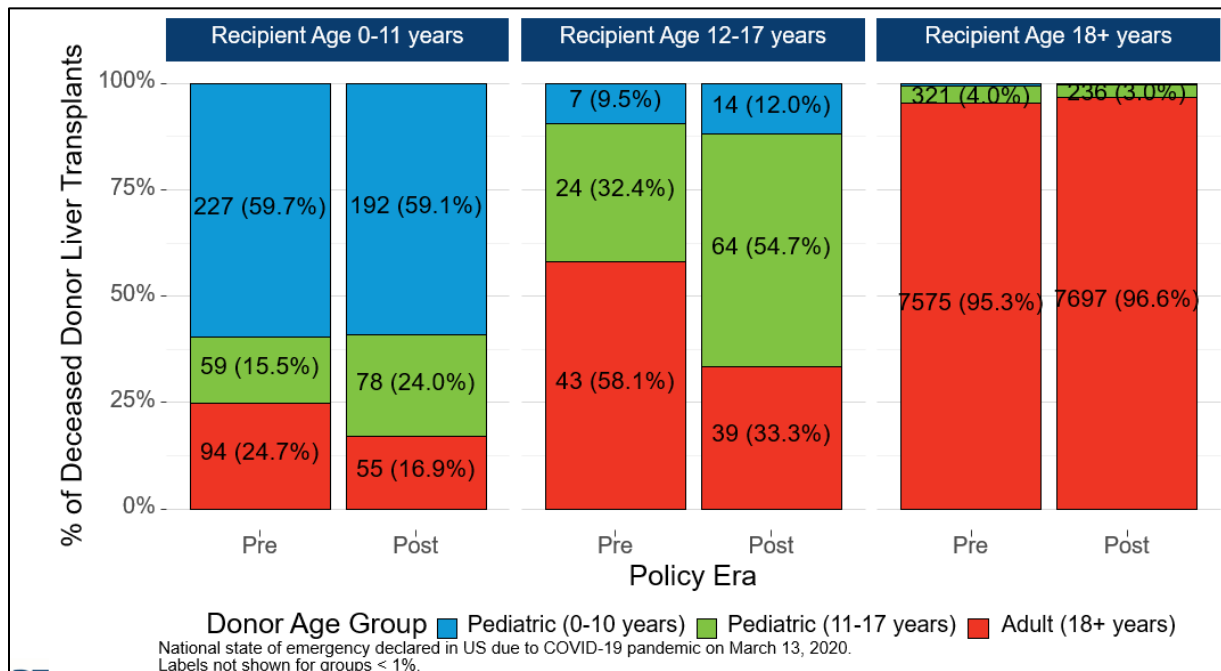


Figure 8: Median Transplant Score (MTS) and Number of Deceased Donor Liver Transplants by Recipient Age and Era

Recipient Age	Pre-Policy MTS (N)	Post-Policy MTS (N)
Pediatric (0-11 years)	35 (222)	35 (214)
Pediatric (12-17 years)	30 (53)	26.5 (92)
Adult (18+ years)	28 (7737)	28 (7759)

⁸⁴ See OPTN Pediatric Transplantation Committee meeting summary, March 30, 2020. Available at <https://optn.transplant.hrsa.gov/>

⁸⁵ See OPTN Liver and Intestinal Organ Transplantation Committee meeting summary, April 2, 2021. Available at <https://optn.transplant.hrsa.gov/>

⁸⁶ The Acuity Circles policy was implemented on February 4, 2020.

Figure 9: Pediatric Deceased Donor Liver Transplants by Recipient Age, Exception Status, Donor Age, and Era

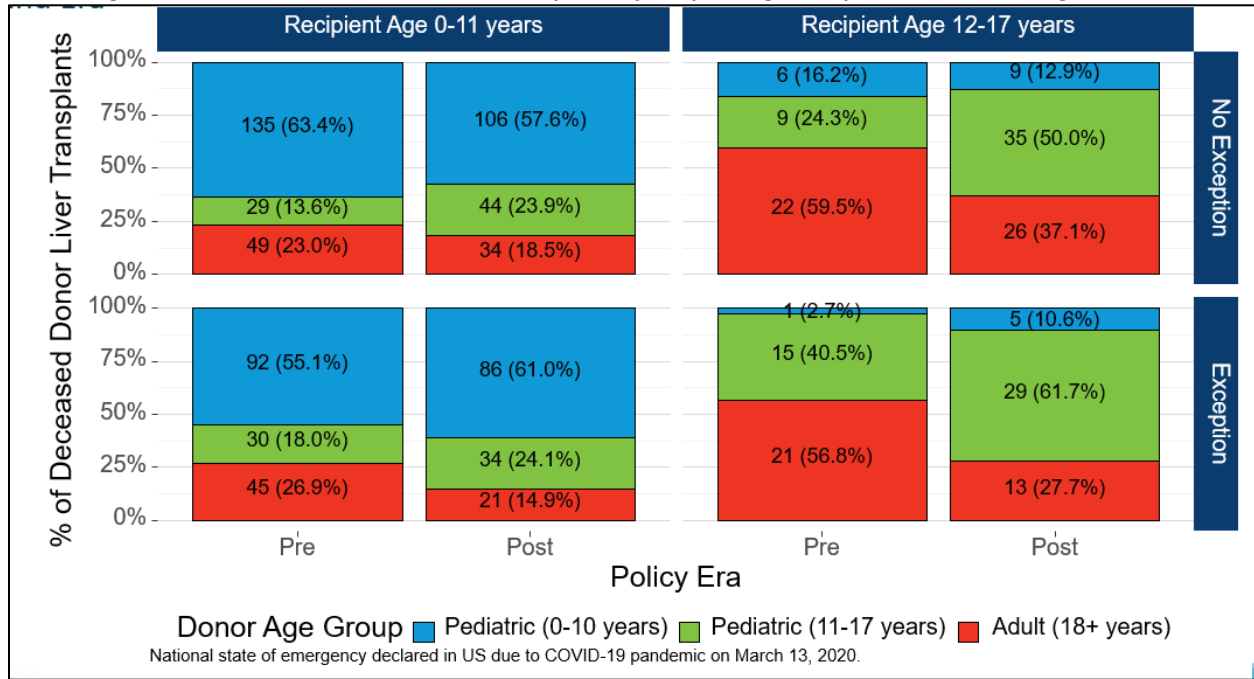


Figure 10: Median Transplant Score (MTS) and Number of Deceased Donor Liver Transplants by Recipient Age, Exception Status at Transplant, and Era

Recipient Age	Exception Status	Pre-Policy MTS (N)	Post-Policy MTS (N)
Pediatric (0-11 years)	No Exception	8 (55)	20 (73)
	Exception	35 (167)	35 (141)
Pediatric (12-17 years)	No Exception	21 (16)	17 (45)
	Exception	31 (37)	30 (47)
Adult (18+ years)	No Exception	28 (5845)	30 (6343)
	HCC Exception	28 (1174)	26 (1030)
	Non-HCC Exception	28 (718)	27 (386)

Figure 11: Pediatric Deceased Donor Liver Transplants by Recipient Age, Allocation MELD or PELD Score, Donor Age, and Era

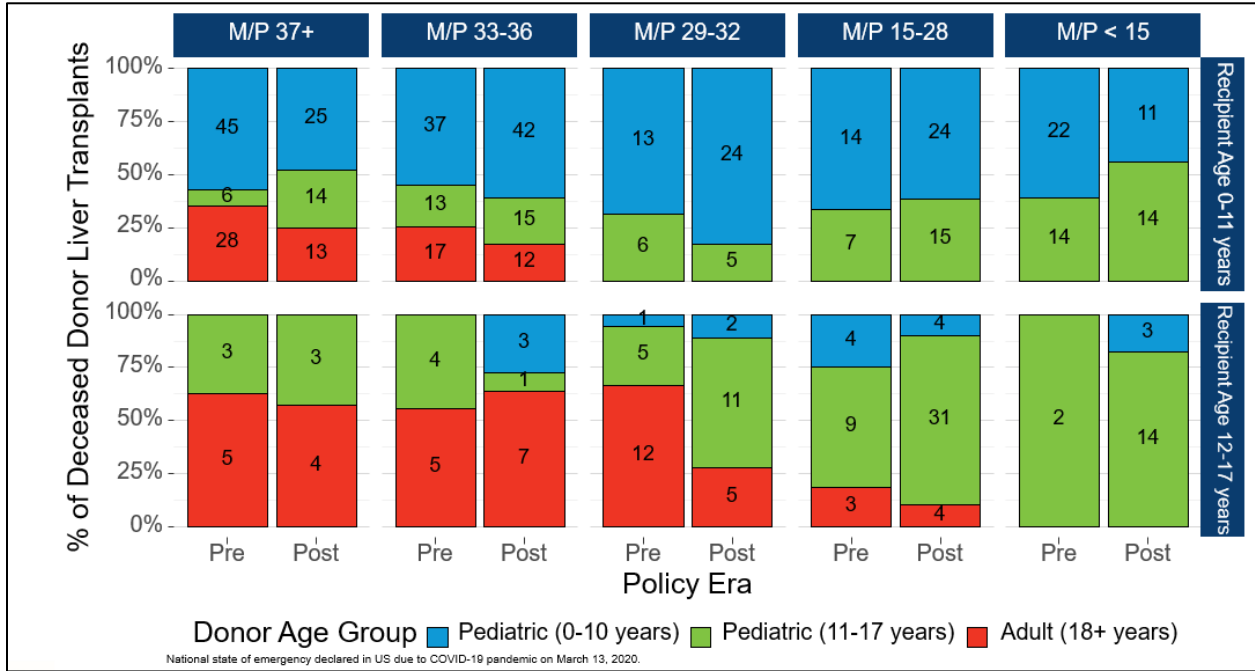


Figure 12: Snapshot of Liver Waitlist Registrations by Age at Listing, Exception Status and Allocation Score or Status at Snapshot Date

Allocation Score or Status	May 31, 2020													
	Pediatric (0-11 years)				Pediatric (12-17 years)				Adult (18+ years)					
	No Exception		Exception		No Exception		Non-HCC Exception		No Exception		HCC Exception	Non-HCC Exception		
	N	%	N	%	N	%	N	%	N	%	N	%		
Status 1A/1B	11	4.9	5	6.1	2	1.7	0	0.0	1	0.0	0	0.0	0	0.0
M/P 37+	2	0.9	26	31.7	0	0.0	2	10.5	20	0.2	0	0.0	3	0.9
M/P 33-36	2	0.9	30	36.6	0	0.0	1	5.3	20	0.2	1	0.1	9	2.6
M/P 29-32	6	2.7	11	13.4	2	1.7	4	21.1	57	0.6	69	3.8	29	8.4
M/P 15-28	27	12.1	8	9.8	18	15.4	12	63.2	2998	29.7	707	38.9	213	61.7
M/P < 15	58	26.0	1	1.2	34	29.1	0	0.0	4552	45.0	724	39.8	21	6.1
Temp. Inactive	117	52.5	1	1.2	61	52.1	0	0.0	2461	24.3	318	17.5	70	20.3
Total	223	100	82	100	117	100	19	100	10109	100	1819	100	345	100

Figure 11: Snapshot of Liver Waitlist Registrations by Age at Listing, Exception Status and Allocation Score or Status at Snapshot Date

Allocation Score or Status	October 31, 2020													
	Pediatric (0-11 years)				Pediatric (12-17 years)				Adult (18+ years)					
	No Exception		Exception		No Exception		Non-HCC Exception		No Exception		HCC Exception		Non-HCC Exception	
	N	%	N	%	N	%	N	%	N	%	N	%	N	%
Status 1A/1B	9	4.2	3	5.5	0	0.0	1	7.1	0	0.0	0	0.0	0	0.0
M/P 37+	1	0.5	13	23.6	1	1.0	1	7.1	17	0.2	1	0.1	4	1.3
M/P 33-36	1	0.5	18	32.7	0	0.0	0	0.0	32	0.3	0	0.0	4	1.3
M/P 29-32	5	2.3	12	21.8	0	0.0	0	0.0	61	0.6	70	3.7	29	9.4
M/P 15-28	35	16.4	8	14.5	14	14.0	9	64.3	3105	31.7	807	42.8	208	67.8
M/P < 15	50	23.5	0	0.0	22	22.0	1	7.1	4341	44.3	680	36.1	6	2.0
Temp. Inactive	112	52.6	1	1.8	63	63.0	2	14.3	2245	22.9	327	17.3	56	18.2
<i>Total</i>	<i>213</i>	<i>100</i>	<i>55</i>	<i>100</i>	<i>100</i>	<i>100</i>	<i>14</i>	<i>100</i>	<i>9801</i>	<i>100</i>	<i>1885</i>	<i>100</i>	<i>307</i>	<i>100</i>

Figure 12: Snapshot of Liver Waitlist Registrations by Age at Listing, Exception Status and Allocation Score or Status at Snapshot Date

Allocation Score or Status	January 31, 2021															
	Pediatric (0-11 years)				Pediatric (12-17 years)				Adult (18+ years)							
	No Exception		Exception		No Exception		HCC Exception		Non-HCC Exception		No Exception		HCC Exception		Non-HCC Exception	
	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%
Status 1A/1B	9	4.3	5	6.8	0	0.0	0	0.0	1	6.2	3	0.0	0	0.0	0	0.0
M/P 37+	1	0.5	13	17.6	0	0.0	1	100	1	6.2	25	0.3	0	0.0	0	0.0
M/P 33-36	0	0.0	28	37.8	1	1.0	0	0.0	0	0.0	31	0.3	2	0.1	9	3.2
M/P 29-32	3	1.4	17	23.0	0	0.0	0	0.0	4	25.0	67	0.7	73	3.9	32	11.4
M/P 15-28	35	16.7	9	12.2	13	13.0	0	0.0	10	62.5	2836	29.7	736	39.4	195	69.4
M/P < 15	62	29.7	0	0.0	24	24.0	0	0.0	0	0.0	4378	45.8	677	36.2	3	1.1
Temp. Inactive	99	47.4	2	2.7	62	62.0	0	0.0	0	0.0	2220	23.2	382	20.4	42	14.9
<i>Total</i>	<i>209</i>	<i>100</i>	<i>74</i>	<i>100</i>	<i>100</i>	<i>100</i>	<i>1</i>	<i>100</i>	<i>16</i>	<i>100</i>	<i>9560</i>	<i>100</i>	<i>1870</i>	<i>100</i>	<i>281</i>	<i>100</i>

Figure 13: Liver Waitlist Removals by Candidate Age at Listing, Removal Reason, and Era

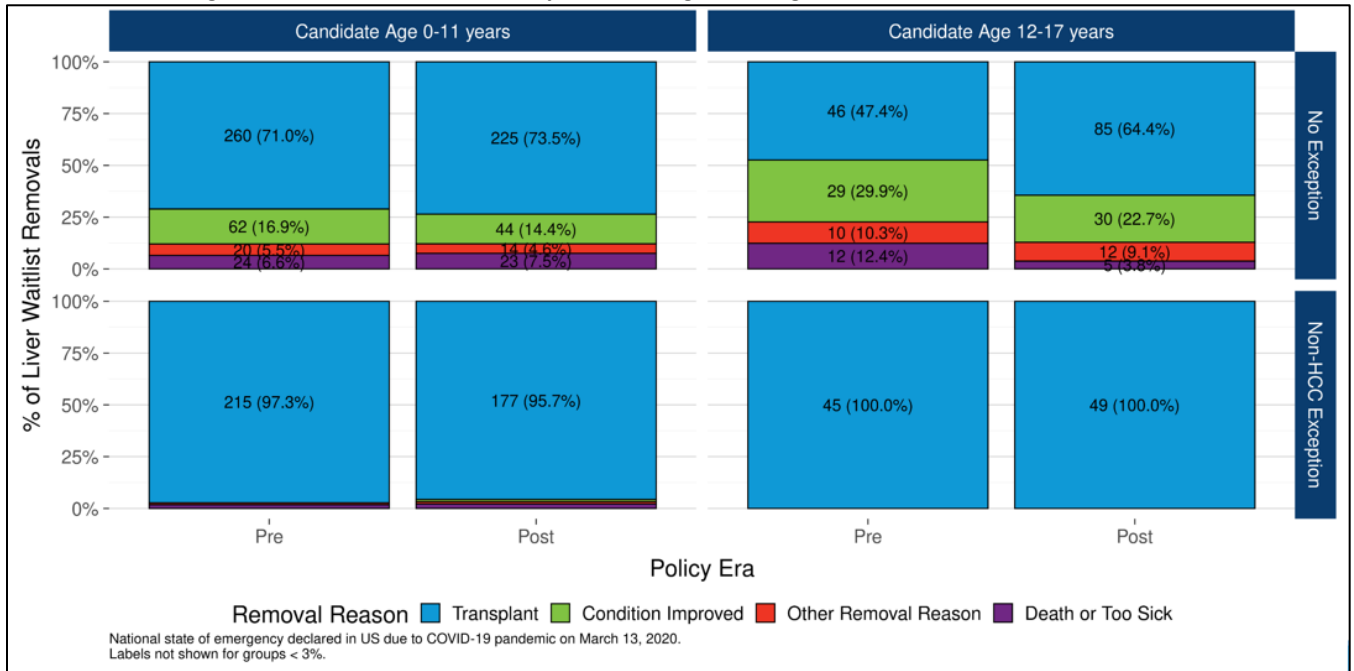


Figure 14: Liver Waitlist Removals by Candidate Age at Listing, Exception Status, Removal Reason, and Era

